

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  09D2177481	<b>(X3) Date Survey Completed</b>  06/27/2025
<b>Name of Provider or Supplier</b>  Epiarx Pllc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory written procedure and interview with the laboratory director (LD), the LD failed to ensure that the lab was enrolled in a proficiency testing (PT) for performing diagnostic death testing when reviewing patient tissue on prepared slides. The LD confirmed on the day of the survey July 10, 2025, at 1:00 PM that PT was not performed for diagnostic death testing when reviewing patient tissue on prepared slides.</p>
<b>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p>

This STANDARD is not met as evidenced by:  
 Based on review of laboratory written procedure, patient slides, tissue cassettes, a sample jar, and interview with the lab director (LD) who is the testing person, the LD failed to document all pertinent information required for specimen identification and integrity and failed to document the slide acceptability nor slide rejection once slides were received in the lab. Findings: 1. Review of 65 patient slides prepared during the year 2025, 65 tissue cassettes, and a specimen container on July 10, 2025, at 12 Noon showed that the slides, cassette, and container were labeled with a case number and the patient initials. 2. The LD stated on the day of the survey July 10, 2025, at 12 Noon that he uses two identifiers when labelling the tissue cassettes and specimen containers. When prepared slides are returned to the lab, the slides are labelled with the same identifiers. 3. The "Autopsy Procedure Standard Operating Procedure" states "using a permanent marker label specimen containers on the lid of the container and the front of the container with the decedent's case number and initials". The "Autopsy Procedure Standard Operating Procedure" states to "label cassettes twice on the top and side with the case number and the decedent's initials". 4. The "Specimen Receipt and Labeling Requirement" procedure states "The requisition and the specimens are assigned a unique identification number" 5. The LD failed to document the slide and stain appearance of slides when received in the lab, which includes the slide acceptability or rejection. 6. The "Specimen Rejection" procedure states "the policy lists the specimen rejection criteria and handling of specimens that are received in suboptimal condition" 7. The LD confirmed on the day of the survey July 10, 2025, at 12 Noon, that the lab failed to document all pertinent information required for specimen identification and integrity and failed to document the slide acceptability nor slide rejection once slides were received in the lab.

**D5409**

**PROCEDURE MANUAL**  
 CFR(s): 493.1251(e)

(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).

This STANDARD is not met as evidenced by:  
 Based on review of the laboratory written procedure and interview with the laboratory director (LD), the LD failed to discontinue procedures for testing that were no longer performed in the lab. Finding: 1. The LD stated on the day of the survey July 10, 2025, at 11:30 AM that tissue processing was no longer performed in the lab. 2. The LD failed to discontinue the "Cryostat Maintenance and Decontamination" and the "Embedding Center" procedures. 3. The LD confirmed on the day of the survey July 10, 2025, at 11:30 AM that the lab failed to discontinued procedures for testing that was no longer being performed in the lab.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
 CFR(s): 493.1252(b)

(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 review of the laboratory written procedure, observation of the lab and mobile van on July 10, 2025, at 2:30 PM, and interview with the laboratory director (LD), the LD failed to monitor exposure, store, and label lab reagents used during tissue collection according to the written procedure and the manufacturer's instructions. Findings: 1. The lab uses Formalin Formaldehyde solution for fixation and preservation of human tissue for transport and storage. 2. Observation of the lab on July 10, 2025, at 2:30 PM showed the lab had a fireproof cabinet that did not have the Formalin Formaldehyde solution stored inside. 3. The LD stated on the day of the survey July 10, 2025, at 2:30 PM that the Formalin Formaldehyde solution was in his van that is used for transporting deceased human bodies that require autopsy. 4. The Formalin Formaldehyde solution was in the original container inside a non labeled plastic blue tub covered with a lid inside the back of the van. 5. The "Formaldehyde Policy" states that "Formaldehyde is stored in closed containers in well ventilated areas." 6. The "Formaldehyde Policy" states "that all designated areas where formaldehyde and formalin solutions are stored will have a sign posted that states danger and hazardous." 7. The "Formaldehyde Policy" states that persons who handles Formaldehyde must have exposure monitoring conducted biannually and the level must not exceed 0.5 ppm. 8. The LD confirmed on the day of the survey July 10, 2025, at 2:30 PM that the lab failed to monitor exposure, store, and label lab reagents used during tissue collection according to the written procedure and the manufacturer's instructions.

**D5787**

**TEST RECORDS**

CFR(s): 493.1283(a)

(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 review of the laboratory written procedure, patient records, and interview with the lab director (LD) who is the testing person, the LD failed to maintain all pertinent specimen records and information once specimens were received in the lab. Findings: 1. The lab reviews slides prepared and stained by a local hospital to determine the cause of death. 2. The lab had one gray slide box containing 12 patient slides, one gray slide box containing 43 patient slides, one white box containing 10 patient slides, and 28 loose slides on a slide holder on a shelf near the microscope. The LD stated that all the slides were different patient cases. 3. The LD stated on the day of the survey July 10, 2025, at 11:30 AM that each gray box contained slides from five different patient cases from the year 2025 that he is still working on. They were incomplete with no diagnosis, and he received the prepared slides from the hospital two weeks ago. 4. The LD stated on the day of the survey July 10, 2025, at 11:30 AM that the white box contained a case from 2024 and that the case was completed and was not filed. 5. The LD failed to maintain the "Reference Histology Work Request"

record that was contained in the gray box and the white box with the slides documenting the location where the slides were prepared, who prepared the slides, the type of stain used to prepare the slides, the number of slides contained in the box, embedding information, section information, block check, QC check, nor did the LD document the date and time that the slides were received in the lab. 6. The LD stated on the day of the survey July 10, 2025, at 11:30 AM that once the slides are received in the lab the "Reference Histology Work Request" record is thrown away. 7. Review of the "Autopsy Procedure Standard Operating Procedure" on July 10, 2025, at 11:30 AM states that "Specimens received from the hospital are checked for case file identifiers and placed in the pending case area. 8. The LD stated on July 10, 2025, at 11:30 AM that the 28 loose slides were from a historical brain case he completed on 2/5/2023. They were mailed back to him from a hospital in Virginia two months ago. 9. The LD failed to maintain the record that came with the slides that showed the slide information, slide identification, nor did the LD document the date and time the slides were received in the lab. 10. The LD confirmed on the day of the survey July 10, 2025, at 11:30 AM that the lab failed to maintain all pertinent specimen records and information once specimens were received in the lab.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

(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 the written procedure manual, patient final reports, and interview with the laboratory director (LD), the LD failed to include the complete name and address where testing was performed. Findings: 1. Review of two patient final reports from the year 2025, two patient final reports from the year 2024, and two patient final reports from the year 2023 on the day of the survey July 10, 2025 at 1:00 PM showed that the final reports did not include the complete name and address where the slides diagnostic review was performed nor did the final reports include the complete name and address where the patient tissue technical component was performed. 2. The LD confirmed on the day of the survey July 10, 2025, at 1:00 PM that the lab failed to include the complete name and address where testing was performed.

**D6089**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(i)

(e)(4)(i) 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 the laboratory written procedure and interview with the laboratory director (LD), the LD failed to ensure that the lab was enrolled in a proficiency testing

program for performing diagnostic death testing when reviewing patient tissue on prepared slides. Findings: Refer to D2000