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. **Serve Registered Agent:** Capitol Corporate Service, Inc. 222 E. Dunklin St., Ste. 102 Jefferson City, MO 65101	)	Cause No.:

COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

COMES NOW Plaintiff, Blue Cross and Blue Shield of Kansas City ("Plaintiff" or "Blue KC"), by and through undersigned counsel, pursuant to 28 U.S.C. §§ 2201 and 2202 and Rule 57 of the Federal Rules of Civil Procedure, or in the alternative Mo. Rev. Stat. Section 527.010, *et seq.*, and for its Complaint for Declaratory Judgment and Injunctive Relief, states as follows:

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

2. Defendant's scheme is, at its core, quite simple. Pursuant to laws Congress enacted in response to the global pandemic, health insurers and plans must cover certain COVID-19 diagnostic testing. Prices for the required coverage could be established in one of two ways: the provider and insurer may negotiate a price or, if negotiations do not result in agreed-upon rates, the price 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. Instead of posting reasonable and accurate cash prices and negotiating with Blue KC in good faith if any pricing dispute remained, Defendant GS Labs posted inaccurate and wildly excessive "cash prices". Defendant then refused to accept reasonable reimbursement rates and now demands that Blue KC pay rates many times higher than the rates other providers charge for the same services.

3. GS Labs's submission of rapid antigen claims illustrates the scheme. Rapid antigen tests are one of several types of COVID-19 tests GS Labs claims to have performed for Blue KC's members. GS Labs submitted over 10,000 claims for COVID-19 rapid antigen testing to Blue KC. These tests can be purchased at wholesale for under $20 per test and sometimes for as little as $11 per test. The Medicare program typically reimburses providers $41.38 to administer this type of test. Other providers charge as little as $35. However, GS Labs's posted cash price for the same test is $380 - ***approximately ten times higher than reasonable rates and twenty times higher than the wholesale cost.*** In negotiations with Blue KC, GS Labs insisted it was entitled to its posted cash price of $380 per test and offered only small discounts in exchange for prompt payment.

4. The Kansas Insurance Department commented in a letter describing GS Labs'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).

5. Moreover, GS Labs's purported cash prices are not only excessive and objectively unreasonable, but its purported cash prices are also intentionally deceptive. While GS Labs represented to insurers that its established and true cash prices were hundreds of dollars per test, GS

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

Labs had, in fact, not established any cash price. GS Labs refused prospective patients that sought to pay cash. Then, when GS Labs updated its website to reflect that it accepted cash-paying customers, it represented that it would accept cash payments at rates only a fraction of the posted cash price.

6. In total, GS Labs submitted over $9.2 million[2] in inflated and otherwise improper claims to Blue KC. Blue KC refuses to submit to GS Labs's demands and files the instant action.

7. A ripe and justiciable controversy exists between the parties, in part, because GS Labs has submitted millions of dollars of claims for reimbursement to Blue KC, GS Labs continues to demand payment of these claims, and the claims are not payable for reasons that include the following:

a.) GS Labs knowingly and willfully concealed or misrepresented material facts or circumstances relating to the claims including, but not limited to, the true cash prices for the services in question;

b.) GS Labs failed to comply with Section 3202 of the CARES Act which requires that GS Labs post accurate cash prices for diagnostic tests;

c.) GS Labs violated its duty of good faith and fair dealing when it purported to set its "cash prices" for COVID-19 diagnostic tests at unreasonable rates;

d.) The claims GS Labs submitted to Blue KC amount to unlawful price gouging and disaster profiteering; and

e.) Other reasons described herein and as may be described in subsequent pleadings.

8. Blue KC also brings this action to enjoin GS Labs from engaging in any efforts to collect the outstanding claims directly from Blue KC members. These collection activities would be prohibited by the CARES Act, would harm innocent Blue KC members, would cause irreparable harm

[2] Upon information and belief, after duplicative, inadvertently paid, and withdrawn claims are excluded, the total disputed claims exceed $5.8 million.

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.

PARTIES

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

10. Blue KC is an independent licensee of the Blue Cross Blue Shield Association.

11. Blue Cross Blue Shield Association is a national trade association of 35 independent, community-based and locally operated Blue Cross Blue Shield companies.

12. Blue Cross Blue Shield Association affiliated companies provide health insurance to more than 110 million people in all 50 states, Washington, D.C., and Puerto Rico.

13. Blue KC provides comprehensive health care coverage, including medical diagnostic services, to approximately one million members[3] in the Greater Kansas City region and Northwest Missouri.

