Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2233521	04/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Being Human Medical, Llc, Am Laboratory	6027 N Cicero Ave, Chicago, 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
D0000	A complaint survey was completed on April 6, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to retain patient test records for the COVID-19 antigen tests and requisition logs for SARS-CoV-2 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) testing for at least 2 years, affecting 203,645 patients tests. Findings include: The laboratory's pre-analytic policies and procedures, collection sites' patient log sheet and notebook, and patients' final reports were reviewed. 1. Interview with Staff A on April 5, 2022 at 3:20 PM, described the following process for Rapid COVID-19 antigen testing and PCR specimen collection: *The collection facilities performed the Rapid antigen tests on-site and collected patients' nasopharyngeal swabs for SARS-CoV-2 RT-PCR testing performed at Being Human Medical [d/b/a AM Laboratory (AM Lab)]. *At the collection sites, the antigen results were written on a 'Patient Log' and entered into the AM Lab's laboratory's information System (OCL-LIS). *The specimens collected for RT-PCR testing were shipped via courier with the Patient log list and specimens mailed to the laboratory were sent without the Patient log list. *Once the specimens were received in the laboratory the log lists were discarded. 2. The collection log sheet and notebook revealed the following: *The log sheet included the patients' name, date

	of birth, Rapid antigen test results, testing personnel name, date of collection, and site name. *The shipment notebook documented the site name and address, telephone number, date specimens were received in the laboratory and the date shipped from collection sites. *The number of specimens received with each shipment, the patients' name, date of birth, testing personnel name, and COVID-19 antigen test results for each specimen in the shipments were not documented in the notebook. 3. The procedure manual revealed the laboratory failed to include a written policy and procedure that instructs the retention of collection sites' patients' log sheets for both courier delivered and mailed patients' specimens for at least 2 years. 4. The patients' log for 13 of 13 patients' final results were unavailable to confirm collection site location, patient's name and date of birth, antigen test results, and date of collection and shipment. 5. The laboratory performed 93,274 antigen tests and 203,645 RT-PCR tests since 09/18/2021. 6. The laboratory director and staff confirmed the above findings on April 6, 2022 at 11:40 AM.
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 and established specimen collection, handling, and storage policies and procedures (D5311); failed to document the date and time specimens were received in the laboratory (D5313); 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 for the SARS-CoV-2 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) performed, affecting 203,645 patients' tests.
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 direct observation, record review, and interview, the laboratory failed to follow written policies and procedures for specimen collection and storage for the SARS-CoV-2 Reverse Transferase (RT) Polymerase Chain Reaction (PCR) testing performed and failed to establish specimen rejection criteria procedures, affecting 203,645 patients' tests. Findings Includes: 1. The Atila Biosystems iAMP-COVID-19 Detection Kit Emergency Use Authorization (EUA) and Information of Use (IFU), the

	laboratory's pre-analytic policy and procedures, and patients' reports were reviewed. Item 1. 2. Direct observation of Staff B on April 5, 2022 at 11:47 AM, demonstration of patient's COVID-19 Antigen test and nasopharyngeal swab collection, and it was observed that the swab specimen collected for PCR testing was placed in viral transport media (VTM). 3. Direct observation on April 5, 2022 at 11:57 AM, the surveyor observed in the laboratory's refrigerators, several racks of previously tested patients' specimens and a rack of patients' samples waiting to be tested for SARS-CoV-2. All the patient's swab in-view were immersed in VTM. In the laboratory was also observed two refrigerators with the temperature ranges from 2-8 degrees Celsius and one freezer with temperatures at -20 to -25 degree Celsius. 4. The Atila EUA/IFU reviewed stated the following: *"...swabs collected dry with the Atila Sample Collection Device (iAMP-COVID19-SCD; provided in the kit). After sample collection, immediately insert swab into the collection tube provided with the Atila COVID-19 Sample Collection Device." *"Specimens can be stored at room temperature for up to 12 hours, or -20 degree Celsius for up to 2 days after collection and before sample processing. If a delay in sample processing is expected, store dry swab specimens at -70 degree Celsius or lower." 5. Interview on April 5, 2022 at 12: 15 PM, Staff A stated specimen swabs collected at the laboratory, shipped, and received by courier were transported in VTM. Item 2. 6. Review of five patients' final reports revealed the following: Patient C1 was collected on 03/29/2022 at 12:18 AM and Results reported 04/05/2022 at 7: 20 PM; and Patient C2 was collected on 11/13 /2021 at 1:46 PM and Results reported 11/16/2021 at 11:26 AM. Patient C3 was collected on 11/14/2021 at 12:00 AM and Results reported 11/18/2021 at 4:00 PM. Patient C4 was collected on 11/14/2021 at 12:00 AM and Results reported 11/18/2021 at 4:01 PM. Patient C5 was collected on 11/14/2021 at 12:00 AM and Results reported 11/18/2021 at 7:25 PM. All the above patients were reported as "NEGATIVE" for SARS-CoV-2. 