

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2245360	(X3) Date Survey Completed 05/20/2022
Name of Provider or Supplier Medlab2020, Inc Db a Vervality	Street Address, City, State 203 Forest Ave, Palo Alto, CA	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory director and laboratory manager interviews and laboratory policies and procedures record review on April 29, 2022 at 11:00 am, the laboratory, which performs a test (SARS-CoV-2) that is not included in subpart I, failed to have a mechanism that at least twice annually verifies the test's accuracy. Findings included: a. It was the practice of the laboratory to perform SARS-CoV-2 tests on patient specimens using the Bio-Speedy Direct RT-qPCR SARS-CoV-2 assay. b. The laboratory director and laboratory manager confirmed that the laboratory maintained no mechanism to verify the accuracy of its SARS-CoV-2 test at least twice annually. c. According to the laboratory manager, since January 1, 2022, when the laboratory began testing patient specimens using its SARS-CoV-2 assay, the laboratory had tested approximately 100,000 patient specimens from January 1, 2022 to April 29, 2022 using its SARS-CoV-2 assay.</p>
D5300	<p>PREANALYTIC SYSTEMS CFR(s): 493.1240</p> <p>Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.</p>

This CONDITION is not met as evidenced by:
Based on the number and severity of the deficiencies cited herein, the Condition: Preanalytic Systems was not met. The laboratory failed to have written or electronic requests for patient testing from an authorized person (see D5301), establish written policies and procedures for patient specimen labeling and processing (see D5311), and establish 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 (see D5391).

D5301

TEST REQUEST
CFR(s): 493.1241(a)

The laboratory must have a written or electronic request for patient testing from an authorized person.

This STANDARD is not met as evidenced by:
Based on laboratory manager interview and laboratory patient specimen assessing information record review on April 29, 2022 at 10:00 am, the laboratory failed to have written or electronic requests for patient SARS-CoV-2 testing from an authorized person. Findings included: a. It was the practice of the laboratory to perform SARS-CoV-2 tests on patient specimens using the Bio-Speedy Direct RT-qPCR SARS-CoV-2 assay. b. During the onsite survey on April 29, 2022, the laboratory was unable to provide written or electronic requests for any patient SARS-CoV-2 tests the laboratory had performed and reported. The laboratory director and laboratory manager confirmed this finding. c. Laboratory records indicated that on April 28, 2022 the laboratory received 1,958 patient specimens for which the laboratory tested using its SARS-CoV-2 assay and reported the SARS-CoV-2 patient test results. For these 1,958 patient specimens, the laboratory was unable to provide any written or electronic requests from an authorized person to perform the SARS-CoV-2 test. d. According to the laboratory manager, since January 1, 2022, when the laboratory began testing patient specimens using its SARS-CoV-2 assay, the laboratory had tested approximately 100,000 patient specimens from January 1, 2022 to April 29, 2022 using its SARS-CoV-2 assay.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
Based on laboratory manager interview and laboratory policies and procedures record review on April 29, 2022 at 10:00 am, the laboratory failed to establish written procedures for patient specimen labeling and processing. Findings included: a. It was the practice of the laboratory to perform SARS-CoV-2 tests on patient specimens using the Bio-Speedy Direct RT-qPCR SARS-CoV-2 assay. b. The laboratory

manager confirmed that the laboratory maintained no written procedures for patient SARS-CoV-2 specimen labeling and processing. c. According to the laboratory manager, since January 1, 2022, when the laboratory began testing patient specimens using its SARS-CoV-2 assay, the laboratory had tested approximately 100,000 patient specimens from January 1, 2022 to April 29, 2022 using its SARS-CoV-2 assay.

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 laboratory director and laboratory manager interviews and preanalytic systems policies and procedures record review on April 29, 2022 at 12:30 pm, the laboratory failed to establish 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. Findings included: a. The laboratory failed to have written or electronic requests for patient SARS-CoV-2 testing from authorized persons. See D5301. b. The laboratory failed to establish written policies and procedures for patient specimen labeling and processing. See D5311. c. Although the laboratory maintained a patient specimen rejection protocol, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified when patient SARS-CoV-2 specimens were not stored and transported appropriately. See D5415 and D5423. d. According to the laboratory manager, since January 1, 2022, when the laboratory began testing patient specimens using its SARS-CoV-2 assay, the laboratory had tested approximately 100,000 patient specimens from January 1, 2022 to April 29, 2022 using its SARS-CoV-2 assay.

