Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2218659	12/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Poseidon Diagnostics Corp	2065 Ne 163rd Street, North Miami Beach, FL	

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 #2021016603 was conducted on 12/09/2021 to 12/10/2021 at Poseidon Diagnostic Corp. The laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories. The laboratory failed to establish all test performance specifications (to include specimen, storage, and transportation conditions of the specimen) since they were using Fastplex Triplex 1-step COVID-19 detection kit (Reverse Transcription polymerase chain reaction (RT-PCR), Ribonucleic Acid (RNA) extraction Free that did not have a (FDA) Food and Drug Administration (EUA) Emergency Use Authorization. The Laboratory failed to follow their policy for specimen collection, specimen storage and transportation of Coronavirus Disease 2019 (COVID-19) patient specimens from May 2021 to December 9, 2021. (D5300). The laboratory failed to validate a control method for testing for unvalidated COVID-19 PCR specimen with Fastplex Triplex 1-step COVID-19 detection kit (Reverse Transcription polymerase chain reaction (RT-PCR), Ribonucleic Acid (RNA) extraction Free before patient testing since 4/21/2021. (See D5423) The following Conditions were not met: D5300 - Preanalytic Systems 493.1240 D5400 - Analytic Systems 493.1250 D6076 - Laboratory Director 493.1441
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 observation, record review and interview, the laboratory failed to ensure uni-directional sample preparation, Reagent prep and amplification of Coronavirus Disease 2019 Polymerase Chain Reaction (COVID-19 PCR) testing since 04/21/2021. The Findings Included: An observation of the Molecular area on 12/09/2021 at 2:00 PM revealed 3 tables set up at 90 degree angles from each other. The first table had a

	hood on the left end of the table, the second table had a hood on the right end of the table, and the third table had the Biorad CFX 96 Real-time System on the left end of the table. Samples arrived right next to the hood on the first table and there were materials used for reagent preparation. Sample tubes were also on the second table on the right hand side. Reagents were located in the refrigerator located on the side of the room directly across from the Biorad CFX 96 Real-time System and in the freezers located off the right end on the third table. The pipettors were shared between the 3 tables. Review of Fastplex Triplex 1-step COVID-19 detection kit (Reverse Transcription polymerase chain reaction (RT-PCR), Ribonucleic Acid (RNA) extraction Free manufacturer instructions stated, "Separate laboratory areas, dedicated to performing predefined procedures of the assay, are required. a) 1st Area: Preparation Area-Prepare testing reagent: b) 2nd Area: Sample processing-Process the specimen and controls: c) 3rd Area: Amplification Area-PCR conducted. All materials used in one area should remain in that area and should not be moved or used in other areas. After the assay procedures, the workbench and lab supplies should be cleaned and disinfected immediately. To avoid contamination, the positive control needs to be prepared in an area separate from the amplification and extraction area." During an interview with the technologist on 12/10/2021 at 3:00 PM, he stated that 18,000 patients were tested for Covid-19 PCR 4/21/2021 to present. During an interview with technologist on 12/10/2021 at 4:19 PM, he confirmed the laboratory did not ensure a uni-directional flow system for COVID-19 PCR testing since starting patient testing on 4/21/2021.