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

15. Documents GS Labs filed with the Missouri Secretary of State indicate that GS Labs was formed to "perform Covid testing."

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

[3] Blue KC refers to all individuals covered under any of the health plans it administers as its "members."

17. GS Labs first became registered to do business in Missouri on February 2, 2021 and in Kansas on December 12, 2020. Upon information and belief, GS Labs operated in Missouri and Kansas before it was authorized to do so.

18. GS Labs 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.

19. GS Labs's principal office address is 222 S. 15th Street Suite 1404S, Omaha, Nebraska 68130.

20. Upon information and belief, GS Labs's members are Christopher Erickson, Daniel White, and Gabriel Sullivan.

21. Upon information and belief, each member of GS Labs is a resident and citizen of Nebraska.

JURISDICTION AND VENUE

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

23. Complete diversity exists because (1) 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 (2) Defendant GS Labs was formed under the laws of Nebraska, has its principal place of business in Nebraska, and, upon information and belief, each of its members are citizens of Nebraska.

24. As is described below, the amount in controversy exceeds $75,000 and involves, among other issues, GS Labs's submission of over $9.2 million in claims for COVID-19 diagnostic testing and related services.

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

26. If the Court exercises federal question jurisdiction over only 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.

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

28. 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 diagnostic services at issue in the 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.

29. This Court may exercise personal jurisdiction over Defendant because Defendant operated a testing clinic in Lee's Summit, Missouri, and the dispute described in this Complaint arises out of services provided, in large part, at that testing clinic.

30. 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.

31. Plaintiff has satisfied all conditions precedent, if any.

THE POLICIES AND HEALTH PLANS AT ISSUE

32. Blue KC operates as both a traditional insurer and as a claims administrator.

33. Blue KC administers a variety of healthcare benefit plans and policies of insurance including: (1) self-funded plans, (2) plans insured under group policies issued by Blue KC in which the plans are established and maintained by private employers, (3) plans covering federal employees, (4) plans covering employees of state governmental entities, (5) church plans, (6) policies issued

directly to individuals, and (7) policies administered pursuant to the Medicare Advantage Program (Medicare Part C).

34. Blue KC insures certain plans and members directly. For these plans and members, Blue KC processes claims and makes benefit payments, as warranted, from its own assets.

35. Blue KC also provides administrative services to self-funded group health plans (either directly or with the assistance of other BCBS licensees).

36. Many of the health plans sponsored by private employers and employee organizations (such as unions) are governed by ERISA, 29 U.S.C. § 100, *et seq*.

37. Blue KC is a plan fiduciary of many of the ERISA-governed plans at issue.

38. Blue KC can supply an exhibit identifying the plans, groups, and types of policies impacted by GS Labs's claims described in this Complaint and will seek the Court's leave to file such a document in an amended pleading after an appropriate protective order is entered.

BLUE KC'S RELATIONSHIPS WITH HEALTH CARE PROVIDERS

39. 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.

40. 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.

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

42. Where 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.

43. Unless a state or federal law provides otherwise, a non-participating provider may "balance bill" the member for portions of services not covered by Blue KC.

THE COVID-19 PANDEMIC

44. 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."[4]

45. 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.[5]

46. At that time, there were "no proven effective specific treatment strategies" and no approved diagnostic testing.[6]

47. 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%. The most recent data suggests the fatality rate in the United States is roughly 1.8%.[7]

[4] https://www.cdc.gov/media/releases/2020/p0121-novel-coronavirus-travel-case.html
[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7569573
[6] *Id.*
[7] https://ourworldindata.org/mortality-risk-covid

48. Kansas Governor Laura Kelly declared a state of emergency in response to the COVID-19 pandemic on March 12, 2020.[8] In Kansas the state of emergency expired on June 15, 2021.

49. In Missouri, Governor Michael Parson declared a state of emergency in response to COVID-19 on March 13, 2020.[9] The state of emergency is currently set to expire on August 31, 2021.

