

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0467415	(X3) Date Survey Completed 02/21/2025
Name of Provider or Supplier Woman's Clinic Diagnostic Services, The	Street Address, City, State 9601 Baptist Health Drive, Suite 1200, Little Rock, AR	
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 observation, review of American Proficiency Institute (API) proficiency testing (PT) reports, review of Laboratory policy and procedure manual, lack of documentation, and interview with staff, it was determined the laboratory failed to have a written procedure for complete blood cell count (CBC) performed on the Sysmex XN-330 hematology analyzer. Survey findings follow: A) During a tour of the laboratory at 08:45 a.m. on 2/21/25 the surveyor observed a Sysmex XN-330 hematology analyzer in the laboratory work area. That was the only analyzer observed that was capable of performing CBC analysis and the surveyor was informed, at that time, by the laboratory staff member (#5 on form CMS 209) that the Sysmex XN-330 was the analyzer used to perform and report CBC analysis. B) Review of the laboratory policy and procedure manual revealed that the only procedure for performing CBC analysis was for performing the anaysis on the Horiba Mico 60 hematology analyzer and no procedure was found for the Sysmex XN-330 hematology analyzer. C) Upon request, the laboratory could not provide a procedure for performing CBC analysis using the Sysmex XN-330 analyzer. D) In an interview on 2/21/2025 at 10:55 a.m., the laboratory staff member (#5 on form CMS 209), confirmed there was no written procedure for performing CBC analysis on the Sysmex XN-330 analyzer and the Sysmex XN-330 analyzer is the only method used to perform CBC analysis since January 2024.</p>