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 record review and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the preanalytic system and correct identified problems. The Findings Included: Cross Reference D5311. Based on record review, observations, and interview the Laboratory failed to establish all test performance specifications to include the type of specimen and the storage and transport condition of the specimen since the Fastplex Triplex 1-step COVID-19 detection kit (Reverse Transcription polymerase chain reaction (RT-PCR), Ribonucleic Acid (RNA) extraction Free does not have an (FDA) Food and Drug Administration (EUA) Emergency Use Authorization and failed to follow their policy for specimen collection, specimen storage and transportation of Coronavirus Disease 2019 (COVID-19) patient specimens from May 2021 to December 9, 2021.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have a written or electronic test request from an authorized person for 9 out of 9 Patient test reports reviewed. The Findings Included: Review of 5 Patients (#1 - #5) pulled from a rack on the counter and 4 Patients (#6-#9) from the Severe Acute Respiratory Syndrome (SARS) worklist revealed no test requisitions. Interview on 12/09/2021 at 2:20 PM the Owner confirmed that the laboratory did not have any electronic or written test requisitions signed by an authorized person.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on record review, observations, and interview, the laboratory failed to accurately enter the date of the Patient test collected for 1 (#8) out of 9 Patient reports pulled. The Findings Included: Review of the Severe Acute Respiratory Syndrome (SARS) worklist revealed that Patient #8 was ran on 12/06/2021. The final report for Patient #8 stated that the test was ran on 12/02/2021. Observations of the saved specimens on 12/09/2021 at 4:30 PM revealed, that Patient #8 had a specimen collection on 12/02/2021 and 12/06/2021 per the bags the specimens were grouped in. The label on both specimens stated it was collected on 12/02/2021 with the same accession number. Interview on 12/09/2021 at 4:30 PM, the Director of Operations of the sister facility stated that the accessioner must have printed a label with the first collection date instead of the correct collection date of 12/06/2021. He confirmed that the final report with the date of 12/02/2021 was not correct and should read that it was collected and ran on 12/06/2021.
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 the manufacturers Instruction for Use (IFU), record review, observations, and interview, the laboratory failed to establish specimen storage and transportation requirements, and follow the manufacturers IFU guidelines and their policy for specimen collection, specimen storage and transportation of Coronavirus Disease 2019 (COVID-19) patient specimens from May 2021 to December 9, 2021. Findings Included: The Laboratory is using the FastPlex 1-step COVID-19 Detection Kit (Reverse Transcription Polymerase Chain Reaction (RT-PCR), Ribonucleic Acid (RNA) extraction Free). The FastPlex 1-step COVID-19 Detection Kit (RT-PCR,

	RNA extraction Free does not have an approved Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA). Laboratory tests without the approval of the FDA are considered a Laboratory Developed Test (LDT). Laboratories that perform a LDT may use the manufactures IFU for guidance, however they must establish specimen storage and transportation requirements by performing stability studies to ensure specimen integrity. Review of the IFU for the FastPlex 1-step COVID-19 Detection Kit (RT-PCR, RNA extraction Free) noted, "Specimen Transport: Specimens must be packaged, shipped, and transported at dry ice overnight. Specimen Storage: Upon receipt, specimens can be immediately processed or stored at 2-8 degrees Celsius (C) for up to 2 hours after collection. For longer term storage, store specimens at -70 degrees C or lower." The IFU also states, "False positive and false negative results can be caused by poor specimen quality, improper sample collection, improper transportation, improper laboratory processing, or a limitation of the testing technology." Review of the laboratory's policy titled, "Specimen Collection" states, "Store at room temperature and it is going picked up after 2hrs, store at 4 degree Celsius." (as seen) On 12/09/2021 at 11:04 AM, four racks with approximately 80 patient samples were observed sitting on the table un-refrigerated. On 12/09/2021 at 11:08 AM, patient samples stored in red bags were observed in the freezer at a temperature of -26 degrees Celsius (C). The laboratory performs COVID-19 testing on specimens collected at its sister laboratory. On 12/10 /2021 at 1:50 PM during a tour of the sister facility located next door to the laboratory, specimens were observed stored un-refrigerated. Three patient samples were examined. Patient #1's specimen was collected on 12/09/2021 at 12:31 PM. Patient #2's specimen was collected on 12/09/2021 at 9:23 PM. Patient #3's specimen was collected on 12/09/2021 at 8:32 PM. On 12/10/2021 at 2:10 PM, bags of patient specimens were observed on the counter of the laboratory un-refrigerated. Review of the "Daily Specimen Transport Log" found in a bag containing the un-refrigerated patient specimens showed the log was date 12/09/2021, time of pickup was 9:45 AM. and contained 11 patient specimens from West Palm Beach. Five patient specimens were examined. Patient #1's specimen was collected on 12/08/2021 at 4:50 PM. Patient #2's specimen was collected on 12/08/2021 at 4:22 PM. Patient #3's specimen was collected on 12/08/2021 at 4:08 PM. Patient #4's specimen was collected on 12/08 /2021 at 3:55 PM. Patient #5's specimen was collected on 12/08/2021 at 4:51 PM. On 12/09/2021 at 1:45pm, the Director of Operations from the sister laboratory stated the patient specimens are not stored or transported on ice and are not refrigerated per the IFU. On 12/10/2021 at 4:00PM, the Laboratory Director confirmed the laboratory had not completed the validation for the FastPlex Triplex 1-step COVID-19 Detection Kit (RT-PCR,RNA extraction Free) before performing patient testing.