50. Prior to March 2020, the U.S. had only completed 459 tests of patients suspected to have COVID-19.[10] Initially, the CDC controlled the only testing operations in the U.S., which *Science Magazine* described as "a fiasco."[11]

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

52. 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.[12]

53. 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:

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

Test Type	Description	Billing Code	MAC Allowable Rates[13]
COVID-19 Rapid Antigen Test	Rapid Antigen tests detect protein fragments specific to the Coronavirus and are used to diagnose active infection.	87811	$41.38
COVID-19 Rapid Antibody Test	Antibody tests are "not [used] used to diagnose an active COVID-19 infection."[14] 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[15]	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 one pathogen it detects 22 target respiratory pathogens including COVID-19.	0202U	$416.78[16]
GenMark ePlex Respiratory Pathogen 2 Panel	This test is like the PCR Test, but instead of detecting only one pathogen it detects 21 target respiratory pathogens including COVID-19.	0225U	$416.78

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

[13] Medicare Administrative Contractors ("MACs") are responsible for developing the allowable 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.

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

[15] 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 administered by GS Labs and designed to detect 21 and 22 target respiratory pathogens.

[16] Not all MACs have established pricing for large panel tests GS Labs administered.

55. To date, Blue KC has completed processing and payment of approximately 510,000 COVID-19 diagnostic testing claims from approximately 1,300 providers.

COVID-19 DIAGNOSTIC TESTING UNDER THE FFCRA AND CARES ACT

56. In response to the deepening pandemic crisis, Congress enacted the Families First Coronavirus Response Act ("FFCRA")[17] on March 18, 2020.

57. 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).

58. Only nine days after the FFCRA was enacted, Congress enacted the Coronavirus Aid, Relief, and Economic Security ("CARES") Act of 2020 on March 27, 2020.

59. The CARES Act describes how the pricing for FFCRA-required coverage for diagnostic testing is to be established. CARES Act § 3202.

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

61. The CARES Act also requires that providers establish and publicly post on their websites an accurate "cash price." *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.").

62. "*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.

GS LABS SUBMITS THOUSANDS OF SUSPECT CLAIMS TO BLUE KC

63. On March 2, 2021, GS Labs sent correspondence to Blue KC regarding the diagnostic testing claims it would soon be submitting to Blue KC. **Exhibit B**.

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

64. In its March 2, 2021 correspondence, GS Labs 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).

65. GS Labs'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

66. GS Labs's statements regarding its cash prices were false since GS Labs had not established cash prices at the rates identified above (as is described in greater detail below).

67. GS Labs then submitted to Blue KC at least 11,149 claim forms ("the claims")[18] totaling over $9.2 million at the reimbursement rates referenced in the March 2, 2021 correspondence.

68. Upon information and belief, the purported dates of service for the claims range from approximately November 29, 2020 to June 28, 2021.

69. To date, GS Labs has submitted to Blue KC over:

a.) 10,167 claims for rapid antigen testing;

b.) 10,277 claims for specimen collection;

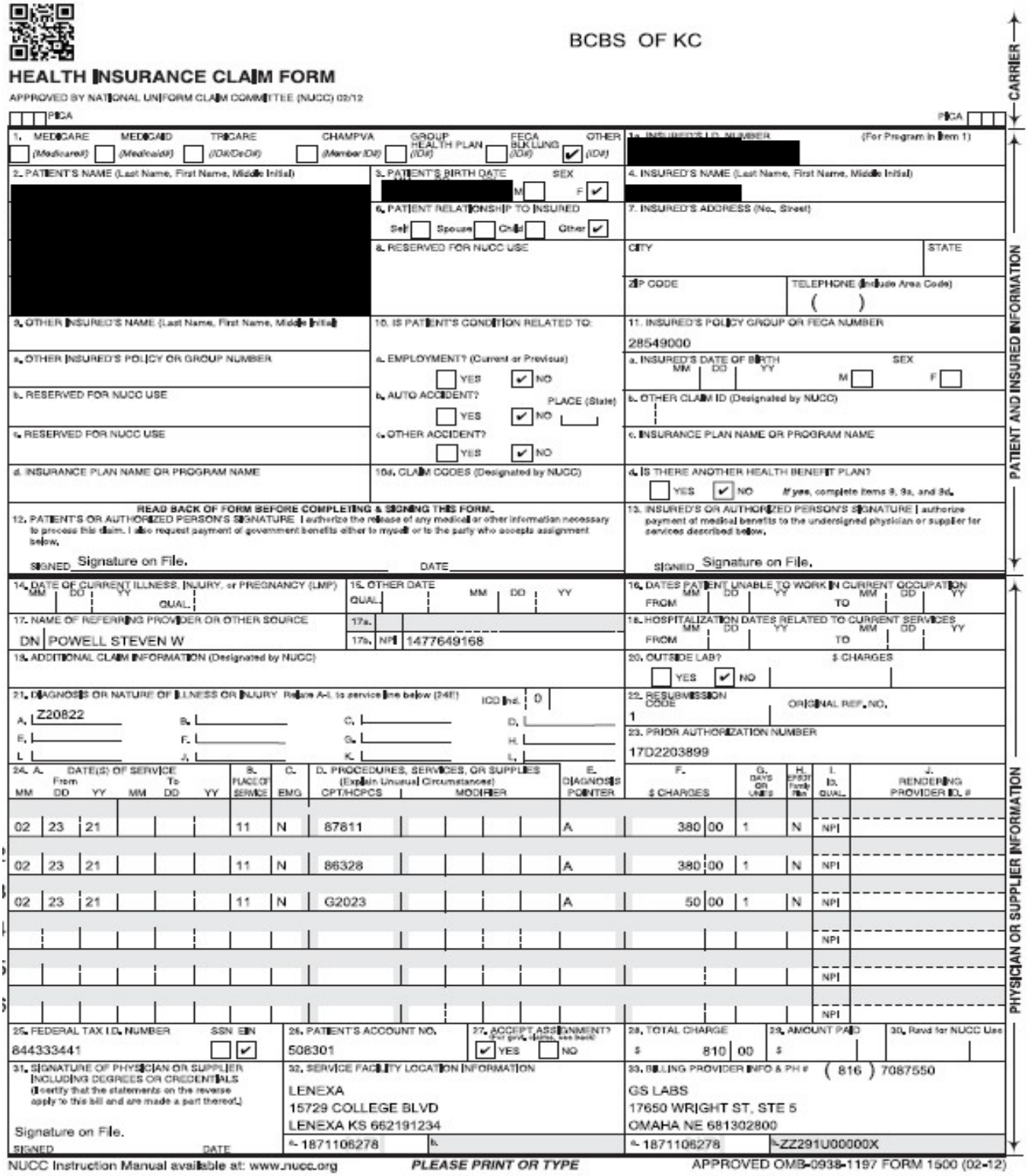
c.) 8,253 claims for rapid antibody testing; and

