UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

BLUE CROSS AND BLUE SHIELD OF KANSAS CITY, Plaintiff, v. GS LABS LLC, Defendant.	)	Cause No.: 4:21-cv-00525-FJG

BLUE KC'S MOTION FOR LEAVE TO FILE ITS SECOND AMENDED COMPLAINT

COMES NOW, Blue Cross and Blue Shield of Kansas City ("Blue KC") and for its Motion for Leave to File its Second Amended Complaint, states as follows:

Blue KC seeks leave to amend its pleading to add additional claim-specific details to existing claims, refine and clarify the legal basis underlying its current claims, and to conform the facts pled to the evidence it has obtained thus far.[1] Blue KC is not seeking to add any new Counts with its proposed Second Amended Complaint, nor would the proposed amendment require modifications of the existing pre-trial schedule. The amendments do not change the central premise of the litigation: (1) GSL's purported cash prices constitutes unlawful price gouging and disaster profiteering and (2) GSL used a false "cash price" and other false statements in connection with its claims. Blue KC requests that it be permitted leave to file its Second Amended Complaint.

Blue KC's proposed Second Amended Complaint is attached to this motion and marked **Exhibit 1**.[2]

[1] The proposed Second Amended Complaint also includes stylistic and other non-substantive changes.

[2] Certain exhibits included with **Exhibit 1** have been deemed "confidential" by GSL pursuant to the Protective Order. Doc. 56. Blue KC also attaches to its proposed Second Amended Complaint extensive claim-specific detail identifying each pre-suit claim at issue in the litigation and all claims for

BACKGROUND

1. Blue KC filed this litigation on July 20, 2021. Doc. No. 1.

2. Pursuant to Federal Rule of Civil Procedure 15(a)(1), Blue KC filed its First Amended Complaint on August 26, 2021. Doc. No. 14.

3. Since the filing of its First Amended Complaint, Blue KC has obtained materials, data, and other information through discovery and its own investigations and analysis which informs, clarifies, and supplements the allegations made in Blue KC's First Amended Complaint. It has also had opportunity to analyze claim data relating to GSL.

4. The Court entered an amended scheduling order on February 2, 2022 setting the deadline to move to amend pleadings as March 1, 2022. Doc. No. 116, pg. 2.

5. Fact discovery is set to close on May 15, 2022. Doc. No. 116, pg. 2.

LEGAL STANDARD

Rule 15(a)(2) states that a court "should freely give leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(2). "Unless there is a good reason for denial, . . . leave to amend should be granted." *Bediako v. Stein Mart, Inc.*, 354 F.3d 835, 840 (8th Cir. 2004). "[A] district court's denial of leave to amend pleadings is appropriate only in those limited circumstances in which undue delay, bad faith on the part of the moving party, futility of the amendment, or unfair prejudice to the non-moving party can be demonstrated." *Roberson v. Hayti Police Dept.*, 241 F.3d 992, 995 (8th Cir. 2001) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

ARGUMENT

Based on the nature of these amendments proposed, GSL will not suffer undue prejudice if leave to file Blue KC's proposed Second Amended Complaint is granted. The proposed amendments:

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which Blue KC seeks relief under its Count III (Unjust Enrichment). Accordingly, Blue KC has contemporaneously moved to file those exhibits to the proposed Second Amended Complaint under seal.

(1) do not attempt to add new counts or seek additional new relief; (2) provide additional factual detail regarding the claims at issue; (3) provide greater clarification of the legal and factual basis of Blue KC's claims and; (4) would not significantly alter the scope of discovery.

Further, Blue KC's Motion for Leave to File its Second Amended Complaint is timely. Blue KC's Motion was filed within the required deadline set forth in the Court's most recent scheduling order. Blue KC's motion for leave to file the proposed Second Amended Complaint is made in good faith.

CONCLUSION

Based on the nature of Blue KC's proposed amendments, lack of prejudice that would be caused by the amendments, and the timeliness of Blue KC's motion, this Court should permit Blue KC's filing of its Second Amended Complaint.

WHEREFORE, Plaintiff Blue Cross and Blue Shield of Kansas City respectfully requests that this Court **GRANT** its Motion for Leave to File its Second Amended Complaint.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing was served on all parties of record by filing a copy of the same with the Court's electronic filing system this 1st day of March, 2022.

. */s/ Aaron E. Schwartz*

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SECOND AMENDED COMPLAINT

COMES NOW Plaintiff, Blue Cross and Blue Shield of Kansas City ("Plaintiff" or "Blue KC"), pursuant to Federal Rule of Civil Procedure 15(a), by and through undersigned counsel and for its Second Amended Complaint, states as follows:

1. Defendant GS Labs LLC ("Defendant" or "GSL"), a provider of COVID-19 testing, is engaging in an abusive scheme to exploit the pandemic by duping health insurers into paying hundreds of thousands of COVID-19 testing claims at grossly inflated rates.

2. Pursuant to laws Congress enacted in response to the global pandemic, health insurers, and plans must cover certain COVID-19 diagnostic testing. Reimbursement rates for the required diagnostic testing are typically established in one of two ways: (a) the provider and insurer may negotiate rates, or (b) if negotiations do not result in agreed-upon rates, the reimbursement rate would then be the provider's publicly posted "cash price." CARES Act § 3202(a).[1] A "cash price" is the price a person that pays cash, or a cash equivalent, would pay for that test. *See* 45 C.F.R. § 182.20.

3. Defendant's scheme, at its core, is quite simple. Instead of posting reasonable and accurate cash prices and negotiating with Blue KC in good faith if any pricing dispute remained,

[1] Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Pub. L. No. 116-136, 134 Stat. 281 (2020).

Defendant posted wildly excessive and false "cash prices." Defendant refused to accept reasonable reimbursement rates for its testing services, and instead, demanded that Blue KC pay its full sham "cash price."

4. GSL's reimbursement claims for rapid antigen tests illustrate its scheme. Rapid antigen tests are one of several types of COVID-19 tests GSL claims to have administered. In terms of clinical sophistication, these tests are comparable to over-the-counter pregnancy tests.[2] These tests can be purchased at wholesale for as little as $5 per test. Nevertheless, GSL's purported "cash price" for antigen tests was ***$380 per test - approximately ten times higher than Medicare's reimbursement rate and seventy-five times higher than the wholesale cost***. In negotiations with Blue KC, GSL insisted it was entitled to its posted purported "cash price" and offered only small discounts in exchange for prompt payment.[3]

5. The egregious nature of GSL's posted prices for individual tests is aggravated by the fact that GSL rarely billed for a single test per patient. Approximately only 1.3 percent of GSL's pre-suit claims sought reimbursement for a rapid antigen or PCR test alone. The large majority of pre-suit charges (approximately $7,969,590 or 78.7% of total charges) seek reimbursement for $810 or more per patient.

6. The Kansas Insurance Department commented in a letter describing GSL's practices ***"[i]f these astronomical costs charged by unscrupulous providers are borne by the health plans and insurers without recompense, consumers will ultimately pay more for their health care as health insurance costs will rise***." **Exhibit A**, page 2. (emphasis in original).

7. On December 22, 2020, the Kansas Attorney General demanded that GSL "immediately and permanently cease and desist from advertising, marketing or selling products and

[2] https://www.yalemedicine.org/news/which-covid-test-is-accurate.
[3] After the suit was filed, GSL reduced its purported "cash price" for rapid antigen testing from $380 to $179 and it reduced its purported cash price for PCR testing from $385 to $229.

services in Kansas in any manner that charges unconscionable prices in relation to prices of testing readily available in the area . . ." **Exhibit B**. Nevertheless, GSL failed to heed these demands and continued to charge unconscionable prices in Kansas and elsewhere.

8. GSL's purported "cash prices" are not only grossly excessive but are also intentionally deceptive. While GSL represented to insurers and group plans that its "cash prices" were hundreds of dollars per test, GSL, in fact, had not established any such "cash prices." At first, GSL refused prospective patients that sought to pay the purported cash price out-of-pocket. On February 17, 2021, GSL's own attorney responded to allegations that GSL was price gouging by arguing "***GS Labs has never charged a consumer for the 'cash price' of a COVID-19 test, even if they have no health insurance.***" *See* Doc. 42-1. Eventually, GSL began accepting uninsured, out-of-pocket customers but instead of collecting its purported "cash prices" from these individuals, GSL accepted cash payments from uninsured individuals at steeply discounted rates. These discounts, available to any uninsured customer who requested, resulted in the vast majority of individuals who paid out-of-pocket only paying a fraction of the posted, purported "cash price." GSL's use of sham "cash prices" constitutes a scheme or false artifice designed to defraud insurers and health plans.

9. GSL submitted over $11 million in inflated and otherwise improper claims to Blue KC and demanded that Blue KC pay these claims at excessive rates. Blue KC refused to submit to GSL's demands and filed the instant action.

10. Blue KC seeks a declaratory judgment finding GSL forfeited its right, if any, to payment for the claims described in this Second Amended Complaint. A ripe and justiciable controversy exists, in part, because GSL submitted millions of dollars of claims for reimbursement to Blue KC, GSL continues to demand payment for these claims, and the claims are not payable for reasons that include the following:

a.) GSL violated its duty of good faith and fair dealing when it purported to set its cash prices for COVID-19 tests at unconscionable, unreasonable, arbitrary, bad faith, and/or grossly excessive rates;

b.) GSL's purported cash prices amount to unlawful price gouging and disaster profiteering under state and federal law and are, therefore, unenforceable;

c.) GSL's claims for reimbursement are contrary to the public policy as embodied by statutes such as 18 USC §§ 1347, 1343, 1035; 18 USC § 1952; RSMo § 375.991; KSA 40-2,118; and other laws as described in this Second Amended Complaint;

d.) GSL engaged in fraudulent insurance acts by knowingly and willfully concealing and misrepresenting material facts or circumstances relating to the claims including, but not limited to, the actual cash prices for the services in question or, in the alternative, the lack of an established cash price;

e.) GSL failed to comply with Section 3202 of the CARES Act and related regulations which requires that GSL accurately display on its website its established cash prices; and

f.) For other reasons described in this pleading and as may be described in subsequent pleadings.

11. Blue KC also brings this action to enjoin GSL from engaging in any efforts to collect the outstanding claims directly from Blue KC's members. These collection activities would harm innocent Blue KC members, would cause irreparable harm to Blue KC in the form of hundreds or thousands of appeals, complaints, and a loss of customer goodwill, and would discourage Blue KC members and others from obtaining necessary and appropriate COVID-19 diagnostic testing in the future.

12. Finally, Blue KC files this action to recoup certain discrete and identified claims paid at GSL's posted sham "cash prices."

PARTIES

13. Blue KC is a Missouri not-for-profit corporation with its principal place of business in Kansas City, Missouri.

14. Blue KC is an independent licensee of the Blue Cross Blue Shield Association ("BCBSA").

15. BCBSA is a national trade association of 35 independent, community-based, and locally operated Blue Cross Blue Shield companies (the "BCBS licensees").

16. The BCBS licensees provide health insurance to more than 110 million people in all 50 states, including Washington, D.C., and Puerto Rico.

17. Blue KC provides comprehensive health care coverage, including medical diagnostic services, to approximately one million members[4] in the greater Kansas City region and Northwest Missouri.

18. GSL is a foreign limited liability company formed under the laws of Nebraska on January 14, 2020.

19. Documents GSL filed with the Missouri Secretary of State indicate that GSL was formed to "perform Covid testing."

20. GSL operates or operated COVID-testing laboratories in Lee's Summit, Missouri; Lenexa, Kansas; Omaha, Nebraska; and approximately two dozen other locations across the country.

[4] In this Second Amended Complaint Blue KC refers to all individuals covered under any of the health plans or policies referenced on Exhibit D as its "members."

21. Upon information and belief, GSL closed its facilities in Lee's Summit, Missouri, and Lenexa, Kansas before this litigation was filed. It later opened a separate facility in Kansas City, Missouri.

22. GSL first became registered to do business in Missouri on February 2, 2021, and in Kansas on December 7, 2020. GSL operated in Missouri and Kansas before it was authorized to do so.

23. GSL may be served with process at the office of its registered Missouri agent at Capitol Corporate Service, Inc., 222 E. Dunklin St., Ste. 102, Jefferson City, MO 65101.

24. GSL's principal office address is 222 S. 15th Street, Suite 1404S, Omaha, Nebraska 68130.

25. Upon information and belief, GSL is 100% owned by CDSK Holdings LLC, which in turn is 100% owned by City Ventures Enterprises, LLC. Upon information and belief, two individuals, Daniel White and Chris Erickson, are the sole 50/50 owners of City Ventures Enterprises LLC. Gabe Sullivan formerly owned 25% of GSL.

26. Upon information and belief, each member of GSL is a resident and citizen of Nebraska.

JURISDICTION AND VENUE

27. The Court may exercise diversity jurisdiction over this matter pursuant to 28 U.S.C. § 1332.

28. Complete diversity exists because (a) Plaintiff Blue KC is incorporated in Missouri, has its principal place of business in Missouri, and is a citizen of the state of Missouri, and (b) Defendant GSL was formed under the laws of Nebraska, it has its principal place of business in Nebraska, and, upon information and belief, each of its members are citizens of Nebraska.

29. As is described below, the amount in controversy exceeds $75,000 and involves, among other issues, GSL's submission of over $11 million in claims for COVID-19 testing and related services.

30. The Court may also exercise federal question jurisdiction over these claims pursuant to 28 U.S.C. § 1331.

31. If the Court exercises federal question jurisdiction over a portion of the claims, this Court may exercise supplemental jurisdiction over the remaining claims under 28 U.S.C. § 1367 because those claims form part of the same case or controversy as the federal claims.

32. The parties have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

33. Venue is proper because the Defendant engaged in the conduct at issue in this judicial district and a substantial part of the events giving rise to the claims occurred in this judicial district. Many of the testing services at issue in this Second Amended Complaint occurred in this judicial district, Defendant submitted bills to Blue KC's offices in this judicial district, and much of Blue KC's work investigating and processing of the claims took place in this judicial district.

34. This Court may exercise personal jurisdiction over Defendant because Defendant operated a testing clinic in Lee's Summit, Missouri, and Kansas City, Missouri, and the dispute described in this Second Amended Complaint arises out of services provided, in large part, at those clinics.

35. All necessary and proper parties are before the Court for the matters in controversy, and there is no other parallel litigation between the parties concerning their respective rights and obligations.

36. Plaintiff has satisfied or obtained waivers of all conditions precedent, if any.

BLUE KC'S RELATIONSHIPS WITH HEALTH CARE PROVIDERS

37. Blue KC has contractual relationships with certain health care providers known as "participating" providers. These providers render medical services to Blue KC members in return for a pre-negotiated fee. Participating providers agree to accept in-network rates as payment in full for their services. Participating providers also agreed to non-litigation dispute resolution procedures.

38. Blue KC members also may receive services from "non-participating" providers who do not have contracts establishing pre-negotiated fees with Blue KC. These are known as "out-of-network" services. Non-participating providers have not agreed to accept in-network rates as payment in full for their services.

39. Typically, non-participating providers set their own prices for services rendered to their patients subject to state and federal laws and regulations.

40. When a member receives care or treatment from a non-participating provider, the member may be exposed to a "balance bill", *i.e.*, the balance remaining after the allowed amount, if any, has been paid.

41. Unless a state or federal law provides otherwise, a non-participating provider may "balance bill" the member for portions of services that remain unpaid by the applicable plan or policy.

42. GSL was, and remains, a "non-participating" provider with respect to Blue KC.

THE POLICIES, PLANS, AND PROGRAMS AT ISSUE

43. Blue KC's role varies depending on the type of programs, plans, or policy at issue. Blue KC's roles may involve underwriting, administration, and/or processing claims for different types of healthcare benefit plans, programs, and policies including, but not limited to:

a.) Plans insured under employer-sponsored group insurance policies issued by Blue KC (fully insured group plans);

b.) Self-insured plans, where Blue KC provides administrative services but the group plan or sponsor pays benefits due (administrative services only plans);

c.) Cost Plus plans (described below);

d.) Programs covering federal employees and their dependents;

e.) Plans or programs covering members of other BCBS licensees who receive care from providers in the Kansas City area;

f.) Plans covering employees of local and state public entities;

g.) Church plans covering employees of religious organizations;

h.) Policies issued directly to individuals (fully insured policies); and

i.) Benefits administered pursuant to the Medicare Advantage Program.

44. With respect to fully insured plans and policies, Blue KC processes claims and makes benefit payments, as warranted, from its own accounts.

45. Many, but not all, of the group health plans administered by Blue KC are sponsored by private employers and employee organizations (such as unions) and are governed by ERISA, 29 U.S.C. § 100, *et seq*.

