

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2036128	(X3) Date Survey Completed 03/17/2025
Name of Provider or Supplier Delta Pathology Group-West Jefferson Medical Cntr	Street Address, City, State 1101 Medical Center Boulevard, Marrero, LA	
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	An Initial survey was performed at Delta Pathology Group-West Jefferson Medical Center, CLIA ID 19D2036128, on March 17, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, personnel records, patient final reports, and interview with personnel, the laboratory failed to follow their established competency assessment procedures for two (2) of three (3) testing personnel who perform grossing procedures for Histopathology testing. Findings: 1. Review of the laboratory's "Laboratory Orientation, Training, and Competency" policy revealed "Competency for technical departments is assessed using all of the following elements for each test/test system: Direct observation of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing; monitoring the recording and reporting of test results, including, as applicable, reporting critical results; review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through testing previously analyzed specimens, internal blind testing specimens or external proficiency testing samples; evaluation of problem-solving skills, written tests to evaluate the knowledge level of specific areas; and any other elements needed to evaluate an employee's performance as recommended by the Laboratory Director." 2.</p>

	<p>Random review of patient reports revealed Testing Personnel 2 performed grossing on Histopathology samples. 3. Review of personnel records revealed the "Professional Competency Assessment Forms" utilized in 2023 and 2024 did not include an assessment of grossing procedures. 4. In interview on March 17, 2025 at 12:49 pm, Compliance Personnel 2 stated the Laboratory Director and Testing Personnel 2 performed grossing procedures on Histopathology samples at the laboratory and the other technical services were done off-site. Compliance Personnel 2 confirmed the laboratory's competency assessment form did not include the assessment of grossing procedures.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of random selection of patient test reports and interview with personnel, the laboratory failed to include the correct address where grossing procedures were performed for seven (7) of seven (7) cases reviewed. Findings: 1. Review of random selection of patient test reports for Histopathology testing revealed the laboratory included a comment that technical services were performed at a sister location in Harahan, Louisiana. 2. Further review of the random selection of patient test reports revealed the grossing portion of the technical services were performed by Testing Personnel 2, in-house, not off-site at the sister location for the following seven (7) patients: Patient JS23-46087 Patient JS23-32773 Patient JS24-04884 Patient JS24-24528 Patient JS24-52042 Patient JS24-69469 Patient JS25-04188 3. In interview on March 17, 2025 at 12:49 pm, Compliance Personnel 2 stated the Laboratory Director and Testing Personnel 2 performed grossing procedures on Histopathology samples at the laboratory and the other technical services were done off-site.</p>
<p>D6098</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8)</p> <p>(e)(8) Ensure that reports of test results include pertinent information required for interpretation;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805.</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p>

(e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.