

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0684364	(X3) Date Survey Completed 05/31/2018
Name of Provider or Supplier Sebeka Medical Clinic	Street Address, City, State 106 Minnesota Ave, Sebeka, 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
D6047	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(i)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the technical consultant (TC) failed to ensure the competency assessment for 1 of 5 testing personnel included direct observation of test performance for all testing performed by the laboratory. Findings are as follows: 1. The laboratory performed Microbiology, General Immunology, Chemistry and Hematology testing as confirmed by the Testing Personnel 5 (TP5) during a tour of the laboratory 05/31/18 at 10:05 a.m. 2. The laboratory established a direct observation of test performance requirements in the competency assessment policy located in the online Policy Manager program. 3. The Competency Assessment Documentation form included a direct observation of test performance requirement for the following tests. Complete Blood Count (CBC) Manual differentials (Diff) Mononucleosis (Mono) Urine sedimentation (UA) Microscopic Examination - skin (KOH) Microscopic examination - wet preparation (WP) 4. Documentation of 2017 direct observation of test performance was not found for testing personnel 2 (TP2) for 4 of the 6 tests. See below where "0" indicates documentation was not found. Test TP2 CBC Diff 0 Mono 0 UA KOH 0 WP 0 5. In an interview on 05/31/18 at 11:00 a.m., TP5 confirmed the finding.</p>
D6051	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed</p>

specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the technical consultant (TC) failed to ensure the competency assessment for 1 of 5 testing personnel included an evaluation of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples for all testing performed by the laboratory. Findings are as follows: 1. The laboratory performed Microbiology, General Immunology, Chemistry and Hematology testing as confirmed by the Testing Personnel 5 (TP5) during a tour of the laboratory 05/31/18 at 10:05 a.m. 2. The laboratory established assessment of test performance through testing blind samples in the competency assessment policy located in the online Policy Manager program. 3. The Competency Assessment Documentation form included assessment of blind sample testing for moderate complexity tests, including Complete Blood Count (CBC). 4. Documentation of a 2017 direct observation of CBC test performance was not found for testing personnel 3 (TP3). 5. In an interview on 05/31/18 at 11:00 a.m., TP5 confirmed the finding.

D6052

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the technical consultant (TC) failed to ensure competency assessments for 5 of 5 testing personnel included an evaluation of problem solving skills for all testing performed by the laboratory. Findings are as follows: 1. The laboratory performed Microbiology, General Immunology, Chemistry and Hematology testing as confirmed by the Testing Personnel 5 (TP5) during a tour of the laboratory 05/31/18 at 10:05 a.m. 2. The laboratory established problem solving skill evaluation requirements in the competency assessment policy located in the online Policy Manager program. 3. The Competency Assessment Documentation form included assessment of problem solving skills for the following tests. Complete Blood Count (CBC) Manual differentials (Diff) Mononucleosis (Mono) Urine sedimentation (UA) Microscopic Examination - skin (KOH) Microscopic examination - wet preparation (WP) 4. Documentation of 2017 problem solving evaluations was not found for all testing personnel for each of the above tests. See below where "0" indicates the problem solving assessment was not found. Test Testing Personnel 1 2 3 4 5 CBC 0 0 0 0 Diff 0 0 0 Mono 0 UA 0 0 0 KOH 0 WP 0 5. In an interview on 05/31/18 at 11:00 a.m., TP5 confirmed the finding.