46. Blue KC is the claims fiduciary for many of the ERISA-governed plans at issue.

47. Certain types of relevant plans and programs administered by Blue KC are discussed in greater detail below.

i. Federal Employees Health Benefits Program

48. The Federal Employees Health Benefits Program ("FEHBP") is a health benefits plan for federal employees, retirees, and their dependents created by the Federal Employees Health Benefits Act ("FEHBA"), 5 U.S.C. §§ 8901-8914.

49. Under FEHBA, the United States, through the Office of Personnel Management ("OPM"), contracts with various private carriers to offer health benefits plans to its employees with a variety of benefits, coverages, and costs.

50. OPM is charged with managing the FEHBP "in the interest of both the employees and the Government," *id.,* and is specifically authorized by Congress to promulgate FEHBA regulations. 5 U.S.C. § 8913.

51. The importance to the federal government of cost controls in the FEHBP is illustrated by the fact that one of the first principles enunciated by Congress in enacting FEHBA was the need to "discourage unnecessary use of expensive facilities and services." S. Rep. No. 86-468, at 4 (1959).

52. The Blue Cross and Blue Shield Service Benefit Plan, also known as the Federal Employee Program or FEP, has been part of the FEHBP since its inception in 1960.

53. OPM contracts with the BCBSA, which sponsors the plan on behalf of various BCBS licensees across the country, which then underwrites the plan for members living or receiving services in the areas where they operate.

54. Nationwide the FEP covers roughly 4.6 million Federal employees, retirees, and their families out of the nearly 8 million people who receive their benefits through the FEHBP.

55. Although Blue KC administers the FEP in the greater Kansas City region, federal employees do not contract for health benefits with Blue KC or BCBSA. Instead, they "enroll" in the FEP pursuant to OPM's regulations. 5 C.F.R. §§ 890.101(a), .102-.104, and subparts C, D, and K. A Statement of Benefits issued annually in accordance with 5 U.S.C. § 8907 governs the benefits provided by FEP.

56. Blue KC administers claims relating to enrollees of FEP who receive covered services in the Kansas City area and through that program makes reimbursement payments from Blue KC's

own accounts (and is, in turn, reimbursed pursuant to a letter of credit account for the FEP via a specially created fund in the U.S. Treasury called the Employees Health Benefits Fund).

ii. Administrative Services Only Service Model

57. Blue KC provides "administrative services only" ("ASO") service models to certain plans.

58. Some plan sponsors elect to have ASO services administered locally by Blue KC (collectively, "Local ASO") while other ASO plan sponsors contract with Blue KC which in turn contracts with another BCBS licensee to administer their respective plans ("National Alliance ASO").

59. Under both of these ASO models, Blue KC directly or indirectly provides administrative services, and the plans or plan sponsors pay claims.

60. The Local ASO Plan administrative services agreements ("ASAs") typically include the following language:

> Plan Sponsor and BCBSKC recognize that BCBSKC or Plan Sponsor may receive notice of a pending class action or other type of litigation that seeks recovery of funds based on third party liability (hereinafter collectively referred to as a "Group Litigation"). BCBSKC has no duty or obligation to notify Plan Sponsor (or the Plan) of BCBSKC's receipt of any notice of such Group Litigation. BCBSKC has no duty or obligation to participate in such Group Litigation on behalf of Plan Sponsor (or the Plan). ***However, BCBSKC may, in its sole discretion, elect to participate in such Group Litigation, on its own behalf, or on behalf of Plan Sponsor, or both, in order to obtain recovery of funds.*** In the event BCBSKC decides to participate in such Group Litigation on behalf of Plan Sponsor, BCBSKC is authorized by Plan Sponsor to recover claims expenses or other amounts on Plan Sponsor's behalf, either during or subsequent to the term of this Agreement, that relate to claims incurred and paid during the term of this Agreement. (emphasis added).

61. Since August of 2021, twelve National Alliance ASO groups directed Blue KC to litigate to seek reimbursement of claims paid to GSL at full, posted cash prices, and have executed additional documents explicitly assigning their rights to seek reimbursement of overpayments from GSL to Blue KC. Written assignments have been produced to GSL and are identified by the following

bates labels: BKC00000953; BKC00000955; BKC00000957; BKC00000961; BKC00000963; BKC00000965; BKC00000967; BKC00000969; BKC00000971; BKC00000974; BKC00277202; and BKC00281154.

iii. The Cost-Plus Option

62. Blue KC also offers a unique funding arrangement, Cost Plus, to afford plan sponsors greater flexibility in the financial management of their plan.

63. Through the Cost Plus model, plan sponsors are responsible for fixed cost fees, such as administrative and access fees, and the plan sponsors pay their health plan claims with certain claims pooling protections.

64. Cost-Plus contract addendums contain the following language:

> Legal Actions. ***BCBSKC may, but has no obligation to, pursue recovery (including class action settlement recoveries) from health care providers, manufacturers of health care or other products, or services on behalf of Employer for any cause of action including, but not limited to, causes of action arising out of violations of antitrust law, fraud, claims relating to fraud (including claims under the Racketeering Influenced and Corrupt Organizations Act).*** Employer acknowledges and agrees for itself and its Covered Persons that BCBSKC shall retain sole and exclusive right to all such recoveries and may use such recoveries in its sole and absolute discretion, including, without limitation, to help stabilize BCBSKC's overall rates and to offset expenses and BCBSKC does not share such recoveries with Employer. (emphasis added).

iv. The BlueCard Program

65. The BlueCard Program offers members of BCBS licensees the ability to receive healthcare services while traveling or living outside of the applicable BCBS licensee's service area.

66. Through the BlueCard Program, Blue KC members may obtain "in-network" medical services from providers that have contracted with other BCBS licensees.

67. Likewise, members of other BCBS licensees who obtain medical services in the Kansas City area may obtain "in-network" medical services from providers who have contracted with Blue KC.

68. Under the BlueCard Program, a Blue KC member can receive medical services within the health care provider network of a BCBS licensee in a different geographic region (a "Host Plan"), and such services are treated, priced, and transmitted as "in-network" to the BCBS licensee with whom the member is enrolled (a "Home Plan").

69. When a Blue KC member obtains medical services from a non-participating provider outside of the Kansas City region, the provider typically will submit the claim for reimbursement not directly to Blue KC but to the Host Plan.[5]

70. And, likewise, when other BCBS licensees' members obtain medical services from a non-participating provider inside the Kansas City metropolitan region, the provider typically will submit the claim for reimbursement to Blue KC.

THE COVID-19 PANDEMIC

71. In a January 21, 2020 press release, the Centers for Disease Control and Prevention ("CDC") noted, "there are growing indications that limited person-to-person spread [of COVID-19] is happening. It's unclear how easily this virus is spreading between people . . . CDC continues to believe the risk of [COVID-19] to the American public at large remains low at this time."[6]

72. Less than two months later, however, the World Health Organization ("WHO") declared the COVID-19 outbreak a global pandemic. The WHO expressed grave concern for both the spread and severity of the disease and alarming levels of government inaction.[7]

73. At that time, there were "no proven effective specific treatment strategies" and no approved diagnostic testing.[8]

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[5] Blue KC may also receive claims through the BlueCard Program where a service is administered in the Kansas City area but the provider submits the claim to another BCBSA licensee.
[6] https://www.cdc.gov/media/releases/2020/p0121-novel-coronavirus-travel-case.html
[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7569573
[8] *Id.*

74. Uncertainty about the fatality rate of COVID-19 caused fear and confusion as the pandemic unfolded. Initial reports from abroad estimated a fatality rate as high as 15%. As more data became available, this estimated fatality rate dropped to a range between 4.3% and 11%. More recent data suggests the fatality rate in the United States is roughly 1.8%.[9]

75. Kansas Governor Laura Kelly declared a state of emergency in response to the COVID-19 pandemic on March 12, 2020.[10] In Kansas, the state of emergency expired on June 15, 2021.

76. In Missouri, Governor Michael Parson declared a state of emergency in response to COVID-19 on March 13, 2020.[11] The state of emergency expired on August 31, 2021.

77. The United States Secretary of Health and Human Services declared a Public Health Emergency on January 31, 2020. It has been extended on multiple occasions.

78. Prior to March 2020, the U.S. had only completed 459 tests of patients suspected to have contracted COVID-19.[12] Initially, the CDC controlled the only testing operations in the U.S., which *Science Magazine* described as "a fiasco."[13]

79. Efficient and accurate testing for the virus was, and remains, a key measure to end the pandemic.

80. In February of 2020, due to the rapid spread of COVID-19, the Secretary of the U.S. Department of Health & Human Services ("HHS") authorized the emergency use of *in vitro* diagnostic devices for the detection of COVID-19.[14]

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[9] https://ourworldindata.org/mortality-risk-covid
[10] https://governor.kansas.gov/governor-issues-emergency-declaration-for-covid-19
[11] https://governor.mo.gov/press-releases/archive
[12] https://www.sciencemag.org/news/2020/02/united-states-badly-bungled-coronavirus-testing-things-may-soon-improve
[13] *Id.*
[14] https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices

81. Since the outset of the pandemic, several types of COVID-19 tests were approved for emergency use and have become available to the public including the following:

Test Type	Description	Billing Code	MAC Allowable Rates[15]
COVID-19 Rapid Antigen Test	Rapid Antigen tests detect protein fragments specific to the Coronavirus and are used to diagnose an active infection.	87811	$41.38
COVID-19 Rapid Antibody Test	Antibody tests are "not [used] used to diagnose an active COVID-19 infection."[16] Instead, these tests detect two different types of antibodies (IgM and IgG) that may develop in patients after exposure to COVID-19. This test requires a blood sample.	86328	$45.23
COVID-19 PCR Test[17]	Also called a molecular test, these tests detect genetic material of the virus using a lab technique called polymerase chain reaction (PCR). Many consider this test to be the most accurate diagnostic test.	87635	$51.33
BIO-Fire PCR Test 2.1	This test is like the PCR Test, but instead of detecting only COVID-19, it detects 22 target respiratory pathogens including COVID-19.	0202U	$416.78[18]
GenMark ePlex Respiratory Pathogen 2 Panel	This test is like the PCR Test, but instead of detecting only COVID-19, it detects 21 target respiratory pathogens including COVID-19.	0225U	$416.78

82. Since February 2020, federal, state, and local governments have worked together with numerous health care providers, group plans, and insurers to build a robust testing infrastructure.

[15] Medicare Administrative Contractors ("MACs") are responsible for developing the allowable reimbursement rates for the Medicare program for newly created procedure codes until the Centers for Medicare & Medicaid Services ("CMS") establishes national rates. CMS has not yet established national payable amounts for these tests.

[16] https://www.fda.gov/consumers/consumer-updates/coronavirus-disease-2019-testing-basics

[17] PCR testing is appropriately billed using CPT code 87637 where the test attempts to detect both COVID-19, influenza, and respiratory syncytial virus. This expanded testing is sometimes referred to as a "small panel test." "Large panel PCR testing", such as the BioFire and ePlex tests, are designed to detect 21 and 22 target respiratory pathogens.

[18] Not all MACs have established pricing for the large panel PCR testing GSL administered.

COVID-19 DIAGNOSTIC TESTING UNDER THE FFCRA AND CARES ACT

83. In response to the deepening pandemic crisis, Congress passed the Families First Coronavirus Response Act ("FFCRA").[19] It was signed into law on March 18, 2020.

84. Among many other provisions, the FFCRA requires certain health plans and insurance providers to cover certain COVID-19 *in vitro* diagnostic testing at no cost to the insured patient. FFCRA § 6001(a).

85. The FFCRA only requires coverage for ***diagnostic*** COVID-19 testing.

86. Guidance jointly prepared by the Department of Labor, Department of Health & Human Services, and the Department of the Treasury (Departmental Guidance) from June 23, 2020 (FAQs Part 43) explains:

> **Q5. Is COVID-19 testing for surveillance or employment purposes required to be covered under section 6001 of the FFCRA?**
>
> No. Section 6001 of the FFCRA requires coverage of items and services only for diagnostic purposes as outlined in this guidance. Clinical decisions about testing are made by the individual's attending health care provider and may include testing of individuals with signs or symptoms compatible with COVID-19, as well as asymptomatic individuals with known or suspected recent exposure to SARS-CoV-2, that is determined to be medically appropriate by the individual's health care provider, consulting CDC guidelines as appropriate. However, testing conducted to screen for general workplace health and safety (such as employee "return to work" programs), for public health surveillance for SARS-CoV-2, or for any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19 or another health condition is beyond the scope of section 6001 of the FFCRA.

87. The FFCRA does not require coverage for non-diagnostic testing, such as testing for surveillance, screening, or return to work purposes.

[19] Pub. L. No. 116-127.

88. Departmental guidance (FAQ No. 43 Q.6) contemplates that all FFCRA-mandated testing only be administered by an attending healthcare provider in accordance with currently accepted standards of medical practice. The guidance states, in part:

> the coverage required under section 6001 of the FFCRA for items and services described in section 6001(a) of the FFCRA is not limited with respect to the number of diagnostic tests for an individual, provided that the tests are diagnostic and medically appropriate for the individual, as determined by an attending health care provider in accordance with currently accepted standards of medical practice.

89. Only nine days after the FFCRA was enacted, Congress passed the Coronavirus Aid, Relief, and Economic Security ("CARES") Act of 2020. It was signed into law on March 27, 2020.

90. The CARES Act describes a pricing framework for FFCRA-required coverage for diagnostic testing. CARES Act § 3202.

91. Pursuant to the CARES Act, when there is no negotiated reimbursement rate agreement between the insurer and provider, the insurer typically reimburses the provider at "an amount that equals the cash price for such service as listed by the provider on a public internet website." *Id. at* § 3202(a).

92. *"Cash price* means the charge that applies to an individual who pays cash (or cash equivalent) for a COVID–19 diagnostic test." 45 C.F.R. § 182.20.

93. The CARES Act also requires that providers establish and publicly post on their websites accurate "cash prices." *See* CARES Act § 3202(b)(1) (stating, "each provider . . . shall make public the cash price for such test on a public internet website of such provider.").

94. The provider must display the "cash price" in a manner that "is easily accessible, without barriers, and ensures that the information is accessible" without having to submit personal identifiable information among other requirements. 45 C.F.R. § 182.40.

95. The pricing mechanism described by CARES Act § 3202 contemplates that state law will inform pricing disputes where there is no negotiated rate.

96. Departmental Guidance provides:

> **Q10. How do the requirements of section 3202(a)(2) of the CARES Act interact with state balance billing laws regarding reimbursement for items and services furnished by out-of-network providers or *providers that do not have a negotiated rate with a plan or issuer for COVID-19 tests*?**
>
> Section 3202(a)(2) of the CARES Act provides that, if a plan or issuer does not have a negotiated rate with a provider of COVID-19 diagnostic testing, the plan or issuer shall reimburse the provider in an amount that equals the cash price for such service as listed by the provider on a public internet website, or the plan or issuer may negotiate a rate with the provider that is lower than the cash price. Plans and issuers that do not already have a negotiated rate with a provider may nevertheless seek to negotiate to determine a rate, and state laws governing reimbursements may apply. For example, many states have balance billing laws that establish dispute resolution processes for issuers and providers to determine reimbursement rates for certain items and services. Such dispute resolution processes would continue to apply in these states to the issuers and providers that do not already have a negotiated rate. *Additionally, to the extent that a state law does not prevent the application of the requirements of section 3202(a) of the CARES Act, the state law is not preempted and continues to apply.*
>
> **Q11. How should plans and issuers determine a reimbursement rate for providers of COVID-19 testing if they do not have a negotiated rate with the provider and the provider has not made available on a public internet website the cash price of a COVID-19 diagnostic test, as required by section 3202(b) of the CARES Act?**
>
> The requirement imposed by section 3202(a) of the CARES Act to reimburse the provider an amount that equals the cash price of a COVID-19 test is contingent upon the provider making public the cash price for the test, as required by section 3202(b) of the CARES Act. If the provider has not complied with this requirement, and the plan or issuer does not have a negotiated rate with the provider, the plan or issuer may seek to negotiate a rate with the provider for the test. However, section 3202(a) is silent with respect to the amount to be reimbursed for COVID-19 testing in circumstances where the provider has not made public the cash price for a test and the plan or issuer and the provider cannot agree upon a rate that the provider will accept as payment in full for the test. The Departments note that section 3202(b) of the CARES Act grants the Secretary of HHS authority to impose civil monetary penalties on any provider of a diagnostic test for COVID-19 that does not comply with the requirement to publicly post the

> cash price for the COVID-19 diagnostic test on the provider's website and has not completed a corrective action plan, in an amount not to exceed $300 per day that the violation is ongoing. ***If the method for determining reimbursement for out-of-network services (or services for which there is no negotiated rate) is governed by applicable state law, then state law continues to apply as described in Q10 above***.

