Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2128284	06/04/2026
Name of Provider or Supplier	**Street Address, City, State**	
Wvu Medicine Fairmont Gateway Clinic	100 Stoney Hill Road, Fairmont, 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	An unannounced, focused complaint survey was conducted at WVU Medicine Fairmont Gateway Clinic on June 4, 2026, by the West Virginia Office of Laboratory Services. The laboratory was found to be performing tests beyond the scope of the issued certificate of waiver for the laboratory and the complaint was found to be substantiated.
D1000	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c) (c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood - non-automated (3) Ovulation tests visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout. (d) Revisions to criteria for test categorization and the list of waived tests. HHS will determine whether a laboratory test meets the criteria listed under paragraph (b) of this section for a waived test. Revisions to the list of waived tests approved by HHS will be published in the FEDERAL REGISTER in a notice with opportunity for comment. This STANDARD is not met as evidenced by: Based on an onsite investigation, entrance interview with the laboratory manager,

	review of ASPEN CLIA database, review of laboratory policies and procedures, Wet Prep/KOH preparation testing logs (January 2025 thru date of survey), American Proficiency Institute (API) proficiency testing (PT) evaluation reports, and interviews with the laboratory manager and clinic coordinator, the laboratory failed to obtain the appropriate CLIA certificate before performing and releasing 13 patient results for tests not categorized as waived (Wet Prep/KOH preparation) from March 11, 2025, thru date of survey. The allegation of the laboratory testing outside the current certificate of waiver was substantiated. Findings: 1. During an onsite visit 6/4/26, the state surveyor verified the laboratory maintained a current certificate of waiver (51D2128284, expiration 3/9/27). During the entrance interview,6/4/26 at 9:30 AM, the laboratory manager stated the laboratory had previously had a Provider Performed Microscopy (PPM) certificate until a certificate change processed by the WV CLIA office 3/10/2025 issued a Certificate of Waiver (CoW). Review of the CLIA Certificate and Billing Inquiry tab in ASPEN for the laboratory revealed a PPM certificate was issued from 3/28/2017 to 3/9/2025 and the PPM certificate changed to a certificate of waiver on 3/10/25. 2. Review of the laboratory's "Wet Prep/KOH Preparation for Vaginal Specimens Microscopy PPM Procedure", signed 4/27/2023, states the purpose, specimen requirements, reagents, equipment, quality controls, procedure, reporting results, limitations of procedure, and references for performing Wet Prep/KOH testing for patients. 3. Review of "KOH/Wet Prep Log" (January 2025 thru date of survey) identified 13 patient results for Wet Prep/KOH testing released after the change of the laboratory CLIA certificate from PPM to CoW on 3/10/2025: 3 /20/25 patient 4 4/9/25 patient 5 4/24/25 patient 6 5/14/25 patient 7 5/17/25 patient 8 3 /6/26 patient 9 3/27/26 patient 10 4/20/26 patient 11 4/24/26 patient 12 4/30/26 patient 13 5/6/26 patient 14 5/21/26 patient 15 5/29/26 patient 16 4. Review of the API PT records for the 1st event of 2026 revealed successful participation for the analyte Wet Prep/KOH prep. 5. An interview with the laboratory manager and clinic coordinator, 6 /4/26 at 10:20 AM, confirmed the laboratory performed Wet Prep/KOH preparation testing outside the scope of the laboratory Certificate of Waiver from March 11, 2025, through date of survey.