Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2192829	05/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Prn Diagnostics, Llc	7007 E Main St, Mesa, AZ	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance Manual and interview with the facility personnel, the laboratory failed to follow established policies and procedures to assess employee competency. Findings include: 1. The laboratory began patient testing on 10/27/2020 in the sub-specialty of Virology, with an approximate annual test volume of 50,000. 2. The laboratory policy reviewed during the survey titled, "Quality Assurance Manual (Personnel Training and Competency)" states, "Initial analyst training and competency is considered complete after the analyst has produced initial demonstration of method capability in the specific method or areas of analysis and this competency must be evaluated by the Technical Supervisor. Competency must be checked again after 6 months of hire, at 1 year, and annually after that... Documentation of evaluation shall be retained in personnel files." 3. The laboratory failed to follow the established policy indicated above to assess employee competency. See D6127 and D6128 for specific findings. 4. The facility personnel interviewed during the survey at 11:30am on 04/05/2022 confirmed the laboratory failed to follow established personnel competency policies to assess employee competency.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on lack of accuracy verification documentation for review and interview with the facility personnel, the laboratory failed to verify the accuracy of testing performed under the sub-specialty of Virology at least twice annually during 2021. Findings include: 1. The laboratory began patient testing on 10/27/2020, using a Lab-Developed PCR test for COVID-19 testing. The laboratory's approximate annual test volume is 50,000. 2. No documentation was presented for review during the survey to indicate the laboratory verified the accuracy of the laboratory-developed PCR COVID-19 test at least twice annually during 2021. 3. At 11:52am on 04/05/2022, the facility personnel interviewed confirmed the laboratory failed to verify the accuracy of the PCR COVID-19 test at least twice annually during 2021.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of patient test requisitions for SARS-CoV-2 (COVID-19) testing performed under the sub-specialty of virology and interview with the facility personnel, two out of two test requisitions failed to include the date and time of specimen collection. Findings include: 1. The laboratory performs SARS-CoV-2 (COVID-19) testing under the sub-specialty of virology, with an approximate annual test volume of 50,000. 2. The laboratory's policy titled, Specimen Collection, Subcontracting and Rejection (BIO-Specimens) states, "Specimens must be accompanied by a paper requisition, prepared either by hand or printed from the electronic ordering system. At a minimum, test requisition requirements for each patient collection include ...Date and time of specimen collection." 3. The test requisitions presented for review during the survey for specimen# 210180074 and specimen# 211110121 failed to include the date and time of specimen collection. 4. The facility personnel interviewed at 1:10pm on 4/05/2022 confirmed the date and time of specimen collection were not documented on the test requisition referenced above.
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 pre-analytic Quality Assessment (QA) policies and procedures, patient test records and interview with the facility personnel, the laboratory failed to establish QA policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the laboratory's preanalytic systems. Findings include: 1. The laboratory performs SARS-CoV-2 (COVID-19) testing under the sub-specialty of virology, with an approximate annual test volume of 50,000. It is the practice of the laboratory to manually transcribe patients' test requisition information into the electronic Laboratory Information System (LIS). 2. Review of the test requisition and test report for specimen# 220330240 revealed the hand written test requisition listed a specimen collection time of 8:53am on 2/01 /2022. The electronic test report for specimen# 220330240 indicated a collection date /time of 2/01/2022 at 11:58am. 3. The 'Quality Assurance Manual' reviewed during the survey failed to include established policies and procedures to monitor, assess, and when indicated, correct problems identified in the pre-analytic systems, including but not limited to, a system to identify and correct errors found when manually transcribing test requisition information from a paper record into an electronic system. 4. The laboratory's established QA policy (ADM-QA Manual) states, "Over the course of the year, at least four samples will be chosen randomly and traced through the entire process...The following Pre-Analytical items must be checked: Name and Address of healthcare provider ordering the test with the NPI number, Patient name or identifier, Patient gender, Date of Birth, Test(s) ordered and source of specimen, Date and time of collection, Physician's signature, Any other pertinent patient inf
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the number and severity of deficiencies cited for quality practices identified during the survey conducted on April 5, 2022, it was determined that the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283, and failed to monitor the overall quality of the analytic systems and correct problems as specified in 493.1289 for patient testing performed by the laboratory in the sub- specialty of Virology. See D5401, D5403, D5413, D5423, D5425, D5429, D5435, D5441, D5445, D5469, D5481, D5775, D5783 and D5791 for findings.
