Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D2177481	03/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Epiarx Pllc	4000 Albemarle St Nw Suite 208, Washington, DC	

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**
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: A. Based on review of laboratory records and interview with the laboratory director (LD), the LD failed to maintain all required COVID-19 proficiency testing (PT) records when PT was performed. Findings: 1. The laboratory did not maintain all PT records including the reporting documents, worksheets, sample raw data, nor the signed attestation. 2. The LD confirmed that he did not have any PT documents nor PT records on the day of the survey. B. Based on observation and interview the laboratory did not maintain records for proficiency testing for histopathology. Findings: 1. The laboratory participates in a peer review for histopathology testing; 2. The laboratory did not have records of the results it obtained for proficiency testing and did not have the proficiency test providers review of their proficiency test results. In addition the laboratory did not have records of the report form submitted to the proficiency test provider for review; and 3. The laboratory director had a certificate of participation from the proficiency and the laboratory director confirmed, During interview conducted on the afternoon on the day of survey with the lab director, the lab director stated that a certificate he produced was evidence of successful

	participation with the proficiency testing program and confirmed that the lab did not have proficiency testing records and reports.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: A. Based on review of the written procedure manual, review of patient histopathology prepared slides, and interview with laboratory director (LD), the LD failed to have written policies and procedures for labeling and identification of patient stained slides for review. Findings: 1. The LD stated that he did not have written procedures for labeling patient slides. That he randomly generated identification numbers for patients. 2. Review of 5 patient cases that had slides prepared with hematoxylin and special Immunofluorescence stains showed that a case from 10/16/20 had three slides prepared. 3. The identification number written on all three slides were incomplete and different from each other with ED201292 CA, 1292-A2 CA, and 1292 CA. 4. A case from 7/23/20 showed on the final report the case number was ED20-130. The number 130 was the only identification number written on two prepared slides. 5. The LD stated he was labeling slides with a one identification method and then later switched to a two identification method. .
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: See D5441for Based on surveyor observation and staff interview, the laboratory failed to maintain records showing that the emperature of the warmer met the labs temperature requirements for patient testing (see D5413); failed to maintain records to ensure reagents and stains were not used past expiration or of substandard quality (see D5417); failed to have a written procedures for performing the validation on the BioRad IQ 5 analyzer used to test qPCR COVID-19 specimens (See D5421); failed to have preventive maintenance records for the equipment used for histopathology testing (see D5429); failed to ensure external quality control test results were performed and internal quality control test results were documented for patient testing for SARS-CoV-2 performed using the rapid BD Veritor test system (see D5441); failed to establish written corrective action procedures when adverse events occurred in the lab (see D5779); and failed to did not maintain histopathology test records to ensure positive patient identification (see D5787)...

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 and interview with the laboratory director, the laboratory did not maintain records showing that the temperature of the warmer met the labs temperature requirements for patient testing. Findings: 1. The laboratory did not maintain temperature records of the warmer used for histopathology testing; and 2. This was confirmed with the laboratory director during the afternoon of the day of survey.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory director, the laboratory did not maintain records to ensure reagents and stains were not used past expiration or of substandard quality. Findings: 1. The laboratory did not keep a record of the lot number and expiration date of stains and chemicals used for histopathology testing; 2. The laboratory did not keep a record of the changes, filtering and rotations of stains and chemicals for staining histopathology slides prepared from patient specimens; 3. The histopathology laboratory did not maintain records of the lot number and chemicals used for the " Tissue tekVP embedder"; 4. The laboratory did not maintain records of the lot number and expiation date of the test kits used for rapid SARS-CoV-2 testing; and 5. This was confirmed with the laboratory director during interview the afternoon of the day of survey.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on review of the qPCR COVID-19 test results and interview the laboratory director (LD), the LD failed to maintain all data obtain during the validation of the BioRad IQ 5 analyzer. Findings: 1. The laboratory did not have a written procedures for performing the validation on the BioRad IQ 5 analyzer used to test qPCR COVID-19 specimens. 2. The LD did not sign and date the validation for approval of results and the validation report did not have the date the validation was performed. 3. A graph with in house test results and reference lab results was not performed by the LD to show the standard deviation and coefficient variation. 4. The LD did not maintain the instrument raw data nor analyzer printouts from test results. 5. The LD confirmed that all records and documentation obtained during the validation of the BioRad IQ 5 analyzer to test qPCR COVID-19 specimens was not maintained.
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 observation and interview with the laboratory director during the afternoon of the survey, the laboratory did not have preventive maintenance records for the equipment used for histopathology testing. Findings: 1. The histopathology laboratory did not keep a record of the cryostat temperature each day of patient testing; 2. The histopathology laboratory did not keep a record of cleaning the cryostat; 3. The histopathology laboratory did not keep a record of defrosting the cryostat; 4. The histopathology laboratory did not keep a record for changing the microtome blade; 5. The histopathology laboratory did not keep a record for manufacturer recommended preventive maintenance for the "Microm HM 3553"; 6. the histopathology laboratory did not keep cleaning records for the "Shendon Histocentr 3"; 7. The histopathology laboratory did not keep an hourly record of the microscope fluorescent bulb usage; 8. The laboratory did not keep a record of the manufacturer required maintenance for both hoods used by the laboratory; 9. The histopathology laboratory did not keep preventive maintenance records for the automated slide stainer; and 10. This was confirmed during interview with the laboratory director during the afternoon of the day of survey.
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 observation and interview with the laboratory director, the laboratory did not test liquid external controls for rapid SARS-Cov-2 testing with the "BD Veritor" test sytem as required by the manufacturer and did not document internal quality control checks as required by the manufacturer. The laboratory performs high complexity testing, the Emergency Use Authorization from the Food and Drug Administration states that a laboratory performing high complexity testingrequiring the laboratory to perform and document both external and internal quality control tests. In addition "Epiarx" is a laboratory that performs high complexity testing. Findings: 1. The manufacturer states that:: "Positive and Negative control swabs are supplied with each kit. These controls provide additional quality control material to assess that the test reagents and the BD Veritor System Instrument perform as expected. Prepare kit control swabs and test using the same procedure as used for patient specimens. BD recommends controls be run once for: each new kit lot, each new operator, as required by internal quality control procedures and in accordance with local, state and federal regulations..."; 2. Section II of the "Emergency Use Authorization states: "The BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B includes the following materials or other authorized materials: BD Veritor System Test Devices, Reagent D, Specimen sampling swabs, SARS-CoV-2 (+) Control Swab, Flu A (+) Control Swab, Flu B (+) Control Swab and Paperboard tube stands. In additional to the positive and negative internal/procedural controls described above, you require use of the external quality controls, or other authorized controls (as may be requested under Condition N. below), that are run as outlined in the Instructions for Use"; 3. During interview the afternoon of the survey, the laboratory director stated that external positive and negative controls were not tested and the test kits were used for patient testing; and 4. . During interview the afternoon of the survey, the laboratory director stated that internal positive and negative control results were not documented and patient testing was performed.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the laboratory director (LD), the LD failed to establish written corrective action procedures when adverse events occurred in the lab. Findings: Refer to D5203 1. The LD did not establish written corrective action procedures when labeling patient hematoxylin and special Immunofluorescence stains for histopathology review. 2. The LD confirmed that written corrective action procedures were not established.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4)

