

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0895831	(X3) Date Survey Completed 06/03/2019
Name of Provider or Supplier Rosemark Women Care Specialists	Street Address, City, State 3450 Potomac Way, Idaho Falls, ID	
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 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 a procedure manual review and an interview with the laboratory manager, the laboratory failed to establish in writing a procedure to ensure positive identification of specimen and integrity of the patient's specimens for the pre-analytic and post-analytic test system requirements for bacteriology tests performed on the MicroProbe Affirm VP since the last survey on July 17, 2017. Findings: 1. A review of the laboratory procedure manual for the Affirm VP revealed the laboratory failed to establish in writing a procedure for the pre-analytic phase of testing to include patient specimen preparation, collection, submission, labeling, storage, processing, and acceptability requirements. 2. A review of the laboratory procedure manual for the Affirm VP revealed the laboratory failed to establish in writing a procedure for the post-analytic phase of testing to include test reporting, corrective actions, testing limitations, and actions to take if the system becomes inoperable. 3. The laboratory performed approximately 1950 bacteriology tests in 2018. 4. An interview with the laboratory manager on June 3, 2019 at 3:35 PM, confirmed the laboratory failed to establish a procedure for testing personnel to follow through the pre- and post-analytic phases of testing.</p>