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 review of the laboratory's test procedure for real-time PCR COVID-19 testing, review of patients' test records and test reports and interview with the facility personnel, the laboratory failed to follow their established test procedure specific to data analysis and test reporting. Findings include: 1. The laboratory performs COVID-19 testing using the Lab-Developed Test (LDT), 'SARS-CoV-2 by Bioneer Exicycler'. Patient testing for this test began on 12/10/2020 and the laboratory tested 57,226 patients from 12/10/2020 through 4/05/2022 (the date of the survey). 2. The laboratory's written test procedure, 'SARS-CoV-2 by Bioneer Exicycler - Section 12.0 Data Analysis and Reporting', lists the test interpretation as "Presumptive SARS-CoV-2" if the E gene result is negative, the SARS-CoV-2 gene (RdRp gene/N gene) result is positive and the Internal Positive Control (IPC) result is positive. The procedure states, "All specimens that have a Presumptive SARS-CoV-2 result must be re-analyzed for confirmation." 3. Analytic test records reviewed for specimen# 220330194 tested on 02/02/2022 at 12:33:34 indicated the E gene result as negative, the SARS-CoV-2 gene (RdRp gene/N gene) result as 33.82 (positive) and the IPC as valid (or positive), resulting in a final test result of negative. The analytic test record reviewed included a highlighted positive SARS-CoV-2 gene (RdRp gene/N gene) result. The highlighted result, according to laboratory personnel, is flagged and interpreted as a Presumptive SARS-CoV-2 test result. 4. Laboratory personnel failed to follow the established test procedure with regard to Data Analysis and Interpretation and re-analyze the above referenced patient specimen for confirmation. The patient's test report was issued with a negative test result, with no repeat analysis.
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 review of the laboratory's procedure manual and interview with the facility personnel, the laboratory's procedure manual failed to include information specific to

	the calibration procedures performed on the Bioneer Exicycler 96 analyzers. Findings include: 1. The laboratory began patient testing using the Lab-Developed Test (LDT), 'SARS-CoV-2 by Bioneer Exicycler', on 12/10/2020 and tested 57,226 patients from 12/10/2020 through 04/05/2022 (the date of the survey). 2. The laboratory's test procedure, "SARS-CoV-2 by Bioneer Exicycler" failed to include written evidence of calibration procedures determined by the laboratory for this test, including the frequency, type, number and concentration of calibration materials used to monitor, detect error and evaluate method performance. The frequency for calibration performance must not be less than the frequency specified in the manufacturer's instructions. 3. The facility personnel interviewed on 04/05/2022 at 3:35pm confirmed the laboratory's test procedure for SARS-CoV-2 by Bioneer Exicycler failed to include calibration procedures.
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 lack of temperature logs for review and interview with the facility personnel, the laboratory failed to document the refrigerator and freezer temperatures where patient specimens and test reagents are stored, and failed to document the room temperature and humidity measurement of the room where testing occurred. Findings include: 1. No temperature logs, including room temperature, freezer and refrigerator, and no evidence of humidity measurements were presented for review for the time period of December 2020 through April 2021. 2. The laboratory utilizes 2 freezers and 5 refrigerators to store patient specimens and test reagents. 3. At 2:37pm on 04/5 /2022, the facility personnel interviewed confirmed that the temperature logs indicated above could not be located at the time of the survey. 4. The laboratory began patient testing in October 2020 and performs approximately 50,000 tests annually.
