Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2182284	02/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Gb Diagnostics	3915 Carlisle Blvd Ne, Albuquerque, NM	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on the number and severity of deficiencies cited for services provided in the subspecialty of General Immunology, the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. See D5217, D5291, D5391, D5400, D5403, D5423, D5425, D5441, D5447, D5775, D5791, D5805 and D5891 for findings.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on the number and severity of deficiencies cited for services provided in the subspecialty of Routine Chemistry, the laboratory failed to meet the requirements specified in 493.1230 through 493.1256 and 493.1281 through 493.1299. See D5217, D5291, D5391, D5400, D5403, D5423, D5425, D5441, D5447, D5775, D5791, D5805 and D5891 for findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on lack of accuracy verification documentation for review for the laboratory-developed tests (LDT) performed by the laboratory and interview with the technical supervisor, the laboratory failed to verify the accuracy of testing performed under the sub-specialties of general immunology and routine chemistry at least twice annually during 2021 and 2022. Findings include: 1. The laboratory began patient testing using a LDT ELISA (enzyme-linked immunosorbent assay) test method on 6/15/2020 under the sub-specialties of General Immunology and Routine Chemistry, with an approximate annual test volume of 7,190. The laboratory performed and reported approximately 12,112 patient tests between 6/15/2020 and the survey date, 1/10/2023. The laboratory's test methods for the testing performed are not FDA-cleared or approved. 2. The laboratory performs their LDT for the following analytes using the ELISA test method: DAO (Diamine Oxidase), Zonulin Family Peptides (Zonulin FP), Histamine, 8-OHdG, Creatinine, Total Bile Acids (TBA), Indican, IgG FS-88 (88 panel Food Sensitivity test), and Candida (IgG, IgA, IgM). 3. No documentation was presented for review during the survey to indicate the laboratory verified the accuracy of each LDT test referenced above at least twice annually during 2021 and 2022. 4. At 12:59pm on 1/10/2023, the technical supervisor interviewed stated the laboratory never verified the accuracy of their tests from the time the laboratory began patient testing through the date of the survey (1/10/2023).
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) policies and procedures and interview with the technical supervisor, the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. Findings include: 1. No QA documentation was provided for review during the survey conducted on 1/10/2023 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the general laboratory systems. 2. The technical supervisor interviewed on 1/10/2023 at 1:50pm confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified with the general laboratory systems.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems

	identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) policies and procedures and interview with the technical supervisor, the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the preanalytic systems. Findings include: 1. No QA documentation was provided for review during the survey conducted on 1/10/2023 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the preanalytic systems. 3. The technical supervisor interviewed on 1/10/2023 at 1:50pm confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified with the preanalytic systems.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the number and severity of deficiencies cited for quality practices identified during the survey conducted on January 10, 2023, it was determined that the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283, and failed to monitor the overall quality of the analytic systems and correct problems as specified in 493.1289 for patient testing performed by the laboratory in the sub-specialties of general immunology and routine chemistry. See D5403, D5423, D5425, D5441, D5447, D5775, and D5791 for findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the

	protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's test procedures and interview with the technical supervisor, the laboratory's test procedures failed to include the information required under 493.1251. Findings include: 1. The laboratory began patient testing using an ELISA (enzyme-linked immunosorbent assay) test method on 6/15/2020 under the sub-specialties of General Immunology and Routine Chemistry, with an approximate annual test volume of 7,190. The laboratory's test methods are not FDA-cleared or approved. 2. The laboratory performs their LDT for the following analytes using the ELISA test method: DAO (Diamine Oxidase), Zonulin Family Peptides (Zonulin FP), Histamine, 8-OHdG, Creatinine, Total Bile Acids (TBA), Indican, IgG FS-88 (88 panel Food Sensitivity test), and Candida (IgG, IgA, IgM). The analytes can be ordered as a test panel or individually. The laboratory uses dried blood and/or dried urine as the specimen type. 3. The test procedures presented for review during the survey for each analyte indicated above failed to include the following information: - Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. - Test calculations and interpretation of results - Calibration procedures - Control procedures - Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. - Limitations in the test methodology, including interfering substances. - Reference intervals (normal values). - Pertinent literature references. - Description of the course of action to take if a test system becomes inoperable. 4. The technical supervisor interviewed on 1/10/2023 at 12:22pm confirmed the laboratory's test procedures were missing the required information listed above. 5. The laboratory performed and reported approximately 12,112 patient tests between 6/15/2020 and the survey date of 1/10/2023.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on lack of documentation for test system performance specifications and interview with the technical supervisor, the laboratory failed to establish the performance specifications for each Laboratory-Developed Test (LDT) performed by the laboratory before reporting patient test results. Findings include: 1. The laboratory began patient testing using an ELISA (enzyme-linked immunosorbent assay) test method on 6/15/2020 under the sub-specialties of General Immunology and Routine

	Chemistry, with an approximate annual test volume of 7,190. The laboratory's test methods are not FDA-cleared or approved. 2. The laboratory performs their LDT for the following analytes using the ELISA test method: DAO (Diamine Oxidase), Zonulin Family Peptides (Zonulin FP), Histamine, 8-OHdG, Creatinine, Total Bile Acids (TBA), Indican, IgG FS-88 (88 panel Food Sensitivity test), and Candida (IgG, IgA, IgM). The analytes can be ordered as a test panel or individually. The laboratory uses dried blood and/or dried urine as the specimen type. 3. The laboratory utilizes test kits distributed by DRG International, Inc for testing Candida (IgG, IgA, IgM). The manufacturer's test kit instructions are labeled "For Research Use Only' (RUO), Not for use in diagnostic procedures." The manufacturer's instructions indicate that serum must be used as the specimen type. 4. The laboratory utilizes test kits distributed by Elabscience for testing Zonulin, 8-OHdG, DAO, TBA and Histamine. The manufacturer's test kit instructions are labeled "For Research Use Only. Do Not Use It In Clinical Diagnostics!". The manufacturer's instructions indicate that serum or plasma must be used as the specimen type. 5. The laboratory utilizes a test kit distributed by Tecan for testing IgG FS-88. The manufacturer's test kit instructions are labeled "For Research Use Only. Not for use in diagnostic procedures." The manufacturer's instructions indicate that serum or plasma samples are required for the specimen type. 6. The LDT used for Creatinine includes using a modified test method of the picric acid method by mixing NaOH, Saturated Picric Acid (SPA) and Creatinine Calibrator. 7. As evidenced by a lack of documentation for review, the laboratory failed to establish the following performance specifications for each analyte listed above prior to reporting patient test results: accuracy, precision, analytical sensitivity, analytic specificity to include interfering substances, reportable range, reference intervals (normal values) and any other performance characteristics required for test performance (including using a different sample matrix). 8. The Technical Supervisor interviewed on 1/10/2023 at 12:14pm confirmed the laboratory failed to establish the performance specifications for each test indicated above prior to reporting patient test results. 9. The laboratory performed and reported approximately 12,112 patient tests between 6/15/2020 and the survey date of 1/10/2023.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on lack of documentation for review during the survey performed on 1/10/2023 and interview with the technical supervisor, the laboratory failed to determine the test system's calibration procedures and control procedures based upon the established performance specifications. Findings include: 1. The laboratory began patient testing using a laboratory-developed ELISA (enzyme-linked immunosorbent assay) test method on 6/15/2020 under the sub-specialties of General Immunology and Routine Chemistry, with an approximate annual test volume of 7,190. . The laboratory's test methods are not FDA-cleared or approved. 2. The laboratory performs their laboratory-developed test (LDT) for the following analytes using the ELISA test method: DAO (Diamine Oxidase), Zonulin Family Peptides (Zonulin FP), Histamine, 8-OHdG, Creatinine, Total Bile Acids (TBA), Indican, IgG FS-88 (88 panel Food Sensitivity test), and Candida (IgG, IgA, IgM). The analytes can be ordered as a test panel or individually. The laboratory uses dried blood and/or dried urine as the

