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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>14D0945905 | <b>(X3) Date Survey Completed</b><br>03/09/2022 |
| <b>Name of Provider or Supplier</b><br>Medstar Laboratory Inc  | <b>Street Address, City, State</b><br>4531 W Harrison St, Hillside, IL |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
|---------------------------|---|
| <b>D0000</b>              | A complaint survey was completed on March 9, 2022. It was determined that Immediate Jeopardy (IJ) existed for the following condition level deficiencies: 42 C.F.R. 493.1240 Condition: Preanalytic systems 42 C.F.R. 493.1250 Condition: Analytic systems 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director   |
| <b>D2010</b>              | <p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b><br/>CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on record review and interview, the laboratory failed to test proficiency samples the same number of times that it routinely tests patient samples, during the year of 2021. Findings: 1. The College of American Pathologists (CAP) Proficiency Testing (PT) program records for the year of 2021, test data from 05/28/2021 and 07/22/2021, the laboratory's SARS-CoV-2 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedures, and PT policies and procedures were reviewed. 2. The laboratory enrolled in the SARS-CoV-2 Molecular Survey PT program to verify the accuracy of it's laboratory developed test (LDT) for SARS-CoV-2 RT-PCR testing. 3. The CAP-PT program documents and laboratory PT policy revealed the following: *Both stated that PT samples are to be analyzed in the same manner as patients. *Event ID3-B-2021 PT samples were tested in two different PCR runs. 4. The SARS-CoV-2 RT-PCR procedure and test data showed patients' samples were tested once and then the results were reported on the dates reviewed 5. On a Complaint survey conducted on March 9, 2022 at 1:30 PM, the owner and Staff-SP confirmed the above findings.</p> |
| <b>D5209</b>              | <b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b>   |

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation, and interview, the laboratory failed to establish and follow written policies and procedures to assess employees performing the SARS-CoV-2 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) test, affecting six out of six testing personnel (TP). Findings include: 1. The Laboratory Personnel Report (CMS 209), employee files, and personnel policies and procedures were reviewed. 2. The laboratory used the SARS-CoV-2 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedures to detect and identify SARS-CoV-2 in patients' samples. 3. CMS 209 listed six TP (TP1, TP2, TP3, TP4, TP5, and TP6) performing the SARS-CoV-2 RT-PCR test procedure. 4. The laboratory failed to establish a step-by-step procedure that includes the following criteria to assess TP competency: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing, as applicable; b). Monitoring the recording and reporting of test results (for example, recording patients and their results in the labs' test log and EMR system); c). Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; d). Direct observation of performance of instrument maintenance and function checks; e). Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; f). Assessment of problem solving skills; and g). Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually. 5. On a Complaint survey conducted March 9, 2022 at 2:00 PM, the Owner and Staff-SP confirmed the above findings.

**D5211**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to evaluate the results received from the College of American Pathologists (CAP) proficiency test (PT) program, during the year of 2021. Findings: 1. The CAP-PT program records for the year of 2021 and PT policies and procedures were reviewed. 2. Review of the 2021 CAP-PT results revealed the following: LABORATORY RESULT INTENDED RESULT Event COV-2-01 COV-2-01 Not Detected (Negative) N.D. (NEG) COV-2-02 Indeterminate Detected (Positive)=(POS) COV-2-03 Indeterminate Detected (POS) Event ID3-B 2021 ID3-06 - N.D.(NEG) N.D.(NEG) ID3-07 - N.D.(NEG) N.D. (NEG) ID3-08 - N.D.(NEG) N.D.(NEG) ID3-09 - N.D.(NEG) N.D.(NEG) ID3-10 - Indeterminate Detected (POS) Event ID3-C 2021 ID3-11 - Detected (POS) Detected (POS) ID3-12 - Invalid ID3-13 - Invalid ID3-14 - N.D.(NEG) N.D.(NEG) ID3-15 - Invalid 3. The laboratory failed to follow its PT policy and implement procedures to

review and evaluate all PT results received. 4. On a Complaint survey conducted March 9, 2022 at 1:30 PM, the owner and Staff-SP confirmed the above findings.