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 review of established performance specification documentation for the Laboratory Developed Test (LDT), 'PRN Mesa Location COVID Detection by Real Time PCR Via Accupower SARS-CoV-2 Kit', interview with the facility personnel, and lack of LIS verification documentation, the laboratory A) failed to produce data to support that performance specifications had been established prior to patient testing and B) failed to produce evidence that the Laboratory Information System (LIS) calculations were verified prior to the initial calculation of patient results. Findings include. A1. Documentation of the performance specifications presented for review on 04/05/2022 for the test, 'PRN Mesa Location Covid Detection by Real Time PCR Via Accupower SARS-CoV-2 Kit', failed to include the raw data obtained by the laboratory to verify the authenticity of the study results listed in the method validation report. No raw data was presented for review to support the studies performed for the accuracy, precision, analytical sensitivity and analytical specificity performance characteristics. A2. The laboratory failed to produce documentation to show they established the performance specifications for the reportable range, reference intervals (normal values), interfering substances and any other performance characteristics required for test performance of the test indicated above. A3. The laboratory director reviewed and approved the performance specifications indicated above on 12/08 /2020. The laboratory began patient testing on 12/10/2020 and tested 57,226 patients from 12/10/2020 through 4/05/2022 (the date of the survey). A4. The laboratory used the test kit, 'Accupower SARS-CoV-2 Multiplex Real-Time-RT-PCR Kit' to establish the performance specifications. The test kit is not FDA-approved for diag
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 lack of calibration performance documentation for review on 04/05/2022 and interview with the testing personnel, the laboratory failed to determine the test system's calibration procedures based upon the established performance specifications. Findings include: 1. The laboratory began patient testing using the Lab-Developed Test (LDT), 'SARS-CoV-2 by Bioneer Exicycler', on 12/10/2020 and tested 57,226 patients from 12/10/2020 through 4/05/2022 (the date of the survey). 2. The laboratory's established performance specifications reviewed during the survey titled, "PRN Mesa Location Covid Detection by Real Time PCR Via Accupower SARS-CoV-2 Kit", approved by the laboratory director on 12/08/2020, failed to include written evidence of calibration procedures determined by the laboratory for this test, including the frequency, type, number and concentration of calibration materials used to monitor, detect error and evaluate method performance. The frequency for calibration performance must not be less than the frequency specified in the manufacturer's instructions. 3. The laboratory's test procedure, "SARS-CoV-2 by Bioneer Exicycler" failed to include written evidence of calibration procedures determined by the laboratory for this test. 4. The laboratory utilizes 3 separate Bioneer Exicycler 96 instruments to perform the test (serial numbers EXI96V4-05N-BXB096, EXI96V4-05N-BXF004 and EXI96V4-05N-BXF006). 5. The Bioneer Exicycler 96 instrument manual reviewed during the survey stated, "Calibration must be done when moving Exicycler 96 to a different location or when changing a light source lamp. A

	periodical calibration of every six months helps to maintain the optimum condition of Exicycler 96." 6. The laboratory maintained no documentation of calibration procedures perfor
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on lack of maintenance records for the Bioneer ExiPrep 96 Lite extraction instruments and interview with the facility personnel, the laboratory failed to perform and document maintenance as required by the manufacturer. Findings include: 1. The laboratory performs SARS-CoV-2 (COVID-19) testing under the sub-specialty of virology, with an approximate annual test volume of 50,000. The laboratory utilizes 2 separate Bioneer ExiPrep 96 Lite extractions instruments (serial numbers: EP96L-BXB007 and EP96L-BXD019), in conjunction with the Bioneer Exicycler 96 test system. 2. No documentation of instrument maintenance was presented for review during the survey to indicate the laboratory performed and documented Daily, Weekly and Biannually/When Required maintenance on either ExiPrep 96 Lite extraction machine from December 2020 through April 2021. 3. The ExiPrep 96 Lite Maintenance Sheet used by the laboratory includes: Daily Maintenance (worktable cleaning, check touch screen operation, elution rack cleaning, layer cartridge rack cleaning, contamination shield cleaning, door moving check, plate cleaning, UV and exterior checks); Weekly Maintenance (self test check, plate cleaning, UV lamp check, exterior check, cooling fan cover damage check); and Biannually or When Required maintenance (pollutants inside the instrument check, heating block temperature check, heating & cooling block temperature check, home position check, and magnetic roads bending check). 4. The facility personnel confirmed during an interview on 04/05/2022 at 4:10pm that the laboratory could not produce maintenance documentation for the ExiPrep 96 Lite extraction instruments for the time period indicated above.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on lack of manual pipette and centrifuge calibration documentation for review from 2021 and interview with the facility personnel, the laboratory failed to follow established policies in regards to pipette calibrations and centrifuge calibrations used

	for patient testing purposes. Findings include: 1. The laboratory's established policy states, "Pipettes, Thermometers and Centrifuges must be calibrated annually." 2. No documentation was presented for review during the survey conducted on 04/05/2022 to indicate the laboratory performed and documented manual pipette calibrations and centrifuge calibrations during 2021. 3. The facility personnel interviewed on 4/05 /2022 at 3:55pm acknowledged that there was no record of annual pipette and centrifuge calibrations from 2021.