	specimen type. 3. The laboratory failed to determine the calibration procedures and control procedures for each LDT (each analyte test system) indicated above. 4. The laboratory failed to establish the performance specifications for their LDT's. See D5423 for findings. 5. The technical supervisor interviewed on 1/10/2023 at 1:10pm confirmed the laboratory failed to determine calibration procedures and control procedures for their LDT as indicated above. 6. The laboratory performed and reported approximately 12,112 patient tests between 6/15/2020 and the survey date of 1/10/2023.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of established control procedure documentation and interview with the technical supervisor, the laboratory failed to have control procedures that monitor the accuracy and precision of the complete analytic process for testing performed by the laboratory using a laboratory-developed test method for ELISA testing. Findings include: 1. The laboratory began patient testing using a laboratory-developed ELISA (enzyme-linked immunosorbent assay) test method on 6/15/2020 under the sub-specialties of General Immunology and Routine Chemistry, with an approximate annual test volume of 7,190. The laboratory's test methods are not FDA-cleared or approved. 2. The laboratory performs their laboratory-developed test (LDT) for the following analytes using the ELISA test method: DAO (Diamine Oxidase), Zonulin Family Peptides (Zonulin FP), Histamine, 8-OHdG, Creatinine, Total Bile Acids (TBA), Indican, IgG FS-88 (88 panel Food Sensitivity test), and Candida (IgG, IgA, IgM). The analytes can be ordered as a test panel or individually. The laboratory uses dried blood and/or dried urine as the specimen type. 3. No evidence was presented for review during the survey conducted on 1/10/2023 to indicate the laboratory established control procedures that monitor the accuracy and precision of the complete analytic process for each LDT indicated above, including the number, type, and frequency of testing control materials. 4. No evidence was presented for review during the survey to indicate the laboratory performed Quality Control (QC) each day of patient testing as required, from the date the test was initially put into use through the date of the survey. 5. The technical supervisor interviewed on 1/10/2023 at 1: 10pm confirmed that the laboratory failed to provide documentation of an approved QC procedure for their LDT's (for each analyte) and did not perform QC from the time the tests were initially put into use through the date of the survey. 6. The laboratory performed and reported approximately 12,112 patient tests between 6/15 /2020 and the survey date of 1/10/2023.
D5447	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient test reports, lack of established control procedures, lack of quality control (QC) documentation and interview with the technical supervisor, the laboratory failed to perform two control materials of different concentrations each day patient testing occured. Findings include: 1. The laboratory began patient testing using a laboratory-developed ELISA (enzyme-linked immunosorbent assay) test method on 6/15/2020 under the sub-specialties of General Immunology and Routine Chemistry, with an approximate annual test volume of 7,190. The laboratory's test methods are not FDA-cleared or approved. 2. The laboratory performs their laboratory-developed test (LDT) for the following analytes using the ELISA test method: DAO (Diamine Oxidase), Zonulin Family Peptides (Zonulin FP), Histamine, 8-OHdG, Creatinine, Total Bile Acids (TBA), Indican, IgG FS-88 (88 panel Food Sensitivity test), and Candida (IgG, IgA, IgM). The analytes can be ordered as a test panel or individually. The laboratory uses dried blood and/or dried urine as the specimen type. 3. No evidence was presented for review during the survey to indicate the laboratory performed two control materials of different concentrations each day of patient testing as required for each test performed by the laboratory, from the date the test was initially put into use through the date of the survey. 4. The laboratory failed to establish control procedures for each LDT performed by the laboratory. See D5441 for findings. 5. The technical supervisor interviewed on 1/10/2023 at 1:10pm confirmed the laboratory failed to perform two control materials of different concentrations each day patient testing occured from the time the tests were initially put into use through the date of the survey. 6. The laboratory performed and reported approximately 12,112 patient tests between 6/15/2020 and the survey date of 1/10 /2023.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on lack of instrument comparison results and interview with the technical supervisor, the laboratory failed to have a system in place that twice a year evaluates and defines the relationship between test results for testing performed in the sub-specialties of general immunology and routine chemistry. Findings include: 1. The laboratory uses two separate Tecan F200 Infinite with Ultra Sensitive PMT (photomultiplier tube) fluorescence plate readers in conjunction with testing their laboratory-developed test using the ELISA test method. The fluorescence plate