**D5300**

**PREANALYTIC SYSTEMS**  
CFR(s): 493.1240

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.

This CONDITION is not met as evidenced by:  
Based on direct observation, record review, and interview, the laboratory failed to follow established specimen collection, handling, and storage policies and procedures (D5311) and failed to monitor and evaluate the overall quality of the preanalytic systems and correct problems identified (5391) as specified in 42 CFR 493.1249.

**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 review of laboratory records, direct observation, and interview with testing personnel (Staff ID#1) the laboratory failed to follow the laboratory's policy for COVID-19 specimen collection, handling, and storage guidance as outlined in the laboratory's procedures affecting 1,777,655 patient test results. Findings Include: Item 1 - Specimen Handling and Storage 1. Review of the laboratory's policy and procedure manual identified the procedure, "Assurance SARS-CoV-2 Panel SOP for Partner Laboratories", which stated on page four under the heading of "6.0 Specimen collection, handling, and storage": "6.1 Specimens are collected according to the guidance by the CDC <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html> 6.2 Upon receipt, samples are stored at approximately 4 degrees Celsius 6.3 Extracted nucleic acid will be stored at -70 degrees or below" 2. Review of the laboratory's policy and procedure manual identified the procedure, "Upper-Respiratory Specimen Collection for COVID-19 Test", which stated under the heading of "Specimen Handling": "Refrigerate all specimen types at 2-8 degrees Celsius after collection and up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70 degrees Celsius or below." This same information is also indicated in the CDC guidance for the for storing and shipping respiratory specimens. 3. Interview with Staff ID#1 at 10:35 am, on 3-8-2022 confirmed the laboratory performs COVID-19 testing on respiratory specimens. 4. During tour of the laboratory facility on 3-8-22 at 10:58 am no refrigerators or freezers were observed for the storage of respiratory specimens received for COVID-

19 testing by the laboratory. 5. Interview with Staff ID#1 at 12:33 pm, on 3-8-22 confirmed the laboratory does not have any refrigerators or freezers to store respiratory specimens received by the laboratory for COVID-19 testing as outlined in the laboratory's procedure or per the CDC guidance for respiratory specimens. 6. During tour of the receiving area at 12:15 pm on 3-8-22 the surveyor observed a trash bag which contained COVID-19 specimens that had been collected on 3-4-22 but were received and were not refrigerated/frozen and had no way to be stored at -70 degrees Celsius or below as indicted in the CDC/laboratory guidance. 7. Review of requisitions from the specimens received on 3-8-22 observed during the tour of the laboratory facility on 3-8-22 at 12:15pm identified 84 patient samples that were received by the laboratory that should have been shipped and stored frozen due to the delay from the date of collection of 3-4-2022, as identified on the test requisitions. 8. Review of the patient test volume records found the laboratory has performed 1,777,655 tests when the laboratory failed to have the proper equipment in order to store COVID-19 respiratory specimens as indicated in the laboratory's procedure and in accordance with CDC guidance. Item 2 - Specimen Collection 1. Interview with Staff ID#1 on 3-8-22 at 10:32 am confirmed the laboratory uses the extraction-less method for SARS-CoV-2 testing. 2. Review of the laboratory's policy and procedure manual identified the procedure, "Assurance SARS-CoV-2 Panel SOP for Partner Laboratories", indicated on page five that for the extraction-less method respiratory samples are to be collected in saline. "9.2 Extraction-less Method (Saline samples ONLY):" 3. During a tour of the laboratory facility on 3-8-22 at 10:58 am, the surveyor observed ~11 racks (72 specimens per rack, ~792 patient samples) of patient specimens collected between 3-5-22 to 3-7-22 being prepared for COVID-19 testing had been collected in Virus Transport Medium (VTM) tubes from the supplier SNT Biotech. 4. Review of invoices for COVID-19 collection kits purchased by Medstar Laboratories from SNT Biotech found for invoices reviewed from December 2021 through February 9, 2022 were for collection kits containing VTM collection tubes. 5. Review of the laboratory protocol, "PCR Specimen Accessioning and Rejecting Protocol" failed to identify proper collection vessel as a criteria for specimen rejection. 6. Review of the patient test volume records found the laboratory has performed 1,777,655 tests for COVID-19 when the laboratory failed to ensure respiratory specimens were collected in the proper medium (Saline) for the test system in use.

