

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 27D0411162	<b>(X3) Date Survey Completed</b> 02/26/2018
<b>Name of Provider or Supplier</b> Urology Specialists	<b>Street Address, City, State</b> 350 Heritage Way, Ste 2300, Kalispell, 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>D0000</b>	Based on an on-site recertification survey conducted on 2/26/18, deficiencies were cited for Urology Associates in Kalispell, MT.
<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 record review and interview, the Laboratory Director failed to sign the attestation statements for four of four proficiency testing events and the individual testing the proficiency samples failed to sign the attestation statements for three of four proficiency testing events. The findings include: 1. A review on 2/26/18 at 2:30 p. m. of attestation statements in the American Proficiency Institute (API) binder were unsigned by the Laboratory Director for both prostate specific antigen (PSA) and testosterone. a. Event 1 of 2016. b. Event 2 of 2016. c. Event 1 of 2017. d. Event 2 of 2017. 2. A review on 2/26/18 at 2:30 p.m. of attestation statements in the API binder were unsigned by the individual testing the samples for both prostate specific antigen (PSA) and testosterone. a. Event 1 of 2016. b. Event 2 of 2016. c. Event 1 of 2017. 3. On 2/26/18 at 2:30 p.m., staff member A stated the laboratory did not know to sign the attestations.</p>
<b>D5411</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as</p>

determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to follow manufacturer directions for prostate specific antigen (PSA) from 9/11/17 through 2/26/18. The findings include: 1. A review on 2/26/18 at 3:30 p.m. of the Urology Associates patient test report lacked the identity of the PSA assay used by the laboratory. 2. A review on 2/26/18 at 3:30 p.m. of the Beckman Coulter PSA Instructions for Use included a warning paragraph stating "the results reported by the laboratory to the physician must include the identity of the PSA assay used." 3. On 2/26/18 at 3:30 p.m., staff member A stated the PSA information was not on the test report.

**D5807**

**TEST REPORT**

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to include the reference range for one of three tests on the patient test report. The findings include: 1. A review on 2/26/18 at 3:30 p.m. of the Urology Associates patient test report lacked a reference range for prostate specific antigen (PSA). 2. On 2/26/18 at 3:30 p.m., staff member A stated the reference range was not on the report.

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(3)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview, the Laboratory Director failed to document review and approval of verification procedures for three of three new tests. The findings include: 1. On 2/26/18 at 2:30 p.m., a Beckman Coulter Access 2 analyzer was observed in the laboratory. 2. On 2/26/18 at 2:30 p.m., staff member A stated prostate specific antigen (PSA), testosterone, and vitamin D were analyzed on the Beckman Coulter Access 2, which was installed in September of 2017. 3. A review on 2/26/18 at 4:00 p.m. of the verification data for PSA, testosterone, and vitamin D lacked documentation of the Laboratory Director's review and approval. 4. On 2/26/18 at 4:00 p.m., staff member A stated the data was reviewed but not signed.