7. The pre-analytic policies and procedures showed that the laboratory failed to include the EUA/IFU specimen storage requirements needed to maintain optimal specimen integrity and failed to include policies and procedures that would identify and reject specimens shipped/mailed or dropped-off that did not meet the EUA/IFU's acceptable testing criteria. 8. The laboratory performed 203,645 RT-PCR tests since 09/18/2021. 9. The laboratory director and laboratory staff confirmed the above findings on April 6, 2022 at 11:40 AM and stated that the laboratory did not have a -70 degree Celsius freezer.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on direct observation, record review, and interview, the laboratory failed to document the date and time received on four of four patients requisitions submitted for SARS-CoV-2 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) testing, affecting 203,645 patients' tests. Findings include: The laboratory's pre-analytic policies and procedures and collection sites' patient log sheet and notebook were reviewed. 1. Direct observation of Staff C on April 5, 2022 at 3:20 PM, demonstration of the receiving process for shipped and courier delivered patients' specimens, and it was observed that a patient log listing four patients from the Brickyard collection site had no visible indication of the date and time these specimens were received in the laboratory. 2. Interview with Staff A on April 5, 2022 at 3:27 PM, stated when specimens were received by courier, the laboratory staff

	would process the specimens for testing, the time and dates received were not added to the log sheets. For the patients' specimens shipped by mail, the data entry staff were responsible for processing, they document the date but not the time received in the laboratory. 3. The manual showed the preanalytic policies failed to include the 'date and time received' requirement and failed to establish a method to document this activity when specimens were received from collection sites via courier or mail. 4. Review of patient test volume records found 203,645 patient samples were received into the laboratory when the date and time received was not documented. 5. The laboratory director and staff confirmed the above findings on April 6, 2022 at 11:00 AM.
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, the laboratory failed to establish policies and procedures to assess, monitor and correct problems with COVID-19 specimen collection, handling, and storage affecting 203,645 patient test results. Findings Include: 1. Surveyor requested all quality assurance documentation from Staff A on 04/05/2022 at 3:30 PM. The laboratory failed to provide the laboratory's quality assessment policy and documentation during the survey that was completed on 04/06/2022. 2. The laboratory failed to identify multiple issues with specimen collection, handling, and storage. See D5311 & D5313. 3. Surveyor requested on 04/05/22 at 2:55 PM patient test reports for 13 of 15 specimens that were received during the tour of the specimen receiving area on 04/05 /22 and found 13 of 13 patient sample reports reviewed were reported out by the laboratory and all were reported as negative for SARS-CoV-2. The remaining 2 patients' reports were marked cancelled. 4. Review of patient testing for SARS-CoV-2 found the laboratory has reported 203,645 patients in the past year 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 direct observation, record review, the Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) Emergency Use Authorization (EUA) for SARS-C0V-2, and interviews, the laboratory failed to have completely written procedures for two of two test systems used detect and identify SARS-CoV-2 (D5401, D5403); failed to establish the performance specifications for the laboratory developed test

	used to detect and identify SARS-CoV-2 (D5423); failed to verify the performance specifications of the LumiraDx EUA(D5421); failed to establish and perform control procedures for two of two RT-PCR procedures performed (D5441); and failed to establish and follow written policies and procedures to perform quality assessment (QA) of all analytic systems (D5791), affecting 203,645 patients' tests.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on direct observation, record review, lack of documentation, and interview, the laboratory failed to establish and follow a written procedure for the Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) performed on the QuantStudio 5 to detect and identify SARS-CoV-2 prior to testing patients, affecting 203,645 patients' tests. Findings include: 1. Direct observation on April 5, 2022 at 11:50 AM, on the workbench in the laboratory stood two PCR analyzers, the Atila Biosystems 9600 Real-Time PCR thermocycler and the Applied Biosystems Quantstudio 5 PCR thermocycler. It was also observed in the -20 degree Celsius freezers the iAMP COVID-19 Detection kits used on the Atila 9600 and the LumiraDx SARS-CoV-2 RNA STAR Complete kits for the Quantstudio 5. 2. The Food and Drug Administration (FDA) website, procedures manual, Quantstudio data logs, and maintenance records were reviewed. 3. The FDA listed the LumiraDx RNA STAR Complete RT-PCR assay for Emergency Use Authorization (EUA) to identify and detect SARS-CoV-2 virus. 4. The manual revealed that an approved written laboratory procedure for the LumiraDx EUA and Information for Use (IFU) assay was not available for the testing personnel to follow. 5. Further review of the manual showed the laboratory had not established any procedures for the LumiraDx RNA RT-PCR test system. 6. From the QC and maintenance records reviewed it could not be determined when the laboratory used the QuantStudio 5 Rt-PCR procedure or how many patient test results were reported. 7. The laboratory performed 203,645 RT-PCR tests since 09/18/2021. 8. The laboratory director and staff confirmed the above findings on April 6, 2022 at 11:00 AM.