**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 review of laboratory records, direct observation, and interview with testing personnel (Staff ID#1) the laboratory failed to establish policies and procedures to assess, monitor and correct problems with COVID-19 specimen collection, handling, and storage affecting 1,777,655 patient test results. Findings Include: 1. Surveyor requested all quality assurance documentation from Staff ID#1 on 3-8-22 at 2:00 pm. The laboratory failed to provide the laboratory's quality assessment policy and documentation during the survey that was completed on 3-9-2022. 2. The laboratory failed to identify multiple issues with specimen collection, handling, and storage. See D5311. 3. Surveyor requested on 3-9-22 at 12:53 pm patient test reports for 22 of the

84 specimens that were received during the tour of the specimen receiving area on 3-8-22 and found 22 of 22 patient sample reports reviewed were reported out by the laboratory and all were reported as negative for SARS-CoV-2. 4. Review of patient testing for SARS-CoV-2 found the laboratory has reported 1,777,655 patients in the past two years when no preanalytical quality assessment policy had been established and performed.

**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 record review, test data and proficiency testing records, lack of documentation, and interview, the laboratory failed to have complete written procedures (D5403); failed to ensure the storage requirements and proper use of reagents, solutions, test plates,, and other pertinent information were identified (D5415); failed to establish the performance specifications for laboratory developed SARS-CoV-2 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) test (D5423); failed to establish control procedures (D5445); failed to document the lot number of each commercially prepared reagent, plate, and solutions used in the SARS-CoV-2 identification system (D5471); and failed to identify each person who performed SARS-CoV-2 PCR test (D5787), affecting 1,777,655 patients' tests.

**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 direct observation, record review, lack of documentation, and interview, the laboratory's procedure manual failed to include all the applicable requirements specified in 493.1251 (b)(1) - (14) for the laboratory developed SARS-CoV-2 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) test performed by the laboratory, affecting 1,777,655 patients' tests. Findings Include: Item 1 The laboratory tested patients' nasopharyngeal swabs with a laboratory developed test to identify SARS-CoV-2 Ribonucleic Acid (RNA). 1. The Medstar Molecular Laboratory COVID-19 Testing SOPs/Procedures/Policies and the Clinical Laboratory Improvement Amendments (CLIA) application (CMS-116) were reviewed. 2. The procedure manual failed to include the following requirements: \*Requirements for storage, preservation, transportation, processing, and referral. \*Step-by-Step performance of the procedure. Direct observation on March 8, 2022, at 10:54 AM, surveyor observed Staff X1 seated at laboratory bench manually creating a 96-well plate map for two 72-specimen racks received from specimen receiving. When the plate map was completed, the specimens were put into a different rack and moved to a hood to be pipetted into the Extraction-less strip tubes by the automated pipettor. When the automated pipettor has completed dispensing the patient specimens into the strip tubes, the tubes began to be processed as described in the Extraction-less method. This process was continued until four 96-well plates were generated. Then the four plates were moved to a second automated pipettor which transferred these specimens into a 384-well plate. The laboratory failed to include this process in the procedure. \* Manufacturer and/or Product specifications, preparations, and storage of 96-well and 384-well plates, solutions, calibrators, controls, reagents, stains, dyes, and other materials used in testing, as applicable. \*Calibration, calibration verification, and maintenance procedures for five BioRad CFXOPUS384 and three C1000 Touch Thermocyclers. \*The reportable range for test results for the test system as established or verified in 493.1253. \*Control procedures - How are controls added to test plates and additional required control procedures. See D5441. \*Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. \*Limitations in the test methodology. This is a Laboratory Developed Test (LDT), the Emergency Use Authorization (EUA) for Assurance SARS-CoV-2 Panel specifications cannot be used without empirical comparison data. \* Imminently life-threatening test results, or panic or alert values. \* The literature the LDT is based upon must be provided and reference. \* The step-by-step procedure for entering results in the patient record and reporting patient results to patients and health departments. \* Description of the course of action to take if a test system becomes inoperable. 3. The owner attested the laboratory performed 1,777,655 patient tests for SARS-CoV-2 RNA. 4. The Owner and Staff-SP confirmed the above findings on March 09, 2022, at 2:15 PM.