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, observation, and interview, the laboratory failed to validate the Fastplex Triplex 1-step Coronavirus 2019 (COVID-19) detection kit (Reverse

	Transcription polymerase chain reaction (RT-PCR), Ribonucleic Acid (RNA) extraction Free) for Covid-19 PCR use before patient testing since 4/21/2021. (See D5423) The findings included: Based on record review, observation, and interview, the laboratory failed to validate a control method for testing for unvalidated COVID-19 PCR specimen with Fastplex Triplex 1-step COVID-19 detection kit (RT-PCR, RNA extraction free) before patient testing since 4/21/2021. (See D5423)
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 record review and interview, the laboratory failed to have a pooling policy for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) testing since pooling started on 11/29/2021. Findings Included: Review of Polymerase chain reaction (PCR) plate maps revealed that specimen pooling was being performed on 12 /06/2021. There was no pooling policy to be reviewed. There was no documentation that the kits and instruments being used for SARS-CoV-2 had an Emergency Use Authorization (EUA) that allowed specimen pooling. Interview on 12/10/2021 at 12: 51 PM the Laboratory Director confirmed that there were no policies on pooling specimens. She could not provide documentation if the test kit and instruments being used were authorized by (EUA) for patient pooling.
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 observation, record review and interview, the laboratory failed to have a procedure for decontamination of surfaces for Coronavirus 2019 Polymerase Chain

	Reaction (COVID-19 PCR) Testing since patient testing on 4/21/2021. The Findings Included: Review of FastPlex Triplex 1-step COVID-19 detection kit (RT-PCR,RNA extraction free) manual stated "Clean and decontaminate all work surfaces, pipettes, centrifuges, ABI 7500 Real Time PCR system and other equipment prior to use. The following decontamination agents may be used: 10% bleach, 70% ethanol, or DNAzap (Trademark) or RNase AWAY to minimize the risk of nucleic acid contamination." Review of COVID-19 procedure manual revealed no procedure for decontamination of surfaces for COVID-19 PCR Testing. During an interview with the technologist on 12/10/2021 at 3:00 PM, he stated that 18,000 patients were tested for COVID-19 PCR 4/21/2021 to present. During an interview with the technologist on 12/10 /2021 at 4:00 PM, they confirmed the laboratory failed to have a policy for decontamination of surfaces for COVID-19 PCR Testing since patient testing on 4/21 /2021.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document that the Laboratory Director approved, signed and dated the procedure manual. The laboratory started testing in May 2021. The Findings Includes: Review of the online procedure manual showed the Laboratory Director had not approved, signed or dated the procedure manual. The Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the Laboratory Director on 12/09 /2021 and reported an estimated annual test volume of 18,400. On 12/10/2021 at 12: 00 PM, the Laboratory Director stated that she had not done that yet.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to store Fastplex Triplex 1-step COVID-19 detection kit (Reverse Transcription polymerase chain reaction (RT-PCR), Ribonucleic Acid (RNA) extraction Free at less than -18 degrees Celsius per the instructions for use (IFU) for 216 days out of 225 in freezer #1 and 171 days out of 225 in freezer #2, and failed to store LumiraDx SARS-CoV-2 Ribonucleic Acid (RNA) Star Complete at -15 to -25 degrees Celsius per the manufacturer's instructions for 96 out of 225 days in freezer #1. The Findings Included: Observation taken on 12/09/2021 at 10:00 AM revealed that Freezer #1 was -13 degrees Celsius and had 20 boxes of Fastplex Triplex 1-step COVID-19 detection