Departmental Guidance FAQ 43 Nos 10-11 (emphasis added).

GSL SUBMITS THOUSANDS OF SUSPECT CLAIMS TO BLUE KC

97. On March 2, 2021, GSL sent correspondence to Blue KC regarding the testing claims it would soon be submitting to Blue KC. **Exhibit C**.

98. In its March 2, 2021 correspondence, GSL informed Blue KC "[y]ou should anticipate that the claims submitted to your company by GS Labs will set out the GS Labs Cash Price on the date of service identified in the claim . . . ***[y]our company must pay GS Labs at its publicly posted cash price rates***." (emphasis added). **Exhibit C**.

99. GSL's correspondence then claimed its established cash prices were the following:

Test Name	Billing Code	Cash Price
COVID-19 RAPID ANTIGEN TEST	87811	$380.00
COVID-19 RAPID ANTIBODY TEST	86328	$380.00
COVID-19 PCR TEST	87635	$385.00
COVID-19 BIO-FIRE PCR TEST	0202U	$979.00
COVID-19 EPLEX PCR TEST	0225U	$979.00

100. GSL's statements regarding its cash prices were material and false. GSL had not established "cash prices" at the rates identified above.

101. GSL's statements regarding its "cash prices" were designed to induce Blue KC to pay GSL for testing at unreasonable rates not required by law.

102. GSL then submitted over 10,000 claims ("the claims")[20] exceeding over $11 million at the rates referenced in the March 2, 2021 correspondence.

103. The purported dates of service for the claims range at least from November of 2020 to the present.

104. To date, GSL has sought reimbursement for over:

a.) 13,417 claims for rapid antigen testing;

b.) 13,484 claims for specimen collection;

c.) 11,504 claims for rapid antibody testing; and

d.) 800 claims for various types of PCR testing.

105. Of the over $11 million in total claims GSL submitted involving Blue KC or its members:

a.) Over $4.3 million arises from services purportedly provided to Blue KC members in the Kansas City area;

b.) Over $1.6 million were received from other BCBS affiliated companies through the BlueCard Program relating to Blue KC members;

c.) Over $4.8 million is the result of other BCBS licensees' members seeking services in the greater Kansas City area; and

d.) Approximately $280,000.00 arise from services purportedly provided to Blue KC members administered through the National Alliance ASO program.

106. Attached to this Second Amended Complaint, and filed under seal, is Blue KC's **Exhibit D** which identifies each claim involving Blue KC that GSL submitted to Blue KC prior to the filing of this litigation. Each claim is identified by (a) claim source (Local, Home, Host, National Alliance), patient name, patient sex, patient DOB, purported date of service, Claim ID, Subscriber

[20] GSL's claims typically seek reimbursement for multiple services.

Group Name, Funding Category, ERISA Status, number of claims, charges, amount paid, and amount paid at GSL's sham cash price. Claims at issue in Blue KC's Count III are highlighted.

107. GSL typically submitted its claims to Blue KC as an 837P electronic record. Upon information and belief, each of its electronic claims submissions contained a data element "Y" for the CLM06 data element, which is equivalent to affirming Box 31 on the standardized NUCC 1500 Health Insurance Claim Form ("Form 1500").

108. Box 31 of Form 1500 states:

> SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made part thereof.)
>
> Signed _____ Date _____

109. On the reverse side of each Form 1500, among other terms and conditions, each provider must certify the following affirmation: "the services listed above [on the claim form] were medically indicated and necessary to the health of this patient and were personally furnished by me or my employee under my personal direction."

110. GSL's certifications in its electronic claims submissions are material and false since the ordering physicians did not personally furnish the tests or personally direct his employees to furnish the tests.

111. In fact, GSL does not exercise patient-specific physician judgment in ordering any of the testings at issue. Instead, GSL purports to rely on standing, blanket orders. *See* **Exhibits E, F, and G**. Upon information and belief, the physicians that signed the standing, blanket orders do not reside in the Kansas City metropolitan area and have little or no role in ensuring that their orders were followed or that testing was medically appropriate as applied to each patient.

112. Many of GSL's claims were submitted under circumstances indicating testing was not performed as billed. For instance:

a.) GSL does not create and maintain adequate documentation to substantiate that the tests in question were administered, were administered under circumstances that would cause the tests to be covered under the FFCRA, or were administered in a manner that produced reliable results. In the alternative, GSL failed to provide such documentation to Blue KC upon request. Blue KC estimates GSL has produced test results for only approximately 15% of billed charges, and patient intake and consent forms for approximately 23% of filed charges;

b.) Certain records indicate a particular type of test (the Aries Luminex test) was administered on a given date, however, other records GSL produced indicate that on the purported date of service GSL was not using the test referenced by the record;

c.) Certain bills contain repeat and duplicative charges - for instance, a claim with the same member, same claimed service(s), with the same purported service date were submitted more than once; and

d.) Records involving GSL's large panel PCR testing (the ePlex and Biofire testing described above) in some circumstances do not reflect results of most of the pathogens for which the tests were designed to detect.

113. Further, many of the claims submitted by GSL include claims for services that, if they were actually administered, appear to have been administered in bad faith, or were non-diagnostic. For instance:

a.) Approximately 74% of the pre-suit claims GSL submitted to Blue KC include a charge for an antibody test. According to the FDA "Antibody tests **should**

not be used to diagnose an active COVID-19 infection."[21] There is no legitimate medical or diagnostic reason to routinely, and as a matter of course, perform both rapid antigen and rapid antibody tests together;

b.) For a number of its claims, GSL conducted repeat antibody tests on the same individuals in the same week or over the course of multiple weeks. In some instances antibody tests were administered after a confirmed COVID-19 infection. There is no legitimate medical or diagnostic reason to perform antibody tests in such a manner;

c.) For a number of its claims, GSL performed antigen testing in circumstances where patients had neither symptoms of COVID-19 nor a concern about a potential exposure to COVID-19. These tests are not diagnostic and are not covered by the FFCRA;

d.) In many cases, approximately 47% of the records received to date, GSL used false diagnostic codes contradicted by patient intake forms; and

e.) GSL submitted claims for large panel PCR testing using various procedure codes. These tests are designed to detect dozens of other pathogens including adenovirus, human metapneumovirus, human rhinovirus, influenzas, para influenzas, Bordetella para pertussis, and chlamydia pneumoniae. Associated medical records identify no symptoms, suspected exposures, other test results, or justifications that would warrant using these expensive and extensive tests rather than simple antigen or targeted PCR tests.

[21] https://www.fda.gov/consumers/consumer-updates/coronavirus-disease-2019-testing-basics (last visited February 15, 2022).

These tests were not diagnostic or administered in accordance with currently accepted standards of medical practice by the patients' attending healthcare provider.

114. One witness, a former employee of GSL, reported:

> ***[GSL was] manipulat[ing] people into thinking they need all three COVID tests (antibody, antigen, and PCR).*** The nurses were told to go to the cars and immediately start doing the antibody test (finger stick) to distract the patient. ***Nurses were being let go if they did not persuade enough people to get all three tests. Management would follow the nurses to make sure they were getting patients to do all three tests (even if they weren't needed). Patients are being lied to just so this company can make a profit***. (emphasis added).

115. Another former employee of GSL working at a different GSL location in a different state-reported GSL was coercing prospective patients to obtain both antigen and antibody tests even when the patient only requested one test. Ultimately, that witness reported that GSL terminated her employment for "not selling enough tests."

116. That former GSL employee reported:

> Starting the week of 1/11/21 we were told we needed to get every person to take the antibody test as insurance will pay for both. I inquired about what the "runners"/check-in people were saying after being yelled at by multiple cars for confirming they were having both tests done when they did not want that. . . On 1/18/21 the lead RN [name omitted], shadowed me after telling me my numbers were the lowest. . . She observed me sell and educate patients on the extra test and ***the following day fired me for not selling enough tests. She claims this came from HQ in Omaha***. (emphasis added).

117. Upon information and belief, the witness statements described in the preceding paragraphs are accurate descriptions of GSL's usual policies and practices.

118. Upon information and belief, after this litigation was filed, GSL stopped administering antibody tests on or about October 20, 2021.

119. Upon information and belief, after this litigation was filed, GSL stopped administering large panel PCR tests on or about August 5, 2021.

GSL'S CASH PRICES ARE EXCESSIVELY UNREASONABLE AND WERE POSTED IN BAD FAITH

120. GSL's purported cash prices are unconscionable, arbitrary, grossly excessive, and unreasonable.

121. For much of the relevant time, GSL states the following are its established cash prices (hereinafter "sham cash prices") which are posted on its website:

Test Name	Description	Billing Code (CPT) (HCPCS)	Price/Cash Price
COVID-19 RAPID ANTIGEN TEST	The COVID-19 rapid antigen test detects protein fragments specific to the Coronavirus. This test requires a nasal swab. For the antigen test, GS Labs is using the CareStart test for Rapid Detection of SARS-CoV-2. Results may come back in as soon as 20 minutes.	87811	$380.00
COVID-19 RAPID ANTIBODY TEST	This test detects two different types of antibodies (IgM and IgG) that may develop in most patients after exposure to SARS-CoV-2. The IgM/IgG test identifies whether a person has developed antibodies for SARS-CoV-2 and can do so as soon as 48 hours after exposure. For the IgM/IgG test, GS Labs is using the Azure Biotech Inc. Assure IgM/IgG Rapid Test Device. At this time, it's unknown how much protection antibodies might provide against reinfection.	86328	$380.00
COVID-19 PCR TEST	When supplies are available, we offer different COVID-19 Polymerase Chain Reaction (PCR) tests. A PCR test is the most accurate test available for detecting COVID-19. The PCR test detects RNA (or genetic material) that is specific to the SARS-CoV-2 virus and can detect the virus within days of infection, even those who have no symptoms. The only pathogen this particular test will check for is COVID-19. The sample is obtained via a nasopharyngeal swab. *THIS TEST IS CURRENTLY UNAVAILABLE DUE TO SUPPLIES.*	87635	$385.00
Biofire – Respiratory Panel PCR	When supplies are available, we offer the Biofire respiratory pathogen panel PCR. A PCR test is the most accurate test available for detecting COVID-19. The BioFire identifies 22 of the most common viral and bacterial organisms associated with upper respiratory infection, including SARS-CoV-2, the virus that causes COVID-19. The sample is obtained via a nasopharyngeal swab.	0202U	$979.00
EPLEX-Respiratory Panel PCR	When supplies are available, we offer the Genmark ePlex respiratory pathogen panel PCR. A PCR test is the most accurate test available for detecting COVID-19. The Genmark ePlex identifies 21 of the most common viral and bacterial organisms associated with upper respiratory infection, including SARS-CoV-2, the virus that causes COVID-19. The sample is obtained via a nasopharyngeal swab.	0225U	$979.00

122. GSL claims its purported cash prices have varied over time.

123. GSL stated the following are its posted cash prices at the dates and times identified:

Date	Time	Test Type	CPT Code	Price
11/24/2020		Antibody	0224U	$ 799.00
11/24/2020		Antigen	0223U	$ 799.00
11/24/2020		PCR	0240U	$ 899.00
11/28/2020		Antibody	0224U	$ 799.00
11/28/2020		Antigen	0223U	$ 799.00
11/28/2020		PCR	0240U	$ 899.00
12/3/2020		Antibody	0224U	$ 899.00
12/3/2020		Antigen	0223U	$ 999.00
12/3/2020		PCR	0240U	$ 1,199.00
12/10/2020		Antibody	0224U	$ 899.00
12/10/2020		Antigen	0223U	$ 999.00
12/10/2020		PCR	0240U	$ 1,199.00
12/14/2020		Antibody	0224U	$ 899.00
12/14/2020		Antigen	0223U	$ 999.00
12/14/2020		PCR	0240U	$ 1,199.00
12/15/2020		Antibody	0224U	$ 799.00
12/15/2020		Antigen	0223U	$ 899.00
12/15/2020		PCR	0240U	$ 999.00
12/17/2020	3:25	Antibody	0224U	$ 599.00
12/17/2020	3:25	Antigen	0223U	$ 699.00
12/17/2020	3:25	PCR	0240U	$ 699.00
12/17/2020	21:38	Antibody	0224U	$ 599.00
12/17/2020	21:38	Antigen	0223U	$ 699.00
12/17/2020	21:38	PCR	0240U	$ 699.00
12/22/2020	2:30	Antigen	0223U	$ 599.00
12/22/2020	2:30	Antibody	0224U	$ 599.00
12/22/2020	2:30	PCR	0240U	$ 599.00
12/22/2020	13:37	Antigen	0223U	$ 365.00
12/22/2020	13:37	Antibody	0224U	$ 365.00
12/22/2020	13:37	PCR	0240U	$ 365.00
12/22/2020	15:03	Antigen	0223U	$ 385.00
12/22/2020	15:03	Antibody	0224U	$ 385.00
12/22/2020	15:03	PCR	0240U	$ 385.00

12/22/2020	17:33	Antigen	0223U	$	379.00
12/22/2020	17:33	Antibody	0224U	$	385.00
12/22/2020	17:33	PCR	0240U	$	385.00
12/23/2020	1:15	Antigen	0223U	$	380.00
12/23/2020	1:15	Antibody	0224U	$	380.00
12/23/2020	1:15	PCR	0240U	$	385.00
1/26/2021	16:22	Antigen	0223U	$	380.00
1/26/2021	16:22	Antibody	0224U	$	380.00
1/26/2021	16:22	PCR	0240U	$	385.00
3/2/2021	4:38	Antigen	87811	$	380.00
3/2/2021	4:38	Antibody	86328	$	380.00
3/2/2021	4:38	PCR	87635	$	385.00
3/2/2021	4:38	PCR - BioFire	0202U	$	979.00
3/10/2021	0:08	Antigen	87811	$	380.00
3/10/2021	0:08	Antibody	86328	$	380.00
3/10/2021	0:08	PCR	87635	$	385.00
3/10/2021	0:08	PCR - BioFire	0202U	$	979.00
		EPLEX	0225U	$	979.00

124. As of January 9, 2022, GSL reduced its posted purported cash price for rapid antigen testing to $179.00, and for a PCR testing to $229.00.

125. Prior to the filing of this litigation, the two types of tests most frequently billed by GSL are the COVID-19 rapid antigen test and the rapid antibody test.

126. Each of these tests is available at wholesale purchase for as low as $5.00 per test.

127. GSL also typically billed Blue KC an additional $50 charge for specimen collection using the "G2023" procedure code along with the purported cash prices identified above.

128. GSL also directly charged many Blue KC members a $49 "administrative fee" in addition to any amounts collected from insurers. This fee was later reduced to $5 and then discontinued.

129. One version of GSL's consent form states the following: "In order to set you up as a user in our system and give you access to same-day scheduling and same-day results, GSL is charging a $49 set up fee at participating locations. It is not a co-pay or coinsurance or a deductible." *See e.g.* **Exhibit H, page 1, paragraph 1.**

130. GSL's sham cash prices for certain tests are up to ten times higher than the MAC allowable rates, and the Kansas City metropolitan area is well-served by many other providers offering the same or similar COVID-19 tests at substantially lower prices.

131. The following chart compares GSL pricing to a sample of other Kansas City area COVID-19 testing providers:

Test Type	GSL's Cash Price	Medicare Allowable Rates	Drive-Thru Clinics	Urgent Care	Hospitals & Health Systems	Independent Labs
Rapid Antigen Test (87811)	$380	$41.38	$0-$80	$75-$100	Ave: N.A. Low: N.A. High: N.A.	$125
Rapid Antibody Test (86328)	$380	$45.23	$35-$95	N.A.	Ave: $95 Low: $90 High: $96	$75
PCR Test Small Panel (87635)	$385	$51.31	$135-$165	$100-$119	Ave: $87 Low: $26 High: $271	$119-$175
PCR Test Large Panel (0202U)	$979	N.A.	N.A.	N.A.	$228	N.A.

132. No unusual or exceptional circumstances justify GSL's exceptionally high purported cash prices.

133. GSL does not operate in remote communities or other communities where unusually high operating costs would be expected.

134. Rather than providing augmented (or even basic) medical services, GSL purports to provide its testing only for "non-diagnostic" or "informational" purposes, disclaims any physician-patient relationship, and demands that each member indemnify it for any claims, damages, or attorney's fees arising out of the testing services.

