

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0307350	<b>(X3) Date Survey Completed</b>  01/06/2025
<b>Name of Provider or Supplier</b>  Perry County Medical Center	<b>Street Address, City, State</b>  115 E Brooklyn St, Linden, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> 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, final patient test review, and staff interviews, the laboratory failed to follow its procedure when the laboratory used the incorrect reagent for vaginal wet prep patient testing in 2024 and 2025. The findings include: 1. Observation of the laboratory on 01/06/2025 at 9:45 a. m. revealed a microscope used for vaginal wet prep examination. A container labeled "Sterile Water for Irrigation" was noted with an additional handwritten label that stated "Wet Preps Nursing." The bottle had an open date of 03/20/2024. During the observation, testing person one stated that nursing personnel came to the laboratory and obtained liquid from the bottle in the laboratory for each patient wet collection. 2. A review of the laboratory procedure titled "Wet Preparation" revealed the following: Section "Specimen Collection and Handling" stated that the swab was to be collected and placed in one milliliter of saline which was obtained from the container in the laboratory. Section "Procedure" stated that the laboratory used a drop of the saline suspended specimen and placed it on a slide for microscopic examination. 3. A review of final patient test reports revealed patient 24137 had a vaginal wet prep reported on 11/19/2024. 4. An interview with testing person two on 01/06/2025 at 12:15 p.m. confirmed that the laboratory did not use saline to perform patient wet prep testing since 03/20/2024. 5. An electronic interview with testing person one on 01/07/2025 at 8:53 a.m. revealed that the laboratory had reported 46 patient wet preps from 03/20 /2024 through the survey date (01/06/2025) using sterile water instead of saline required by the laboratory procedure.</p>