	kit (Reverse Transcription polymerase chain reaction (RT-PCR), Ribonucleic Acid (RNA) extraction Free in it (Lot # 202103002) that IFU stated to store at below -18 degrees Celsius and 3 boxes of LumiraDx SARS-CoV-2 RNA Star Complete (Lot # P2100498) that IFU stated to store at -15 to -25 degrees Celsius. Review of freezer #1 temperature log revealed the temperatures from 05/01/2021 to 12/10/2021 were not below -18 degrees 216 days out of 225 days reviewed and was not -15 to -25 degrees Celsius for 96 out of 225 days reviewed. Observation taken on 12/09/2021 at 10:00 AM revealed that Freezer #2 was -19 degrees Celsius and has 2 boxes of Fastplex Triplex 1-step COVID-19 detection kit (Reverse Transcription polymerase chain reaction (RT-PCR), Ribonucleic Acid (RNA) extraction Free in it (Lot# 202103002) that the IFU stated to store at below -18 degrees Celsius. Review of freezer #2 temperature log revealed, the temperatures from 05/01/2021 to 12/10/2021 were not below -18 degrees for 171 out of 225 days reviewed. The temperature logs for freezer #1 and #2 had an acceptable range of -29 to 0 degrees Celsius which was not acceptable for what was being stored in them. Observations taken on 12/10/2021 at 12: 18 PM revealed, that all of the aforementioned reagents were still in freezer #1 (-14 degrees Celsius). Interview on 12/10/2021 at 12:18 PM, the Laboratory Director confirmed that the freezer temperatures were not cold enough for what was stored in them.
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 observation and interview, the laboratory failed to have expiration and preparation dates written on alcohol bottles used in Coronavirus 2019 Polymerase (COVID-19 PCR) Testing. Findings included: During an observation of the Molecular Room on 12/10/2021 at 2:30 PM, there were 2 alcohol bottles sitting on the table with no labeling of a preparation and expiration dates. During an interview with the technologist on 12/10/2021 at 4:19 PM, he confirmed the laboratory did not write expiration and preparation dates on alcohol bottles in the laboratory.
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 record review, observation, and interview, the laboratory failed to validate the Fastplex Triplex 1-step Coronavirus Disease 2019 (COVID-19) detection kit (Reverse Transcription polymerase chain reaction (RT-PCR), Ribonucleic Acid (RNA) extraction Free) for COVID-19 PCR use before patient testing since 4/21 /2021. The Findings Include: Review of the Food and Drug Administration (FDA) COVID-19 Molecular Diagnostic Database revealed Fastplex Triplex 1-step COVID-19 detection kit (RT-PCR, RNA extraction free) was not listed as a Molecular Diagnostic Test Emergency Use Authorization (EUA). Review of the FastPlex Triplex 1-step COVID-19 detection kit (RT-PCR, RNA extraction free) manual revealed, "Components Required but Not Included within the Test: Real-Time PCR Instrument(s): ABI 7500 Real-Time PCR System. The performance of the FastPlex Triplex 1-Step COVID-19 detection kit (RT-PCR, RNA extraction free) was established using oropharyngeal swabs. Nasal swabs, nasopharyngeal, and mid-turbinate nasal swabs. Bronchoalveolar lavage fluid specimens are also considered acceptable specimen types for use with the kit but performance has not been established. Unverified interfering substances or PCR inhibitors may lead to false negative or invalid results." During an observation of the Molecular Room on 12/10 /2021 at 2:30PM, it was revealed that the equipment used for COVID-19 PCR testing was the Bio-Rad CFX96 Real-time System. Review of Fastplex Triplex 1-step COVID-19 detection kit (RT-PCR,RNA extraction free) validation revealed no documentation of interfering substances, limit of detection, use of the Bio-Rad CFX 96 and procedure for testing oral and nasal collection. There was no documentation of a signature from the laboratory director for the completion of the validation. Review of Patient logs revealed 18,400 patients had been tested for COVID-19 from 4/21 /2021 to the present. During an interview with the technologist on 12/10/2021 at 3:00 PM, he stated that 18,000 patients were tested for COVID-19 PCR 4/21/2021 to present. During an interview on 12/10/2021 at 4:00PM, the laboratory director confirmed the laboratory had not completed the validation for the FastPlex Triplex 1-step COVID-19 detection kit (RT-PCR, RNA extraction free) before performing patient testing.