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 Atila Biosystems SARS-CoV-2 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) testing performed by the laboratory, affecting 203,645 patients' tests. Findings Include: Item 1 The laboratory tested patients' nasopharyngeal swabs with the Atila Biosystems 9600 Real-Time PCR system PCR kit to detect and identify SARS-CoV-2. 1. The Atila Biosystems 9600 Real-Time PCR system Instructions for Use (IFU) and Emergency Use Authorization (EUA) manual, laboratory's procedures manuals, the Atila 9600 thermocycler data and maintenance records, and patients test reports were reviewed. 2. The procedures manual failed to include the following requirements: *Requirements for patient preparation; storage, preservation, transportation, and processing, specimen referral procedures and criteria for specimen rejection. See D5300 & D5311. *Control Procedures and Interpretation of results. Direct observation on April 5, 2022 at 11:55 AM, observed results from Atila thermocycler for RT-PCR testing. The laboratory failed to establish quality control criteria for acceptability and define how the laboratory determined and processed inconclusives, potentials, control failures, and re-runs. See D5441. *Step-by-step calibration and calibration verification procedures for the Thermocyclers. *Pertinent literature references. *The Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. *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. *To describe the course of action to take if a test system becomes inoperable. 3. From the Atila data and maintenance records reviewed it could not be determined when the laboratory used the 9600 Thermocycler for PCR procedures or how many patients' test results were reported. 4. The laboratory performed 203,645 RT-PCR tests since 09/18/2021. 5. The laboratory director and staff confirmed the above findings on April 6, 2022 at 11:00 AM.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to demonstrate that it could obtain performance specifications comparable to those

	established by the LumiraDx SARS-Cov-2 RNA Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) Emergency Use Authorization (EUA)/ Information for Use (IFU) procedure prior to testing patients, affecting 203,645 patients' results. Findings: 1. The Food and Drug Administration (FDA) website, LumiraDx SARS-CoV-2 RNA STAR Complete EUA/IFU manual, validation records performed on 09 /15/2021, Quantstudio 5 test data, and patient results were reviewed. 2. Direct observation on April 5, 2022 at 11:50 AM, on the workbench in the laboratory stood an Applied Biosystems Quantstudio 5 PCR thermocycler (S/N-272532862) and LumiraDx SARS-CoV-2 RNA STAR Complete kits in the -20 degree Celsius freezer. 3. The FDA listed the LumiraDx RNA STAR Complete RT-PCR assay for emergency use to identify and detect SARS-CoV-2. The LumiraDx test RT-PCR procedure was unavailable for testing personnel. See D5401. 4. The validation data shown failed to provide any evidence the LumiraDx verification procedures were performed to determine/confirm the accuracy and precision of the assay prior to testing patients. 5. From the QC and maintenance records reviewed it could not be determined when the laboratory started to used the QuantStudio 5 RT-PCR procedure or how many patients' test results were reported. 6. The laboratory performed 203,645 RT-PCR tests since 09/18/2021. 7. The laboratory director and staff confirmed the above findings on April 6, 2022 at 11:00 AM.