**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 direct observation, record review, lack of documentation, and interview, the laboratory failed to ensure the storage requirements and proper use of reagents,

solutions, test plates, and other pertinent information were implemented to assure accurate and reliable results, affecting 1,777,655 patients' test. Findings: 1. The Molecular Designs' Assurance FDA EUA Covid Assay Information procedure, the Chemical Lysis (Extraction-less) procedure, and laboratory invoices were reviewed. 2. During a tour of the laboratory on March 9, 2022, at 9:15 AM, the surveyor observed the following items in the refrigerator used to store the SARS-CoV-2 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) supplies: \*Boxes marked "Lysis Buffer" \*Boxes with plates labeled "COVID-19 94 Panel Plate" \*Boxes with plates labeled "384-Well COVID-19 382 Panel Plate" \*The plates and Lysis Buffer labels provided lot numbers but no expiration dates. The surveyor asked Staff-PS and owner for the package or product inserts for the above supplies. Staff-PS stated that the reagents and plates shipments were received without package or product inserts. The owner failed to provide any documentation that confirm the identity, storage requirements, expiration dates, and any other pertinent information required for proper use for the supplies used in their laboratory developed test (LDT). 3. Staff SP and Owner confirmed the above findings on March 09, 2022, at 2:15 PM.

**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 direct observation, records review, and interviews, the laboratory failed to establish and verify the performance specifications of the laboratory developed test (LDT) that used unextracted nasopharyngeal swabs specimens to identify SARS-CoV-2 prior to testing patients, affecting 1,777,655 reported patients' tests. Findings Include: 1. Direct observation on March 08, 2022, at 11:15 AM, the surveyor observed three C1000 Touch and five CFXOPUS-384 Thermocyclers. Staff SP stated these thermocyclers were used to identify SARS-CoV-2 Ribonucleic Acid (RNA) in a laboratory developed test called Molecular Designs' Assurance FDA EUA Covid Assay. 2. Review of the Assurance SARS-CoV-2 Panel Emergency Use Authorization (EUA) and the Assurance SARS-CoV-2 Panel SOP for Partner Laboratories procedures manuals, the Molecular Designs' Assurance FDA EUA Covid Assay, proficiency testing records for 2021, and performance verification records revealed the following: \*The laboratory's performance verification for the Assurance SARS-CoV-2 Panel extraction method EUA using the CFXOPUS-96 was conducted and approved by the laboratory director (LD) in January of 2021. \*The proficiency testing results for 3 out of 3 events in 2021 were based on the Assurance SARS-CoV-2 EUA test system using the CFXOPUS-96 thermocycler. \*The date the laboratory began to tests patients' specimens with the Molecular Design Assurance extraction-less PCR procedure could not be determined. \*No visible evidence was provided that showed the Molecular Design PCR assay procedure had been approved by the LD, the