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

70. Upon information and belief, all PCR testing claims submitted is large panel PCR testing irrespective of the coding used by GS Labs.

[18] Each claim form typically includes claims for multiple services.

71. Reproduced below is a typical claim form GS Labs submitted to Blue KC (with patient identifying information redacted):



BCBS OF KC

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

CARRIER

PATIENT AND INSURED INFORMATION

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#) ✔

1a. INSURED'S I.D. NUMBER (For Program in Item 1) [redacted]

2. PATIENT'S NAME (Last Name, First Name, Middle Initial) [redacted]

3. PATIENT'S BIRTH DATE [redacted] SEX M F ✔

4. INSURED'S NAME (Last Name, First Name, Middle Initial) [redacted]

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other ✔

7. INSURED'S ADDRESS (No., Street)

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER 28549000

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO ✔

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO ✔ PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO ✔

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO ✔ If yes, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED Signature on File. DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED Signature on File.

PHYSICIAN OR SUPPLIER INFORMATION

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE DN POWELL STEVEN W

17a.

17b. NPI 1477649168

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO ✔ $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0

A. Z20822 B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE 1 ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER 17D2203899

24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
02	23	21				11	N	87811		A	380 00	1	N	NPI	
02	23	21				11	N	86328		A	380 00	1	N	NPI	
02	23	21				11	N	G2023		A	50 00	1	N	NPI	
														NPI	
														NPI	
														NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN 844333441

26. PATIENT'S ACCOUNT NO. 508301

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES ✔ NO

28. TOTAL CHARGE $ 810 00

29. AMOUNT PAID $

30. Rsvd for NUCC Use

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

Signature on File.

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

LENEXA

15729 COLLEGE BLVD

LENEXA KS 662191234

a. 1871106278 b.

33. BILLING PROVIDER INFO & PH # (816) 7087550

GS LABS

17650 WRIGHT ST, STE 5

OMAHA NE 681302800

a. 1871106278 b. ZZ291U00000X

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

72. On the reverse side of each claim form, GS Labs certifies, "the services listed above [on each 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."

73. GS Labs's statements are false since the ordering physicians did not personally furnish the tests or personally direct his employees to furnish the tests.

74. In fact, GS Labs does not exercise patient-specific judgment in ordering any of the testing at issue. Instead, GS Labs apparently relies on standing, blanket orders. *See* **Exhibits C, D, and E**. 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.