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, record review, lack of documentation, and interview, the laboratory failed to establish the performance specifications of the modified Emergency Use Authorized (EUA) Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedure used on unextracted nasopharyngeal swabs specimens to detect and identify SARS-CoV-2 prior to testing patients, affecting 203,645 reported patients' tests. Findings include: 1. Direct observation on April 5, 2022 at 11:50 AM, on the workbench in the laboratory stood two PCR analyzers, the Atila Biosystems 9600 Real-Time PCR system Thermocycler and the Applied Biosystems Quantstudio 5 PCR system Thermocycler. It was also observed in the refrigerator, racks of patients' nasoopharyngeal swabs previously tested and swabs waiting to be tested immersed in viral transport media (VTM). 2. Interview on April 5, 2022 at 11:57 AM, Staff B stated the specimens swabs received for SARS-CoV-2 RT-PCR testing were received in VTM. The surveyor asked Staff B if they had ever tested dry patients' swabs using the Atila SARS PCR procedure. Staff B replied "No". 3. The Atila Biosystems iAMP-COVID-19 Detection Kit EUA and Information of Use (IFU), laboratory manual, patients' results, and the Atila Biosystems 9600 Real-Time PCR system data performed on 09/15/2021 were reviewed. 4. The Atila iAMP-COVID-19

	EUA/IFU listed nasal swabs, nasopharyngeal swabs and/or oropharyngeal swabs collected dry with the Atila Sample Collection Device provided in the kit as acceptable specimens. See D5311 and D5313. 5. The laboratory's performance verification documents and Atila EUA/IFU revealed the following: *The Atila iAMP extraction method EUA/IFU (using dry swabs) conducted on 09/15/2021 had not been approved by the previous laboratory director (LD) or current LD. *The laboratory began to put collected patients' nasopharyngeal swabs into viral transport media (VTM) instead of leaving the patients' swabs dry as required by the Atila EUA. *The laboratory stopped performing the extraction procedure as required by the Atila EUA. *The date the laboratory began to tests patients' specimens with the Atila laboratory developed test (LDT) could not be determined. *The Atila iAMP wet extraction-less assay procedure had not been approved by the previous LD or current LD, prior to testing patients. 6. Further review of the provided documentation revealed the laboratory failed to perform and document the following performance studies for the Atila-LDT: a). Specimen stability studies for patient specimens shipped through all weather conditions. b). Specimen comparison studies between the Atila iAMP-LDT (wet) swabs and the Atila iAMP EUA/IFU (dry) swabs. c. Accuracy - Comparison of the SARS-CoV-2 PCR test systems: Atila iAMP EUA versus the Atila iAMP LDT. d. Precision - Empirical proof the Atila iAMP LDT identifies SARS-CoV-2. e. Analytical specificity to include interfering substances. Must provide data 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. 7. The laboratory performed 203,645 RT-PCR tests since 09/18/2021. 8. The laboratory director and staff confirmed the above findings on April 6, 2022 at 11: 00 AM.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to establish control procedures for two of two Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedures used to detect and identify SARS-CoV-2 prior to testing patients, affecting 203,645 patients' results. Findings: 1. Direct observation on April 5, 2022 at 11:50 AM, on the workbench in the laboratory stood an Applied Biosystems Quantstudio 5 PCR thermocycler (S/N-272532862) and Atila Biosystems 9600 PCR Thermocycler. 2. The LumiraDx SARS-CoV-2 RNA STAR Complete EUA and Information for Use (IFU) procedure, the Atila Biosystems 9600 Real-Time PCR system data performed on 09/15/2021, procedure manual, and patient results were reviewed. 3. The laboratory performed the LumiraDx test RT-PCR assay without a copy of the Food and Drug Administration (FDA) approved EUA/IFU

	procedures which included established controls procedures. See D5401. 4. The procedure manual and Atila documents for the laboratory developed test (LDT) using the Atila 9600 revealed the laboratory had not established control procedures that monitored the accuracy and precision of the Atila-LDT complete process. See D5403 and D5423. 5. The laboratory performed 203,645 RT-PCR tests since 09/18/2021. 6. The laboratory director and staff confirmed the above findings on April 6, 2022 at 11: 00 AM.
