

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0522069	(X3) Date Survey Completed 01/05/2021
Name of Provider or Supplier North Idaho Urology	Street Address, City, State 980 W Ironwood Dr #104, Coeur D'Alene, ID	
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
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 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.</p> <p>This STANDARD is not met as evidenced by: Based on Proficiency Testing (PT) record review, and an interview with the testing person on 01/05/2021, the laboratory director failed to sign and date the PT attestation statements provided by the American Association of Bioanalytics (AAB). The findings include: 1. A record review of PT documents revealed that there were no AAB PT attestation statements signed and dated by the laboratory director for 3 of 3 events in 2020. 2. An interview with the testing person on 01/05/2021 at 3:50 PM confirmed the above findings. 3. The laboratory reports performing 3,600 urine microscopic examinations and 2,600 Prostate Specific Antigen (PSA) patient specimens and 280 hematology patient specimens annually.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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,</p>

consultant competency.

This STANDARD is not met as evidenced by:

Based on record review of competency assessments, the CMS-209 personnel form, and an interview with the testing person on 01/05/2021, the laboratory failed to follow written policies and procedures to assess competency for testing personnel. The findings include: 1. A record review of competency assessments revealed that one of one testing personnel listed on the CMS-209 personnel form did not have competency assessments performed in 2019 and 2020. 2. An interview with the testing person on 01/05/2021 at 1:40 PM confirmed the above findings. 3. The laboratory reports performing 3,600 urine microscopic examinations and 2,600 Prostate Specific Antigen (PSA) patient specimens and 280 hematology patient specimens annually.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

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.

This STANDARD is not met as evidenced by:

Based on record review of the laboratory's routine urinalysis procedure, and an interview with the testing person on 01/05/2021, the laboratory failed to follow the written procedure for centrifuging urine sediment for microscopic examination. The findings include: 1. A record review of the laboratory's routine urinalysis procedure revealed the laboratory was not following the written procedure to centrifuge the urine for 5 minutes, urine specimens are centrifuged for 2 minutes. 2. An interview with the testing person on 01/05/2021 at 4:35 PM confirmed that patient urine specimens are centrifuged for 2 minutes. 3. The laboratory reports performing 3,600 urine sediment microscopic examinations annually.