

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1054769	(X3) Date Survey Completed 02/09/2024
Name of Provider or Supplier Michael Woodbury, Md	Street Address, City, State 3002 N Germantown Road, Bartlett, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on patient record review, lack of documentation, and staff interview, the laboratory failed to verify the accuracy of scabies detection twice a year in 2022. The findings include: 1. Review of patient number one revealed results reported for scabies detection on 07/06/2022. 2. There was no documentation of twice a year verification of accuracy in 2022 for scabies detection. 3. During an interview on 02/09/2024 at 12:00 pm, the laboratory director confirmed the laboratory failed to verify the accuracy of scabies detection twice a year in 2022 with patient testing performed.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory procedure manual, lack of records, and staff interview, the laboratory failed to follow its' policy for instrument maintenance for the cryostat instrument and microscope used for patient testing in 2022, 2023, and 2024. The findings include: 1. Observation of the laboratory on 02/09/2024 at 11:30 am revealed a Shandon Cryostat instrument used for processing patient</p>

tissue sample for MOHS surgical procedures and a Nikon YS2-T microscope used to view potassium hydroxide (KOH) patient slides for fungal and parasite presence and stained tissue slides from MOHS surgical procedures. 2. A review of the laboratory procedure titled "Quality Control Program" section "Test Methods, Equipment, Reagents, Materials, and Supplies" revealed all maintenance and repairs would be documented and reviewed by the laboratory director with a schedule as follows: Microscope= Three months: Stages and ocular eyepieces cleaned Once annually: Grounding check Cryostat: Each day of use: Defrost and clean interior Every six months: Thermometer check Once annually: Air filter cleaned, flywheel and moving components oiled, preventative maintenance and grounding check 3. Records of microscope and cryostat maintenance were not available on the date of the survey (02/09/2024) for 2022, 2023, or 2024. 4. An interview on 02/09/2024 at 12:00 pm with the laboratory director confirmed the laboratory failed to follow its' policy for microscope and cryostat instrument maintenance in 2022, 2023, and 2024 when the maintenance frequency was not maintained or documented.