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 record review, lack of documentation, and interview, the laboratory failed to establish and follow written policies and procedures to perform quality assessment (QA) for the SARS-CoV-2 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedures performed since September of 2021, affecting 203,645 patents' tests. Findings Include: 1. Surveyor requested all quality assurance documentation from Staff A on 04/05/2022 at 3:30 PM. The laboratory failed to provide the laboratory's quality assessment policy and documentation during the survey that was completed on 04/06/2022. 2. The laboratory failed to identify multiple issues with procedures, performance verifications, and control procedures. See 5401, D5403, D5421, D5423, and D5441. 3. Surveyor requested on 04/05/22 at 2:55 PM patient test reports for 13 of 15 specimens that were received during the tour of the specimen receiving area on 04/05/22 and found 13 of 13 patient sample reports reviewed were reported out by the laboratory and all were reported as negative for SARS-CoV-2. The remaining 2 patients' reports were marked cancelled. 4. Review of patient testing for SARS-CoV-2 found the laboratory has reported 203,645 patients since 09/15/2021 when no analytical quality assessment policy had been established and performed.
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 ensure Emergency Use Authorized (EUA) and laboratory developed tests (LDT) provided quality laboratory services (D6082); failed to establish quality control (QC) (D6093) and quality assurance (QA) procedures (D6094) prior to testing patients, to ensure accurate and reliable results, affecting 203,645 patients' tests.
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 203,645 patients' tests. Findings: 1. The Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for Atila Biosystems iAMP-COVID-19 Detection Kit and Information for Use (IFU) procedures, laboratory's procedures manual, patient results, and Atila 9600 validation data performed on 09/15/2021 were reviewed. 2. The laboratory used Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedures to detect and identify SARS-CoV-2 in patients' nasopharyngeal specimens. 3. The procedures manual and Atila iAMP EUA/IFU revealed the LD failed to ensure the laboratory performed the FDA authorized SARS-CoV-2 RT-PCR procedure (Atila iAMP EUA- dry swab). See D5400, D5421 4. The LD failed to establish performance specifications for any modifications made to the Atila iAMP EUA/IFU procedure (e.g. Atila iAMP-swab in viral transport media (VTM), specimens shipped and mail at temperatures above -20 degree Celsius, etc.). See D5400, D5423. 5. The laboratory reported 203,645 patients results since testing began in 09/15/2021. 6. The laboratory director and staff confirmed the above findings on April 6, 2022 at 11:00 AM.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview; the laboratory director (LD) failed to establish quality control (QC) procedure for the laboratory required to ensure accurate and reliable testing affecting 203,645 patients' results. Findings include: 1. The laboratory developed Atila iAMP COVID-19 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) test, the LumiraDx SARS-CoV-2 RNA STAR Complete kit Emergency Use Authorization (EUA) and Information For Use (IFU), Atila 9600 validation data performed on 09/15/2021 were reviewed. 2. The LD failed to ensure performance verification procedures were performed to verify the number, type, and frequency of testing control materials required to monitor the accuracy and precision of the LumiraDx RT-PCR system. See D5441. 3. The LD failed to ensure performance specifications were performed to establish the number, types, and frequency of testing control materials the RT-PCR assay would require monitoring the accuracy and precision of the Atila iAMP laboratory developed test. See D5441. 4. The laboratory reported 203,645 patients results since testing began in 09/15/2021.
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, lack of documentation, and interview; the laboratory director (LD) failed to establish quality assurance (QA) programs for the laboratory required to ensure accurate and reliable testing, affecting 203,645 patients, tests. Findings include: 1. The Atila iAMP COVID-19 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) Emergency Use Authorization (EUA) and Information for Use (IFU), the LumiraDx SARS-CoV-2 RNA STAR Complete kit EUA/IFU, and procedure manual 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: *practices/issues related to test requests, specimen submission, handling, rejection, and referral. See D5391. 3. The LD failed to establish an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions for the Analytic process: Test procedures; Accurate and reliable test systems, equipment, instruments, reagents, materials, and supplies; Specimen and reagent storage condition; Equipment/instrument/test/system maintenance and function checks; Establishment and verification of method performance specifications; Calibration and calibration verification; Control procedures; Comparison of test results; Corrective actions; and Test records. See D5791. 4. The laboratory reported 203,645 patients results since testing began in 09/15/2021. 5. The laboratory director and staff confirmed the above findings on April 6, 2022 at 11:00 AM.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on record review, the laboratory personnel report (CMS-209), and interview, the laboratory failed to employ a technical supervisor (TS) who meets the qualification requirements (D6111) to provide technical supervision in the subspecialty of Virology, affecting 51,065 patients tests.
