

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0696913	(X3) Date Survey Completed 03/15/2018
Name of Provider or Supplier Ccm Health - Clara City	Street Address, City, State 140 Nw 1st Ave, Clara City, 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
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to establish a Quality Assessment Plan (QAP) for an Individualized Quality Control Plan (IQCP) developed by the laboratory. Findings are as follows: 1. The laboratory performed General Chemistry testing as confirmed by the general supervisor (GS) during a tour of the laboratory on 3/15/18 at 11:05 a.m. 2. The laboratory developed an IQCP to reduce quality control requirements for the MicroAlbumin method 3. A QAP to monitor and assess the the effectiveness of the IQCP for 2017 was not found in laboratory records. The laboratory was unable to provide the requested document. 4. In an interview on 3/15/18 at 2:10 p.m., the GS confirmed the above finding. .</p>