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 review of the laboratory's established performance specifications, review of the laboratory's test procedure and interview with the facility personnel, the laboratory failed to establish control procedures according to the performance specifications established by the laboratory. Findings include: 1. The established performance specifications documented in the 'PRN Mesa Location COVID Detection By Real-Time PCR Via Accupower SARS-CoV-2 Kit' analytical method validation report listed the controls utilized during the test establishment included: Negative Template Control (NTC), Positive Control (PC), Internal Positive Control (IPC), and Negative Extraction Control (NEC). The control procedures established by the laboratory as indicated in the performance specifications stated that the NTC, PC, IPC and NEC must be performed with each test run and assessed to determine that the controls are valid and acceptable. 2. The laboratory's test procedure (SARS-CoV-2 by Bioneer Exicycler - 10.0 Quality Control) reviewed during the survey listed the control procedure as follows: 10.2 Every analytical run must include a Negative Control (NTC); 10.3 Every analytical run must include a Positive Control (PC); and 10.4 Every sample includes an Internal Positive Control (IPC). 3. The laboratory's test procedure referenced above (specific to Quality Control) failed to include the NEC. 4. Control procedures established by the laboratory did not reflect the number, type and frequency of control procedures established in the test performance specifications. 5. The facility personnel interviewed on 4/05/2022 at 12:18pm acknowledged that the written control procedures listed in the laboratory's test procedure did not reflect the number, type and frequency of control materials using t
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified

	in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of performance specifications established by the laboratory for the laboratory-developed test 'SARS-CoV-2 by Bioneer Exicycler', review of the laboratory's test procedure, review of Quality Control (QC) records, and interview with the facility personnel, the laboratory failed to perform control procedures using the number and frequency established by the laboratory. Findings include: 1. The laboratory began patient testing using the Lab-Developed Test (LDT), 'SARS-CoV-2 by Bioneer Exicycler', on 12/10/2020 and tested 57,226 patients from 12/10/2020 through 04/05/2022 (the date of the survey). 2. The laboratory's established performance specifications reviewed during the survey titled, "PRN Mesa Location Covid Detection by Real Time PCR Via Accupower SARS-CoV-2 Kit", approved by the Laboratory Director on December 8, 2020, listed the following control procedures for the Real-Time PCR COVID test performed by the laboratory: a). A "no template" (negative) control (NTC) is used on every assay plate. The negative control must be negative (undetermined; no detectable Ct value) for the test result to be valid. b). A positive (external positive) is used to verify proper assay set-up and SARS-CoV-2 reagent integrity. The positive control must be positive for both SARS-CoV-2 targets in order for the test result to be valid. c). The Negative Extraction Control (NEC) is processed with each batch of samples. The NEC should only show an amplification curve for IPC with a Ct of less than or equal to 33 but must be negative for all SARS-CoV-2 targets (Ct undetermined). d). IPC (Internal Positive Control) in a patient sample indicates that PCR amplification occurred in the well. The presence of IPC and no detectable
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) lot change documentation and interview with the facility personnel, the laboratory failed to establish the criteria for acceptability of quality control materials. Findings include: 1. The laboratory performs patient testing on three Bioneer Exicycler 96 analyzers using the Bioneer Accupower SARS-CoV-2

	Multiplex Real-Time RT-PCR kit (RUO). The test kit includes the following components: Master-mix, Enzyme Mix, Positive Control (PC), Internal Positive Control (IPC), and Negative Template Control (NTC). The test kit is not FDA-approved for diagnostic purposes and the laboratory had not submitted a request for Emergency Use Authorization (EUA) from the FDA as of the date of the survey, 04/05 /2022. 2. Testing personnel interviewed during the survey confirmed that the laboratory uses one new kit for each patient run and the laboratory usually receives 100 kits per shipment. 3. No documentation was presented for review to indicate the laboratory established the criteria for acceptability of each lot of control materials included with each shipment of test kits used on the Exicycler 96 analyzers from December 2020 through the date of the survey. 4. The laboratory maintained no documentation of an established policy and procedure related to the establishment of control material acceptability. 5. Testing personnel interviewed on 04/05/2022 at 3: 05pm confirmed the laboratory had not established the criteria for acceptability of each lot of control material used on the analyzers stated above. 6. The number of control lots used by the laboratory during the timeframe indicated above could not be determined at the time of the survey.