135. GSL's consent forms include the following language:

a.) "I am electing to have this antibody test for informational purposes only." **Exhibit H, page 1, paragraph 3;**

b.) "Any results [with respect to antigen testing] I receive are for informational purposes only and do not constitute a medical diagnosis." **Exhibit H, page 1, paragraph 4;**

c.) "I understand that I am not creating a patient relationship with GSL or its affiliates or providers by participating in testing. The lab is not acting as my medical provider and does not replace treatment by my primary medical provider. I assume complete and full responsibility to seek and obtain medical and other advice relating to this testing and any results I receive. Should I have questions [sic] or concerns regarding my results, or a worsening of my condition, I shall promptly seek advice and treatment from an appropriate medical provider." **Exhibit H, page 2, paragraph 2;** and

d.) "I agree to indemnify and hold harmless GSL and its staff against any and all claims, suits, or actions of any kind whatsoever for liability, damages, compensation, or otherwise brought by me or anyone on my behalf, including attorney's fees and any related costs, if litigation arises pursuant to any claims made by me or anyone else acting on my behalf. If GSL or its staff or representatives incurs any of these types of expenses, I agree to reimburse GSL for these expenses." **Exhibit H, page 2, paragraph 4.**

136. In light of the locations of GSL's operations, its actual operational costs, its disclaimer of any actual physician-patient relationship, and its insistence on full indemnification from the patients

it supposedly serves, GSL's purported cash prices are unconscionable, arbitrary, grossly excessive, and unreasonable, and were not set in good faith.

137. GSL stated that its and excessive prices were due to the fact that it is a "top notch lab" operating thirty sites in multiple states, it worked with consultants to develop a "unique model," and it offers "a call line," "extended hours," "prompt results," and "same day appointments."

138. Multiple reports contradict GSL's claims regarding the quality of its services including the following:

a.) "*I walked around with COVID for a week, because of late results*" December 19, 2020;[22]

b.) "*Kansas looks at whether Lenexa lab price gouged on Covid-19 tests*" December 22, 2020;[23]

c.) "*Lab's 3-month data delay leads to abnormally high daily Covid total in Allegheny County*" April 14, 2021;[24]

d.) "*Slow reporting from labs can hinder coronavirus response, create doubt*" May 7, 2021 (stating, "The late reports potentially sow doubt in data used to gauge the severity of virus spread");[25] and

e.) The Better Business Bureau rates GSL a 1.42 out of five stars – an F ranking.[26]

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[22] https://www.kctv5.com/i-walked-around-with-covid-for-a-week-because-of-late-results-gs-labs-subcontractor/article_be3f0647-7948-5cd1-ba8e-fb5f75c432cd.html

[23] https://www.bizjournals.com/kansascity/news/2020/12/22/covid-19-test-price-gouging-inquiry-gs-labs.html

[24] https://triblive.com/local/westmoreland/labs-3-month-data-delay-leads-to-abnormally-high-daily-covid-total-in-allegheny-county

[25] https://triblive.com/local/westmoreland/slow-reporting-from-labs-can-hinder-response-to-coronavirus-outbreaks

[26] https://www.bbb.org/search?find_country=USA&find_loc=kansas%20city&find_text=gs%20labs&page=1&sort=Relevance (last visited 2/21/2022).

139. Moreover, public records describe serious quality and public health concerns at GSL facilities. These concerns include the following:

a.) GSL informing patients their COVID-19 test results were negative when they were in fact positive;

b.) GSL providing patients with incorrect lab results (another patient's results);

c.) GSL not providing results to patients;

d.) GSL providing results to patients, but only days after the testing;

e.) GSL providing false or unverified testing results to patients so that those patients could board airplanes or otherwise use proof of a negative test result;

f.) GSL operating in unsafe and non-sterile working conditions;

g.) GSL failing to provide employees sufficient protective medical equipment, such as medical gloves; and

h.) GSL failing to properly handle medical waste.

140. Via correspondence on February 26, 2021, GSL admitted that "the validity of the positive results on the rapid antigen test for COVID-19 obtained from GS Labs between Feb. 17 – Feb. 22, 2021, may be inaccurate . . . it is impossible at this point to tell which of the positive results are true positive and which ones are false positives." **Exhibit I.**

141. On March 18, 2021, the Nebraska Department of Health and Human Services sent correspondence to GSL noting, GSL "is not in compliance with all of the Conditions required for certification in the CLIA[27] program." **Exhibit J , page 1, paragraph 2.**

[27] CLIA (Clinical Laboratory Improvement Amendments) is a CMS program with the objective of ensuring quality laboratory testing.

142. Via correspondence dated May 14, 2021, GSL admitted that it failed to follow certain unidentified "applicable laboratory standards for testing facilities" protocols. **Exhibit K, paragraph 1.**

143. On October 5, 2021, GSL was notified that its lab "was not in compliance with Condition-level Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements."

144. One report noted GSL failed to timely report three months' worth of covid test result data to government health officials. "The late reports potentially sow doubt in data used to gauge the severity of virus spread."[28]

145. Commenting on an instance in which GSL provided incorrect results to a patient, one Jackson County, Missouri Health Department employee commented, "[t]his raises additional concerns about [GSL] providing incorrect information to not only clients but the state of Missouri as well. ***In a [ ]sense of surveillance and control of infectious disease, this situation makes it much more difficult to control the spread of COVID-19.***" (emphasis added)

146. GSL has been unable to offer any credible justification or explanation regarding its excessive sham cash prices.

147. GSL did not operate a "top notch" lab and, instead, operated facilities that produce flawed, delayed, and unreliable results injurious to public health.

148. Furthermore, GSL's purported cash pricing would still be objectively excessive and unreasonable even if its statements regarding the quality of its services were true.

149. GSL's purported cash prices are arbitrary, grossly excessive, unconscionable, and unreasonable, and were not set in good faith.

[28] https://www.yahoo.com/now/slow-reporting-labs-hinder-coronavirus-000700957.html (last visited 2/21/2022).

150. GSL obtained testing materials for the purposes of resale at prices in excess of prevailing market prices. These testing materials in question were designated as "scarce materials" pursuant to the Defense Production Act.

151. GSL's posted "cash prices" and claims for those prices amount to unlawful price gouging and disaster profiteering. *See generally* 50 U.S.C. § 4512, KSA 50-6,106; Mo. Rev. Stat. § 407.010, *et seq.*, 15 C.S.R. 60-8.030.

152. The prices posted and claimed by GSL are unenforceable, contrary to the public interest as articulated by 50 USC § 4512, KSA. 50-6,106; KSA 50-627; Mo. Rev. Stat. § 407.010, *et seq.*, 15 C.S.R. 60-8.030-.04.

GSL USED A FALSE "CASH PRICE" IN CONNECTION WITH ITS CLAIMS

153. Not only are GSL's sham cash prices unconscionable, arbitrary, grossly excessive, and unreasonable, and were not set in good faith, but they were intended to dupe Blue KC, health care benefit programs, and health care benefit plans into paying excessive fees to GSL.

154. GSL knowingly and intentionally posted on its website sham cash prices that did not represent GSL's established cash prices.

155. Despite the CARES Act's requirement that GSL post accurate cash prices on its website, GSL did not post accurate cash prices.[29]

156. Instead, GSL posted inflated and illusory prices designed to mislead insurers and health plans and unjustly enrich GSL.

[29] *See* CARES Act § 3202(b)(1) ("each provider … shall make public the cash price for such test on a public internet website of such provider."). "Cash price means the charge that applies to an individual who pays cash (or cash equivalent) for a COVID–19 diagnostic test." 45 C.F.R. § 182.20 (effective January 1, 2021).

157. The use of sham cash prices as described herein constitutes the use of a "fraudulent insurance act" under state law. *See* MO. Rev. Stat. § 375.991; KSA 40-2,118; 18 USC §§ 1347, 1343, 1035; 18 USC § 1952.

158. At the same time GSL posted its excessive purported cash prices and demanded that insurers pay those sham cash prices, GSL routinely, and as a matter of policy, refused to provide treatment to patients who sought to pay cash for COVID-19 testing.

159. After one GSL patient complained to her state Attorney General's office about GS Labs' "ridiculously high" posted prices, ***GSL attempted to defend itself by admitting to that state Attorney General's office that GSL's posted cash prices were only meant for insurance companies and not cash-paying customers***.

160. In responding to that consumer's complaint, on February 17, 2021, GSL told the State Attorney General's office, "***it is important to note that the 'cash prices' listed on GS Labs' website generally are charged only to insurance companies, and <u>not</u> consumers. . . Again, these 'cash prices' apply to insurance companies only***. . ." (underline in original, additional emphasis added). GSL admitted it "never charged" an individual the posted cash price.

161. GSL admitted that the cash prices it posted were not true "cash prices" or "charge[s] that appl[y] to an individual who pays cash (or cash equivalent) for a COVID-19 test." *See* 45 CFR § 18.20.

162. Instead, GSL's purported cash pricing is a scheme or artifice designed to dupe insurers and group health plans into paying claims at grossly inflated rates.

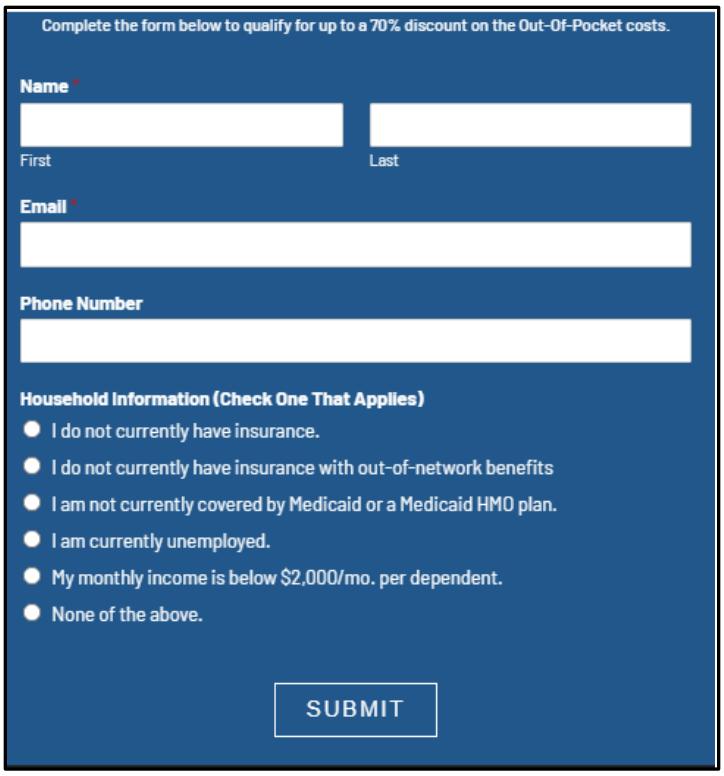
163. The publicly posted sham cash prices were not a true "cash prices" as that term is used by Section 3202 of the CARES Act.

164. Although GSL began its operations in the Kansas City area in the autumn of 2020 it claims it did not accept any purported cash price payments from out-of-pocket payees prior to December 22, 2020.

165. After December 22, 2020, GSL may have changed its practices and began accepting patients that paid the full cash price under very limited circumstances. However, when GSL began to accept cash patients, it always, or nearly always, made available a substantially lower price to any uninsured patient who requested the lower price.

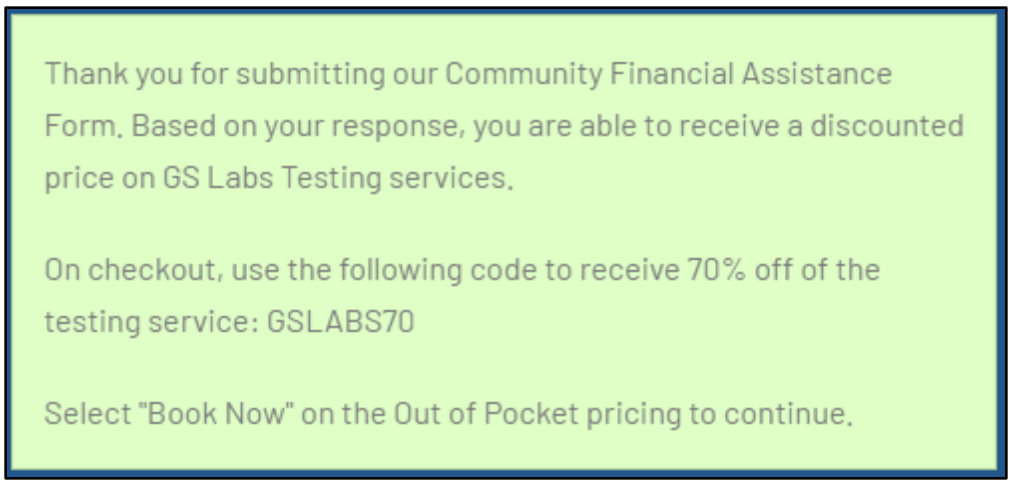
166. For instance, at the same time GSL told uninsured patients that it would accept $114.00 to conduct basic rapid antigen testing (irrespective of that patient's financial need), GSL represented to insurers that its "cash price" for the same service was $380.00.On February 19, 2021 correspondence GSL sent to the Missouri Department of Commerce and Insurance, GSL represented that the cash price for tests is $380-$385, but any uninsured individual could receive a 70% discount[30] – irrespective of that person's financial need. **Exhibit L**. When booking a testing appointment through GSL's website, there are two options: "Bill My Insurance" and "Out-of-Pocket." The "Out-of-Pocket" option directs patients to "Complete the form below to qualify for up to a 70% discount on the Out-Of-Pocket costs." The following is that form:

[30] After this suit was filed, GSL reduced the discount to 50%.



163. As reflected above, the form includes radio buttons allowing the user to select "I do not currently have insurance," "I do not currently have insurance with out-of-network benefits," "I am not currently covered by Medicaid or a Medicaid HMO Plan," and "My monthly income is below $2,000/mo. per dependent."

164. Upon information and belief, if the user selects any option except "none of the above," and without providing any additional information or verification, he or she receives the following message:



165. GSL has admitted it offered a lower rate for uninsured patients and a higher rate for insured patients.

166. GSL knowingly and willfully executed a scheme or artifice to defraud health insurers and plans by posting a sham cash price and demanding that group health plans and insurers pay its sham cash prices.

GSL MAKES UNREASONABLE DEMANDS

167. After receiving the March 2, 2021 correspondence and the claims, Blue KC approached GSL to negotiate reasonable rates for the claims, as envisioned by applicable law. *See* CARES Act 3202(a)(2) (stating, "[i]f the health plan or issuer does not have a negotiated rate with such provider, such plan or issuer . . . may negotiate a rate with such provider for less than such cash price").

168. After March 2, 2021, Blue KC and GSL negotiated regarding GSL's claims. These negotiations included several discussions regarding the services offered, lack of medical records, and excessive posted cash prices.

169. GSL continued to insist it was entitled to be reimbursed at its full sham cash prices.

170. For instance, on April 20, 2021, an agent of GSL negotiating on GSL's behalf wrote Blue KC, stating, in part: "It is important to our negotiations that you understand that past testing services have been performed for enrollees and booked at the cash prices published by GSL on its website. These fees are already due and owing by [Blue KC]."

171. Later, the negotiations reached an impasse after GSL refused Blue KC's offer to accept reasonable rates and demanded that Blue KC pay its sham cash prices less a small discount.

COUNT I. DECLARATORY JUDGMENT

172. The preceding paragraphs are incorporated by reference as if set forth fully herein.

173. Plaintiff brings this action seeking declarations of the parties' rights and obligations under various health insurance plans, programs, and policies that Blue KC administers or insures and each claim GSL has made on any one of them.

174. The above-described events give rise to a substantial, ripe, and justiciable dispute between the parties to this action, namely whether Blue KC is obligated to pay the claims described above.

175. Further, with respect to unpaid claims arising from ERISA-governed plans in which Blue KC is a plan fiduciary, Blue KC seeks a bill for instructions or other equivalent equitable relief under ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3). *See generally Dakotas & W. Minnesota Elec. Indus. Health & Welfare Fund by Stainbrook & Christian v. First Agency, Inc.*, 865 F.3d 1098, 1103 (8th Cir. 2017).

176. GSL knowingly and willfully concealed or misrepresented material facts or circumstances relating to its claims and, in so doing, forfeited its rights, if any, to reimbursement for the claims made.

177. GSL knowingly and willfully acted in bad faith in connection with the claims described above and, in so doing, has forfeited its rights, if any, to reimbursement for the claims made.

178. GSL knowingly and willfully disregarded its statutory obligations under the CARES Act to post its actual cash prices for the services in question and, in so doing, has forfeited its rights, if any, to reimbursement for the claims made.

179. GSL knowingly and willfully violated state and federal law regarding disaster profiteering and price gouging and, in so doing, has forfeited its rights, if any, to reimbursement for the claims made.

180. The sham cash prices GSL purported to establish are contrary to public policy, unlawful, unconscionable, arbitrary, grossly excessive, and unreasonable, and were not set in good faith and are impermissible under the CARES Act, state law, and federal common law.