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to validate a control method for testing for unvalidated Coronavirus Disease 2019 (COVID-19) Polymerase Chain Reaction (PCR) specimen with Fastplex Triplex 1-step COVID-19 detection kit (Reverse Transcription polymerase chain reaction (RT-PCR), Ribonucleic Acid (RNA) extraction Free before patient testing since 4/21/2021. The Findings Included: Review of the Food and Drug Administration (FDA) COVID-19 Molecular Diagnostic Database revealed Fastplex Triplex 1-step COVID-19 detection kit (RT-PCR, RNA extraction free) was not listed as a Molecular Diagnostic Test Emergency Use Authorization (EUA). Review of the Precigenome website revealed Catalog #: 02.01.1020 Fastplex Triplex 1-step COVID-19 detection kit (Reverse Transcription polymerase chain reaction (RT-PCR), Ribonucleic Acid (RNA)

	extraction Free is not FDA cleared. The kit includes Positive Control and Negative Control. Positive Control contains Gblocks for ORF1ab, N gene and Human RNA for internal control RNase P gene. Negative Control contains Nuclease-free water. Review of Fastplex Triplex 1-step COVID-19 detection kit (Reverse Transcription polymerase chain reaction (RT-PCR), Ribonucleic Acid (RNA) extraction Free procedure manual revealed, "SARS-CoV-2 Positive Control: The SARS-CoV-2 Positive Control consists of a mix of gblocks for ORF1ab, N gene and Human RNA for internal control RNase P gene. The positive control should be positive for the ORF1ab gene (Ct equals or less than 39), the N gene (Ct equals or less than 39) and the RNase P gene targets (Ct equals or less than 39). If the results are not positive, the rRT- PCR run is invalid. Positive and negative are defined based on a cutoff of Ct = 39. " During an interview with the technologist on 12/10/2021 at 4:16 PM, he stated the thresholds to determine a result was positive is 0 to 41 CT for FAM and HEX and 0 to 37 CT for CY5. Review of the COVID-19 PCR Plates Maps revealed positive and negative controls run in duplicates from 4/21/2021 to present. Review of the PCR Control validation revealed no documentation of a validation and method for COVID-19 positive and negative controls the for Fastplex Triplex 1-step COVID-19 detection kit (Reverse Transcription polymerase chain reaction (RT-PCR), Ribonucleic Acid (RNA) extraction Free to determine positive and negative results. During an interview with the technologist on 12/10/2021 at 3:00 PM, he stated that 18,000 patients were tested for COVID-19 PCR 4/21/2021 to present. During an interview on 12/10/2021 at 4:01 PM, the laboratory director confirmed the laboratory had not completed the validation for COVID-19 PCR positive and negative controls before performing patient testing.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to have the calibration certificate from the manufacturer or documentation showing a calibration was performed for the Eppendorf pipettes from May 2021 to December 9, 2021. The Findings Included: On 12/09/2021 at 10:30 AM during a tour of the laboratory Eppendorf pipettes were observed in the laboratory. According to the user guide "Calibration and Adjustment of Dispensing Systems in the Laboratory" calibration for pipettes on the Eppendorf website stated, "The test norm most commonly used for pipettes and dispensers and their calibration is the standard DIN EN ISO 8655. This standard lays down the maximum permissible random and systematic measurement deviations for the various liquid handling systems. The error limits specified in the standard always refer to the overall system, consisting of the dispensing device and accessories such as the pipette tip. Compliance with regard to error limits must be checked by the user under the control of inspection, measuring and test equipment or analytical quality assurance at least once a year." On 12/10/2021 at 4:30 PM, the Director of Operations from the sister laboratory stated they were unable to locate the calibration certificates for the pipettes.
