Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	46D2084337	05/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Sacred Circle Healthcare Clinic	660 S 200 E, Ste 250, Salt Lake City, UT	

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	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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. This CONDITION is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to enroll in an approved proficiency testing program for prothrombin time testing performed using a plasma specimen and the addition of Calcium Chloride on the Coagusence instrument which is a modification of the waived method that uses whole blood without additional reagents. Modification changes the categorization to High Complexity. Findings include: 1. The laboratory failed to document proficiently testing enrollment confirmation for prothrombin time testing of a non-waived test method. 2. In an interview with staff on 05/21/2019 at approximately 3:00 P.M. the laboratory manager stated they did not have confirmation of Proficiency testing enrollment prior to 05/21/2019 for prothrombin tests performed on the Congusence instrument using Calcium Chloride with a plasma specimen.
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 proficiency testing records review, lack of documentation, and interview with staff, the laboratory failed to verify they could accurately and precisely report quantitative drug concentrations at the stated cut off limits for 47 of 47 drugs included in the laboratory test menu. The laboratory lacked documentation of verification they could accurately detect the presence of (Alprozolam, Aminoclonazapam, Butalbital, Carisopodol, Clonazepam, Diazepam, Nordiazepam, Hydroxyalprazolam, Meprobamate, Oxazepam, Temazepam, Desmethyltapentadol, Desmethlytramadol, EDDP, Fentanyl, Meperidine, Methandone, Naloxone, Naltrexone, Norbuprenorphine, Norfentanyl,Normeperidine, Propoxypene, Tapentadol, Tramadol, EXTC, PCP, Methamphetamine, Cocaine, Benzodiazepine, Barbiturates, Amphetamines, Oxycodone, 6AM, MDEA, Despramine, Doxepam, Cyclobenzapine, Tizadine, Morphine, Oxymorphine, Noroxycodone, Norhydrocodone, Hydroxycodone, Oxymorphone, and Codeine) drugs using the accepted cut off concentrations for their presence or absence at least twice annually from July 2017 to May 2019. The laboratory performed approximately 100,000 drug analysis concentrations for the presence or absence of drugs of abuse and prescribed drugs per year. Findings include: 1. Proficiency test records review failed to include twice annual verification the laboratory could accurately measure the presence of the listed drugs by quantitative methods.. Proficiency records reviewed failed to include the laboratory confirmed their concentration of drugs measured twice annually. 2. In an interview with staff on 05/22/2019 at approximately 12:00 Noon staff confirmed the proficiency program included a selected set of drugs in each of 2 CAP (DMPM module) events sent per year included a presence or absence drug screen and concentration confirmation for approximately 47 drugs listed above for confirmation of drug presence through screening and quantitation and the concentration.
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 procedure manual review, quality control test records review and interview

	with staff, the laboratory procedure for liquid chromatography (LC) and mass spectrometry (MS) failed to include instructions to summarize the requirements for an acceptable test result for each drug analyzed and reported. The laboratory performed approximately 100,000 drug concentration analysis per year using the LC/MS test system. Findings include: 1. Procedure manual review provided rejection criteria but failed to include an interpretation for the analysis of reagent blank, linearity standards performance, urine quality control at the cut off and abnormal ranges, and PM100 controls for acceptance. 2. The procedure failed to provide the step by step instructions to the analysts the number or priority of the controls that must be within the stated range(s), or guidelines for test run acceptance, and how many standard points were the minimum to ensure the test run was linear and those that bracketed the patient samples throughout the test run. 3. In an interview with staff on 05/22/2019 at approximately 10:30 A.M. staff stated they understood the criteria for rejection of some data but some criteria could be rejected and using all of the data available still have enough acceptable data to accept the test run and report patient test results. Staff stated they needed a better summarization using all of the quality control data generated with specific criteria for an acceptable test run.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on manufacturer's package insert review, patient test report review and confirmation by staff, the laboratory failed to follow the Prostate Specific Antigen (PSA) manufacturer's instructions to include the test method in the test report with the notice that PSA test results from different test methods can not be used interchangeably to monitor PSA concentration. The laboratory performed approximately 5 tests per month. Findings include: 1. The PSA report for patient Accession ID 19142/17552 collected on 05/06/2019, a 38 year old male, was reported as 0.38 ng/ml. The results failed to include the manufacturer's test method and notice not to compare results from different test methods. 2. Staff confirmed the test report did not include the manufacturer's instructions to include the test method and the notification not to compare different test method's results.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

	This STANDARD is not met as evidenced by: Based on direct observation, email communication with the Coagusence manufacturer's representative observation, Federal Food and Drug Administration (FDA) test categorization list review, and interview with staff, the laboratory failed to verify the analytical sensitivity and specificity of plasma prothrombin time (PT) tests performed using the addition of calcium chloride on the coagusense instrument. The laboratory tested approximately 4 patient samples per month from February 29, 2019 to May 21, 2019. Findings include: 1. Direct observation of PT testing on 05/21/2019 at 13:44 P.M. staff performed testing using an instrument categorized as waived using a plasma specimen with addition of Calcium Chloride. The email from the manufacturer's representative stated the change in methods changed the test's categorization. 2. FDA test categorization lists the test as a waived test. The waived test manufacturer's instructions state whole blood is to be used as the specimen type. Changing the specimen type and the addition of calcium chloride modify the approved waived test method and move the complexity from a waived to a high complexity test. 3. The laboratory verification failed to include the revised test's analytical sensitivity or specificity (including interfering substances). 4. In an interview with the laboratory manager on 05/21/2019 at approximately 3:45 P.M. and on 05/22/2019 at approximately 10:00 A.M. following an email confirmation by the manufacturer, the laboratory manager stated the method was a complex method and that analytical sensitivity and analytical specificity verification studies were not performed to verify the least amount time detectable for prothrombin presence and verification that the time reported included lack of interference with other substances.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to verify calibration for 3 of approximately 80 tests reviewed (Sodium, Potassium, and

	Chloride) using materials of known concentrations with at least a low or zero level, mid level, and a level at the upper level of the reportable range of the reportable range once every 6 months for 18 months of testing reviewed. Findings include: 1. The laboratory lacked documentation they checked Sodium, Potassium and Chloride once every six months between July 2017 and May 2018 to verify the Dimension EXL reportable range for these analytes. 2. Staff confirmed they had not verified the reportable range once every six months since verification studies were performed in the first half of 2017.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control records review, patient testing records review, lack of documentation, and confirmation by staff, the laboratory failed to perform two levels of control each day of Prothrombin Time testing for 8 of 12 test days. The laboratory performed testing approximately 4 times per month from February 2019 to May 2019. Findings include: 1. Quality control records review included documentation the laboratory performed prothrombin time (PT) testing once per month (usually the first test day of the month). 2. Patient test records review included documentation the laboratory performed PT testing on 02.26.2019, 03/06/2019, 03/13/2019, 03/27/2019, 03/28/2019, 04/03/2019, 04/10/2019, 04/17/2019, 05/01/2019, 05/06/2019, 05/08 /2019, and 05/21/2019 reviewed and failed to perform two levels of quality control each day tests were performed. 3. In an interview conducted on 05/21/2019 at approximately 1:40 P.M. staff stated they had conducted a quality control study but failed to establish an Individualized Quality Control Plan that included a risk assessment, quality control plan and quality assessment plan that had been approved by the laboratory director for reducing the frequency of quality control performance.