

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0666165	(X3) Date Survey Completed 08/11/2026
Name of Provider or Supplier Wv Office Of Laboratory Services	Street Address, City, State 167 11th Avenue, South Charleston, 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 Federal Surveyor from the Division of Clinical Laboratory Improvement and Quality (DCLIQ) Survey Branch conducted an announced CLIA recertification survey at WV Office of Laboratory Services on 08/11/2026. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and was found to be out of compliance with standard level CLIA requirements. The following standard level deficiencies were found.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: I. Based on a review of the laboratory's Form CMS-209, laboratory supervisory personnel competency assessment records, laboratory's competency assessment standard operating procedure, and an interview with Technical Supervisor #1 (TS#1), the laboratory failed to follow its own competency assessment procedure for performing competency assessments on three of six Technical Supervisors (TSs) in 2025. 1. A review of the laboratory's Form CMS-209 indicated there were six total TSs. 2. A review of 2025 competency assessment records for TS#4, TS#5 and TS#6 revealed the assessments were performed by TS#1. 3. A review of the laboratory's competency assessment standard operating procedure revealed the following statement: "7.2 Supervisory Personnel ... The competency assessment of the Technical Supervisor must be performed and signed by the Laboratory Director." 4. In an interview on 08/11/2026 at 1:15 PM the TS#1 confirmed the 2025 competency assessments for TS#4, TS#5 and TS#6 were performed by TS#1. II. Based on review of the laboratory's Form CMS-209, personnel competency assessment records, laboratory's competency assessment standard operating procedure, and an interview

	with the Technical Supervisor #1 (TS#1), the laboratory failed to perform competency assessments for four of four General Supervisors (GS) in 2024 and three of six TSs in 2024 and 2025. 1. A review of the laboratory's Form CMS-209 indicated there were six TS's and four GS's. 2. A review of personnel competency assessment records revealed the following: GS#1, GS#2, GS#3, and GS#4 had no competency assessment completed in 2024 TS#1, TS#2, and TS#3 had no competency assessments completed in 2024 and 2025. 3. A review of the laboratory's competency assessment standard operating procedure revealed the following statement: "7.3 Frequency. Testing and supervisory personnel must have competency assessments performed after initial training, 6 months after initial training, and then at 12 months. Further assessments are annually thereafter." 4. In an interview on 08/11/2026 at 1:12 PM, the TS#1 confirmed no competency assessments were completed for four of four GSs in 2024 and for three of six TSs in 2024 and 2025.
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 direct observation in the Microbiology laboratory, review of test kit manufacturer's instruction for use (IFU), room temperature log sheets, and an interview with the General Supervisor #2 (GS#2), the laboratory failed to define temperature conditions consistent with the manufacturer's requirements for 97 out of 183 days between January 4, 2026, and August 11, 2026, when room temperature exceeded the test kit manufacturer's acceptable limits. 1. During a tour of the General Microbiology room on 08/11/2026 at 2:00 PM, the ImmunoCard STAT EHEC rapid test kit was observed being used for patient sample testing for Shiga toxins 1 and 2 in human stool. 2. A review of the manufacturer's IFU for the ImmunoCard STAT EHEC for Shiga Toxins 1 and 2 revealed the following room temperature requirements: "Broth method test procedure. Bring all test devices, reagents and samples to room temperature (20-25C) before testing." "External control tests - SMAC Agar or Broth method. Bring all test devices and reagents to (20-25C) before testing." 3. A review of the Bacteriology room temperature log sheet showed an acceptable room temperature range of 15-30C. Below are dates and room temperature readings that were outside the test kit manufacturers requirements: 01/07/26 19.8C 01/08/26 19.9C 01/09/26 19.7C 01/14/26 18.5C 01/15/26 19.8C 01/26/26 18.3C 03/04/26 19.8C 03/06/26 19.7C 03/11/26 19.9C 03/12/26 19.8C 03/16/26 19.5C 03/17/26 19.8C 03/20/26 19.7C 03/23/26 19.6C 04/01/26 19.6C 04/02/26 19.5C 04/03/26 19.5C 04/06/26 19.2C 04/07/26 19.0C 04/08/26 18.0C 04/09/26 19.1C 04/13/26 19.2C 04/15/26 19.3C 04/16/26 19.3C 04/17/26 19.2C 04/20/26 19.1C 04/23/26 18.8C 04/24/26 18.8C 04/27/26 19.0C 04/28/26 19.3C 04/29/26 19.5C 04/30/26 19.9C 05/01/26 19.5C 05/04/26 19.3C 05/05/26 19.0C 05/06/26 19.5C 05/08/26 19.6C 05/12/26 18.9C 05/13/26 19.7C 05/15/26 19.3C 05/18/26 19.8C 05/19/26 18.7C 05/20/26 18.8C 05/21/26 19.3C 05/22/26 19.1C 05/26/26 19.3C 05/27/26 19.7C 05/28/26 19.3C 05/29

	/26 19.0C 06/01/26 18.8C 06/02/26 19.0C 06/03/26 18.8C 06/04/26 19.0C 06/05/26 19.3C 06/08/26 19.6C 06/09/26 19.8C 06/10/26 19.5C 06/11/26 19.7C 06/12/26 19.5C 06/15/26 19.0C 06/16/26 19.3C 06/17/26 18.5C 06/18/26 19.0C 06/22/26 18.0C 06/23/26 19.2C 06/24/26 19.1C 06/25/26 19.6C 06/26/26 19.9C 06/29/26 19.8C 06/30/26 19.9C 07/02/26 18.8C 07/06/26 19.3C 07/07/26 19.5C 07/08/26 18.8C 07/09/26 18.8C 07/10/26 19.0C 07/13/26 19.2C 07/14/26 19.2C 07/15/26 19.5C 07/16/26 18.8C 07/20/26 18.5C 07/21/26 18.0C 07/22/26 19.0C 07/23/26 18.5C 07/24/26 18.7C 07/27/26 19.2C 07/28/26 19.2C 07/29/26 18.9C 07/30/26 19.0C 07/31/26 18.5C 08/03/26 18.8C 08/04/26 18.8C 08/05/26 19.0C 08/06/26 19.0C 08/07/26 19.2C 08/10/26 18.5C 08/11/26 18.8C 4. In an interview on 08/11/2026 at 2:15 PM, the GS#2 confirmed the findings stated above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation in the Molecular Microbiology laboratory and an interview with the General Supervisor #4 (GS#4), the laboratory failed to ensure that one of one expired specimen testing kit was not available for use. 1. During a tour of the Molecular Microbiology laboratory on 08/11/2026 at 2:40 PM, one box of Cepheid Xpert Xpress CoV-2/Flu/RSV plus test kit, Lot number 1001481701, with an expiration date of 04/19/2026, was observed stored for use on top of the Cepheid GeneXpert Dx System. 2. In an interview on 08/11/2026 at 2:40 PM, the GS#4 confirmed the finding stated above.