181. GSL continues to demand that Blue KC pay grossly and unnecessarily excessive reimbursement rates for the claims described above.

182. Blue KC refuses to submit to GSL's demands.

183. Accordingly, pursuant to 28 U.S.C. § 2201, ERISA § 502(a)(3), and Mo. Rev. Stat. Section 527.010, *et seq*, a judicial declaration or other appropriate equitable relief is necessary and appropriate to specify that the rights of the parties with respect to claims GSL submitted to Blue KC or involving Blue KC's members.

184. Plaintiff has sustained damage as a result of GSL's bad faith, concealments, misrepresentations, and use of objectively unreasonable and excessive sham "cash prices," in that it has incurred substantial costs and expenses for claim response, investigation, and attorneys' fees, which continue to accrue.

185. Plaintiff is entitled to recover its attorneys' fees and litigation expenses accrued in investigating and litigating this matter and such an award is proper under Federal Rules of Civil Procedure 54 and 58, 28 U.S.C. § 2202, 29 U.S.C. § 1132(g)(1), and/or Missouri's declaratory judgment statute, Mo. Rev. Stat. Section 527.010, *et seq*.

COUNT II. INJUNCTIVE RELIEF

186. The preceding paragraphs are incorporated by reference as if set forth fully herein.

187. At all times relevant, GSL was a "non-participating" provider purportedly providing "out of network services" to Blue KC members.

188. In a section titled "ATTENTION BLUE CROSS/BLUE SHIELD MEMBERS," GSL's consent forms state, "I hereby authorize GS Labs to charge my credit card for the full amount of all services rendered by GS Labs or its contractors fifteen (15) days after the test." **Exhibit M, page 2, paragraph 5.**

189. In a section titled "Financial Responsibility," GSL's consent forms state, "I agree that I am personally financially responsible for payment of fees for all tests ordered and collected by GSL or its representatives or contractors at my request. It is my responsibility to know my own insurance benefits, including whether GSL is a contracted provider and any covered benefits and exclusions . . . " and "**I understand that if my insurance company denies coverage or payment for the services provided to me, or fails to remit timely payment on my claim (within thirty (30) days), I assume full financial responsibility and will pay all charges in full.**" **Exhibit M, page 3, paragraph 3.** (emphasis in original).[31]

190. Prior to filing this lawsuit, Blue KC demanded that GSL agree that it would not balance bill Blue KC's members.

191. GSL did not promptly agree to refrain from balance billing Blue KC members.

192. In light of the unique circumstances of this dispute, GSL should be enjoined from balance billing Blue KC members.

193. Joint Departmental Guidance states:

[31] GSL's website makes contradictory representations to stating, "*You are not responsible for paying any outstanding balance shown on your [Explanation of Benefits]*." https://gslabstesting.com/covid-19-pricing-transparency

> **Q9. Does section 3202 of the CARES Act protect participants, beneficiaries, and enrollees from balance billing for a COVID-19 diagnostic test?**
>
> The Departments read the requirement to provide coverage without cost sharing in section 6001 of the FFCRA, together with section 3202(a) of the CARES Act establishing a process for setting reimbursement rates, as intended to protect participants, beneficiaries, and enrollees from being balance billed for an applicable COVID-19 test. Section 3202(a) contemplates that a provider of COVID-19 testing will be reimbursed either a negotiated rate or an amount that equals the cash price for such service that is listed by the provider on a public website. In either case, the amount the plan or issuer reimburses the provider constitutes payment in full for the test, with no cost sharing to the individual or other balance due. Therefore, ***the statute generally precludes balance billing for COVID-19 testing***. However, section 3202(a) of the CARES Act does not preclude balance billing for items and services not subject to section 3202(a), although balance billing may be prohibited by applicable state law and other applicable contractual agreements.[32] (emphasis added).

194. Blue KC has a substantial interest in preventing GSL from balance billing its members.

195. If GSL were to balance bill Blue KC's members, it would inevitably cause hundreds or thousands of complaints, appeals, and a substantial and unnecessary administrative burden.

196. Additionally, if GSL were to balance bill Blue KC's members, Blue KC would be harmed in that a portion of its members and the employers and other entities who select Blue KC to administer its plans would likely, incorrectly, fault Blue KC for GSL's bills. Balance billing could result in a loss of membership that would be practicably difficult to prevent or precisely quantify.

197. Further, if GSL were to attempt to collect the claims from Blue KC members directly, it would discourage Blue KC members and others who learn of the balance billing from obtaining additional appropriate COVID-19 diagnostic testing services in the future. Balance billing under these circumstances would create the real possibility of harm to both Blue KC members, Blue KC, and the broader community.

[32] https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf (emphasis added).

198. Neither public health nor innocent Blue KC members should be harmed by Blue KC's efforts to thwart GSL's scheme.

COUNT III. UNJUST ENRICHMENT AND MONEY HAD AND RECEIVED

199. The preceding paragraphs are incorporated by reference as if set forth fully herein.

200. Several plans and programs administered by Blue KC paid at least some of GSL's claims at GSL's full sham cash prices.

201. Defendant intentionally omitted material facts and made intentional misrepresentations of material facts relating to the claims submitted to Plaintiff for reimbursement with the intent to induce Plaintiff and others to rely on those misrepresentations. Further, Defendant omitted material facts relating to the claims submitted to Plaintiff for reimbursement. Defendant engaged in unlawful price gouging and related misconduct.

202. Defendant had superior and special knowledge of the scheme or artifice, as set forth herein, and took steps designed to prevent Plaintiff and others from identifying the scheme or artifice used in conjunction with the claims submitted to Plaintiff.

203. When monies were paid to GSL or to members at the full sham cash prices, the payors did not know or fully appreciate that GSL had made materially false statements and material omissions in connection with the claims.

204. Had the individuals with discretion to pay or reject the claims been aware of the misrepresented facts, omitted facts, and bad faith, the claims would not have been paid.

205. When these claims were paid at the sham cash prices the payors were not obligated to pay, GSL obtained a benefit that it was not entitled to receive.

206. Therefore, it would be inequitable for GSL to retain these benefits.

207. Claims at issue in this Count and for which Blue KC seeks relief in its Count III are highlighted on the attached **Exhibit D.**

208. Blue KC has standing to sue for restitution for each of the types of plans identified above because: (a) with respect to the National Alliance ASO groups identified above, Blue KC obtained explicit written assignments of rights from those groups after August 2021 and was directed to litigate these claims, (b) with respect to Local ASO and Cost Plus plans, existing ASAs give Blue KC the right and discretion to sue on behalf of the plans to recover overpayments, and (c) with respect to the other plans or programs, including the FEP program, the payments were made from Blue KC's accounts.

209. Allowing the Defendant to retain the money received for services allegedly rendered to members of Blue KC's various health care plans — to which the Defendant was not entitled — would unjustly enrich Defendant.

210. The excessive amounts paid to Defendant should be returned in equity and good conscience.

211. Blue KC demanded that all amounts paid to GSL at the sham cash prices be returned.

212. GSL has neither returned the money paid at its sham cash rates nor has it provided assurances that it will return such amounts.

213. Accordingly, Blue KC seeks the return of money had and received.

214. Blue KC seeks a judgment for:

a.) Unjust enrichment or, in the alternative, money had and received;

b.) Restitution or disgorgement of ill-gotten profits;

c.) An order enjoining the Defendant from disposing of or transferring any of the ill-gotten funds still in their possession and control except as ordered by the Court;

d.) An order requiring a tracing of any portion of the funds no longer in the Defendant's possession or control;

e.) Imposition of a constructive trust for the benefit of Plaintiff and the impacted employee benefit plans; and

f.) Attorneys' fees incurred by the Plaintiff as a result of the investigation and prosecution of this matter.

PRAYER FOR RELIEF

WHEREFORE, Blue KC respectfully requests that this Court determine the rights and obligations of the parties with respect to each of GSL's claims for payment and enter a judgment in favor of Blue KC and against GSL:

a.) Declaring that GSL forfeited its right to payment for the claims described in this Second Amended Complaint, if any, because it intentionally concealed or misrepresented one or more material facts or circumstances relating to the claims;

b.) Declaring the claims GSL submitted to Blue KC are the product of an unlawful, abusive, or fraudulent scheme or artifice and, therefore, Blue KC has no obligation to pay the claims;

c.) Declaring that GSL violated state and federal law and its duty of good faith and fair dealing when it purported to set an unconscionable, arbitrary, grossly excessive, and unreasonable "cash price" for COVID-19 tests no reasonable relationship to the economic value of the product supplied and, therefore, Blue KC has no obligation to pay the claims;

d.) Declaring the claims are defective and non-payable for the reasons stated in this pleading and any subsequent pleading filed by Blue KC;

e.) Enjoining GSL from balance billing or otherwise attempting to collect the claims from Blue KC's members;

f.) Awarding Blue KC equitable relief in a form sufficient to restore payments Blue KC or the plans it administers paid at GSL full, sham cash prices;

g.) Establishing a constructive trust for the benefit of Blue KC or the plans and programs it administers;

h.) Awarding Blue KC its costs and expenses incurred in bringing this action, including a reasonable provision for attorneys' fees and litigation expenses;

i.) Awarding Blue KC its prejudgment interest at the rate established by RSMo § 408.020; and

j.) Entering any other and further relief as the Court deems just and appropriate under the circumstances.

Respectfully Submitted,

CAPES, SOKOL, GOODMAN & SARACHAN, P.C.

By: */s/ Aaron E. Schwartz*
Aaron E. Schwartz, #58745
8182 Maryland Avenue, Fifteenth Floor
St. Louis, MO 63105
Phone: 314-721-7701
Fax: 314-721-0554
schwartz@capessokol.com

Attorney for Blue Cross and Blue Shield of Kansas City

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing was served on all parties of record by filing a copy of the same with the Court's electronic filing system this 1st day of March, 2022.

/s/ Aaron E. Schwartz

KANSAS INSURANCE DEPARTMENT
Vicki Schmidt, Commissioner

December 16, 2020

Dear Provider:

As Kansans continue to battle COVID-19, it is imperative that the public be able to trust medical providers, health plans and insurers, and governmental regulatory bodies. Further, it is widely accepted that efficient and effective testing for the virus is a key measure to eventually restoring public health and ending the pandemic.

The State of Kansas, through Department of Health and Environment Secretary Dr. Lee Norman, has issued a standing order for COVID-19 testing.[1] That standing order allows individuals to undergo testing for SARS-CoV-2, the virus that causes COVID-19, subject to certain terms. The standing order authorizes antigen or PCR testing for individuals that meet criteria that, in essence, equate to a diagnostic, i.e., non-screening or surveillance, circumstance. For example, persons who have had close contact with a person that has laboratory-confirmed COVID-19 and develops one or more of certain listed symptoms, or if no source of exposure has been identified and the person has one or more of certain listed symptoms, constitute a diagnostic testing circumstance. The stated purpose of the standing order is to alleviate a patient from having to get an order from their health care provider.

Pursuant to the requirements of the federal Families First Coronavirus Response Act and the CARES Act, health plans and health insurers must provide coverage, without imposing cost sharing responsibilities, for diagnostic COVID-19 testing, and the administration of such test, including certain items and services is also covered without cost sharing. While this is a benefit for individuals, the cost of such tests are borne by health plan issuers and insurers. Federal law permits the testing provider to be reimbursed at the negotiated rate or, if the plan or issuer does not have a negotiated rate with the provider, the cash price for such service that is listed by the provider on its public website.

According to a survey by the America's Health Insurance Plans,[2] price gouging in COVID-19 testing is a significant problem. Recently, the Kansas Insurance Department was made aware of concerning behavior by providers conducting COVID-19 testing in Kansas. Specifically, the Department was informed of a provider in Lenexa, Kansas that lists a cash price of nearly $1,000 for a PCR test.[3] This far exceeds the average price for a PCR COVID-19 test, which, according to AHIP, is less than $185.

[1] https://www.coronavirus.kdheks.gov/DocumentCenter/View/1599/Secretary-Norman-COVID-19-Testing-Standing-Order
[2] https://www.ahip.org/wp-content/uploads/202008-AHIP_COVID-PriceGouging.pdf
[3] https://gslabstesting.com/covid-19-pricing-transparency/

Legal Division ▸ 1300 SW Arrowhead Road, Topeka, KS 66604 ▸ kid.webcomplaints@ks.gov ▸ www.ksinsurance.org ▸
785-296-3071 ▸ Fax 785-291-3190

EXHIBIT A

If these astronomical costs charged by unscrupulous providers are borne by the health plans and insurers without recompense, consumers will ultimately pay more for their health care as health insurance costs will rise.

Also related to COVID-19 testing, the Kansas Insurance Department has been made aware of providers conducting unnecessary tests in conjunction with a COVID-19 diagnostic test. This often results in thousands of dollars of unnecessary charges that are passed on to health plans and insurers. This too, will ultimately lead to increased health insurance costs. The KDHE standing order should obviate the need for a specific order from a physician and thus eliminate the need to conduct many screening exams and other tests currently being provided by health care providers. Conducting unnecessary medical procedures under the guise of emergency care will not be tolerated.

The purpose of this letter then, is to advise providers that the Kansas Insurance Department is collecting data on these issues and will fully cooperate with law enforcement and administrative enforcement authorities, including the Kansas Attorney General's Office, the Kansas Department of Health and Environment, and the Centers for Medicare and Medicaid Services to ensure Kansas consumers are protected. **Providers are advised that price gouging and insurance fraud will be fully investigated and prosecuted.**

Consequently, providers conducting COVID-19 testing should review their pricing and billing practices to ensure they comply with Kansas law.

Questions regarding this letter can be addressed to Justin L. McFarland, General Counsel, Kansas Insurance Department, at Justin.L.McFarland@ks.gov.

Individuals affected by COVID-19 testing costs should contact the Kansas Insurance Department's Consumer Assistance Division at kid.webcomplaints@ks.gov and the Kansas Attorney General at https://ag.ks.gov/complaint-center/price-gouging-and-coronavirus-scams-investigative-request.

Respectfully submitted,

Justin L. McFarland
General Counsel
Kansas Insurance Department
Justin.L.McFarland@ks.gov

cc: Governor Laura Kelly
Kansas Attorney General Derek Schmidt
Senator Jim Denning
Secretary Dr. Lee Norman, KDHE
AHIP-Kansas
Health insurers licensed in Kansas

EXHIBIT A

STATE OF KANSAS
OFFICE OF THE ATTORNEY GENERAL
ROOFING REGISTRATION UNIT

DEREK SCHMIDT
ATTORNEY GENERAL

MEMORIAL HALL
120 SW 10TH AVE., 2ND FLOOR
TOPEKA, KS 66612-1597
(785) 368-6644 • FAX (785) 291-3699
TOLL FREE IN KANSAS (800) 432-2310
WWW.AG.KS.GOV/ROOFING

December 22, 2020

GS Labs LLC - Lenexa
15729 College Blvd.,
Lenexa, KS 66219

Attn: Heather Allred
Brouse McDowell
300 Madison Avenue, Ste. 100
Toledo, OH 42604

Via email to: hallred@brouse.com

RE: Cease and Desist Notice

Dear Ms. Allred,

The Consumer Protection Division of Attorney General Derek Schmidt's office is charged with enforcing the Kansas Consumer Protection Act, K.S.A. 50-623 *et seq.* ("KCPA"). In order to provide consumer protection against fraudulent, deceptive, or unconscionable business practices, the KCPA empowers this Office to initiate formal proceedings to obtain necessary information regarding suspected violations. Those who violate the KCPA may be subject to civil penalties of up to $10,000 per violation.

We have learned that GS Labs LLC (hereinafter "you" or "your") is marketing or promoting COVID-19 tests at prices that grossly exceed the price at which similar tests or services are readily obtainable in the State and region around GS Labs testing facility. Specifically, on December 15, 2020, this office became aware that GS Labs LLC was advertising COVID-19 testing at cash prices as high as $999 for PCR testing, as high as $699 for rapid antigen testing, and $599 for rapid antibody testing. According to an August evaluation of hospital cash prices for COVID-19 testing in the Journal for General Internal Medicine,[1] the median cash price ranged from $57 to $124, with the highest cash price at $525 for a PCR test. Setting the price in a consumer transaction to grossly

[1] Roy Xiao and Vinay K. Rathi, *Price Transparency for COVID-19 Testing Among Top US Hosptials*, 2020 J. GEN. INTERN MED. 1, Https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7500717/.

