

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1068788	(X3) Date Survey Completed 02/08/2018
Name of Provider or Supplier Ivanhoe Medical Center	Street Address, City, State 315 N Norman St, Ivanhoe, 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
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 laboratory failed to ensure reference intervals were consistent between procedure and patient test report. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory on 2/8/18 at approximately 12:10 p.m. 2. A Sysmex pocH-110i hematology analyzer was observed as present and available for use during the tour. 3. The reference intervals listed in the Tests Performed / Critical Values Table, located in the Ivanhoe Medical Center On-line Procedure Folder, were not consistent with those included on the patient test reports reviewed on date of survey, 2/8/18. Patient reports reviewed: MRN Date of Test Sex/Age 166052 4/6/16 M / 93 179848 8/2717 M / 86 Analyte Procedure Report Neutrophil % Male: 49-80% 45-80% Lymphocyte % Male: 11-36% 12-41% Neutrophil # Male: 2.2-6.5 1.8-5.3 Lymphocyte # Male: 0.3-3.0 0.7-2.2 MRN Date of Test Sex/Age 183601 1/23/18 F / 84 Analyte Procedure Report Neutrophil % Female: 45-80% 49-80% Lymphocyte % Female: 12-41% 11-36% Neutrophil # Female: 1.8-5.3 2.2-6.5 Lymphocyte # Female: 0.7-2.2 0.3-3.0 4. In an interview at approximately 2:15 p.m. on 2/8/18, the LD confirmed the above findings. .</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least</p>

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 (TC) failed to assess the competency of 2 of 2 new Testing Personnel at least twice annually during the first year of testing. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory on 2/8/18 at approximately 12:10 p.m. 2. Testing Personnel 1 (TP-1) was listed on Form CMS-209 Laboratory Personnel Report (CLIA) as a new employee performing moderate complexity testing. Laboratory records indicated TP-1 began working in the lab in December 2015 and was initially assessed for competency on 12/14/16. 4. Testing Personnel 3 (TP-3) was also listed on Form CMS-209 Laboratory Personnel Report (CLIA) as a new employee performing moderate complexity testing. Laboratory records indicated TP-3 began working in the lab in December 2016 and was initially assessed for competency on 12/29/17. 3. Semi-annual competency assessments for TP-1 and TP-3 were not found during review of laboratory records. The laboratory was unable to provide the required documentation upon request. 4. In an interview on 2/8/18 at approximately 12:30 p.m., the LD confirmed the above finding. .