

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D1093164	(X3) Date Survey Completed 02/04/2025
Name of Provider or Supplier Hahn Medical Practices Inc	Street Address, City, State 215 South Louisiana Avenue, Martinsburg, WV	
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	A routine recertification survey was conducted at Hahn Medical Practices on February 4, 2025, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. Specific deficiencies cited are explained below.
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on a tour of the laboratory, review of written policies and procedures, and interview with testing personnel (TP1) the laboratory failed to update the (b)(3) step</p>

by step procedure for the Hematoxylin and Eosin (H&E) staining process on the Takura Tissue-Tek automatic slide stainer. Findings: 1. A tour of the laboratory, 2/4/25 at approximately 12:45 PM, identified 1 staining process (H&E) used by the laboratory. 2. A review of MoHs policies and procedures for staining (Hematoxylin and Eosin Stain) revealed set times for each step in the staining method. 3. During an interview with testing personnel (TP1), 2/4/25 at approximately 12:50 PM, the settings for the H&E staining program were reviewed on the Takura Tissue-Tek automatic slide stainer. 11 of the 15 times set in the H&E staining program for each step did not match the times defined in the written policy. TP1 stated the written procedure for the MoHs staining process had not been updated with the timed settings currently in use by the laboratory.

D6170

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(a)

Each individual performing high complexity testing must-- (a) possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

This STANDARD is not met as evidenced by:
Based on review of testing personnel training and competency records, interview with testing personnel (TP1), and primary source verification (West Virginia state licensure primary source verification portal) one of one laboratory testing personnel (TP1) failed to possess a current West Virginia laboratory license as required by the West Virginia 64 CSR 57 Clinical Laboratory Practitioner and Licensure Certification rule. Findings: 1. Review of TP training and competencies revealed the following: initial training and competency completed 4/1/2024, semi-annual competency completed 9/5/2024 with documented observation by the lab director of inking and mapping on both sets of records. 2. During an interview, 2/4/25 at approximately 1:14 PM, TP1 stated they had been performing the inking and mapping of patient MoHs specimens alongside the laboratory director since March 2024 and did not have a valid laboratory testing license for high complexity testing. 3. A review of the WV state licensure primary source verification portal confirmed TP1 did not have a current laboratory testing license to perform high complexity testing.