EXHIBIT B

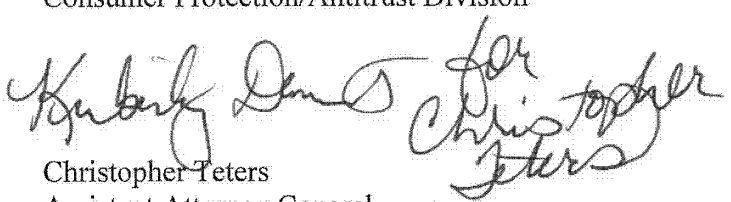
exceed the price at which similar property or services are or were readily obtainable in similar transactions, pursuant to and profiteering from a disaster are unconscionable acts and practices, pursuant to K.S.A. 50-627(b)(2) and K.S.A 50-6,106(b)(1)(B) respectively, and violations of the KCPA.

Additionally, this office believes that GS Labs is misleading consumers about the out-of-pocket expenses for testing in your Kansas facility. According to the GS Labs website, consumers will pay "$0 out-of-pocket." However, our office has learned that GS Labs may be charging some consumers $49 as an administrative fee. Charging this fee despite your advertising would be a deceptive act or practice in violation of K.S.A. 50-626(b)(2) and (3), also violations of the KCPA.

The Kansas Attorney General's Office demands that you immediately and permanently cease and desist from advertising, marketing or selling products and services in Kansas in any manner that charges unconscionable prices in relation to prices of testing readily available in the area and by failing to disclose all fees for associated products and services. Additionally, by no later than January 15, 2020, please provide a response to this notice describing the specific steps you have taken to address the concerns identified in this notice. Include copies of any related documentation with your response. Finally, you are hereby directed to preserve all written and electronic materials related to your purchase, sale or advertisement of any products or services related to COVID-19 until further notice from this Office. This notice does not preclude legal action by this Office and failure to respond to this notice may result in legal action by this Office.

Feel free to contact Assistant Attorney General Christopher Teters if you have questions or wish to discuss the matter.

Sincerely,
OFFICE OF ATTORNEY GENERAL
DEREK SCHMIDT
Consumer Protection/Antitrust Division



Christopher Teters
Assistant Attorney General

CC:

GS Labs LLC - Headquarters
Attn: Aaron B. Johnson
1700 Farnam Street
Omaha, Nebraska 68102

EXHIBIT B

BAIRD HOLM LLP
ATTORNEYS AT LAW
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bperson@bairdholm.com
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Also admitted in Iowa

March 2, 2021

VIA U.S. MAIL-AND EMAIL (MARK.NEWCOMER@BLUEKC.COM)

Mark Newcomer
Vice President & General Counsel
Blue Cross Blue Shield of Kansas City
2301 Main Street
8th Floor, NW
Kansas City, MO 64108

******NOTICE OF CARES ACT REQUIREMENTS******
PLEASE ENSURE REVIEW BY LEGAL COUNSEL
AS SOON AS POSSIBLE

Payment of Claims for COVID-19 Testing as an Out-of-Network Provider

Dear Mr. Newcomer:

We are writing on behalf of our client, GS Labs, LLC, which is an out-of-network provider that performs rapid antigen, rapid antibody and PCR COVID-19 testing.

GS Labs will soon be submitting $4,527,380.00 in claims for COVID-19 testing of your insurance company's enrollees. The dual purposes of this letter are:

1. To advise that GS Labs has been registered with your company as an out-of-network ("OON") provider through a medical claims clearinghouse, and will soon be submitting claims for COVID-19 test provided to your enrollees; and

2. To ensure that your company is fully aware of the requirements of section 3202 of the Cares Act, and electronically prepared to process and reimburse claims from GS Labs as an OON provider of COVID-19 tests, consistent with the requirements of the CARES Act.

Under Section 3202 of the CARES Act, if a payer does not have a negotiated rate with a provider furnishing COVID-19 testing (i.e., if the provider is out-of-network ("OON")), the payer "**shall reimburse the provider in an amount that equals the cash price for such service as listed by the provider on a public internet website**" or the payer may enter into negotiations with the provider for a contracted rate. For COVID-19 testing conducted by an

EXHIBIT C

out-of-network provider, payment for testing **must be paid directly to the provider**, even if your normal process for out-of-network claims would be to reimburse plan members directly for such services. The plan members are to be charged no co-payment, and balance billing is prohibited.

Since GS Labs began performing COVID-19 tests, it has seen a broad spectrum of health insurer responses to its OON claims for these tests. At least initially, very few health insurers were in compliance with the CARES Act. Some insurers boldly posted notices on their websites advising of policies on payment for COVID-19 testing, which were clearly in violation of the CARES Act. Other health insurers paid identical claims for COVID-19 tests inconsistently, with random explanations provided on EOBs: some with unilateral discounts, others discounted for enrollee co-pays or calculated in relation to the Medicare fee schedule. We have interpreted these types of responses as arising from the health insurer's lack of familiarity with the CARES Act.

That brings us back to the second reason for this letter: Since GS Labs will shortly be submitting its claims for COVID-19 tests provided to your company's enrollees, we want to give you an opportunity to ensure that your claims system is ready to handle these claims properly and compliantly.

In their Frequently Asked Questions guidance, the Departments of Labor, Health and Human Services, and Treasury (the "Departments") issued a response on April 11, 2020, to a question directly on point to this scenario:

> **Q7. Are plans and issuers required to provide coverage for items and services that are furnished by providers that have not agreed to accept a negotiated rate as payment in full (i.e., out-of-network providers)?**
>
> **Yes.** Section 3202(a) of the CARES Act provides that a plan or issuer providing coverage of items and services described in section 6001(a) of the FFCRA shall reimburse the provider of the diagnostic testing as follows:
>
> 1. If the plan or issuer has a negotiated rate with such provider in effect before the public health emergency declared under section 319 of the PHS Act, such negotiated rate shall apply throughout the period of such declaration.
>
> 2. **If the plan or issuer does not have a negotiated rate** with such provider, the plan or issuer **shall reimburse the provider** in an amount that equals the **cash price** for such service as listed by the provider on a public internet website, or the plan or issuer **may negotiate a rate** with the provider for less than such cash price.

(Emphasis added). You should anticipate that the claims submitted to your company by GS Labs will set out the GS Labs Cash Price on the date of service identified in the claim. GS labs expects to be reimbursed in the full amount of the Cash Price, and to receive payment directly.

EXHIBIT C

Please note that Blue Cross Blue Shield of Nebraska has confirmed its agreement to pay $385 per test for both antigen and antibody tests for COVID-19, and to pay GS Labs directly as an OON provider.

GS Labs also expects that your company will **not** show a balance owing by the enrollee in responsive EOBs. This was confirmed by a subsequent FAQ issued by the Departments on June 23, 2020. The Departments clarified that balance billing of plan members was prohibited. The FAQ regarding balance billing prohibitions provides:

> **Q9. Does section 3202 of the CARES Act protect participants, beneficiaries, and enrollees from balance billing for a COVID-19 diagnostic test?**
>
> The Departments read the requirement to provide coverage without cost sharing in section 6001 of the FFCRA, together with section 3202(a) of the CARES Act establishing a process for setting reimbursement rates, as **intended to protect participants, beneficiaries, and enrollees from being balance billed for an applicable COVID-19 test**. Section 3202(a) contemplates that a provider of COVID-19 testing will be reimbursed either a negotiated rate or an amount that equals the cash price for such service that is listed by the provider on a public website. In either case, the amount the plan or issuer reimburses the provider constitutes payment in full for the test, **with no cost sharing to the individual or other balance due** . . .

(Emphasis added).

As indicated in the FAQ guidance quoted above, your company must pay GS Labs at its publicly posted cash price rates, which are currently:

Test Name	Description	Billing Code (CPT)	Cash Price
COVID-19 RAPID ANTIGEN TEST	The COVID-19 rapid antigen test detects protein fragments specific to the Coronavirus.	87811	$380.00
COVID-19 RAPID ANTIBODY TEST	This test detects two different types of antibodies (IgM and IgG) that may develop in most patients after exposure to SARS-CoV-2.	86328	$380.00

EXHIBIT C

COVID-19 PCR TEST	When supplies are available, we offer COVID-19 Polymerase Chain Reaction (PCR) test	87635	$385
COVID-19 BIO-FIRE PCR TEST	Test detects 22 target organisms including respiratory syndrome coronavirus 2 (COVID-19).	0202U	$979
COVID-19 EPLEX PCR Test	Test similar to Bio-Fire	0225U	$979

See www.gslabstesting.com/covid-19-pricing-transparency/. If you wish to negotiate a lower rate with GS Labs on future COVID-19 tests, you may contact me to open discussions regarding pricing and payment terms. The preceding is, however, without prejudice to GS Labs' right to obtain payment at its publicly posted rates if negotiations are unproductive.

We would appreciate your confirmation that your insurance company is prepared to meet the requirements for compliance with the CARES Act. If you determine that it will take a few days to make the necessary programming changes, we would be willing to hold the claims for a couple of days to ensure that they are processed properly the first time. For confirmation or negotiations, my contact information is above.

Sincerely,

Barbara E. Person
FOR THE FIRM

Cc: Evan White

EXHIBIT C

Exhibit D – List of Claims
Confidential - Filed Under Seal

Standing Order for Performing COVID-19 Rapid Antigen Testing on Adults and Children

Purpose: To prevent the spread of infectious diseases through identification of specific organisms leading to appropriate treatment and public health disease control actions and recommendations.

Policy: Under this standing order, nurses working for GS Labs and other healthcare professionals working for GS Labs as allowed by state law, may perform a Nasopharyngeal swab (NP), Oropharyngeal swab, Nasal swab or saliva collection on adults or children over the age of 12 months, who have been identified by GS Labs as in need of testing, for COVID-19 via the patient eligibility criteria listed below.

All staff performing this test will be trained in specimen collection and proper personal protective equipment specific to this test and be prepared to perform this procedure.

Patient Eligibility:
The following criteria are required for the Provider to collect a specimen for SARS-CoV-2 testing by this standing order:

1. Individual who is concerned that he or she has been exposed to and infected with COVID-19.

2. And/or an individual with any of the following symptoms consistent with COVID-19:

   - Fever (100.4° Fahrenheit or higher), chills, or shaking chills
   - Cough (not due to other known cause, such as chronic cough)
   - Difficulty breathing, shortness of breath or wheezing
   - New loss of taste or smell
   - Sore throat
   - Headache, when in combination with other symptoms
   - Muscle aches or body aches
   - Nausea, vomiting, or diarrhea
   - Fatigue, when in combination with other symptoms
   - Nasal congestion or runny nose (not due to other known causes, such as allergies) when in combination with other symptoms

Procedure:
1. Verify that the individual has been identified as needing testing for COVID-19 based off the patient eligibility criteria listed above.

2. Review and be familiar with personal protective equipment (PPE) required for doing the specimen collection.

3. Review and be familiar with the procedure for performing a nasopharyngeal swab, oropharyngeal swab and anterior nasal swab.

4. Ensure proper handling, storage, and shipment of specimens.

EXHIBIT E

5. Ensure all supplies including specimen test kits, PPE, storage, and shipment of specimens, and required forms for testing and documentation are available.

6. Although prior written consent from the individual will be obtained, inform everyone to be tested of the procedure and receive verbal agreement for testing. If individual to be tested is a minor, obtain verbal or written agreement from a parent or legal guardian.

7. After the specimen is obtained and the COVID rapid antigen test has been performed, GS Labs personnel will inform the individual of their results. In addition, GS Labs personnel will report the results to the health departments at both the county and state level.

This order is amended on an as needed basis as new medical information relating to the COVID-19 Pandemic and the United States, HHS Public Health Emergency becomes available to the medical community.

This order shall remain in effect until rescinded or until 12/31/2021.

Steven W. Powell, MD

12/20/2020

Date

EXHIBIT E

Standing Order for Performing COVID-19 PCR Testing on Adults and Children

Purpose: To prevent the spread of infectious diseases through identification of specific organisms leading to appropriate treatment and public health disease control actions and recommendations.

Policy: Under this standing order, nurses working for GS Labs and other healthcare professionals working for GS Labs as allowed by state law, may perform a Nasopharyngeal swab (NP), Oropharyngeal swab, Nasal swab or saliva collection on adults or children over the age of 12 months, who have been identified by GS Labs as in need of testing, for COVID-19 via the patient eligibility criteria listed below.

All staff performing this test will be trained in specimen collection and proper personal protective equipment specific to this test and be prepared to perform this procedure.

Patient Eligibility:
For the Provider to collect a specimen and for the patient to be eligible and have the testing considered medically necessary, the patient must meet the criteria listed below:

1. Individual who is concerned that he or she has been exposed to and/or infected with COVID-19.

2. And/or an individual with any of the following symptoms consistent with COVID-19:
   - Fever (100.4° Fahrenheit or higher), chills, or shaking chills
   - Cough (not due to other known cause, such as chronic cough)
   - Difficulty breathing, shortness of breath or wheezing
   - Sore throat
   - Headache
   - Muscle aches or body aches
   - Nausea, vomiting, or diarrhea
   - Fatigue
   - Nasal congestion or runny nose (not due to other known causes, such as allergies)
   - New loss of taste or smell

Procedure:

1. Verify that the individual has been identified as needing testing for COVID-19 based off the patient eligibility criteria listed above.

2. Review and be familiar with personal protective equipment (PPE) required for doing the specimen collection.

3. Review and be familiar with the procedure for performing a nasopharyngeal swab, oropharyngeal swab, anterior nasal swab or saliva collection.

4. Ensure proper handling, storage, and shipment of specimens.

5. Ensure all supplies including specimen test kits, PPE, storage, and shipment of specimens, and required forms for testing and documentation are available.

6. Although prior written consent from the individual will be obtained, inform everyone to be tested of the procedure and receive verbal agreement for testing. If individual to be tested is a minor, obtain verbal or written agreement from a parent or legal guardian.

7. GS Labs will use an algorithm and consider the patient's exposure history, symptoms and risk factors in categorizing the patients into Low-Risk, Intermediate-Risk and High-Risk groups. The risk groups listed below

EXHIBIT F

will determine which PCR test is performed. The Low-Risk Group will receive the single pathogen COVID-19 test. The Intermediate-Risk Group will receive the small respiratory panel test including COVID-19, influenza and RSV. The High-Risk Group will receive the full respiratory panel that tests for multiple viral and bacterial respiratory pathogens including COVID-19.

High Risk Group Criteria: (full respiratory panel PCR test ordered)

- Patients over 65 years of age
- Patients 10 years of age and younger
- History of Chronic pulmonary disease (COPD, Emphysema, Asthma, Interstitial lung disease, etc)
- History of Chronic cardiovascular disease (Angina, Heart attack, Stroke, Arrythmia etc)
- History of diabetes
- BMI 30 or higher
- Patients that are immunocompromised
- History of autoimmune disease
- Patients that smoke
- Patients that are currently pregnant
- Difficulty breathing, shortness of breath, or wheezing
- Cough (not due to other known cause such as chronic cough)
- Nasal congestion or runny nose (not due to other known causes, such as allergies)
- Sore throat

Intermediate Risk Group Criteria: (small respiratory panel PCR test ordered)

- Fever (100.4 Fahrenheit or higher), chills, or shaking chills
- Muscle aches or body aches
- Headache
- Fatigue

Low Risk Group Criteria: (single pathogen COVID-19 PCR test)

- Exposure history and no symptoms
- Nausea, vomiting, diarrhea
- New loss of taste or smell
- Cash pay patient getting test for non-medical reasons (Travel purposes)

8. After the specimen is obtained and the COVID PCR test has been performed, GS Labs personnel will inform the individual of their results. In addition, GS Labs personnel will report the results to the health departments at both the county and state level.

This order is amended on an as needed basis as new medical information relating to the COVID-19 Pandemic and the United States, HHS Public Health Emergency becomes available to the medical community.

This order shall remain in effect until rescinded or until 12/31/2021.

Steven W. Powell, MD

12/20/2020

Date

EXHIBIT F

Standing Order for Performing COVID-19 Rapid Antibody Testing on Adults and Children

Purpose: To prevent the spread of infectious diseases through identification of specific organisms leading to appropriate treatment and public health disease control actions and recommendations.

Policy: Under this standing order, nurses working for GS Labs and other healthcare professionals working for GS Labs as allowed by state law, may perform a fingerstick blood test for rapid COVID-19 IgM/IgG antibodies on adults or children over the age of 12 months, who have been identified by GS Labs as in need of testing, for COVID-19 based off the patient eligibility criteria listed below.

All staff performing this test will be trained in specimen collection and proper personal protective equipment specific to this test and be prepared to perform this procedure.

