

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  27D0707089	<b>(X3) Date Survey Completed</b>  10/12/2021
<b>Name of Provider or Supplier</b>  Five Valleys Urology	<b>Street Address, City, State</b>  2875 Tina Avenue Suite 101, Missoula, MT	
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>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the hematology and urinalysis procedures, and interview with laboratory Director (LD) #1, the laboratory failed to have a step-by-step procedure for post vasectomy semen analysis and failed to include in their procedure manuals reference intervals (normal values) for microscopic urinalysis. Findings: 1. Policy 5.25 - Urinalysis with Microscopy lacked reference intervals (normal values) in the procedure. 2. No procedure for post vasectomy semen analysis was available for review. 3. Interview with the LD #1 on October 12, 2021 at 11:00 AM confirmed the laboratory failed to have a step-by-step procedure for post vasectomy semen analysis</p>

and failed to include in their procedure manuals reference intervals (normal values) for microscopic urinalysis.