

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1003288	(X3) Date Survey Completed 07/29/2024
Name of Provider or Supplier Jackson Clinic Pa, The	Street Address, City, State 87-B Murray Guard Drive, Jackson, TN	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, review of the laboratory's alternative proficiency testing (PT) assessment records, and staff interview, the laboratory failed to follow the quality assessment policy for laboratory director review and evaluation of alternative proficiency testing results for three of three events reviewed from 2023 and 2024. The findings include: 1. A review of the laboratory procedure manual, under the section for Proficiency Testing, revealed the following statements: "Purpose. To evaluate the diagnostic abilities of the Mohs surgeon and the quality of the slides produced by the histotechnologist." "The results of proficiency testing are reviewed by the Laboratory Director. Any errors encountered will be addressed to determine any pre-analytical, analytical or post-analytical errors that may be contributing." 2. A review of the laboratory's alternative PT records showed that the laboratory director did not document review and evaluation of the alternative PT assessment for the following PT periods: 04/01/23 through 06/30/23, 07/01/23 through 12/31/23, and 01/01/24 through 06/30/24. 3. The laboratory director confirmed the survey findings during an interview on 07/29/24 at 11:15 a.m.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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</p>

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 of the chemical storage area, review of the manufacturer instructions for use, lack of documentation, and staff interview, the laboratory failed to monitor the temperature of the area where chemicals were stored in 2023 and 2024. The findings include: 1. The surveyor observed the area where tissue processing chemicals and stains were stored on 07/29/24 at 8:15 a.m. Chemicals and stains observed were 100% Reagent Alcohol, Xylene substitute, Vintage Bluing, 95% Plus Alcohol, Eosin-Y vintage, Hematoxylin Vintage, and Toluidine Blue Stain. A thermometer was noted during in the storage area. 2. A review of the instructions for the Xylene Substitute, 100% Alcohol and 95% Alcohol revealed the following statements: 'Storage: Store in a dry, cool, and well-ventilated place. Keep container closed when not in use. Store locked up. Keep/store away from direct sunlight, extremely high or low temperatures, and incompatible materials.' 3. The laboratory did not document temperatures for the chemical/stain storage area. 4. During an interview on 07/29/24 at 8:15 a.m., the lead histotech stated that she checked the temperatures in the storage area, but did not document the temperature readings. This confirmed the survey findings.