75. Provision of these tests without a licensed clinician's order, upon information and belief, amounts to laboratory staff's practice of medicine without an appropriate licence in violation of Mo. Rev. Stat. § 334.010 and/or K.S.A. 65-2803 as the ordering physician has no part in the actual (1) patient evaluation, (2) patient counseling, (3) interpretation of results, (3) patient diagnosis, or (4) patient treatment or referral.

76. Moreover, GS Labs violated the terms of its own standing orders by providing testing even when not called for by its own standing orders. The standing orders state that the patient must be "concerned that he or she has been exposed to and/or infected with COVID-19" or present with symptoms consistent with COVID-19. Some, but not all, of the claims GS Labs submitted for reimbursement indicate the patient denied exposure and symptoms but was still tested.

77. Furthermore, GS Labs does not create and maintain adequate documentation to substantiate that the tests in question were administered or administered in a manner that resulted in reliable results. In the alternative, GS Labs has failed to provide such documentationto Blue KC upon request. For example, records involving GS Labs's large panel PCR testing (the ePlex and Biofire

testing described above) do not record results of most of the pathogens for which the tests were designed to detect.

78. Further, many of the claims submitted by GS Labs include claims for services that appear to have been administered in bad faith and performed solely to generate fees. For instance:

a.) GS Labs routinely performs antigen and antibody tests together. There is no legitimate medical reason to routinely perform both rapid antigen and rapid antibody tests together;

b.) GS Labs 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 parapertussis and chlamydia pneumoniae. Associated medical records identify no symptoms, suspected exposures, other test results, or justifications which would warrant using these expensive and extensive tests rather than simple antigen or targeted PCR tests; and

c.) In some instances, PCR, antigen, and antibody testing were performed at the same time, on the same member, without an apparent reason to do so.

GS LABS'S CASH PRICES ARE OBJECTIVELY UNREASONABLE AND WERE ESTABLISHED IN BAD FAITH

79. GS Labs's purported cash prices are excessive, objectively unreasonable, and were set in bad faith.

80. GS Labs states the following are its established "cash prices" and posts the same 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

81. The two types of tests most frequently billed by GS Labs are the COVID-19 rapid antigen test and the COVID-19 rapid antibody test.

82. GS Labs demands a $380 reimbursement per test administered and each of these tests are often priced at wholesale below $20 per test.[19]

83. GS Labs also typically bills an additional $50 charge for specimen collection using the "G2023" procedure code along with the purported cash prices identified above.

[19] *See e.g.* https://www.covidtests.shop/product/healgen-antibody-rapid-test/; https://www.covidtests.shop/product/covid-19-antigen-rapid-test-kit/

84. Upon information and belief, GS Labs also directly charged some Blue KC members a $49 "administrative fee" in addition to any amounts collected from insurers.

85. One version of GS Labs'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, GS Labs 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 F, page 1, paragraph 1.**

86. GS Labs's claims for certain diagnostic 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 tests at substantially lower prices.

87. The following chart compares GS Labs pricing to a small sample of other local testing providers:

Test Type	GS Labs's "Cash Price"	MAC Allowable Rates	Rapid Test KC Drive-Thru Clinic[20]	CVS[21]	Performance Health KC[22]	Truman Med. Ctr.[23]
Rapid Antigen Test (87811)	$380	$41.38	$35	No out of pocket cost	$150[24]	N.A.
Rapid Antibody Test (86328)	$380	$45.23	N.A.	$38[25]	$45	$52[26]
PCR Test (87635)	$385.00	$51.33	$190	$139 ($100 for the laboratory services, $39 for clinic visit)	$170 ($85 for visit and sample collection, $85 for lab fee)	$33.35

88. No unusual or exceptional circumstances justify GS Labs's exceptionally high purported cash prices.

89. GS Labs does not operate in remote communities or other communities where unusually high operating costs would be expected.

90. GS Labs does not provide additional services to its patients.

[20] https://www.rapidtestkc.com/book?gclid=EAIaIQobChMI5J7Vgund8QIV0z2tBh3aTgj_EAAYASAAEgIyAPD_BwE

[21] https://www.cvs.com/minuteclinic/covid-19-testing/?cid=ps_questtest&gclid=Cj0KCQjw5PGFBhC2ARIsAIFIMNdOO4zobpmC5BFAGy0574lHFK66-6uJxuKIMuerK80Icxbb-dhGPeEaAtZKEALw_wcB&gclsrc=aw.ds; Walgreens has a pricing structure similar to CVS. *See* https://www.walgreens.com/findcare/covid19/testing

[22] https://performancehealthkc.com/covid19-testing

[23] https://www.trumed.org/patients-visitors/billing-information/understanding-costs/ (downloadable spreadsheets at bottom of webpage)

[24] Performance Health KC's website does not indicate it charges an additional collection fee for this test.