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 the deficiencies cited herein, the Condition: Analytic Systems was not met. The laboratory failed to label patient specimen transport tubes with expiration dates (see D5415), ensure that components of reagent kits of different lot numbers were not interchanged (see D5419), establish performance specifications for a modified FDA-cleared test system (see D5423), perform maintenance as defined by the manufacturer with at least the frequency specified by the manufacturer (see D5429), and establish written policies and

procedures for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the analytic systems specified at 493.1251 through 493.1283 (see D5791).

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on laboratory director and laboratory manager interviews and SARS-CoV-2 specimen collection devices record review on April 29, 2022 at 12:30 pm, the laboratory failed to use SARS-CoV-2 specimen transport tubes labeled with expiration dates. Findings included: a. It was the practice of the laboratory to store and transport patient SARS-CoV-2 specimens using sterile transport tubes containing 2-3 ml of viral transport medium (VTM). These transport tubes were purchased and stored in boxes labeled "Genesis Biomedical Viral Transport Tube." b. The laboratory director and laboratory manager confirmed that the SARS-CoV-2 transport tubes used to store and transport patient SARS-CoV-2 specimens that were reviewed on April 29, 2022 were not labeled with expiration dates. Consequently, upon receipt of a patient SARS-CoV-2 specimen, the laboratory could not determine whether the patient's specimen had been stored and transported in a transport tube that had not expired or contained VTM that had not expired. The laboratory tested and reported SARS-CoV-2 test results from patient specimens stored and transported in these transport tubes. c. According to the laboratory manager, since January 1, 2022, when the laboratory began testing patient specimens using its SARS-CoV-2 assay, the laboratory had tested approximately 100,000 patient specimens from January 1, 2022 to April 29, 2022 using its SARS-CoV-2 assay.

D5419

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(e)

Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on laboratory director and laboratory manager interviews and reagent log record review on April 29, 2022 at 11:30 am, the laboratory failed to ensure that components of SARS-CoV-2 reagent kits of different lot numbers were not interchanged. Findings included: a. It was the practice of the laboratory to perform SARS-CoV-2 tests on patient specimens using the Bio-Speedy Direct RT-qPCR SARS-CoV-2 assay. b. The laboratory maintained a record titled "Reagent Log Sheet" which listed the lot numbers of reagents and quality control materials used to perform its SARS-CoV-2 assay. The laboratory maintained no documentation to indicate the kit lot number from which these reagents and quality control materials were obtained to ensure that components of different kit lot numbers were not interchanged. In addition, the laboratory maintained no documentation to indicate which kit lot number

of SARS-CoV-2 assay components was used to test any specific SARS-CoV-2 patient specimen. The laboratory director and laboratory manager confirm these findings. c. According to the laboratory manager, since January 1, 2022, when the laboratory began testing patient specimens using its SARS-CoV-2 assay, the laboratory had tested approximately 100,000 patient specimens from January 1, 2022 to April 29, 2022 using its SARS-CoV-2 assay.

