Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2036436	04/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Donaldson Medical Clinic	1577 Dewar Drive, Ste 8, Rock Springs, WY	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on patient record review, instrument printouts review, and interview with staff, the laboratory failed to establish a written policy to ensure positive patient sample identification was maintained from the time of collection to reporting of results for 3 of 3 tests performed on the Tosoh A1A 360 instrument (Thyroid Stimulating Hormone, Prostate Specific Antigen, and Testosterone) for 3 of 5 days reviewed when the bar code reader failed. The laboratory performed approximately 1200 tests per year on the A1A instrument. Findings include: 1. Patient test record review included test reports for Thyroid Stimulating Hormone (TSH), Prostate Specific Antigen (PSA), and/or Testosterone for patients: #16122004 on 12/20/2016 for a PSA test, and #161207007 on 12/08/2016 for Testosterone and PSA. 2. Instrument printouts from the Tosoh A1A for specimens #16122004 on 12/20/2016 for a PSA test, and #161207007 on 12/08/2016 for Testosterone and PSA failed to include the specimen identification number or patient name for identification. 3. In an interview conducted on 04/30/2018 at approximately 2:00 P.M., the laboratory manager stated the barcode reader did not identify the test results by specimen accession number 100% of the time. The manager also confirmed that when the barcode reader did not read the bar code, the specimen result on the instrument printout was not labeled with the patient's name or the patient's accession number and that test results were then manually entered into the laboratory information system from the instrument printout by the

	laboratory manager. The manager stated the specimen identification was confirmed as observed by the order of the specimen as placed on the instrument specimen sampling queue.