Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0864231	03/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Shakopee Dakota Clinic	2330 Sioux Trail Nw, Prior Lake, 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
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 document review and interview with laboratory personnel, the laboratory failed to investigate an unacceptable Hematology proficiency testing (PT) result for 1 analyte in 2018. Findings are as follows: 1. The laboratory performed proficiency testing (PT) through the American Proficiency Institute (API) program. 2. The laboratory received an unacceptable PT result in the 2018 Hematology / Coagulation 3rd Event for Mean Platelet Volume (MPV) on sample HEM-15. 3. An investigation of the unacceptable PT result was not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 4. In an interview on 03/13/19 at 3:30 p.m., Testing Personnel 7 (TP7) confirmed the above finding. .
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory

	failed to verify the accuracy of Hematology proficiency testing (PT) scores when the PT program returned evaluations of 4 analytes as Not Graded in 2017. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 3/13/19 at 9:5 a.m. 2. The laboratory performed proficiency testing (PT) through the American Proficiency Institute (API) program. 3. The following PT results from 2017 were not graded by the PT provider. Survey: Hematology / Coagulation 3rd Event Sample ID: HEM-15 Tests: White Blood Cell Count Granulocytes Lymphocytes Monocytes 5. The API expected results data summaries were not present in laboratory records. Evaluations for accuracy of the non-graded results were not found during review of laboratory documents. The laboratory was unable to provide evaluations of non-graded results upon request. 6. In an interview on 03/13/19 at 3:30 p.m., Testing Personnel 7 (TP7) confirmed the above finding. .
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements. Findings are as follows: 1. The Laboratory Procedures Manual did not include a Proficiency Testing (PT) procedure by which to monitor, assess, and, when indicated, correct problems identified in the PT process. 2. The laboratory was unable to provide the above document upon request. 3. In an interview on 3/13/19 at 10:00 a.m., the General Supervisor confirmed the above findings. .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values.

	(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to include accurate Chemistry reference intervals in the procedure manual. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 3/13/19 at 9:05 a.m. 2. A Picollo Point-of-Care Chemistry analyzer was observed as present and available for use during the tour of the laboratory. 3. The reference ranges for Alanine aminotransferase (ALT) in the Comprehensive Metabolic Panel Employing the Picollo Point-of-Care Chemistry Analyzer procedure did not reflect the reference intervals on the patient test report reviewed on date of survey. See below. Analyte Procedure Report ALT 42 - 141 10 - 47 4. In an interview on 3/13/19 at 3:10 p.m., the Testing Personnel 7 (TP7) confirmed the above findings. .
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to establish a system to evaluate and define the relationship between test results obtained from different analyzers or methodologies at least twice annually. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 3/13/19 at 9:05 a.m. 2. Multiple Picollo Point-of-Care Chemistry analyzers were confirmed by the GS as present and available for use during the tour of the laboratory. 3. The General Supervisor (GS) indicated the laboratory used serum and/plasma, in addition to whole blood, to perform Comprehensive Metabolic Panels for Chemistry testing on either Picollo analyzer, thus rendering such testing as of Moderate complexity. 4. The laboratory's procedure manuals did not include a system to define and evaluate the relationship between test results obtained from different test methodologies or analyzers at least twice annually. Documentation of such an evaluation was not found during review of laboratory records. 5. In an interview on 3/13/19 at 3:10 p.m., the Testing Personnel 7 (TP7) confirmed the above findings. .