

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  46D0991303	<b>(X3) Date Survey Completed</b>  04/09/2024
<b>Name of Provider or Supplier</b>  Orem Family Medicine	<b>Street Address, City, State</b>  173 N 400 W Ste C-11, Orem, UT	
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 record review, lack of documentation and an interview with Testing Personnel #2 (TP #2), the laboratory failed to establish written procedures for the moderately complex Affirm VP III assay for bacteriology testing since the last survey performed on 4/11/2022. The laboratory performs 240 bacteriology tests annually. Findings include: 1. Record review on 4/9/2024 at approximately 12:20 PM, revealed that the laboratory failed to establish written procedures for the Affirm VP III assay since the last survey performed on 4/11/2022 . 2. An interview with TP #2 on 4/9/24 at approximately 12:20 PM, confirmed that the laboratory failed to establish written procedures for the Affirm VP III assay.</p>