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of performance specifications established by the laboratory for the laboratory-developed test 'SARS-CoV-2 by Bioneer Exicycler', review of the laboratory's test procedure, review of Quality Control (QC) records, and interview with the facility personnel, it was determined the laboratory reported patient test results when the QC testing did not meet the laboratory's criteria for acceptability. Findings include: 1. The laboratory began patient testing using the Lab-Developed Test (LDT), 'SARS-CoV-2 by Bioneer Exicycler', on 12/10/2020 and tested 57,226 patients from 12/10/2020 through 4/05/2022 (the date of the survey). 2. The laboratory's established performance specifications reviewed during the survey titled, "PRN Mesa Location Covid Detection by Real Time PCR Via Accupower SARS-CoV-2 Kit", approved by the laboratory director on December 8, 2020, listed the following control procedures for the Real-Time RT-PCR COVID test performed by the laboratory: a). A "no template" (negative) control (NTC) is used on every assay plate. The negative control must be negative (undetermined; no detectable Ct value) for the test result to be valid. b). A positive (external positive) is used to verify proper assay set-up and SARS-CoV-2 reagent integrity. The positive control must be positive for both SARS-CoV-2 targets in order for the test result to be valid. c). The Negative Extraction Control (NEC) is processed with each batch of samples. The NEC should only show an amplification curve for IPC with a Ct of less than or equal to 33 but must be negative for all SARS-CoV-2 targets (Ct undetermined). d). IPC (Internal Positive Control) in a patient sample indicates that PCR amplification occurred in the well. The pr
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)

	(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on lack of instrument comparison results from 2021 and interview with the facility personnel, the laboratory failed to have a system in place that twice a year evaluates and defines the relationship between test results for testing performed in the sub-specialty of Virology. Findings include: 1. The laboratory utilizes three separate Bioneer Exicycler 96 analyzers to perform Real-Time RT-PCR COVID-19 testing on patient specimens. The analyzer serial numbers include: EXI96V4-05N-BXB096, EXI96V4-05N-BXF004 and EXI96V4-05N-BXF006. The laboratory utilizes two separate extraction machines (ExiPrep 96 Lite) in conjunction with the Bioneer Exicycler 96 analyzers. The serial numbers of the extraction machines include: EP96L-BXD019 and EP96L-BXB007. 2. During the survey conducted on 04/05 /2022, no documentation was presented for review to indicate the laboratory had a system in place that twice a year evaluates and defines the relationship between the test results generated from each Bioneer Exicycler 96 analyzer used by the laboratory. 3. The laboratory began patient testing using the Bioneer Exicycler 96 test systems on 12/10/2020. The laboratory performed 57,226 patient tests on the analyzers from 12/10 /2020 through 04/05/2022, the date of the survey. 4. At 3:10pm on 4/05/2022, the facility personnel interviewed confirmed the laboratory did not have a system in place at the time of the survey to evaluate and document a comparison of test results between the instruments mentioned above.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with the facility personnel, it was determined the laboratory failed to document corrective action for QC results that failed to meet the laboratory's established criteria for acceptability. Findings include: 1. No Negative Extraction Control (NEC), as established in the test performance specifications for the Lab-Developed Test (LDT), 'SARS-CoV-2 by Bioneer Exicycler', was performed with any patient test from 12/10/2020 through the date of the survey, 4/05/2022. See D5445 for specific findings. 2. No corrective action documentation was presented for review for control results that failed to meet the criteria for acceptability as indicated in the laboratory's established test performance specifications for test system failure referenced above. 3. The laboratory failed to obtain valid quality control results (NTC, PC and IPC) for testing performed on 8/19 /2021 and 8/20/2021. See D5445 for specific findings. 4. No documentation was

	presented for review during the survey to indicate the laboratory documented corrective action for the testing dates indicated above for control results that failed to meet the laboratory's established criteria for acceptability. 5. No evidence of corrective action was presented for review during the survey on 4/05/2022 to indicate the laboratory evaluated all patient test results obtained in the unacceptable test runs to determine if patient test results had been adversely affected, for each day of patient testing in which control failures occurred. 6. The facility personnel interviewed on 4 /05/2022 at 2:35pm confirmed the laboratory failed to document corrective actions for control results that did not meet the laboratory's established criteria for acceptability, including evaluation of p
