

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0394232	(X3) Date Survey Completed 09/21/2022
Name of Provider or Supplier Clear Lake Clinic	Street Address, City, State 357 3rd Ave, Clear Lake, WI	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of proficiency testing records and interview with the technical consultant, the laboratory did not enroll in a proficiency testing program in 2020 for the regulated hematology testing performed on the Sysmex KX-21N analyzer. Findings include: 1. Review of proficiency testing records showed no evidence the laboratory enrolled in an approved proficiency testing program in 2020 for the regulated analytes in the Complete Blood Count (CBC) testing performed on the Sysmex KX-21N hematology analyzer. 2. Interview with the technical consultant on September 21, 2022 at 10:05 AM confirmed the laboratory tested 180 patient samples on the Sysmex KX-21N analyzer in 2020 and confirmed the laboratory had not enrolled in an approved proficiency testing program for testing performed on the hematology analyzer in 2020.</p>
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the</p>

laboratory's routine methods

This STANDARD is not met as evidenced by:

Based on surveyor review of the CMS (Centers for Medicare and Medicaid Services) Form 209 'Laboratory Personnel Report (CLIA)' and proficiency testing records and interview with the technical consultant, all hematology proficiency samples from five of five events were tested by one of the six testing personnel who perform hematology testing at this laboratory. Findings include: 1. Review of the CMS Form 209, signed by the laboratory director on September 16, 2022, showed six testing personnel perform moderate complexity testing in this laboratory. 2. Review of attestation statements for API (American Proficiency Institute) Hematology / Coagulation surveys for the 2021 events two and three, the 2022 events one and two, and a remedial event in 2021, showed staff A performed the complete blood count (CBC) testing on the Sysmex KX-21N analyzer for all six events. 3. Interview with the technical consultant on September 21, 2022 at 10:05 AM confirmed staff A performed CBC testing on all proficiency testing samples in 2021 and 2022 and confirmed the other staff who perform CBC testing did not test proficiency samples at this laboratory.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on surveyor review of competence evaluation documentation and interview with the technical consultant, the competence assessment performed for six of six testing personnel and the technical consultant was not specific for this laboratory. Findings include: 1. Review of the competence assessment forms for the six testing personnel (staff A - F) showed the forms included the laboratories at three clinic locations; Luck, Clear Lake, and Turtle Lake. 2. Interview with the technical consultant on September 21, 2022 at 9:30 AM confirmed the competence evaluations for the six testing personnel were not specific for this laboratory and revealed evaluations may have been performed at any of the three clinic locations. Further interview confirmed the competence evaluation of the technical consultant was not specific for this laboratory.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on surveyor review of proficiency testing records and interview with the technical consultant, the laboratory did not review the API (American Proficiency Institute) remedial (non-routine, off-cycle) proficiency testing event performed in 2021 and did not evaluate the 80% score for MCH (Mean Corpuscular Hemoglobin).

Findings include: 1. Interview with the technical consultant on September 21, 2022 at 10:05 AM revealed the laboratory recognized early in 2021 they had not enrolled in a proficiency program for CBC testing. When the laboratory enrolled with API for the rest of 2021, samples for the first event were no longer available, and the laboratory enrolled for a remedial off-cycle event. 2. Review of proficiency testing records showed results for a remedial event in 2021 from API. No evaluation report for this remedial event was available in the record. 3. Review of the API evaluation of results obtained during the survey showed an 80% score for MCH. 4. Further interview with the technical consultant on September 21, 2022 at approximately 11:00 AM confirmed the laboratory had not evaluated the unacceptable result for MCH reported in the remedial event.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
Based on surveyor review of proficiency testing records and interview with the technical consultant, the laboratory did not verify the accuracy of microscopic urinalysis testing twice annually in 2021 or 2022. Findings include: 1. Review of proficiency testing records showed no evaluation of accuracy of microscopic urinalysis testing in 2021 or 2022. 2. Interview with the technical consultant on September 21, 2022 at 10:45 AM confirmed staff A performed microscopic urinalysis testing in 2021 and 2022 and confirmed the laboratory had not verified the accuracy of the test twice annually in 2021 or 2022.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on surveyor review of procedures and interview with the technical consultant, the current laboratory director had not approved the operating procedure for the KX-21N or the urinalysis procedure. Findings include: 1. Review of the 'KX-21N Operating Procedure' and the 'Urinalysis, Clinitek Status' procedure showed no evidence of approval by the current laboratory director. The 'Urinalysis, Clinitek Status' procedure includes instructions for performing microscopic urinalysis testing and was revised May 17, 2022. 2. Interview with the technical consultant on September 21, 2022 at 11:15 AM confirmed the laboratory director had not approved, signed, and dated the KX-21N procedure and had not approved, signed, and dated the revised urinalysis procedure before putting the procedure into use.