[25] https://www.cvs.com/content/antibody-testing?icid=coronavirus-lp-nav-antibody-testing

[26] Truman Medical offers a slightly different antibody test using CPT Code 86769. CPT Code 86769 is used to report multiple-step antibody testing for severe acute respiratory syndrome coronavirus while 86328, the code used by GS Labs, is used to report to report single step antibody testing for severe acute respiratory syndrome coronavirus 2. *See generally* https://www.ama-assn.org/practice-management/cpt/covid-19-cpt-coding-and-guidance

91. Rather than providing augmented (or even basic) medical services, GS Labs purports to provide its testing only for "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.

92. GS Labs's consent forms include the following language:

a.) "I am electing to have this antibody test for informational purposes only." **Exhibit F, page 1, paragraph 2;**

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

c.) "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 [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 F, page 2, paragraph 2;** and

d.) "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 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 GS Labs or its staff or

representatives incurs any of these types of expenses, I agree to reimburse GS Labs for these expenses." **Exhibit F, page 2, paragraph 4.**

93. In light of the locations of GS Labs operations, its disclaimer of any actual physician-patient relationship, and its insistence on full indemnification from the patients it supposedly serves, GS Labs's purported cash prices are objectively unreasonable and excessive.

94. GS Labs was unable to offer any credible justification or explanation regarding its facially excessive purported cash prices. Instead, GS Labs stated that its high 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."

95. Multiple media reports contradict GS Labs'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;[27]

b.) "*Kansas looks at whether Lenexa lab price gouged on Covid-19 tests*" December 22, 2020;[28]

c.) "*Lab's 3-month data delay leads to abnormally high daily Covid total in Allegheny County*" April 14, 2021;[29] and

[27] 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
[28] https://www.bizjournals.com/kansascity/news/2020/12/22/covid-19-test-price-gouging-inquiry-gs-labs.html
[29] https://triblive.com/local/westmoreland/labs-3-month-data-delay-leads-to-abnormally-high-daily-covid-total-in-allegheny-county

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").[30]

96. Moreover, public records describe serious quality control and public health concerns at the GS Labs Lee's Summit, Missouri facility. These concerns include the following:

a.) GS Labs informing patients their test results were negative when they were in fact positive;

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

c.) GS Labs not providing results to patients;

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

e.) GS Labs 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.) GS Labs operating in unsafe and non-sterile working conditions; and

g.) GS Labs failing to properly handle medical waste.

97. Via correspondance dated February 15, 2021, GS Labs admitted that testing it performed "may be inaccurate due to incomplete equipment validation studies and quality control records." **Exhibit H.**

98. On March 18, 2021, the Nebraska Department of Health and Human Services sent correspondance to GS Labs noting, GS Labs "is not in compliance with all of the Conditions required for certification in the CLIA[31] program." **Exhibit I, page 1, paragraph 2.**

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

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

99. Via correspondance dated May 14, 2021, GS Labs admitted that it failed to follow certain unidentified "applicable laboratory standards for testing facilities" protocols. **Exhibit J, paragraph 1.**

100. GS Labs did not operate a "top notch" lab and, instead, operated testing facilities that produce flawed, delayed, and unreliable results.

101. GS Labs's purported cash pricing would still be objectively excessive and unreasonable even if its statements regarding the quality of its services were true.

102. GS Labs's purported cash prices are objectively excessive and unreasonable and were not set in good faith.

103. Instead, GS Labs's posted "cash prices" and claims for those prices amount to unlawful price gouging and disaster profiteering. *See generally* K.S.A. 50-6,106; Mo. Rev. Stat. § 407.010, *et seq.*, 15 C.S.R. 60-8.030.

104. The prices posted and claimed by GS Labs are contrary to the public interest as articulated by K.S.A. 50-6,106; Mo. Rev. Stat. § 407.010, *et seq.*, 15 C.S.R. 60-8.030-.04.

GS LABS USED A FALSE "CASH PRICE" IN CONNECTION WITH ITS CLAIMS

105. Not only are GS Labs's charges excessive, objectively unreasonable, and posted in bad faith, they are also fraudulent.

106. GS Labs knowingly and intentionally posted on its website sham cash prices which did not represent the actual cash prices GS Labs offered to the public.