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 review of established Quality Assessment (QA) policies and procedures on 4 /05/2022 and interview with the facility personnel, the laboratory failed to follow policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in the analytic systems. Findings include: 1. The laboratory's established QA policy (ADM-QA Manual) states, "Each laboratory is responsible for providing a monthly QA packet...The packet includes at a minimum: Daily Temperature/Humidity Log(s), Daily Run Logs, Daily QC results, Lab Maintenance Log, Monthly Background Calibration Report, Corrective Action Reports/Incident Management Reports, Reagent Log, Lot to Lot Comparison Log, and Continuous Education. The packet must be reviewed by the Supervisor/QA Office and the Laboratory Director. The packet should be reviewed for completeness and acceptable criteria. Trends should be readily identifiable." 2. No completed monthly QA packet from December 2020 through March 2022 was presented for review during the survey to indicate the laboratory followed the established policy indicated above to monitor, assess, and correct problems identified in the analytic systems. 3. Additionally, the laboratory's established QA policy (ADM-QA Manual) states, "Over the course of the year, at least four samples will be chosen randomly and traced through the entire process...The following Analytical items must be checked: The SOP(s) is available and followed by all staff, The SOP(s) is current and has been approved by the Lab Director, The instruments are properly calibrated, Reagents are properly documented and can be traced back to a Certificate of Analysis, Reagents are not expired, Components of kits with different lot numbers are not interchanged, All Quality Control criteria are analyzed and within acceptable rang
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to

	network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the facility personnel, the laboratory failed to have a system in place to ensure the accuracy of test results that are electronically interfaced into the Laboratory Information System (LIS). Findings include: 1. The laboratory performs approximately 50,000 patient tests annually under the sub-specialty of Virology. 2. The laboratory utilizes the 3 separate Bioneer Exicycler 96 instruments to perform a laboratory-developed Real-Time RT-PCR COVID-19 test. The test result data obtained from the analyzers is electronically interfaced into an Excel spreadsheet and then electronically interfaced into the LIS, TrueMed. 3. No documentation was presented for review during the survey to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are electronically interfaced from the analyzers to the Excel Spreadsheet and then to the LIS. 4. The facility personnel interviewed on 04/05/2022 at 1:20pm confirmed the laboratory did not have a system in place to verify the accuracy of patient test results that are electronically interfaced from the analyzers to the LIS.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) documentation and interview with the facility personnel, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems . Findings include: 1. The laboratory's established QA policy (ADM-QA Manual) states, "Over the course of the year, at least four samples will be chosen randomly and traced through the entire process...The following Post-Analytical items must be checked: Lab Name and address is on the report, Patient information on report matches the requisition form, Analyst name and date is listed on report, Results reported match instrument results, and Expected turn-around-time was met. If any deficiencies are identified, a corrective action must be implemented. A follow up review will be conducted within three months to ensure that corrective actions met intended goals." 2. No QA documentation from December 2020 through April 5, 2022 was provided for review during the survey to indicate the laboratory followed the established policy and procedure indicated above to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. 3. The facility personnel interviewed on 4/05/2022 at 5:10pm confirmed the laboratory failed to provide documentation of completed QA activities indicated above to monitor, assess and correct problems identified with the postanalytic systems.
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: The Condition of Laboratory Director is not met as evidenced by the failure to provide overall management and direction in accordance with 493.1445 of this subpart. See D6082, D6086, D6093, D6094, D6095, D6096 and D6102 for specific findings.
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 review of the laboratory's established test systems for COVID-19 testing and the number and severity of deficiencies cited herein, the laboratory director failed to ensure that test systems developed and used for COVID-19 testing provided quality laboratory services for all aspects of test performance including preanalytic, analytic and postanalytic phases of testing. See D5305, D5391, D5401, D5403, D5413, D5423, D5425, D5429, D5435, D5441, D5445, D5469, D5775, D5783, and D5801 for specific findings.
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 lack of documentation and supporting data for the establishment of performance specifications for the "AccuPower SARS-CoV-2 Multiplex Real-Time RT-PCR" laboratory-developed test, the laboratory director failed to ensure that verification procedures were adequate to determine the performance characteristics of the test method used by the laboratory to perform patient testing. See D5423 and D5425 for findings.
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 lack of quality control records and unacceptable quality control results, the

	laboratory director failed to ensure that quality control programs are maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5441, D5445, D5469, D5481, and D5783 for findings.