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 and interview, the Laboratory Director failed to provide overall management and direction of the laboratory. The Findings Included: Cross Reference D6082. Based on record review and interview, the Laboratory Director failed to ensure testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance in the preanalytic phase of testing from May 2021 to December 10, 2021. Cross Reference D6086. Based on record review and interview, the laboratory director failed to validate the Fastplex Triplex 1-step Coronavirus Disease 2019 (COVID-19) detection kit (Reverse Transcription polymerase chain reaction (RT-PCR), Ribonucleic Acid (RNA) extraction Free) for Covid-19 PCR along with positive and negative controls use before patient testing since 4/21/2021.
D6081	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(d) Each individual may direct no more than five laboratories. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director was the director of seven (#1, #2, #3, #4, #5, #6, #7) laboratories. The Findings Included: Review of the Centers for Medicare and Medicare Services Aspen website, showed the Laboratory Director as being the director for seven laboratories. Review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 12/09/2021 for laboratory #5, listed the Laboratory Director as being the director for laboratories #2, #3, #4, and #7. On 12/09 /2021 at 4:55 PM, the Laboratory Director stated she was unaware that she was listed as the laboratory director for laboratory #1 and that she was resigning from laboratory #2.
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 failed to ensure testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance in the preanalytic phase of testing from May 2021 to December 9, 2021. The Findings Included: The Laboratory Director failed to establish all test performance specification that included the type of specimen, the storage and

	transport conditions of the specimen (since the test kit used did not have an FDA EUA) and failed to follow their policy for specimen collection, specimen storage and transportation of Coronavirus Disease 2019 (COVID-19) patient specimens from May 2021 to December 9, 2021. (See D5311)
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on record review, observation and interview, the laboratory director failed to validate the Fastplex Triplex 1-step Coronavirus Disease 2019 (COVID-19) detection kit (Reverse Transcription polymerase chain reaction (RT-PCR), Ribonucleic Acid (RNA) extraction Free) for COVID-19 PCR along with postive and negative control use before patient testing since 4/21/2021. The Findings Included: Based on record review, observation, and interview, the laboratory failed to validate the Fastplex Triplex 1-step COVID-19 detection kit (RT-PCR, RNA extraction free) for COVID-19 PCR use before patient testing since 4/21/2021. (See D5423) Based on record review and interview, the laboratory failed to validate a control method for testing for unvalidated COVID-19 PCR specimen with Fastplex Triplex 1-step COVID-19 detection kit (RT-PCR, RNA extraction free) before patient testing since 4/21/2021. (See D5425) During an interview on 12/10/2021 at 4:10 PM, the laboratory director confirmed the laboratory had not completed the validation for COVID-19 PCR along with positive and negative controls before performing patient testing.
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 failed to document quality assessment (QA) activities to assure the quality of laboratory services from May 2021 to December 9, 2021. The Findings Included: Review of the policy titled, "Quality Assessment Plan" in the section titled, "Annual Calendar of QA Review" stated, "1. Review the monitor(s) assigned for each month. Document the review on the appropriate form and attach all supporting data and information. 2. Each month, complete the Monthly Checklist of the Analytical Phase as part of the routine laboratory operation." Review of the Annual Calendar QA showed the following QA Systems that are to be reviewed. January - Monthly Checklist, Personnel, Procedure Manual February - Monthly Checklist, Patient Test Management March - Monthly Checklist, Proficiency Testing, Critical Values, Turnaround Time, Error Correction April - Monthly Checklist, Complaints, Communication, Incidents May - Monthly Checklist, Patient Test Management June - Monthly Checklist, Critical Values, Turnaround Time, Error Correction July - Monthly Checklist, Proficiency Testing August - Monthly Checklist, Patient Test Management September - Monthly

	Checklist, Critical Values, Turnaround Time, Error Correction October - Monthly Checklist, QA Plan November - Monthly Checklist, Patient Test Management, Proficiency Testing December - Monthly Checklist, Critical Values, Turnaround Time, Error Correction The Monthly Checklist and the monitor forms were not available for review. On 12/10/2021 at 12:15 PM, the Laboratory Director stated they have the forms but have not performed any QA yet.