

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D2036436	(X3) Date Survey Completed 01/27/2020
Name of Provider or Supplier Donaldson Medical Clinic	Street Address, City, State 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
D5779	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(a)</p> <p>Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing records review, proficiency testing corrective action policy review, and interview with staff, the laboratory failed to ensure a corrective action policy was available to ensure the laboratory reported accurate and reliable Total Iron Binding Capacity (TIBC) test results. The laboratory continued to report patient test results after 3 consecutive proficiency testing failures (2019 American Proficiency Institute [API] events 1, 2, and 3). The laboratory performed approximately 91 tests per year. Findings include: 1. Proficiency testing records review included documentation the laboratory failed : API 2019 event 3 with a score of 40%. Specimen C13 was reported as 292 (Acceptable range was 227 - 291); Specimen C14 was reported as 314 (Acceptable range was 243 - 307); and Specimen C15 was reported as 364 (Acceptable range was 267 - 346). API 2019 event 2 with a score of 20%. Specimen C07 was reported as 333 (Acceptable range was 272 - 311); Specimen C08 was reported as 274 (Acceptable range was 229- 267); Specimen C09 was reported as 335 (Acceptable range was 267 - 302); and Specimen C10 was reported as 257 (Acceptable range was 211 - 252). API 2019 event 1 with a score of 0% Specimen C01 was reported as 609 (Acceptable range was 523 - 598); Specimen C02 was reported as 207 (Acceptable range was 308- 369); Specimen C03 was reported as 311 (Acceptable range was 254- 303); Specimen C04 was reported as 188 (Acceptable range was 126 - 182); and Specimen C05 was reported as 254 (Acceptable range was 202 - 244). 2. The laboratory procedure manual included instructions to document corrective actions for proficiency testing failures. The procedure failed to include a limitation for the number of times the laboratory failed</p>

proficiency testing before suspending patient testing until the root cause of the failures could be determined and documentation of accuracy and precision was confirmed. 3. In an interview with staff on 01/27/2020 at approximately 2:00 P.M., staff stated the corrective actions taken were not sufficient to prevent TIBC proficiency testing failures for two events subsequent to the first failure totaling 3 consecutive failures.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on proficiency testing records review, corrective actions review, and interview with staff, the analytic systems quality assessment failed to include a review of the effectiveness of the corrective actions taken for Total Iron Binding Capacity (TIBC) proficiency testing failures for 3 consecutive American Proficiency Institute proficiency testing events in 2019 to prevent recurrence. (See D5779).