D6109	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

	This STANDARD is not met as evidenced by: Based on record review, the Laboratory Personnel Report (CMS 209), and interview, the laboratory failed to ensure a technical supervisor (TS) was employed to provide technical oversight for Reverse Transcriptase (RT) Polymerase Chain Testing (PCR) testing, affecting 51,065 patients' tests. Findings: 1. The Laboratory Personnel Report (CMS 209), employee file, and patient results were reviewed. 2. The CMS 209 revealed the position of TS was not filled. 3. The employee records of Staff-A, who functioned as the laboratory director, resigned on February 3, 2022. 4. The laboratory reported 51,065 patients' results since the TS resigned. 5. The current laboratory director and staff confirmed the above findings on April 6, 2022 at 11:40 AM.
D6134	CLINICAL CONSULTANT CFR(s): 493.1453 The laboratory must have a clinical consultant who meets the requirements of 493. 1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart. This CONDITION is not met as evidenced by: Based on record review, the Laboratory Personnel Report (CMS 209), and interview, the laboratory failed to have an employee who meet the qualification requirements and provide clinical consultation (CC) for the highly complex testing performed (D6135), affecting 51,065 patients results.
D6135	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1455 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443(b)(6); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on record review, the Laboratory Personnel Report (CMS 209), and interview, the laboratory failed to ensure a clinical consultant (CC) was employed to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care in relations to the SARS-CoV-2 testing performed, affecting 51,065 patients' tests. Findings: 1. The Laboratory Personnel Report (CMS 209), employee file, and patient results were reviewed. 2. The CMS 209 listed Staff F as CC for the laboratory. 3. The laboratory failed to provide documentation that Staff F was designated as CC by the previous or current laboratory director and failed to provide documentation that showed Staff F met the requirements to function as CC. 4. The employee records of Staff-A, who functioned as the laboratory director (LD), resigned on February 3, 2022. 5. The laboratory reported 51,065 patients' results since the LD/CC resigned. 6. The current laboratory director and staff confirmed the above findings on April 6, 2022 at 11:40 AM.

D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on record review, the laboratory personnel report (CMS-209), and interview, the laboratory failed to employ a general supervisor (GS) who meets the qualification requirements (D6142) and provide general day-to-day supervision in the subspecialty of Virology, affecting 203,645 patients' tests.
D6142	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results. This STANDARD is not met as evidenced by: Based on record review, the Laboratory Personnel Report (CMS 209), and interview, the laboratory failed to employ a general supervisor (GS) who provide day-to-day supervision for Reverse Transcriptase (RT) Polymerase Chain Testing (PCR) testing performed in the laboratory, affecting 203,645 patients' tests. Findings: 1. The CMS 209, pre-analytic policies, procedures and records, analytic policies, procedures and records, and patients' results were reviewed. 2. The CMS 209 listed Staff-D as the GS. 3. Review of pre-analytic and analytic documents revealed that Staff-D failed to fulfill the following GS responsibilities: *be accessible to testing personnel at all times testing is performed to provide on-site, telephone or electronic consultation to resolve technical problems; *to provide day-to-day supervision of RT-PCR testing; *to monitor test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained; *to assure that all remedial actions are taken whenever test systems deviate from the laboratory ' s established performance specifications; *to ensure that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning; and *to providing orientation to all testing personnel; and document annual performance evaluations of all testing personnel. 4. The laboratory reported 203,645 patients results since testing began in 09/15/2021. 5. The laboratory director and staff confirmed the above findings on April 6, 2022 at 11:40 AM.
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 record review, the Laboratory Personnel Report (CMS 209), and interview, the laboratory failed to employ two of three individuals who meet the education qualification requirements to perform the functions of highly complex testing (D6171) in the subspecialty of Virology, affecting 203,645 patients' tests.
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 record review and interview, the laboratory failed to ensure employees meet the education qualification requirements to perform Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedures for two of three testing personnel (TP) prior to testing patients, affecting 203,645 patients' tests. Findings: 1. The Laboratory Personnel Report (CMS 209), employee files, test records from the Quantstudio and Atila 9600 PCR analyzers, and patients' reports were reviewed. 2. The CMS 209 listed TP1, TP2 and TP3 as performing highly complex Reverse Transcriptase (RT) PCR procedures in the laboratory. 3. The employee documentation provided revealed the education credentials for 2 of 3 TP were unavailable for review to verify that the education criteria for personnel performing highly complex testing was met. 4. The laboratory reported 203,645 patients results since testing began in 09/15/2021. 5. Test data and patients' reports showed that TP1 and TP2 performed RT-PCR analysis and reported patients' test result during the time period reviewed. 6. The laboratory director and staff confirmed the above findings on April 6, 2022 at 11:00 AM.