Patient Eligibility:
The following criteria are required for the Provider to collect a specimen for SARS-CoV-2 testing by this standing order:

1. Individual who is concerned that he or she has been exposed to and infected with COVID-19.

2. And/or an individual with any of the following symptoms consistent with COVID-19:

    - Fever (100.4° Fahrenheit or higher), chills, or shaking chills
    - Cough (not due to other known cause, such as chronic cough)
    - Difficulty breathing, shortness of breath or wheezing
    - New loss of taste or smell
    - Sore throat
    - Headache, when in combination with other symptoms
    - Muscle aches or body aches
    - Nausea, vomiting, or diarrhea
    - Fatigue, when in combination with other symptoms
    - Nasal congestion or runny nose (not due to other known causes, such as allergies) when in combination with other symptoms

Procedure:
1. Verify that the individual has been identified as needing testing for COVID-19 via the patient eligibility criteria listed above.

2. Review and be familiar with personal protective equipment (PPE) required for doing the specimen collection.

3. Review and be familiar with the procedure for performing a fingerstick blood sample collection.

4. Ensure proper handling, storage, and shipment of specimens.

EXHIBIT G

5. Ensure all supplies including specimen test kits, PPE, storage, and shipment of specimens, and required forms for testing and documentation are available.

6. Although prior written consent from the individual will be obtained, inform everyone to be tested of the procedure and receive verbal agreement for testing. If individual to be tested is a minor, obtain verbal or written agreement from a parent or legal guardian.

7. After the specimen is obtained and the COVID rapid IgM/IgG antibody test has been performed, GS Labs personnel will inform the individual of their results, including that a negative antibody test does not exclude a new active infection as antibodies may lag behind infection. In addition, GS Labs personnel will report the results to the health departments at both the county and state level if required.

This order is amended on an as needed basis as new medical information relating to the COVID-19 Pandemic and the United States, HHS Public Health Emergency becomes available to the medical community.

This order shall remain in effect until rescinded or until 12/31/2021.

Steven W. Powell, MD

12/20/2020
Date

EXHIBIT G

INSURANCE: GS LABS COVID-19 RAPID ANTIGEN, RAPID IgM/IgG ANTIBODY AND PCR TEST CONSENT & RELEASE FORM

GS Labs (for internal use only)

GS Labs to Complete: Date:_____

_____ Antigen Test Result: Positive (__) Negative (__) Inoculated Time: _____

_____ Confirmatory PCR, Eligible and Sent: Yes (__) No (__)

_____ IgG AB Test Result: Positive (__) Negative (__) Inoculated Time: _____

_____ IgM AB Test Result: Positive (__) Negative (__)

INITIAL BELOW

RN: ____ Lab Tech (QC ok for all tests performed): ____

Results: _____ Insurance: _____ State Filing: _____

Admin Fee

In order to set you up as a user in our system and give you access to same-day scheduling and same-day day results, GS Labs is charging a $49 set up fee at participating locations. It is not a co-pay or coinsurance or a deductible.

Rapid Antibody Test -- Informed Consent

The purpose of this form is to obtain consent to obtain a blood sample and analyze it to determine if you have the antibodies directed against SARS-CoV-2, the virus that causes COVID-19.

I have reviewed the Frequently Asked Questions sheet regarding the Assure COVID-19 IgG/IgM Rapid Test Device/SARS-CoV-2 antibody test. I authorize GS Labs to draw my blood to complete this test, recognizing that there are certain inherent risks associated with having my blood sample analyzed. The risks of a blood draw include, but are not limited to, discomfort at the site of the blood draw, possible bruising, redness and swelling around the site, bleeding at the site, feeling of lightheadedness when blood is being drawn, and rarely, an infection at the site of the blood draw. I understand that this test looks for antibodies to COVID-19, NOT the virus itself. I am electing to have this antibody test for informational purposes only.

Rapid Antigen Test -- Informed Consent

I voluntarily consent and authorize GS Labs to conduct collection, testing, and analysis for the purposes of the CareStart COVID-19 Antigen test. I have reviewed the Frequently Asked Questions sheet regarding this test. This test will require the collection of an appropriate sample through a nasopharyngeal swab or anterior nasal swab. I understand that there are risks and benefits associated with undergoing an antigen test for COVID-19 and there may be a potential for false positive or false negative test results. Any results I receive are for informational purposes only and do not constitute a medical diagnosis.

PCR Test – Informed Consent

I voluntarily consent and authorize GS Labs to conduct collection, testing, and analysis for the purposes of performing a COVID-19 PCR test. I acknowledge and understand that my COVID-19 PCR test will require the collection of an appropriate sample through a nasopharyngeal swab, oropharyngeal swab, anterior nasal swab or saliva sample. I understand that there are risks and benefits associated with undergoing a PCR test for COVID-19 and there may be a potential for false positive or false negative test results. Any results I receive are for informational purposes only and do not constitute a medical diagnosis.

Confirmatory PCR Test Consent

GS Labs has the capability of performing a PCR test if you choose to provide a PCR specimen while doing your rapid antigen test. The PCR test is more sensitive than the rapid antigen test. If you are symptomatic or have had a recent high-risk exposure and your rapid antigen test is negative, it is possible that this represents a false negative. A confirmatory PCR test is recommended in those circumstances. The confirmatory PCR test results can take 3-5 business days to conclude.

**The availability of confirmatory PCR testing is subject to each location's testing supply.*

*In the event of a negative rapid antigen test result, I authorize GS Labs to conduct a confirmatory PCR test if I choose to provide a PCR specimen at the point of care. I understand that this is an additional fee and that the financial responsibility provisions will apply to this test.

GENERAL LANGUAGE FOR ALL TESTS

EXHIBIT H

I understand that GS Labs will disclose my COVID-19 screening test results to public health authorities and any governmental entity that requires the reporting of COVID-19 results, or as otherwise required by law.

I understand that a physician or other health care provider who is licensed under state law to order the testing may do so. I understand that I am not creating a patient relationship with GS Labs or its affiliates or providers by participating in testing. The lab is not acting as my medical provider and does not replace treatment by my primary medical provider. I assume complete and full responsibility to seek and obtain medical and other advice relating to this testing and any results I receive. Should I have question or concerns regarding my results, or a worsening of my condition, I shall promptly seek advice and treatment from an appropriate medical provider

Release and Indemnification. On behalf of myself and my heirs and personal representatives, I knowingly and voluntarily agree to have my sample(s) analyzed for the SARS-CoV-2 antibodies and/or virus and hereby waive any and all rights, claims, or causes of action of any kind whatsoever arising out of my participation in this activity, and do hereby release and forever discharge GS Labs, its affiliates, contractors, providers agents, staff, representatives, predecessors, and successors for any physical or psychological injury, economical or emotional loss that I may suffer as a direct result of my participation in this activity, including, but not limited to any claim arising out of or related to, inaccurate, un-interpreted, misinterpreted results or results not received, and including traveling to and from any location related to this activity. If I should require medical care or treatment, I agree to be financially responsible for any costs incurred as a result of such treatment.

I agree to indemnify and hold harmless GS Labs and its staff against any and all claims, suits, or actions of any kind whatsoever for liability, damages, compensation, or otherwise brought by me or anyone on my behalf including attorneys' fees and any related costs, if litigation arises pursuant to any claims made by me or by anyone else acting on my behalf. If GS Labs or its staff or representatives incurs any of these types of expenses, I agree to reimburse GS Labs for these expenses.

FDA Guidance. These tests have not been FDA cleared or approved and have been authorized by FDA under an Emergency Use Authorization (EUA). Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow up testing with a molecular diagnostic should be considered to rule out infection in these individuals. Results from antibody and antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E. This test is not for the screening of donated blood.

Authorization for Use and Disclosure of Protected Health Information (PHI)

I understand and agree that GS Labs will report the results of the testing directly to me, my physician, or any health professional that I request. I understand and agree that the service provided by GS Labs and the test results from the lab will be maintained as confidential protected health information by GS Labs as required by federal and state law, including but not limited to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). GS Labs may use contractors to administer or perform the testing and GS Labs or its contractors will collect and process my personal information, including name, date of birth, email address, responses to COVID-19 screening questions (including symptoms), and test results who are also subject to the same federal and state laws regarding protected health information, including HIPAA.

I have read all of the above as well as GS Labs' Notice of Privacy Practices and I understand that I have the opportunity to have any questions answered that I have regarding my rights to privacy by of GS Labs by contacting GS Labs at 402-334-5433.

Request and Authorization of Disclosure of PHI Via E-mail

I request that GS Labs and its contractors disclose my laboratory results, which include protected health information, directly to me at the email address provided when the primary user account was created online at the GS Labs' secure portal. It is my responsibility to notify GS Labs of any change in this information. I understand that this email will be unencrypted, and that GS Labs has no control over who may have access to the email address that I provided to receive my protected health information and that there are inherent risks to email. The information disclosed by email will no longer be protected under HIPAA and may be subject to re-disclosure. Future disclosure is not the responsibility of GS Labs.

Financial Responsibility

I agree that I am personally financially responsible for payment of fees for all tests ordered and collected by GS Labs or its representatives or contractors at my request. It is my responsibility to know my own insurance benefits, including whether GS Labs is a contracted provider and any covered benefits and exclusions. I warrant that the health insurance information I provide is current, complete, accurate, and take all responsibility for any errors or omissions in this information. I authorize GS Labs to verify my insurance benefits and submit my claim to my insurance carrier. I assign to GS Labs all rights and claims for the medical benefits to which I am entitled for the services provided.

I understand that if my insurance company denies coverage or payment for the services provided to me, or fails to remit timely payment on my claim (within thirty (30) days), I assume full financial responsibility and will pay all charges in full.

[redacted]

EXHIBIT H

GS LABS
17650 Wright St #5, Omaha, NE 68130 | (402) 334-5433

2/26/21

Dear Patient,

I am writing you to inform you the validity of the positive results on the rapid antigen test for COVID-19 obtained from GS Labs between Feb. 17 – Feb 22, 2021 may be inaccurate. There was some inter-user variability between the lab personnel interpreting the results on those dates. Unfortunately, it is impossible at this point to tell which of the positive results are true positives and which ones are false positives. The state health department is aware of the discrepancies on those dates. I encourage you to get a repeat molecular test (NAAT or PCR) for confirmation at a different testing site. We are not currently offering PCR testing in Lenexa.

For those of you that paid cash for your testing you will be reimbursed. For those that paid with insurance your insurance company will not be billed for the antigen test. My apologies for any inconvenience this may have caused.

Sincerely,

Darin Jackson, MD
Medical Direct
GS Labs

EXHIBIT I

NEBRASKA

Good Life. Great Mission.

DEPT. OF HEALTH AND HUMAN SERVICES

Pete Ricketts, Governor

March 18, 2021

CLIA Number: 28D2183799

Darin Jackson, MD
GS Labs LLC
17650 Wright Street Ste 5
Omaha, NE 68130

Dear Director:

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the PublicHealth Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Laboratories are required to be in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The Nebraska Department of Health and Human Services conducted a initial survey of your laboratory that was completed on March 16, 2021. As a result of the survey, it was determined that your facility is not in compliance with all of the Conditions required for certification in the CLIA program. Specifically, the following Conditions were not met:

D5400 -42 C.F.R.§ 493.1250 Condition: Analytic systems

In addition, other standards were also found to be not met. Enclosed is Form CMS-2567, Statement of Deficiencies, listing all the deficiencies found during the survey.

Laboratories that do not meet the Condition-level requirements of CLIA may not be certified to perform laboratory testing under the CLIA program. You must take steps to bring any unmet Conditions into compliance immediately.

You are directed to submit a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited. Please document your allegation of compliance using the enclosed CMS-2567, Statement of Deficiencies, in the columns labeled “Provider Plan of Correction” and “Completion Date” located on the right side of the form, keying your responses to the deficiencies on the left. The laboratory director must sign, date and return the completed CMS-2567 documented with a credible allegation of compliance to our office **WITHIN 10 CALENDAR DAYS FROM RECEIPT** of this notice. You must also submit documented evidence that verifies that the corrections were made. We may conduct a follow-up onsite survey in approximately 30-45 days to verify the corrections if we find your allegation of compliance to be credible and the submitted evidence to be acceptable. If your laboratory does not submit a credible allegation of compliance and acceptable evidence of correction, we will not conduct a follow-up survey. (Your allegation of compliance will be included in the public record of the inspection.)

A credible allegation of compliance is a statement or documentation that is:

1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;

EXHIBIT J

2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and

3) Indicates resolution of the problems.

For your information, acceptable evidence of correction must include:

1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;

2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;

3) What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and

4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

If you do not submit a credible allegation of compliance and acceptable evidence of correction, or if you submit an allegation of compliance that is determined to be credible but are found to be still out of compliance with any CLIA Condition-level requirements at the time of the follow-up visit, Nebraska Department of Health and Human Services will recommend to the Western and Central Operations Branch, Kansas City Office of the Centers for Medicare & Medicaid Services (CMS) that sanctions be taken against your laboratory's CLIA certificate. These may include alternative sanctions (Civil Money Penalty of up to $21,410 per day of noncompliance or per violation per 42 C.F.R.§ 493.1834, Directed Plan of Correction per 42 C.F.R.§ 493.1832, State Onsite Monitoring per 42 C.F.R.§ 493.1836) and principal sanctions (suspension, limitation and/or revocation of your laboratory's CLIA certificate and cancellation of you laboratory's approval for Medicare payments per 42 C.F.R.§ 493.1814).

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature, the routine survey may not find every violation that the laboratory may have committed. It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assurance measures to ensure that the deficient practices do not recur.

In addition to the routine CLIA certification surveys, announced or unannounced investigations/ surveys may be conducted by the State agency at any time to address complaints or other non-compliance issues. These investigations/surveys may well identify violations that may not have surfaced during a routine survey using random sampling, but for which the laboratory and its director will still be held responsible.

If you have any questions regarding this survey, please contact this office by e-mail at DHHS.AcuteCareFacilities@nebraska.gov

Jean Ellis, RN BSN - Program Manager
DHHS Public Health - Licensure Unit - Office of Acute Care Facilities
PO Box 94986, Lincoln, NE 68509-4986
Email: jean.ellis@nebraska.gov

JE/smm

Enc: CMS-2567

May 14, 2021

To whom it may concern:

During a recent internal quality control audit of practices our involving GenMark's ePlex Respiratory Panel we discovered a brief period of inconsistency in our practices that we are obligated to report to patients. While our quality control practices for the GenMark ePlex Respiratory Panel have always met the testing manufacturer's standards, from 03/17/2021 to 04/09/2021, our quality control process for this test inadvertently deviated from applicable laboratory standards for testing facilities. There is a chance that this circumstance may have impacted your test results.

We have also reported the issues with your testing to your local Department of Health and are continuing to work with the Nebraska Public Health CLIA program Facilities Surveyor to ensure all required quality control practices are implemented going forward.

Sincerely,

Darin Jackson, MD
Medical Director
GS Labs

EXHIBIT K

Sherry L. Doctorian
Direct **T** 573.634.7149
sdoctorian@atllp.com

February 19, 2021

Ms. Jodi Lehman, Special Investigator
Division of Consumer Affairs
Missouri Department of Commerce and Insurance
301 West High Street, Room 530
Jefferson City, MO 65101

Re: GS Labs NE, LLC - Response to January 7, 2021 Letter

Dear Ms. Lehman

This will acknowledge your letter of January 7th addressed to Atul Narkhede at GS Labs Headquarters which we later determined was meant for GS Labs NE, LLC. Following are our responses to your questions:

a. Are you registered to conduct business in the State of Missouri? If so, provide evidence of the Company registered.

Response: Yes, see attached Missouri Secretary of State Certificate of Registration.

b. Provide the address(s) for each location in Missouri.

Response:

1103 SW Oldham Parkway, Lee's Summit, MO 64081
2541 Broadway Bluffs Drive, Columbia, MO 65201
12228 St. Charles Rock Road, Bridgeton, MO 63044

c. Does an individual need a doctor referral to visit a facility?

Response: Early on in the pandemic there was some confusion over this issue. However, the Centers for Medicare and Medicaid Services published "CMS NEWS" for immediate release on April 30, 2020, clarifying that "a written practitioner's order is no longer required for the COVID-19 test". The CDC Lists the following indications for getting a Covid-19 Test:

- **People who have symptoms of COVID-19.**

EXHIBIT L

- **People who have had close contact (within 6 feet for a total of 15 minutes or more) with someone with confirmed COVID-19.**

- **People who have taken part in activities that put them at higher risk for COVID-19 because they cannot socially distance as needed, such as travel, attending large social or mass gatherings, or being in crowded indoor settings.**

- **People who have been asked or referred to get testing by their healthcare provider, local or state health department.**

Note that only the last of four indicators for COVID-19 testing anticipates a referral by a healthcare provider.

d. Discuss who is administrating the test(s).

Response: Registered Nurses who are employed by GS Labs.

e. Discuss which locations are conducting the Rapid Antigen, Rapid Antibody and Polymerase Chain Reaction tests.

Response: All locations offered the three tests in 2020, however all three locations stopped offering the PCR test in late December but continued to offer the Rapid Antigen and Rapid Antibody tests.

f. What is the cost of each test at each location?

