

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D1048734	<b>(X3) Date Survey Completed</b>  12/02/2020
<b>Name of Provider or Supplier</b>  Rosemark Women Care Specialists	<b>Street Address, City, State</b>  808 Pancheri Dr, Idaho Falls, ID	
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>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on Proficiency testing (PT) record review and an interview with the nurse manager on 12/02/2020, the laboratory failed to ensure that the individual testing the PT samples and the laboratory director attested to the routine integration of the samples into the patient workload. The findings include: 1. A PT record review revealed that the American Proficiency Institute (API) 2018 microbiology 3rd event attestation statement was not signed by the person performing the BD Affirm testing or by the laboratory director. 2. An interview with the nurse manager on 12/02/2020 at 09:40 am confirmed that the API 2018 microbiology 3rd event attestation was not signed by the person performing the BD Affirm testing or by the laboratory director. 3. The laboratory reports performing 2184 BD Affirm test annually.</p>
<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 a review of procedures and an interview with the nurse manager on 12/02</p>

/2020, the laboratory failed to have a written procedure for Proficiency Testing (PT) available for the laboratory personnel to follow. 1. A review of procedures for the laboratory revealed that there was no policy or procedure for PT testing, documentation, signing of attestation and reporting results to the PT provider. 2. The attestation statement for 2018 event 3 PT from the American Proficiency Institute was not signed by the person performing testing or the laboratory director. 3. An interview with the nurse manager on 12/02/2020 at 9:40am, confirmed that the laboratory did not have a procedure for Proficiency Testing. 4. The laboratory reports performing 2184 BD Affirm tests annually.