

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0707089	(X3) Date Survey Completed 03/13/2019
Name of Provider or Supplier Five Valleys Urology	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	Based on an on-site recertification survey conducted on 3/13/18, deficiencies were cited for Five Valleys Urology in Missoula, MT.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES 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 record review and interview, the laboratory director and testing personnel failed to sign 18 of 18 attestation statements in 2017 and 2018. The findings include: 1. A review on 3/13/19 at 2:00 p.m. of the American Association of Bioanalysts (AAB) proficiency testing documentation lacked attestation signatures for urinalysis, clinical microscopy, and special chemistry for events 1, 2, and 3 of 2017 and 2018. 2. On 3/13/19 at 2:00 p.m., staff member A stated the laboratory did not know to sign the attestation statements. 3. A review on 3/13/19 at 4:00 p.m. of the laboratory checklist for verifying attestation statements were signed was last completed for event 3 of 2016.</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing</p>

samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document handling, preparation, processing, examination, and each step in the testing and reporting of results for 18 of 18 proficiency testing samples in 2017 and 2018. The findings include: 1. A review on 3/13/19 at 2:00 p.m. of the American Association of Bioanalysts (AAB) proficiency testing documentation lacked handling, preparation, processing, examination, testing, and reporting records for urinalysis, clinical microscopy, and special chemistry specimens for events 1, 2, and 3 of 2017 and 2018. 2. On 3/13/19 at 4:00 p.m., staff member B stated the proficiency testing documentation was not located in the laboratory.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to establish and follow a written policy to assess employee competency from 4/17/17 through 3/13/19. The findings include: 1. On 3/13/19 at 2:45 p.m., staff member A stated initial training and competency assessments for the current testing personnel were not documented. 2. A review on 3/13/19 at 3:45 p.m. of the competency assessments on file lacked competency assessments for four testing personnel (staff members A, D, E, and F). 3. A review on 3/13/19 at 3:15 p.m. of the Five Valleys Urology Policy and Procedure binder lacked a written employee competency policy.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and interview, the technical consultant failed to evaluate the competency of four of four testing personnel. The findings include: 1. On 3/13/19 at 2:45 p.m., staff member A stated initial training and competency assessments for testing personnel was not documented. 2. A review on 3/13/19 at 3:45 p.m. of the competency assessments on file lacked competency assessments for four testing personnel in 2018. a. Staff members A, D, E, and F.