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 laboratory director and laboratory manager interviews and the laboratory's SARS-CoV-2 test system policies, procedures, and test specifications document record review on April 29, 2022 at 11:45 am, the laboratory modified a SARS-CoV-2 test system that had Food and Drug Administration (FDA) Emergency Use Authorization (EUA) and failed to establish test performance specifications before reporting patient SARS-CoV-2 test results. Findings included: a. The laboratory manager stated that the laboratory used the "Bio-Speedy Direct RT-qPCR SARS-CoV-2" assay, which had received FDA EUA on September 2, 2020, to perform and report patient SARS-CoV-2 test results. b. Upon review, it was determined that the laboratory had modified the FDA EUA "Bio-Speedy Direct RT-qPCR SARS-CoV-2" assay as follows: i. In the EUA package insert and the laboratory's written protocol, under the heading "Transporting Specimens," it stated: "Store specimens at 2-8 [degrees] C and ship overnight to the laboratory on ice pack. If a specimen is frozen at -70 [degrees] C or lower, ship overnight to the laboratory on dry ice." In addition, under the heading "Storing Specimens," the EUA package insert and the laboratory's written protocol stated: "Specimens can be stored at 2-8 [degrees] C for up to 72 hours after collection. If a delay in extraction is expected, store specimens at -70 [degrees] C or lower in accordance with the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19. Extracted nucleic acid should be stored at -70 [degrees] C or lower. It is important to avoid repeated freezing and thawing of specimens." ii. According to the laboratory manager, patient SARS-CoV-2 specimens received from specimen collection sites local to the laboratory were received by the laboratory stored with ice packs. However, patient SARS-CoV-2 specimens received from out-of-State specimen collection sites were received by the laboratory in boxes without any means to ensure that the specimens were stored at 2-8 [degrees] C. iii. According to the laboratory manager, the laboratory maintained no records, such as written or electronic test requests (see D5301), to indicate the location of where each patient SARS-CoV-2 specimen had been collected. That is, the laboratory maintained no records and could not determine whether any specific patient SARS-CoV-2 specimen had been received from a local or an out-of-State

specimen collection site. The laboratory, therefore, could not determine which patient SARS-CoV-2 specimen had or had not been properly stored and transported pursuant to the EUA package insert and the laboratory's written protocol. c. In the laboratory's document titled "VAL.001 BioSpeedy CFX Validation Summary 123121," there was no indication that the laboratory established test performance specifications for analytical sensitivity, analytical specificity to include interfering substances, reportable range of test results for the test system, and any other performance characteristic required for test performance, for patient SARS-CoV-2 specimens that did not meet the criteria for patient specimen storage and transportation as indicated in the EUA package insert and the laboratory's written protocol before reporting patient test results using the laboratory's SARS-CoV-2 test system. d. According to the laboratory manager, since January 1, 2022, when the laboratory began testing patient specimens using its SARS-CoV-2 assay, the laboratory had tested approximately 100,000 patient specimens from January 1, 2022 to April 29, 2022 using its SARS-CoV-2 assay.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on laboratory manager interview and instrument maintenance record review on April 29, 2022 at 1:00 pm, the laboratory failed to perform and document maintenance on its Tecan Fluent instrument as defined by the manufacturer and with at least the frequency specified by the manufacturer. Findings included: a. It was the practice of the laboratory to process patient SARS-CoV-2 specimens using the Tecan Fluent instrument in preparation for testing using the Bio-Speedy Direct RT-qPCR SARS-CoV-2 assay. b. According to the manufacturer's operating manual, the Tecan Fluent's daily maintenance included the "beginning of the day Daily System Care" method and the "end of the day Daily System Care" tasks. Weekly maintenance included the "Weekly System Care" method, which was to be "performed on the last working day of each week." Monthly maintenance included the "Monthly System Care" tasks. c. According to the laboratory manager, the laboratory began using the Tecan Fluent instrument to process patient SARS-CoV-2 specimens at the "end of January 2022." d. As confirmed by the laboratory manager, as of the day of this survey, April 29, 2022, the laboratory maintained no documentation to indicate that the manufacturer's required daily, weekly, and monthly maintenance for the Tecan Fluent instrument had been performed. e. According to the laboratory manager, since January 1, 2022, when the laboratory began testing patient specimens using its SARS-CoV-2 assay, the laboratory had tested approximately 100,000 patient specimens from January 1, 2022 to April 29, 2022 using its SARS-CoV-2 assay. Specifically, laboratory records indicated that on April 28, 2022 the laboratory received 1,958 patient specimens for which the laboratory tested using its SARS-CoV-2 assay and reported the SARS-CoV-2 patient test results.