107. Despite the CARES Act's requirement that GS Labs post accurate cash prices on its website, GS Labs did not post accurate cash prices.[32]

[32] *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).

108. Instead, GS Labs posted inflated and illusory prices.

109. At the same time GS Labs posted its excessive purported cash prices and demanded that insurers pay those false "cash prices," GS Labs facilities in both Lenexa, Kansas and Lee's Summit, Missouri routinely refused to provide treatment to patients who sought to pay cash for COVID-19 diagnostic testing.

110. In fact, GS Labs's consent forms include the following language: GS Labs "***only accepts insurance patients*** who are seeking testing for diagnostic purposes." **Exhibit G, page 3, paragraph 4.** (emphasis added).

111. For a large portion, or even all of the period in which testing services were purportedly provided, GS Labs refused patients who sought to pay GS Labs in cash (or cash equivalents). Therefore, the publicly posted purported cash prices were a sham and not a true "cash prices" as that term is used by Section 3202 of the CARES Act.

112. Upon information and belief, at an unknown time in 2021 GS Labs may have changed its practices and began accepting cash patients. However, when GS Labs began to accept cash patients, the actual rates charged to these patients were substantially lower than the purported cash prices GS Labs posted on its website.

113. GS Labs's website currently states it accepts patients who pay cash. However, GS Labs does not collect the posted "cash price" from uninsured patients. Instead, GS Labs accepts less than one-third of the posted purported cash price as payment in full for testing services offered.

114. For instance, at the same time GS Labs told uninsured patients that it would accept $114.00 to conduct basic rapid antigen testing, GS Labs represented to insurers that its "cash price" for the same service is $380.

115. GS Labs knowingly and willfully executed a scheme or artifice to defraud health insurers and plans by posting a false "cash price" that GS Labs never actually collected from individual

cash-paying consumers and then demanded payment of those same false cash prices from insurance companies.

GS LABS MAKES UNREASONABLE DEMANDS

116. After receiving the March 2, 2021 correspondence and the claims, Blue KC approached GS Labs 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").

117. Blue KC and GS Labs had several discussions regarding the services offered, lack of medical records, and excessive cash prices.

118. Nevertheless, the negotiations reached an impasse, after GS Labs 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

119. Plaintiff realleges each and every allegation set forth in paragraphs 1 – 118 as if fully set forth herein.

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

121. 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.

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

123. GS Labs 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.

124. GS Labs knowingly and willfully disregarded its statutory obligation 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.

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

126. The cash prices GS Labs purported to set establish are objectively unreasonable and grossly excessive and are impermissible under the CARES Act.

127. GS Labs continues to demand that Blue KC pay grossly and unnecessarily excessive reimbursement rates for the claims described above.

128. Blue KC refuses to submit to GS Labs's demands.

129. Accordingly, pursuant to 28 U.S.C. § 2201, a judicial declaration is necessary and appropriate to specify that the rights of the parties with respect to claims submitted to Blue KC by GS Labs.

130. Plaintiff has sustained damage as a result of GS Labs's bad faith, concealments, misrepresentations, and use of sham "cash prices," in that it has incurred substantial costs and expenses for claim response, investigation, and attorney's fees, which continue to accrue.

131. Plaintiff is entitled to recover its attorneys' fees in this matter and such an award is proper under Federal Rules of Civil Procedure 54 and 58, 28 U.S.C. § 2202 or, in the alternative, Missouri's declaratory judgment statute, Mo. Rev. Stat. Section 527.010, *et seq*.

COUNT II. INJUNCTIVE RELIEF

132. Plaintiff realleges each and every allegation set forth in paragraphs 1 – 131 as if fully set forth herein.

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

134. In a section titled "ATTENTION BLUE CROSS/BLUE SHIELD MEMBERS," GS Labs'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 G, page 2, paragraph 5.**

135. In a section titled "Financial Responsibility," GS Labs's consent forms state, "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 . . . " 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 G, page 3, paragraph 3.** (emphasis in original).[33]

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

137. GS Labs has not promptly agreed to refrain from balance billing Blue KC members.

138. In light of the unique circumstances of this dispute, GS Labs should be enjoined from balance billing Blue KC members.

139. Guidance issued by CMS provides that the CARES Act generally precludes balance billing:

[33] GS Labs's website makes contradictory representations to its patients 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.[34]

140. Blue KC has a substantial interest in preventing GS Labs from balance billing its members.

141. If GS Labs 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.

142. Additionally, if GS Labs 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 GS Labs's bills. Balance billing could result in a loss of membership that would be practicably difficult to prevent or precisely quantify.