performance specifications had been determined by the laboratory, or test system comparison with Assurance SARS-CoV-2 panel EUA was performed, prior to use for patient testing. 3. Further review of the provided documentation revealed the laboratory failed to perform and document the following performance studies for the LDT named Molecular Design Assurance SARS-CoV-2 RT-PCR Assay: a). Specimen stability studies for patient specimens shipped through all weather conditions. b). Specimen comparison studies for using the Extraction-less procedure meant for Saliva in saline only, as the patient sample source (EUA) versus using the Extraction-less procedure on nasopharyngeal swab in viral transport media as the patient's sample source (Molecular Design). c. Accuracy - Comparison of the SARS-CoV-2 PCR test systems: Assurance swab EUA and Assurance Saliva EUA versus the Extraction-less swab Molecular Design PCR d. Precision - Empirical proof the Molecular Design procedure identifies SARS-CoV-2. e. Analytical specificity to include interfering substances. Must provide empirical proof and summary. f. Reportable range of test results for the test system. g. Reference intervals (normal values). h. Any other performance characteristic required for test performance. 4. Review of test volume records received from the laboratory on 3-22-22 found the laboratory performed 1,777,655 tests using the LDT. 5. The Owner and Staff-PS confirmed the above findings on March 09, 2022, at 2:15 PM.

**D5445**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(1)(2)(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--  
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with testing personnel (Staff ID#1) the laboratory failed to follow the laboratory's quality control procedures for analysis for polymerase chain reaction (PCR) data sets as required for COVID-19 testing performed for 1,777,655 patients tested. Item 1 - Failure to perform two independent reviews of COVID-19 PCR data Findings Include: 1. Eight PCR data sets were reviewed for Assurance SARS-CoV-2 testing performed by the laboratory. File Names 12252021\_PLATE1@4\_RESULT.pcrd 12302021\_PLATE1\_RESULT.pcrd 1-20220215-P1-RESULT.pcrd 122121\_PLATE5\_RESULT.pcrd 1-20220208-P1-RESULT.pcrd 1-20220204-P1-RESULT.pcrd 1-20220119-P1-RESULT.pcrd 1-20220213-P2-RESULT.pcrd 2. Review of the laboratory's policy and procedure manual identified the procedure, "Run Data Evaluation on BioRad CFX and Parsing Data Files", which stated on page two under the heading of "4.1 Evaluating patient Results": "4. When evaluation of the plate map is complete, initial under "Data Review" at the bottom of the plate map. 5. Another reviewer must now repeat Steps 1-3. Initial under "Secondary Review" at the bottom of the plate map. Each patient plate MUST have two reviews by two separate individuals." 3. Eight of eight PCR data sets reviewed failed to be reviewed by two separate individuals as outlined in the laboratory's procedure affecting 1,040 patient samples tested. 4. Interview with testing personnel - Staff ID#1 on 03-9-22 at 11:33 am confirmed the laboratory does not

identify the testing personnel that perform the analysis of the PCR data for COVID-19 testing. 5. Review of the patient test volume records found the laboratory has performed 1,777,655 tests for COVID-19 when the laboratory failed to ensure the identity of testing personnel performing the data analysis for COVID-19 testing. Item 2 - Reporting results when endogenous control has failed 1. Review of the laboratory's policy and procedure manual identified the procedure, "Run Data Evaluation on BioRad CFX and Parsing Data Files", which stated under the heading of "4.1 Evaluating Patient Results": "If an endogenous control fails, then the results for that patient are considered invalid and the patient specimen should be re-extracted" 2. Assurance SARS-CoV-2 testing PCR data was reviewed for eight separate data sets. See D5787. 3. Review of the PCR data sets identified 32 of 44 patient test results that were reported as negative for COVID-19 when the endogenous control result was invalid and therefore should not have been reported by the laboratory as a negative result. 4. Review of the patient test volume records found the laboratory has performed 1,777,655 tests for COVID-19 when the laboratory failed to ensure specimen integrity and results were reported in accordance with the laboratory's procedure.

**D5471**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on record review, lack of documentation, and interview, the laboratory failed to document the lot number of each commercially prepared reagent, plate, and solutions used in the SARS-CoV-2 identification system, each day of patient testing, affecting 1146 patients' tests. Findings include: 1. The laboratory procedures manual, test data from the months of December 2021, January 2022, and February 2022 were reviewed. 2. The laboratory used the SARS-CoV-2 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedure to detect and identify SARS-CoV-2 in patients' samples. 3. The test plate maps and PCR test results for 13 out of 13 days reviewed revealed the following: \*The lot numbers and expiration dates of the reagents and solutions were not recorded, and \*The expiration dates of the test plates were not documented. 4. The laboratory's manual failed to include a method to document the above information. 5. The laboratory tested 1146 patients' samples during the period reviewed. 6. Staff SP and Owner confirmed the above findings on March 09, 2022, at 2:15 PM.

