Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0945905	12/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Medstar Laboratory Inc	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on direct observation, laboratory standard operating procedures (SOP), and interview with testing personnel (TP); the laboratory failed to meet the requirements of this condition. The laboratory failed to maintain a unidirectional workflow for molecular amplification procedures to minimize contamination of patient specimens, equipment, instruments, reagents, materials, and supplies. (See D3005).
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on direct observation, laboratory standard operating procedures (SOP), and

	interview with testing personnel (TP); the laboratory failed to maintain a unidirectional workflow for molecular amplification procedures to prevent cross-contamination in specimen processing, preparation, amplification, and detection for one of one specimen tests plates processed on 12/14/2022 for SARS-CoV-2. Findings Include: 1. Review of the Medstar Laboratory Policy and Standard Operative Procedure (SOP) for Molecular Designs' Assurance FDA-EUA SARS-CoV-2 Extraction-less Assay revealed the following: a. Section 1.0 Intended Use - Item 1.5: "The Molecular Design's Assurance Scientific Laboratories SARS-CoV-2 assay is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures." b. Section 3.0 Warning and Precautions- Item 3.9: "Amplification technologies such as PCR are sensitive to accidental introduction of PCR product from previous amplifications reactions. Incorrect results could occur if either the clinical specimen or the real-time reagents used in the amplification step become contaminated by accidental introduction of amplification product (amplicon). Workflow in the laboratory should proceed in a unidirectional manner." c. Section 12.0 Data Analysis and Reporting - Item 12.18: "Save negative patient samples in refrigerator at 2 - 8 degrees Celsius for one week and positive patient samples in the freezer at -20 degrees Celsius for a month. 2. Direct observation on 12/14/2022 from 8:22 a.m. to 10: 15 a.m. of Molecular Designs' Assurance SARS-CoV-2 assay performed by TP 2 and TP 4 and review of the SOP revealed the following: a. Review of SOP Section 1.0 Intended Use - Item 1.5 and direct observation revealed the laboratory failed to prevent contact with patient sample tubes with the body of the one pipette utilized for the transfer patient samples to one of one specimen tests plates processed. b. Review of SOP Section 3.0 Warning and Precautions- Item 3.9 and direct observation revealed the laboratory failed to provide a separate biological safety cabinet for each process, the preparation of lysis buffer reagent and specimen preparation for one of one specimen tests plates processed affecting 69 patient specimens. c. Review of SOP Section 1.0 Intended Use - Item 1.5 and direct observation revealed the laboratory failed to ensure specimen amplification procedures were conducted in a dedicated biological safety cabinet with adequate space to perform clean molecular technique for one of one specimen tests plates processed affecting 69 patient specimens. d. Review of SOP Section 3.0 Warning and Precautions- Item 3.9 and direct observation revealed the laboratory failed to remove and change personal protective equipment (PPE) when rotating between the laboratory designated areas for specimen preparation and specimen amplification and detection for a minimum of five of five room rotations for one of one specimen tests plates processed affecting 69 patient specimens. e. Review of SOP Section 12.0 Data Analysis and Reporting - Item 12.18 and direct observation revealed the laboratory failed to provide storage of negative patient samples for one week at 2 - 8 degrees Celsius and positive amplified patient samples for one month at -20 degrees Celsius for 27 of 27 specimen tests plates processed from 12/01/2022 to 12/13/2022. 3. On 12/14/2022 at 10:15 a.m., the above findings were confirmed by TP 2.
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 review of laboratory personnel records, employee training records, and employee competency records; the laboratory failed to meet the condition for high complexity testing personnel. The laboratory failed to ensure all testing personnel (TP) met the qualification requirements of 493.1489 for high complexity SARS-CoV-2 testing for one of four testing personnel listed on the CMS-209 (Laboratory Personnel Report). 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 review of laboratory employee training records, employee competency records, and testing personnel (TP) records, CMS-209 (Laboratory Personnel Report), the laboratory failed to ensure the Clinical Laboratory Improvement Amendments (CLIA) education requirements for high complexity SARS-CoV-2 testing for one of four testing personnel. Findings Include: 1. Review of laboratory employee training records revealed TP 4 was trained on 9/15/2022 by TP 3 to perform the following task: a. PCR Laboratory Procedures b. Patient Sample Testing: Correct specimen handling c. Patient Sample Testing: Extraction d. Patient Sample Testing: Amplification e. Patient Sample Testing: Reporting of Results f. Instruments Use and Maintenance 2. Review of laboratory employee competency records revealed TP 4 was evaluated on 9/15/2022 by TP 3 to perform the following task: a. Molecular Laboratory Procedures b. Patient Sample Testing: Correct specimen handling c. Patient Sample Testing: Extraction d. Patient Sample Testing: Amplification e. Patient Sample Testing: Reporting of Results f. Instruments Use and Maintenance 3. Review of CLIA education requirements for laboratory TP 4 revealed the laboratory failed to ensure TP 4 earned a doctoral, master's or bachelor's degree in a chemical, physical, biological, clinical laboratory science, or medical technology from an accredited institution. a. TP 4 - highest degree on record - High School Diploma 4. On 12/14/2022 at 11:56 a.m., surveyor requested education records to qualify TP 4 for high complexity testing; no additional education records were provided.