143. Further, if GS Labs were to attempt to collect the claims from the 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 and the broader community.

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

144. Neither public health nor innocent Blue KC members should be harmed by Blue KC's efforts to thwart GS Labs's scheme.

PRAYER FOR RELIEF

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

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

b.) Declaring the claims GS Labs submitted to Blue KC are the product of a fraudulent scheme or artifice and, therefore, Blue KC has no obligation to pay the claims;

c.) Declaring that GS Labs violated its duty of good faith when it purported to set a "cash price" for COVID-19 diagnostic tests covered by the CARES Act and, therefore, Blue KC has no obligation to pay the claims;

d.) Declaring the claims are defective or otherwise non-payable for the reasons stated in this pleading;

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

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

g.) 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*
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Attorney for Blue Cross and Blue Shield of Kansas City

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/

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

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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

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.

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

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

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.

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

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.

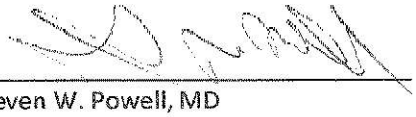
5. Ensure all supplies including specimen test kits, PPE, storage, and shipment of specimens, and required forms for testing and documentation are available.

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

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

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

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

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.

PLEASE COMPLETE THE FOLLOWING WITH THE PATIENT'S INFORMATION ONLY

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

[redacted]

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.

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

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 symtoms in the last 14 days?

[redacted]

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

February 15, 2021

Testing performed at GS Labs between 7/1/2020 and 10/31/2020 may be inaccurate due to incomplete equipment validation studies and quality control records. While the lab results were used as a guide, prescribed therapy was based on symptom relief. I have reviewed the test results and treatment protocol and I do not recommend any changes to therapy based on the lab results from GS Labs.

DocuSigned by:
DARIN JACKSON
04ECE03552194E1...

Darin Jackson, MD
Medical Director/Lab director
GS Labs

EXHIBIT H

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;

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

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

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 J

JS 44 (Rev 09/10)

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI

CIVIL COVER SHEET

This automated JS-44 conforms generally to the manual JS-44 approved by the Judicial Conference of the United States in September 1974. The data is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. The information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law. This form is authorized for use only in the Western District of Missouri.

The completed cover sheet must be saved as a pdf document and filed as an attachment to the Complaint or Notice of Removal.

Plaintiff(s):

First Listed Plaintiff:
Blue Cross and Blue Shield of Kansas City ;
1 Citizen of This State;
County of Residence: Jackson County

Defendant(s):

First Listed Defendant:
GS Labs, LLC ;
2 Citizen of Another State; Nebraska
County of Residence: Douglas County

County Where Claim For Relief Arose: Jackson County

Plaintiff's Attorney(s):

Aaron E. Schwartz (Blue Cross and Blue Shield of Kansas City)
Capes, Sokol, Goodman & Sarachan, P.C.
8182 Maryland Avenue, 15th Floor
St Louis, Missouri 63105-3916
Phone: 314-721-7701
Fax: 314-721-0554
Email: schwartz@capessokol.com

Defendant's Attorney(s):

Barbara E. Person (GS Labs, LLC)
Baird Holm, LLP
1700 Farnam Street, Suite 1500
Omaha, Nebraska 68102-2068
Phone: 402-344-0500
Fax: 402-344-0588
Email: bperson@bairdholm.com

Basis of Jurisdiction: 4. Diversity of Citizenship

Citizenship of Principal Parties (Diversity Cases Only)

Plaintiff: 1 Citizen of This State

Defendant: 2 Citizen of Another State

Origin: 1. Original Proceeding

Nature of Suit: 110 Insurance Contracts

Cause of Action: Plaintiff seeks a judgment declaring it has no obligation to pay thousands of abusive claims for Covid-19 diagnostic testing.

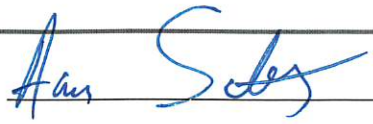
Requested in Complaint

Class Action: Not filed as a Class Action

Monetary Demand (in Thousands):

Jury Demand: No

Related Cases: Is NOT a refiling of a previously dismissed action

Signature: 

Date: 07/20/2021

If any of this information is incorrect, please close this window and go back to the Civil Cover Sheet Input form to make the correction and generate the updated JS44. Once corrected, print this form, sign and date it, and submit it with your new civil action.