**D5787**

**TEST RECORDS**  
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4)

The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with testing personnel (Staff ID#1) the laboratory failed to identify each person who performed the polymerase chain reaction (PCR) data analysis for COVID-19 testing performed for 1,777,655 patients tested. Findings Include: 1. PCR data set were reviewed for Assurance SARS-CoV-2 testing for eight separate data sets. File Names 12252021\_PLATE1@4\_RESULT.pcrd 12302021\_PLATE1\_RESULT.pcrd 1-20220215-P1-RESULT.pcrd 122121\_PLATE5\_RESULT.pcrd 1-20220208-P1-RESULT.pcrd 1-20220204-P1-RESULT.pcrd 1-20220119-P1-RESULT.pcrd 1-20220213-P2-RESULT.pcrd 2. Review of the laboratory's policy and procedure manual identified the procedure, "Run Data Evaluation on BioRad CFX and Parsing Data Files", which stated on page two under the heading of "4.1 Evaluating patient Results": "4. When evaluation of the plate map is complete, initial under "Data Review" at the bottom of the plate map. 5. Another reviewer must now repeat Steps 1-3. Initial under "Secondary Review" at the bottom of the plate map. Each patient plate MUST have two reviews by two separate individuals." 3. The PCR data set files failed to indicate the testing personnel that performed the two separate data analysis reviews for eight of eight PCR data sets reviewed. 4. Interview with testing personnel - Staff ID#1 on 03-9-22 at 11:33 am confirmed the laboratory does not identify the testing personnel that perform the analysis of the PCR data for COVID-19 testing. 5. Review of the patient test volume records found the laboratory has performed 1,777,655 tests for COVID-19 when the laboratory failed to ensure the identity of testing personnel performing the data analysis for COVID-19 testing.

**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 record review, lack of documentation and interview, the laboratory director (LD) failed to be accessible to provide onsite consultation when needed (D6080), failed to ensure that testing systems developed and used for SARS-CoV-2 detection and identification provide quality laboratory services for all aspects of test performance (D6082), failed to ensure that laboratory personnel are performing the test methods as required for accurate and reliable results (D6087), failed to establish quality assurance (QA) programs for the laboratory's processes and procedures (D6094), failed to ensure laboratory personnel was trained and competent, prior to testing patients (D6102), affecting 1,777,655 patients' tests.

**D6080**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(c)

The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

This STANDARD is not met as evidenced by:  
 Based on record review and interview, the laboratory director (LD) failed to be accessible to provide onsite telephone or electronic consultation as needed affecting 1,777,655 patients' tests. Findings: 1. The Assurance SARS-CoV-2 Panel Emergency Use Authorization (EUA), the Assurance SARS-CoV-2 Panel SOP for Partner Laboratories procedures manuals, the Molecular Designs' Assurance FDA EUA Covid Assay, proficiency testing (PT) records for 2021, and test records for the months of December 2021, January 2022, and February 2022 were reviewed. 2. The laboratory performed the Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedures to detect and identify SARS-CoV-2 in patients' nasopharyngeal specimens. 3. The procedures manuals, PT results, and SARS-CoV-2 EUAs showed no documented evidence that \*the LD approved any SARS-CoV-2 procedural changes since January of 2021 (See D6087), \*the LD approved the Molecular Designs Assurance FDA EUA Covid Assay in-use, \*the LD reviewed any test data since January of 2021, and \*provided any consultation or communication with the laboratory staff (i.e. technical supervisor or general supervisor) concerning the laboratory's PT performance which was used to assess the accuracy of its SARS-CoV-2 PCR procedures. 4. The laboratory reported 1,777,655 patients results during the time period reviewed. 5. During a Complaint survey conducted on March 8, 2022, at 9:40 AM and 2:30 PM, and March 9, 2022 at 1:00 PM, the surveyors requested to have direct communication with the LD, the Owner stated the following: "The LD had mouth surgery and was unavailable."