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 lack of quality assessment (QA) documentation for review, the laboratory director failed to ensure that a QA program is established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5391, D5791 and D5891 for findings.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's test system for COVID-19 testing and the number and severity of deficiencies cited herein, the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for the testing performed by the laboratory. See D5403, D5423, D5425, D5429, D5435, D5441, D5445, D5469, D5783 and D5481 for findings.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on lack of remedial action documentation for unacceptable control results and lack of remedial action documentation for control procedures not performed as established for the Negative Extraction Control (NEC), the laboratory director failed to ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. See D5441, D5445, D5783 and D5481 for findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate

	training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of education documentation and lack of training documentation for three out of three testing personnel (TP) listed on the CMS-209, Laboratory Personnel Form and interview with the facility personnel, the laboratory director failed to ensure that all testing personnel have the appropriate education and experience, receive the appropriate training and demonstrate that they can perform all testing operations reliably and accurately prior to testing patients' specimens. Findings include: 1. The laboratory failed to produce evidence of education credentials for three out of three testing personnel listed on the CMS-209, Laboratory Personnel form presented for review during the survey, to indicate the three testing personnel have the appropriate education to perform high complexity testing in the sub-specialty of Virology. 2. No initial training documentation was presented for review during the survey for three out of three testing personnel, who perform high complexity COVID-19 testing on patient specimens in the sub-specialty of Virology. TP-1 began patient testing in October 2020, TP-2 began patient testing in November 2020 and TP-3 began patient testing in December 2020. 3. At approximately 11:20 am on April 5, 2022, the facility personnel interviewed confirmed the laboratory failed to present documentation of education credentials and initial training documentation for the testing personnel indicated above.
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: The Condition of Technical Supervisor is not met as evidenced by: D6115 - failure to establish the laboratory's test performance characteristics for the test system used by the laboratory and failure to verify the test procedures performed; D6117 - failure to establish a quality control program appropriate for the testing performed and failure to ensure that acceptable levels of analytic performance are maintained throughout the entire testing process; D6118 - failure to ensure remedial actions were taken whenever test systems deviated from the laboratory's established performance specifications; D6127 - failure to evaluate and document semi-annual competency for testing personnel; and D6128 - failure to evaluate and document annual competency for testing personnel.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

	This STANDARD is not met as evidenced by: Based on incomplete performance specification records and lack of documentation showing the supporting raw data for the COVID-19 test performed by the laboratory, the technical supervisor failed to establish the laboratory's test performance characteristics for the test system used by the laboratory and failed to verify the test procedures performed. See D5403, D5423, D5425, and D5441 for findings.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of quality control records and procedures and review of the established performance specifications for the laboratory-developed test, "AccuPower SARS-CoV-2 Multiplex Real-Time RT-PCR", the technical supervisor failed to establish a quality control program appropriate for the testing performed and failed to ensure that acceptable levels of analytic performance are maintained throughout the entire testing process. See D5401, D5403, D5413, D5423, D5425, D5429, D5441, D5445, D5469, D5481, D5775, and D5783 for findings.
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on lack of remedial action documentation for review, the technical supervisor failed to ensure remedial actions were taken whenever test systems deviated from the laboratory's established performance specifications. See D5783 and D5481 for findings.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of documentation of semi-annual competency evaluations for three out of three testing personnel (TP) and interview with the facility personnel, the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individuals

	tested patient specimens. Findings include: 1. No semi-annual competency evaluation documentation was presented for review for three testing personnel who perform high complexity COVID-19 testing in the sub-specialty of Virology. 2. TP-1 began patient testing in October 2020, TP-2 began patient testing in November 2020 and TP-3 began patient testing in December 2020. 3. The facility personnel interviewed at approximately 11:20 am on April 5, 2022 confirmed that the laboratory failed to have documentation of semi-annual competency evaluations for the testing personnel indicated above.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on lack of testing personnel (TP) competency records for review and interview with the facility personnel, the laboratory failed to document the annual competency evaluation of three out of three testing personnel. Findings include: 1. No annual competency evaluation documentation was presented for review during the survey conducted on April 5, 2022 for three testing personnel who perform high complexity COVID-19 testing in the sub-specialty of Virology. 2. TP-1 began patient testing in October 2020, TP-2 began patient testing in November 2020 and TP-3 began patient testing in December 2020. 3. The facility personnel interviewed at approximately 11: 20 am on April 5, 2022 confirmed that the laboratory failed to have documentation of annual competency evaluations for the three testing personnel indicated above.