Response: Antigen- $380, Antibody- $380, PCR $385 are the costs for the tests at each location.

g. Discuss if insurance is accepted and the claim process.

Response: Insurance is accepted. Patients enter insurance information on their intake consent form online before scheduling an appointment. After the test is administered, the claim is submitted by our billing department to the applicable insurance company. In accordance with the CARES Act, the patient is advised that they will not be billed by GS Labs.

h. Name of the insurance company(s) which claims have been submitted

Response: See attached.

i. Number of claims filed with each insurance company.

Response: See attached.

EXHIBIT L

j. Are you accepting Medicare, Medicaid and TriCare Insurance?

Response: No.

k. Is there concierge fee to schedule a tests? If so, discuss the fee assessed and the costs for each location.

Response: We do not currently charge a concierge fee at any location. Previously we charged an administrative fee of $49 per test at each location. We have since determined the fee is not needed so it was discontinued in December 2020.

l. Discuss the fee for self-pay testing for consumer.

Response: The fee for a self-pay consumer is the same as the amount charged the insurance carrier ($380) however, if the consumer needs financial assistance, it is available at up to 70% off the test price. For consumers who indicate they have no insurance or an economic hardship, at the time of signing up on the web-site there is an invitation to request financial assistance, by interacting with GS Labs online or by phone.

Very truly yours,

ARMSTRONG TEASDALE LLP

Sherry L. Doctorian

Enclosures

EXHIBIT L

STATE OF MISSOURI

John R. Ashcroft
Secretary of State

CERTIFICATE OF REGISTRATION

WHEREAS,

GS LABS LLC

Using in Missouri the name

GS LABS LLC

FL1434834

existing under the laws of the State of Nebraska has filed with this state its Application of Registration and whereas this Application of Registration conforms to the Missouri Limited Liability Company Act.

NOW, THEREFORE, I, JOHN R. ASHCROFT, Secretary of State of State of Missouri, by virtue of the authority vested in me by law, do hereby certify and declare that on the 2nd day of February, 2021 the above Foreign Limited Liability Company is duly authorized to transact business in the State of Missouri and is entitled to any rights granted Limited Liability Companies.

Effective Date: February 2, 2021

IN TESTIMONY WHEREOF, I hereunto set my hand and cause to be affixed the GREAT SEAL of the State of Missouri. Done at the City of Jefferson, the 2nd day of February, 2021.

Secretary of State

EXHIBIT L

Carrier	Total
Meritain Health	6
Administrative Concepts Inc	1
Aetna	39
AmBetter	8
Cigna	385
Emblem Health	2
Health Partners	1
UMR	14
United Healthcare	636
All Savers UHC	68
Aspen STM - Insurance Benefit System	1
Benefit Administrative Systems	4
First Health Network	4
GEHA - UHC Shared Services	17
Golden Rule	18
Golden Rule UHC	11
Humana	9
Molina Healthcare of Washington	1
NALC - Natl Assn of Letter Carriers	1
WellFirst Health	2
Healthlink	5
Care Management Resources	1
United Healthcare Student Resources	3
HealthScope Benefits	1
Lucent Health	1
Alliance Health	1
Allied National - Global Care, Inc	1
National General Health Insurance	1
Oscar Health Insurance	1
Allied Benefit Systems	1
Cerner	4
Insurance Management Services	1
Blue Cross Blue Shield of Nebraska	2
Freedom Life	1
MEDCOST	1
Meritian	1
Mid American Benefits	1
PHCS	1
Tricare	1
Lifestyle Health Plan	1
Total Claims	**1258**

EXHIBIT L

INSURANCE: GS LABS COVID-19 RAPID ANTIGEN, RAPID IgM/IgG ANTIBODY AND PCR TEST CONSENT & RELEASE FORM

GS Labs (for internal use only)

GS Labs to Complete: Date:_____

_____ Antigen Test Result: Positive (__) Negative (__) Inoculated Time: _____

_____ IgG AB Test Result: Positive (__) Negative (__) Inoculated Time: _____

_____ IgM AB Test Result: Positive (__) Negative (__)

_____ Confirmatory PCR, Eligible and Sent: Yes (__) No (__)

GS Labs (internal use only) - INITIAL BELOW

RN: _____ Lab Tech - Internal QC Pass for: Antigen: _____ Antibody: _____ PCR: _____

Results: _____

Rapid Antibody Test – Informed Consent

The purpose of this form is to obtain consent to obtain a blood sample and analyze it to determine if you have the antibodies directed against SARS-CoV-2, the virus that causes COVID-19.

I have reviewed the Frequently Asked Questions sheet regarding the Assure COVID-19 IgG/IgM Rapid Test Device/SARS-CoV-2 antibody test. I authorize GS Labs to draw my blood to complete this test, recognizing that there are certain inherent risks associated with having my blood sample analyzed. The risks of a blood draw include, but are not limited to, discomfort at the site of the blood draw, possible bruising, redness and swelling around the site, bleeding at the site, feeling of lightheadedness when blood is being drawn, and rarely, an infection at the site of the blood draw. I understand that this test looks for antibodies to COVID-19, NOT the virus itself. I am electing to have this antibody test for informational purposes only.

Rapid Antigen Test – Informed Consent

I voluntarily consent and authorize GS Labs to conduct collection, testing, and analysis for the purposes of the CareStart COVID-19 Antigen test. I have reviewed the Frequently Asked Questions sheet regarding this test. This test will require the collection of an appropriate sample through a nasopharyngeal swab or anterior nasal swab. I understand that there are risks and benefits associated with undergoing an antigen test for COVID-19. The risks of a nasal or nasopharyngeal swab include, but are not limited to, discomfort, bloody nose, ear pain, headache, and a runny nose. There may be a potential for false positive or false negative test results. Any results I receive are for informational purposes only and do not constitute a medical diagnosis.

Covid 19 PCR and Respiratory Panel – Informed Consent

I voluntarily consent and authorize GS Labs to conduct collection, testing, and analysis for the purposes of a COVID-19 PCR test. I acknowledge and understand that my COVID-19 PCR test will require the collection of an appropriate sample through a nasopharyngeal swab, oropharyngeal swab, anterior nasal swab or saliva sample. I also understand that the PCR test performed by GS Labs will also check for multiple other viral and bacterial respiratory pathogens. I understand that there are risks and benefits associated with undergoing a PCR test for COVID-19. Risks of a nasal or nasopharyngeal swab include but are not limited to: discomfort, ear pain, headache, bloody nose or runny nose. There may also be a potential for false positive or false negative test results. I assume complete and full responsibility to seek and obtain medical and other advice relating to this testing and any results I receive. Should I have questions or concerns regarding my results, or a worsening of my condition, I shall promptly seek advice and treatment from an appropriate medical provider.

GS Labs has the capability of performing a PCR test if you choose to provide a PCR specimen while doing your rapid antigen test. The PCR test is more sensitive than the rapid antigen test. If you are symptomatic or have had a recent high-risk exposure and your rapid antigen test is negative, it is possible that this represents a false negative. A confirmatory PCR test is recommended in those circumstances. The PCR test for COVID-19 obtained at GS Labs also tests for multiple other viral and bacterial respiratory pathogens. The confirmatory PCR test results can take 1-3 days to conclude.

EXHIBIT M

I have been informed about the purpose of the COVID-19 PCR test, procedures to be performed, potential risks and potential benefits. I have been provided an opportunity to ask questions before proceeding with a COVID-19 antigen test and I understand that if I do not wish to continue with the collection, testing, or analysis of a COVID-19 PCR test, I may decline to receive continued services.

**The availability of confirmatory PCR testing is subject to each location's testing supply.*

*In the event of a negative rapid antigen test result, I authorize GS Labs to conduct a confirmatory PCR test if I choose to provide a PCR specimen at the point of care. I understand that this is an additional fee and that the financial responsibility provisions will apply to this test.

ATTENTION BLUE CROSS/BLUE SHIELD MEMBERS:

GS Labs is not currently a participating provider with any Blue Cross/Blue Shield ("BCBS") plans. GS Labs will submit claim(s) on your behalf, however, if any payment for the claims are made directly to you, as the member, you are responsible for remitting this payment from BCBS to GS Labs. To make it easier for you to remit payment pursuant to the assignment of benefits above, and to avoid collection activity, we can charge the credit card we have on file for this amount if the patient's direct reimbursement from BCBS is not forwarded to GS Labs within 15 days.

I hereby authorize GS Labs to charge my credit card for the full amount of all services rendered by GS Labs or its contractors fifteen (15) days after the test.

GENERAL LANGUAGE FOR ALL TESTS

I understand that GS Labs will disclose my COVID-19 screening test results to public health authorities and any governmental entity that requires the reporting of COVID-19 results, or as otherwise required by law.

I understand that a physician or other health care provider who is licensed under state law to order the testing may do so. I understand that I am not creating a patient relationship with GS Labs or its affiliates or providers by participating in testing. The lab is not acting as my medical provider and does not replace treatment by my primary medical provider. I assume complete and full responsibility to seek and obtain medical and other advice relating to this testing and any results I receive. Should I have question or concerns regarding my results, or a worsening of my condition, I shall promptly seek advice and treatment from an appropriate medical provider

Release and Indemnification. On behalf of myself and my heirs and personal representatives, I knowingly and voluntarily agree to have my sample(s) analyzed for the SARS-CoV-2 antibodies and/or virus and hereby waive any and all rights, claims, or causes of action of any kind whatsoever arising out of my participation in this activity, and do hereby release and forever discharge GS Labs, its affiliates, contractors, providers agents, staff, representatives, predecessors, and successors for any physical or psychological injury, economical or emotional loss that I may suffer as a direct result of my participation in this activity, including, but not limited to any claim arising out of or related to, inaccurate, un-interpreted, misinterpreted results or results not received, and including traveling to and from any location related to this activity. If I should require medical care or treatment, I agree to be financially responsible for any costs incurred as a result of such treatment.

I agree to indemnify and hold harmless GS Labs and its staff against any and all claims, suits, or actions of any kind whatsoever for liability, damages, compensation, or otherwise brought by me or anyone on my behalf, including attorneys' fees and any related costs. If litigation arises pursuant to any claims made by me or by anyone else acting on my behalf. If GS Labs or its staff or representatives incurs any of these types of expenses, I agree to reimburse GS Labs for these expenses.

FDA Guidance. These tests have not been FDA cleared or approved and have been authorized by FDA under an Emergency Use Authorization (EUA). Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals. Results from antibody and antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E. This test is not for the screening of donated blood.

Authorization for Use and Disclosure of Protected Health Information (PHI)

I understand and agree that GS Labs will report the results of the testing directly to me, my physician, or any health professional that I request. I understand and agree that the service provided by GS Labs and the test results from the lab will be maintained as confidential, protected health information by GS Labs as required by federal and state law, including but not limited to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). GS Labs may use contractors to administer or perform the testing and GS Labs or its contractors will collect and process my personal information, including name, date of birth, email address, responses to COVID-19 screening questions (including symptoms), and test results who are also subject to the same federal and state laws regarding protected health information, including HIPAA.

I have read all of the above as well as GS Labs' Notice of Privacy Practices and I understand that I have the opportunity to have any questions answered that I have regarding my rights to privacy by of GS Labs by contacting GS Labs at 402-334-5433.

Request and Authorization of Disclosure of PHI Via E-mail

EXHIBIT M

I request that GS Labs and its contractors disclose my laboratory results, which include protected health information, directly to me at the email address provided when the primary user account was created online at the GS Labs' secure portal. It is my responsibility to notify GS Labs of any change in this information. I understand that this email will be unencrypted, and that GS Labs has no control over who may have access to the email address that I provided to receive my protected health information and that there are inherent risks to email. The information disclosed by email will no longer be protected under HIPAA and may be subject to re-disclosure. Future disclosure is not the responsibility of GS Labs.

Financial Responsibility

I agree that I am personally financially responsible for payment of fees for all tests ordered and collected by GS Labs or its representatives or contractors at my request. It is my responsibility to know my own insurance benefits, including whether GS Labs is a contracted provider and any covered benefits and exclusions. I warrant that the health insurance information I provide is current, complete, accurate, and take all responsibility for any errors or omissions in this information. I authorize GS Labs to verify my insurance benefits and submit my claim to my insurance carrier. I assign to GS Labs all rights and claims for the medical benefits to which I am entitled for the services provided.

I understand that if my insurance company denies coverage or payment for the services provided to me, or fails to remit timely payment on my claim (within thirty (30) days), I assume full financial responsibility and will pay all charges in full.

PLEASE COMPLETE THE FOLLOWING WITH THE PATIENT'S INFORMATION ONLY

GS Labs only accepts insurance patients who are seeking testing for diagnostic purposes. Patients must be experiencing Covid-19 symptoms or have had a potential exposure to Covid-19 to qualify for a medically necessary diagnostic test. *

☑ I acknowledge that I am seeking a diagnostic test.

Have you had any of the following symptoms in the last 14 days?

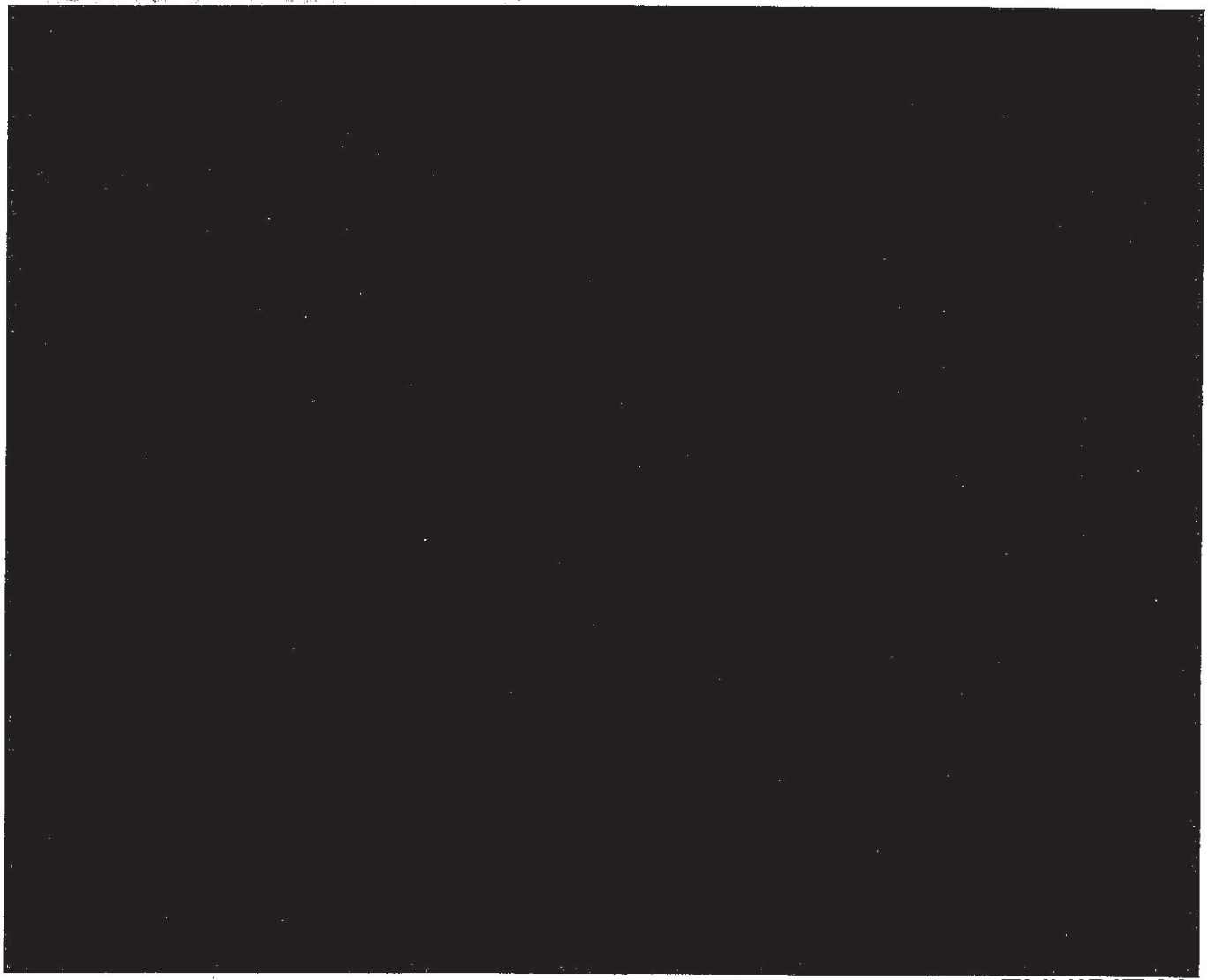

EXHIBIT M