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 laboratory director and laboratory manager interviews and analytic systems policies and procedures record review on April 29, 2022 at 12:30 pm, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified at 493.1251 through 493.1283. Findings included: a. The laboratory failed to label patient SARS-CoV-2 specimen transport tubes with expiration dates. See D5415. b. The laboratory failed to ensure that components of reagent kits of different lot numbers were not interchanged. See D5419. c. The laboratory, which modified an FDA-cleared SARS-CoV-2 test system, failed to establish performance specifications before reporting patient SARS-CoV-2 test results. See D5423. d. The laboratory failed to perform maintenance as defined by the manufacturer with at least the frequency specified by the manufacturer. See D5429. e. According to the laboratory manager, as part of the laboratory's quality assurance mechanism for analytic systems, daily quality control and instrument maintenance records are to be reviewed monthly, as evidenced by monthly signature and date lines on quality control and instrument maintenance forms used by laboratory personnel. Even though the laboratory began patient testing on January 1, 2022, as of April 29, 2022, the laboratory maintained no documentation to indicate that quality control and instrument maintenance records had been reviewed monthly. In addition, in the laboratory's protocol titled "QA 0001 Quality Assurance Plan," there were no written procedures describing this monthly review process. f. According to the laboratory manager, since January 1, 2022, when the laboratory began testing patient specimens using its SARS-CoV-2 assay, the laboratory had tested approximately 100,000 patient specimens from January 1, 2022 to April 29, 2022 using its SARS-CoV-2 assay.

D5800

POSTANALYTIC SYSTEMS

CFR(s): 493.1290

Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493.1299 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on the number and severity of the deficiencies cited herein, the Condition: Postanalytic Systems was not met. The laboratory failed to maintain all patient SARS-CoV-2 test reports or records of information on the test reports in a manner that permits ready identification and timely accessibility (see D5819), and establish 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 (see D5891).

D5819

TEST REPORT

CFR(s): 493.1291(j)

All test reports or records of the information on the test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.

This STANDARD is not met as evidenced by:

Based on laboratory manager interview and laboratory patient specimen assessing information record review on April 29, 2022 at 10:00 am, the laboratory failed to maintain all patient SARS-CoV-2 test reports or records of information on the test reports in a manner that permits ready identification and timely accessibility. Findings included: a. It was the practice of the laboratory to perform SARS-CoV-2 tests on patient specimens using the Bio-Speedy Direct RT-qPCR SARS-CoV-2 assay. b. During the onsite survey on April 29, 2022, the laboratory was unable to provide written or electronic copies of test reports or records of information on the test reports for any patient SARS-CoV-2 tests the laboratory had performed and reported. The laboratory director and laboratory manager confirmed this finding. c. Laboratory records indicated that on April 28, 2022 the laboratory received 1,958 patient specimens for which the laboratory tested using its SARS-CoV-2 assay and reported the SARS-CoV-2 patient test results. For these 1,958 patient specimens, the laboratory was unable to provide any written or electronic copies of test reports or records of information on the test reports for any of these patient SARS-CoV-2 tests the laboratory had performed and reported. d. According to the laboratory manager, since January 1, 2022, when the laboratory began testing patient specimens using its SARS-CoV-2 assay, the laboratory had tested approximately 100,000 patient specimens from January 1, 2022 to April 29, 2022 using its SARS-CoV-2 assay.

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 laboratory director and laboratory manager interviews and postanalytic systems policies and procedures record review on April 29, 2022 at 10:00 am, the laboratory failed to establish 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. Findings included: a. The laboratory failed to maintain all patient SARS-CoV-2 test reports or records of information on the test reports in a manner that permits ready identification and timely accessibility. See D5819. b. According to the laboratory manager, since January 1, 2022, when the laboratory began testing patient specimens using its SARS-CoV-2 assay, the laboratory had tested approximately 100,000 patient specimens from January 1, 2022 to April 29, 2022 using its SARS-CoV-2 assay.

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:
 Based on the number and severity of the deficiencies cited herein, the Condition: Laboratories Performing High Complexity Testing, Laboratory Director was not met. The laboratory director failed to ensure that the test system developed and used by the laboratory provided quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing (see D6082), the test system selected has the capability of providing the quality of results required for patient care (see D6085), quality assessment programs are established to assure the quality of laboratory services provided and to identify failures in quality as they occur (see D6094), prior to testing patients' SARS-CoV-2 specimens, all testing personnel had the appropriate education (see D6102), and specify, in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing (see D6107).