	readers are used for reading the IgG FS-88 test results. 2. The laboratory uses two separate Biotek ELX808 absorbance plate readers in conjunction with testing their laboratory-developed tests using the ELISA test method. The absorbance plate readers are used for all tests performed by the laboratory except the IgG FS-88 test. 3. During the survey conducted on 1/10/2023, no documentation was presented for review to indicate the laboratory had a system in place that twice a year evaluates and defines the relationship between the test results generated from each fluorescence plate reader and each absorbance plate reader used by the laboratory. 4. The laboratory began patient testing using the plate readers indicated above on 6/15/2020. The laboratory performed approximately 12,112 patient tests from 6/15/2020 through 01/10/2023, the date of the survey. 5. At 1:42pm on 1/10/2023, the technical supervisor interviewed confirmed the laboratory did not have a system in place at the time of the survey to evaluate and document a comparison of test results between the instruments mentioned above.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) policies and procedures and interview with the technical supervisor, the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the analytic systems. Findings include: 1. No QA documentation was provided for review during the survey conducted on 1/10/2023 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the analytic systems. 2. The technical supervisor interviewed on 1/10/2023 at 1:50pm confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified with the analytic systems.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the technical supervisor, the laboratory failed to include on the test report the laboratory address where the testing was performed and failed to include required disclaimers regarding the tests

	performed. Findings include: 1. The laboratory began patient testing using an ELISA (enzyme-linked immunosorbent assay) test method on 6/15/2020 under the sub-specialties of General Immunology and Routine Chemistry, with an approximate annual test volume of 7,190. The laboratory performed and reported approximately 12,112 patient tests between 6/15/2020 and the survey date, 1/10/2023. The laboratory's test methods are not FDA-cleared or approved. 2. The laboratory performs their LDT for the following analytes using the ELISA test method: DAO (Diamine Oxidase), Zonulin Family Peptides (Zonulin FP), Histamine, 8-OHdG, Creatinine, Total Bile Acids (TBA), Indican, IgG FS-88 (88 panel Food Sensitivity test), and Candida (IgG, IgA, IgM). 3. The test reports reviewed during the survey (Accession# 100048870 and 100044493) were missing the laboratory address where the testing was performed. 4. The test reports reviewed during the survey (Accession# 100048870, 100044493, 100048131, 100043145, 100047327, 100036354 and 100053784) were missing the required disclaimer as referenced below: For tests that have not been FDA-cleared or approved (including test systems not subject to FDA clearance or approval, methods developed in-house, standardized methods such as textbook procedures, and FDA-cleared or approved test systems modified by the laboratory), the test report must include the statement "The performance characteristics of this test were determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration". 5. The technical supervisor interviewed on 1/10/2023 at 12:05pm confirmed that the laboratory address where the diagnosis was made and the required disclaimer listed above were not indicated on the patient test reports issued by the laboratory.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) policies and procedures and interview with the technical supervisor, the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the postanalytic systems. Findings include: 1. No QA documentation was provided for review during the survey conducted on 1/10/2023 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. 3. The technical supervisor interviewed on 1/10/2023 at 1:50pm confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified with the postanalytic systems.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by:

