

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0011492	(X3) Date Survey Completed 04/15/2026
Name of Provider or Supplier Corry Memorial Hospital	Street Address, City, State 965 Shamrock Lane, Corry, PA	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) 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 review of the laboratory's procedure manual, lack of documentation and interview with Technical Supervisor (TS) #1, the laboratory failed to follow an established procedure for Post vasectomy (PV) semen analyses performed for 22 of 22 months from 6/12/2024 to 04/15/2026. Findings include: 1. The laboratory's PV semen analysis procedure stated, "Quality Control: To verify the accuracy of the procedure, the test will be performed in duplicate by reviewing slides made from 2 aliquots of sample". 2. On the day of the survey, 04/15/2026 at 11:15 am, the laboratory failed to provide documentation of the duplicate slide review performed for 22 of 22 months to verify the accuracy of post vasectomy semen analysis from 6/12/24 to 4/15/26. 3. Further review of the laboratory's PV semen analysis policy revealed the laboratory failed to ensure the policy was updated to include the positive and negative control used when PV semen (qualitative) testing was performed. 4. Review of the laboratory's Post-Vasectomy Sperm Presence Patient Log revealed the laboratory performed 4 semen analyses from 6/12/2024 to 04/15/2026. 5. TS #1 confirmed the findings on 04/15/2026 at 2:35 pm.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1)</p>

Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory and interview with Technical Supervisor (TS) #1, the laboratory failed to label 3 of 3 containers used to aliquot reagents with the pertinent information required for proper use when hematology examinations were performed from 6/12/2024 to 4/15/2026. Findings include: 1. On the day of survey, 4/15/2026 at 1:30 pm, during the laboratory tour, observation revealed 3 of 3 containers of aliquoted QUIK Dip stain were not properly labeled with the following when used for hematology examinations performed from 6/12/2024 to 4/15/2026: - Storage requirements - Preparation and expiration dates 2. The laboratory performed 24,026 hematology examinations in 2025 (CMS 116, estimated volume, dated 04/14/2026). 3. TS #1 confirmed the findings above on 04/15/2026 at 2:30 pm.