

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0876698	(X3) Date Survey Completed 05/05/2026
Name of Provider or Supplier West Virginia University Hospitals	Street Address, City, State 1 Medical Center Dr (Attn Poct Coordinator Lab), Morgantown, 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	<p>An announced CLIA validation survey was conducted at West Virginia Hospital, Inc., on May 5, 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 cited.</p>
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 a review of laboratory procedures, lack of supervisory competency assessment documentation, and an interview with the performance excellence manager, the laboratory failed to establish policies for assessing the competency for 1 of 2 clinical consultants (CC), 6 of 6 technical consultants (TC), and 2 of 2 General Supervisors (GS) from May 2024 to May 2025. Findings: 1. A review of the laboratory's competency assessment procedures revealed that the established policy included competency assessment procedures for laboratory testing personnel, but not for laboratory personnel who were delegated supervisory responsibilities by the laboratory director. 2. On Forms Centers for Medicare and Medicaid Services (CMS) 209, signed by the laboratory director on May 7, 2025, the form included the following supervisory personnel who were delegated supervisory responsibilities: - 1 of 3 CC - 2 of 2 GS - 6 of 6 TC 3. The laboratory was unable to provide competency assessment documentation based on their delegated responsibilities. 4. In an interview on May 5, 2026, at 4:00 pm, the performance excellence manager confirmed the findings above.</p>

(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:

I. Based on observations in the laboratory, a review of the manufacturer's instructions, the lack of room-temperature records, and an interview with the performance excellence manager, the laboratory failed to monitor and document the room temperature where 1 of 1 Leica DM 100 Microscope was kept from May 2024 to May 2026. Findings: 1. During a tour of the hospital at 3:15 PM, one Leica DM 100 microscope (Serial Number: 306434-062008) was observed in use for Fern microscopic examinations in room 203. a. Review of the Leica DM 100 user manual revealed, "Humidity during use and storage 20-90 %" and Temperature for use +10 Celsius (C) ... +40 C. 2. The laboratory was unable to provide documentation of monitored temperature and humidity conditions for room 203. 3. In an interview on May 5, 2026, at 4:00 PM, the performance excellence manager confirmed the temperature and humidity were not monitored and documented in room 203. II. Based on observations in the laboratory, a review of the manufacturer's instructions, a review of laboratory temperature records, and an interview with the performance excellence manager, the laboratory failed to define humidity ranges in accordance with manufacturer instructions for a sample of 12 of 12 Werfen Gem 5000 Pak and 4 of 4 Werfen Gem 7000 Pak stored in the perfusion workroom. Findings: 1. During a tour of the hospital at 3:30 PM, a sampling of 12 Werfen Gem 5000 Paks and 4 Werfen Gem 7000 Paks were observed being stored in the perfusion workroom with manufacturer temperature requirements of 15-20Celsius (C). 2. Review of the laboratory temp track system revealed the laboratory's set temperature ranges were 18-30C. 3. The following sampling of Werfen Gem 5000 and 7000 Paks lots were stored in the perfusion workroom: a. Werfen Gem 5000 Pak - On pack of lot# 260302W - On pack of lot# 260306P - On pack of lot# 26030107 - On pack of lot# 260304H - On pack of lot# 260304E - Two packs of - Lot#26039X - Two packs of - Lot#260310C - Three packs of - Lot#260406B b. Werfen Gem 7000 Pak - Two packs of - Lot#260306D - Two packs of - Lot#260121C 4. In an interview on May 5, 2026, at 4:00 PM, the performance excellence manager confirmed that the defined room temperature ranges did not follow the manufacturer's instructions.