

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405917	(X3) Date Survey Completed 11/16/2018
Name of Provider or Supplier Glacial Ridge Health System	Street Address, City, State 10 4th Avenue Se, Glenwood, MN	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure a blood collection vacutainer used for Coagulation tests was not used after the expiration date had been exceeded. Findings are as follows: 1. The laboratory performed Coagulation testing as confirmed by the General Supervisor 1 (GS1) during a tour of the laboratory on 11/15/18 at 11:05 a.m. 2. Bectin Dickinson Sodium Citrate 3.2% Vacutainer Venous Blood Collection Tubes (P/N 363080) with lot number 8099543 and expiration date 10/31/2018 were observed as present in the tube rack located in the Patient Draw Area #2 and available for use during the tour. The intended use of these blood collection tubes was for pediatric coagulation testing as per the manufacturers package insert. 3. In an interview on 11/15/18 at 11:15 a.m., GS1 confirmed the above finding. .</p>
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the</p>

laboratory failed to ensure accurate reference ranges were listed on Hematology test reports reviewed during the survey. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor 1 (GS1) during a tour of the laboratory on 11/15/18 at 11:05 a.m.. 2. A Sysmex XN-1000 hematology analyzer was observed as present and available for use during the tour. 3. The reference ranges found in the Hematology Reference Ranges, Sysmex XN procedure, located in the Laboratory Specimen Collection manual, were not consistent with that included on the test report (Female - 87 years, Date of testing = 3/1/18) reviewed on the date of survey, as follows: Parameter: Procedure: Test Report: % Neutrophils 37 - 92 37 - 87 % Monocytes 2 - 12 0 - 12 4. In an interview on 11/16/18 at 10:15 a.m., GS1 confirmed the above findings. .

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the technical consultant failed to ensure competency was assessed at least semiannually during the first year of patient specimen testing for 1 of 4 new testing personnel. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry, Hematology and Immunohematology testing as confirmed by General Supervisor 1 (GS1) during a tour of the laboratory on 11/15/18 at 11:05 a.m. 2. Testing Personnel 9 (TP9) was listed on the Laboratory Personnel Report (CLIA) Form CMS-209 as a full time employee performing moderate and high complexity testing. 3. Laboratory records indicated TP9 was trained and initially assessed for testing competency in April 2018 through July 2018. 4. A semiannual competency assessments for TP9 was not found during review of laboratory records. 5. In an interview on 11/15/18 at 12:15 p.m., GS1 confirmed the above finding. .