**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 record review and interview, the laboratory director (LD) failed to ensure that the laboratory developed test (LDT) used for SARS-CoV-2 detection and identification provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing, affecting 1,777,655 patients' tests. Findings: 1. The Assurance SARS-CoV-2 Panel Emergency Use Authorization (EUA), the Assurance SARS-CoV-2 Panel SOP for Partner Laboratories procedures manuals, the Molecular Designs' Assurance FDA EUA Covid Assay, proficiency testing (PT) records for 2021, performance verification records, and test records for the months of December 2021, January 2022, and February 2022 were reviewed. 2. The laboratory performed the Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedures to detect and identify SARS-CoV-2 in patients' nasopharyngeal specimens. 3. The procedures manuals and SARS-CoV-2 EUAs revealed the LD failed to ensure the laboratory performed the approved SARS-CoV-2 PCR procedure (Assurance EUA) and defined performance specifications for any new or modified SARS-CoV-2 PCR procedure (Molecular Design's). 4. The PT documents showed the LD failed to ensure the method selected to determine the accuracy of the test system in-use was evaluated and corrective actions, if needed,

were implemented. 5. The laboratory reported 1,777,655 patients results during the time period reviewed. 6. The Owner and Staff-SP confirmed the above findings on March 09, 2022, at 2:15 PM.

**D6087**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with testing personnel (Staff ID#1) the laboratory director (LD) failed to ensure testing personnel followed the laboratory procedure and only reported patients' test results when test methods were followed to ensure accurate and reliable results for 1,777,655 patients' tested in the past two years. Findings Include: 1. See D5311, D5403, D5415, D5423, D5445, D5471, and D5787. 2. Review of the patient test volume records found the laboratory has performed 1,777,655 tests for COVID-19 when the laboratory failed to ensure specimen integrity and results were reported in accordance with the laboratory's procedure.

**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 record review and interview; the laboratory director (LD) failed to establish quality assurance (QA) programs for the laboratory required to ensure accurate and reliable testing, Findings include: 1. The Assurance SARS-CoV-2 Panel Emergency Use Authorization (EUA), the Assurance SARS-CoV-2 Panel SOP for Partner Laboratories procedures manuals, the Molecular Designs' Assurance FDA EUA Covid Assay, proficiency testing (PT) records for 2021, performance verification, were reviewed. 2. The LD failed to establish an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions for the Preanalytic process: \*assessing practices/issues related to test requests, specimen submission, handling and referral. 3. The LD failed to ensure the analytic QA procedures were maintained by the continuously assessing: \*practices/issues related to the Molecular Designs' test procedures and ensuring it is an accurate and reliable test system; \*ensuring the identification and documenting of reagents; materials; and supplies; \*ensuring specimen and reagent storage conditions are maintained at optimal conditions; \*practices/issues related to control procedures; \*comparative of test results and ensuring they are routinely performed, \*ensuring corrective actions are implemented and monitored; and test records routinely reviewed. 4. The Owner and Staff-SP confirmed the above findings on March 09, 2022, at 2:15 PM.

**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 record review and interview, the laboratory director (LD) failed to ensure prior to testing patients' specimens, all personnel have the appropriate training and have demonstrated that they can perform all testing operations reliably to provide and report accurate results for six out of six testing personnel (TP). Findings include: 1. The laboratory personnel documents, Laboratory Personnel Report (CMS 209), and the laboratory's competency policy and procedures were reviewed. 2. The CMS 209 list six TP (TP1, TP2, TP3, TP4, TP5, and TP6) performing the SARS-CoV-2 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedure in the laboratory. 3. The personnel records showed six out of six TP failed to have any documented proof of training and competency assessment to perform the SARS-CoV-2 procedures. 4. The laboratory's competency policy and procedure failed to include the assessment of TP performing PCR testing. 5. Interview with the Staff-PS on 03/09 /2022 at 12:30 PM confirmed the above findings.