D6082

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:
 Based on laboratory director and laboratory manager interviews and laboratory preanalytic, analytic, and postanalytic document record review on April 29, 2022, the laboratory director, high complexity testing, failed to ensure that the SARS-CoV-2 testing system developed and used by the laboratory provided quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. Findings included: a. The laboratory failed to meet the Condition: Preanalytic Systems. See D5300. b. The laboratory failed to meet the Condition: Analytic Systems. See D5400. c. The laboratory failed to meet the Condition: Postanalytic Systems. See D5800. d. According to the laboratory manager, since January 1, 2022, when the laboratory began testing patient specimens using its SARS-CoV-2 assay, the laboratory had tested approximately 100,000 patient specimens from January 1, 2022 to April 29, 2022 using its SARS-CoV-2 assay.

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 laboratory director and laboratory manager interviews and the laboratory's SARS-CoV-2 test system policies, procedures, and test specifications document record review on April 29, 2022 at 11:45 am, the laboratory director, high complexity testing, failed to ensure that the SARS-CoV-2 test system selected had the capability of providing the quality of results required for patient care. Findings included: The laboratory, which modified a SARS-CoV-2 assay that had received Food and Drug

Administration (FDA) Emergency Use Authorization (EUA), failed to establish test performance specifications before reporting patient SARS-CoV-2 test results. See D5423.

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 laboratory director and laboratory manager interviews and preanalytic policies and procedures record review on April 29, 2022 at 12:30 pm, the laboratory director, high complexity testing, failed to ensure that quality assessment programs were established to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings included: a. The laboratory failed to establish 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. D5391. b. The laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified at 493.1251 through 493.1283. See D5791.

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 laboratory personnel interviews and testing personnel qualifications record review on May 12, 2022 at 07:00 am, the laboratory director, high complexity testing, failed to ensure that prior to testing patients' SARS-CoV-2 specimens, all testing personnel had the appropriate education. Findings included: Testing personnel, who were performing tests on patient SARS-CoV-2 specimens, failed to meet the qualification requirements of 493.1489. See D6168.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on laboratory director and laboratory manager interviews and laboratory policies and procedures record review on April 29, 2022 at 12:30 pm, the laboratory director, high complexity testing, failed to specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. The laboratory maintained no such documentation. According to the laboratory manager, since January 1, 2022, when the laboratory began testing patient specimens using its SARS-CoV-2 assay, the laboratory had tested approximately 100,000 patient specimens from January 1, 2022 to April 29, 2022 using its SARS-CoV-2 assay.

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:
Based on the number and severity of the deficiencies cited herein, the Condition: Laboratories Performing High Complexity Testing, Testing Personnel was not met. It was the practice of the laboratory to perform SARS-CoV-2 tests on patient specimens using the Bio-Speedy Direct RT-qPCR SARS-CoV-2 assay. Testing personnel, who were performing tests on patient SARS-CoV-2 specimens, failed to meet qualification requirements (see D6171).

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 laboratory personnel interviews and testing personnel qualifications record review on May 12, 2022 at 07:00 am, testing personnel, high complexity testing, who were performing tests on patient SARS-CoV-2 specimens, failed to meet qualification requirements. Findings included: a. It was the practice of the laboratory to perform SARS-CoV-2 tests on patient specimens using the Bio-Speedy Direct RT-qPCR SARS-CoV-2 assay. b. Based on a review of the laboratory's submitted "Laboratory Personnel Report (CLIA)," Form CMS-209, signed by the laboratory director and dated May 11, 2022, and testing personnel qualifications information provided by the laboratory's compliance manager, 2 (TP (testing personnel) #12 and #13) of 15 testing personnel listed on the Form CMS-209 did not possess the qualifications for testing personnel, high complexity testing. Although TP #12 and #13, earned master's or bachelor's degrees, their degrees were not in a chemical, physical, biological, or clinical laboratory science. c. According to the laboratory's compliance manager, from January 1, 2022 to April 29, 2022, TP #12 had not been involved in any patient specimen testing. TP #13 was involved in the testing and reporting of approximately 326 patient SARS-CoV-2 test results. d. According to the laboratory manager, since

January 1, 2022, when the laboratory began testing patient specimens using its SARS-CoV-2 assay, the laboratory had tested approximately 100,000 patient specimens from January 1, 2022 to April 29, 2022 using its SARS-CoV-2 assay.