

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D2006846	(X3) Date Survey Completed 02/25/2026
Name of Provider or Supplier Hubcare Pathology - Merit Health Wesley	Street Address, City, State 5001 Hardy Street, Hattiesburg, MS	
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 announced CLIA validation survey was conducted at Wesley Medical Center-Hubcare Pathology Lab on February 25, 2026, by a federal surveyor from the CMS CLIA Survey Branch. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and was found to be in compliance with condition-level CLIA requirements. The following standard-level deficiencies were found onsite.
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 the lack of laboratory procedures, review of laboratory personnel competency assessment records, and interview with technical supervisor (TS) #2, the laboratory failed to establish a competency assessment procedure to assess the competency of 2 of 2 testing personnel and two of three TS / general supervisors (GS) for their supervisory competency in 2024 and 2025. Findings: 1. Review of laboratory procedures on February 25, 2026, revealed the laboratory failed to establish a competency assessment procedure for testing personnel and supervisors performing Histology frozen section examinations. 2. The laboratory was unable to provide competency assessment documents for two of three TS /GS listed on form CMS 209 Laboratory personnel report (CLIA). 3. The laboratory was unable to provide complete competency assessment documentation for 2 of 2 TP. 4. On February 25, 2026, at 11:30 am, TS#2 confirmed the laboratory did not establish a competency assessment procedure.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p>

(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 the lack of a laboratory testing procedure and interview with technical supervisor (TS) #2, the laboratory failed to have a histology frozen-section microscopic examination procedure available and followed by testing personnel for 2 of 2 years (February 25, 2024, to February 25, 2026). Findings: 1. On February 25, 2026, the laboratory was unable to provide a procedure for histology frozen section microscopic examinations that was available to testing personnel for 2 years (February 25, 2024, to February 25, 2026). 2. On February 25, 2026, at 12:00 pm, TS#2 confirmed the laboratory did not establish a test procedure for histology frozen section microscopic examinations performed onsite.

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 a review of the laboratory room temperature/humidity records, a review of manufacturer procedures, and an interview with technical supervisor (TS) #2, the laboratory failed to ensure room temperature and humidity conditions were consistent with the manufacturer's instructions for 1 of 1 Leica CM 1900 cryostat in use. Findings: 1. On February 25, 2026, review of the frozen section laboratory revealed the laboratory established the following room temperature and humidity conditions: a. Temperature: 15C (degrees Celsius) to 30C. b. Humidity: 30 - 75%. 2. Review of the Leica CM 1900 cryostat manufacturer's instructions revealed the manufacturer stated the following room temperature and humidity conditions for the Leica CM 1900 cryostat under technical data, conditions: a. Ambient temperature: 8C to 40 C. b. Relative humidity: max. 60%, non-condensing. 3. On February 25, 2026, at 12:00 pm, TS#2 confirmed conditions for room temperature and humidity were not consistent with the manufacturer's instructions for the cryostat in use.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.

This STANDARD is not met as evidenced by:
Based on the review of Hematoxylin and Eosin (H&E) staining quality control (QC) documentation, and interview with technical supervisor (TS) #2, the laboratory failed to check and document H&E materials for their intended reactivity each day of use for 2 of 2 years (February 25, 2024, to February 25, 2026). Findings: 1. On February 25, 2026, the laboratory was unable to provide H&E QC documentation, which stated that stain materials in use met their intended reactivity each day frozen section microscopic examinations were analyzed from February 25, 2024, to February 25, 2026. 2. Per the CMS 116, signed by the laboratory owner, the laboratory performs 80 frozen section microscopic examination cases annually. 3. On February 25, 2026, at 12:40 pm, TS#2 confirmed the laboratory did not check and document the H&E stain quality.

D6125

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(v)

(b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

This STANDARD is not met as evidenced by:
Based on the review of testing personnel competency assessment records and an interview with technical supervisor (TS) # 2, the TS failed to assess 1 of 2 testing personnel (TP) for their assessment of test performance (peer review) for microscopic frozen sections examinations analyzed in 2 years (2024 and 2025). Findings: 1. Review of testing personnel competency assessment records on February 25, 2026, revealed the TS failed to document the peer review performed for 1 of 2 TP (TP#1). 2. TS#2 was unable to provide documentation showing TP#1 was involved in the peer reviews, performed for microscopic frozen sections examinations analyzed in the laboratory. 3. On February 25, 2026, at 11:30 am, TS#2 confirmed TP#1 was not assessed for peer review in 2024 and 2025.