

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0456369	(X3) Date Survey Completed 09/11/2018
Name of Provider or Supplier Gothenburg Memorial Hospital	Street Address, City, State 910 20th Street, Gothenburg, NE	
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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the demonstration of performance specifications and an interview with the general supervisor at 12:25 PM on 9/11/2018, the laboratory failed to demonstrate the accuracy for a new erithrocite sedimentation rate (ESR) instrument. Findings are: 1. Review of the validation of performance specifications for a new ESR instrument (started on 9/29/2017) revealed no checks for accuracy had been included in the instrument validation. 2. Interview with the general supervisor confirmed a test comparison with another laboratory or instrument had not been performed prior to patient testing.</p>
D6085	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)</p> <p>The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of procedure, a review of manufacturer's instructions and an interview</p>

with the general supervisor at 1:25 PM on 9/11/2018, the laboratory failed to have adequate newborn testing procedures. Findings include: 1. No procedure could be presented at the time of survey for the steps taken for newborn screening for Rh/D negative mothers. 2. Review of the manufacturer's instructions for the Micro Typing System used by the laboratory revealed that it was unable to detect weak D antigen. 3. The general supervisor stated routine follow up testing was not routinely performed for fetal maternal bleeding on Rh positive babies born to Rh negative mothers unless the physician suspected a larger than normal bleed and ordered it specifically. The general supervisor also stated that weak D testing had not been sent out on Rh negative babies born to Rh negative mothers.