	The Condition of Laboratory Director was found to be not met based on the failure to fill the position as required under 493.1441. Findings include: 1. No laboratory director name or signature was documented on the CMS-116 form or the CMS-209, Laboratory Personnel Form presented for review during the survey conducted on 01/10 /2023. 2. The Technical Supervisor (TS) inteviewed on 01/10/23 at 10:45am stated that the laboratory failed to have a qualified laboratory director at the time of the survey. 3. The laboratory director listed in the CLIA database on the CLIA certification for GB Diagnostics, CLIA# 03D2182284, sent the laboratory an email on 9/07/2022 indicating his immediate resignation. Upon the laboraory director's notice of resignation, the laboratory failed to notify the Arizona State Agency to assign a new laboratory director.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on review of the CMS-209, Laboratory Personnel Report presented for review during the survey and interview with the Technical Supervisor, the laboratory failed to have a qualified Laboratory Director at the time of the survey. Findings include: 1. The laboratory performs high complexity testing using a lab-developed ELISA test

	method, with an approximate annual test volume of 7,190. 2. During the survey conducted on January 10, 2023, it was discovered that the Laboratory Director listed in the CMS database at the time of the survey for CLIA# 03D2182284 was no longer affiliated with the facility as of 9/07/2022. The State Agency received no notification of a Laboratory Director change for this CLIA certification. 3. The laboratory director listed in the CLIA database at the time of the survey for GB Diagnostics, CLIA# 03D2182284, sent the laboratory an email on 9/07/2022 indicating his immediate resignation. Documentation of this email was provided for review to the surveyor. 4. The position of laboratory director was not filled as required under regulation 493. 1443 from 9/07/2022 through the date of the survey, 1/10/2023. 5. The Technical Supervisor interviewed on 1/10/2023 at 11:10am acknowledged that the laboratory failed to provide evidence of a qualified Laboratory Director at the time of the survey.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care. This STANDARD is not met as evidenced by: Based on lack of records for the establishment of performance specifications, lack of established calibration and control procedures, lack of quality control records and lack of test accuracy verification records, the laboratory director failed to ensure that the ELISA test methodologies developed by the laboratory have the capability of providing the quality of results required for patient care. See D5217, D5423, D5425, D5441, and D5447 for findings.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on lack of quality control records and procedures, the laboratory director failed to ensure that quality control programs are established to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5425, D5441 and D5447 for findings.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) documentation for review, the laboratory director failed to ensure that a QA program is established and maintained to assure the

	quality of laboratory services provided and to identify failures in quality as they occur. See D5291, D5391, D5791 and D5891 for findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of initial training documentation for one testing personnel who performs testing in the specialties of Diagnostic Immunology and Chemistry and interview with the technical supervisor, the laboratory director failed to ensure that all testing personnel receive the appropriate training and demonstrate that they can perform all testing operations reliably and accurately prior to testing patients' specimens. Findings include: 1. No initial training documentation was presented for review for one out of one testing personnel who performs patient testing in the specialties of Diagnostic Immunology and Chemistry. 2. The technical supervisor interviewed on 1/10/2023 at 11:15am confirmed the laboratory failed to have documentation of initial training for the testing personnel indicated above.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on lack of policies and procedures for review and interview with the technical supervisor, the laboratory director failed to ensure that policies and procedures are established for monitoring individuals who perform patient testing to assure that they are competent and maintain their competency to perform test procedures and report test results promptly and proficiently. Findings include: 1. No policies and procedures as described above were presented for review during the survey. 2. The technical supervisor confirmed that the laboratory failed to have established policies and procedures in place at the time of the survey for monitoring individuals who perform patient testing.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