	The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director, the laboratory did not maintain histopathology test records to ensure positive patient identification. Findings: 1. The laboratory maintains a log book for histopathology testing. The laboratory records each specimen received in the log; 2. The laboratory only logs the number assigned by Epiarx in the log, but does not record the lab number assigned by the user (from the patient requisition) to track the specimen as it is received by the laboratory and provide a link between the specimen number assigned from the requisition and the number assigned by Epiarx; 3. Specimen SD21-0026 received for testing was reported with this identification number 211076 (the number assigned by Epiarx); and. 4. On the afternoon of the day of survey, the laboratory director confirmed that the log book did not link the number assigned from the requisition to the number assigned by Epiarx and had to link the two numbers based on the day the specimen was received.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient reports and interview with the laboratory director (LD), the LD failed to ensure the location where testing was performed was included on the patient final report. Findings: 1. The LD performs histopathology and evaluations of patient slides stained in house with Hematoxylin stains. 2. Review of five patient final reports showed an address of 700 12th Street NW, Suite 700 in the District of Columbia where patient testing is not performed. 3. The address included on the five patient final reports is not the address where the survey was performed and not where actual patient testing is performed at 700 Windom PL NW. 4. The LD stated that he did not want to include on the final reports his home address where patient testing is performed.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by:

	Based on surveyor observation and staff interview, the laboratory director failed to provide overall management and direction of the laboratory; failed to ensure external quality control test results were performed and internal quality control test results were documented for patient testing for SARS-CoV-2 performed using the rapid BD Veritor test system(refer to D6093); failed to maintain all required COVID-19 and histopathology proficiency testing (PT) records when PT was performed (refer to D6089);failed to ensure that all laboratory staff had the required education to perform histopathology specimen testing (refer to D6102); And failed to have written duties and responsibilities for each person involved with histopathology and COVID testing (refer to D6107)
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD), the LD failed to maintain all required COVID-19 and histopathology proficiency testing (PT) records when PT was performed. Findings: Refer to D2015
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 observation and interview with the laboratory director, the laboratory director did not ensure that the quality control program for rapid SARS-CoV-2 testing ensured accurate and reliable tes results, as the laboratory did not perform external quality control testing and did not document internal quality control test results. See D5441 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 record review and interview with the laboratory director (LD), the LD failed to ensure that all laboratory staff had the required education to perform histopathology specimen testing. Findings: 1. The LD did not ensure that the testing person (TP) hired to perform tissue grossing and inking of specimens had the required education

	and training. 2. The LD stated that the TP did not have a four degree nor a two degree in a clinical lab science to perform grossing and inking. 3. The LD stated that he trained the TP according to his professional experience to perform grossing and inking of patient specimens.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based review of the written procedure manual and interview with the laboratory director (LD), the LD failed to have written duties and responsibilities for each person involved with histopathology and COVID testing. Findings: The LD did not have written duties and responsibilities for all phases of performing histopathology and COVID patient testing.