	This CONDITION is not met as evidenced by: The Condition of Technical Supervisor is not met as evidenced by: D6115 - failure to establish the laboratory's test performance specifications for the test system used by the laboratory and failure to verify the test procedures performed; D6117 - failure to establish a quality control program appropriate for the testing performed and failure to ensure that acceptable levels of analytic performance are maintained throughout the entire testing process; D6127 - failure to evaluate and document semi-annual competency for testing personnel; and D6128 - failure to evaluate and document annual competency for testing personnel.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on a lack of performance specification records for the laboratory-developed ELISA test method, the technical supervisor failed to establish the laboratory's test performance characteristics for the test system used by the laboratory. See D5423, D5425, and D5441 for findings.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on lack of quality control records and procedures and lack of established performance specifications for the laboratory-developed ELISA test method, the technical supervisor failed to establish a quality control program appropriate for the testing performed and failed to ensure that acceptable levels of analytic performance are maintained throughout the entire testing process. See D5423, D5425, D5441, and D5447 for findings.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by:

	Based on lack of performance evaluation documentation and interview with the technical supervisor, the technical supervisor failed to evaluate and document the performance of one testing personnel, at least semiannually during the first year the individual tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation was presented for review for one out of one testing personnel who began patient testing in June 2020. 2. The testing personnel interviewed on 1/10/2023 at 12:05pm confirmed that the laboratory failed to have documentation of a semiannual competency evaluation for the testing personnel indicated above.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on lack of testing personnel (TP) competency records for review and interview with the technical supervisor, the laboratory failed to document the annual competency evaluation of one out of one testing personnel during 2021 and 2022. Findings include: 1. No 2021 and 2022 annual competency evaluation documentation was presented for review during the survey conducted on 1/10/2023 for one testing personnel who performs high complexity testing in the sub-specialties of General Immunology and Routine Chemistry. 2. The testing personnel indicated above began patient testing in June 2020. 3. The technical supervisor interviewed at 12:05pm on January 10, 2023 confirmed that the laboratory failed to have documentation of annual competency evaluations for the testing personnel indicated above.
D6134	CLINICAL CONSULTANT CFR(s): 493.1453 The laboratory must have a clinical consultant who meets the requirements of 493. 1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart. This CONDITION is not met as evidenced by: Based on review of the CMS-209, Laboratory Personnel Form, and interview with the laboratory technical supervisor on January 10, 2023, the laboratory failed to have a clinical consultant identified that met the qualifications as listed in 42 C.F.R. 493.1455. See D6135.
D6135	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1455 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443(b)(6); or

	(b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on review of the submitted CMS-209, Laboratory Personnel form and interview with the laboratory Technical Supervisor on January 10, 2023, the laboratory failed to identify a qualified clinical consultant to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. Findings include: 1. The laboratory initiated a laboratory developed test (LDT) using the ELISA test method on June 15, 2020, under the sub-specialties of General Immunology and Routine Chemistry. 2. The Technical Supervisor confirmed by interview on January 10, 2023 the lack of designation of a qualified clinical consultant. 3. The laboratory's approximate test volume from June 15, 2020 through January 10, 2023 was reported as 12,112 test results.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: The Condition of Testing Personnel was found to be not met based on education verification documentation presented during the survey for two out of two testing personnel who failed to meet the required qualifications for individuals performing high complexity testing. See D6171 for findings.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the

	individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on the education documentation presented for review during the survey for two out of two testing personnel (TP), the laboratory failed to ensure that testing personnel have the required education qualifications prior to testing patients' specimens. Findings include: 1. The laboratory performs approximately 7,190 patient tests annually under the sub-specialties of General Immunology and Routine Chemistry. The laboratory began high complexity testing on 6/15/2020. 2. During the survey performed on January 10, 2023, the CMS-209, Laboratory Personnel form submitted for review indicated two testing personnel: TP-1 began patient testing in September 2020 and TP-2 began patient testing in August 2021. 3. No documentation was presented for review during the survey to indicate that the two testing personnel referenced above met the required qualifications under 493.1489 in the CLIA regulations for Testing Personnel who perform high complexity testing. 4. The Technical Supervisor interviewed on 1/10/2023 at 12:05pm confirmed that the testing personnel stated above lacked the appropriate education documentation for the complexity of testing performed by the laboratory.