

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2084337	(X3) Date Survey Completed 04/14/2022
Name of Provider or Supplier Sacred Circle Healthcare Clinic	Street Address, City, State 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Mass Spec Drug Testing procedure manual and an interview with the technical supervisor (TS), the laboratory failed to include reference intervals (normal values), limitations in the test methodology, reportable range for test results, and pertinent literature references for toxicology testing. Findings: 1. Review of the procedure manual revealed a lack of reference ranges for confirmatory toxicology testing. 2. Review of the procedure manual revealed a lack of limitations in the test methodology, including interfering substances. 3. Review of the procedure manual revealed a lack of reportable range for test results for the test system. 4. Review of the</p>

	<p>procedure manual revealed a lack of pertinent literature references. 5. Interview with the TS #2 on April 14, 2022 at 2:15 pm confirmed the laboratory failed to include reference ranges, limitations in the test methodology, reportable range, and literature references for toxicology testing.</p>
<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Cerilliant manufacturer's instructions, observation of Cerilliant toxicology internal standards stored in the freezer, and interview with the technical supervisor (TS), the laboratory failed to follow the manufacturer's instructions for storage of Cerilliant internal standard material. Findings: 1. Review of Cerilliant manufacturer's instructions for Oxymorphone-D3-3-beta-D-glucuronide showed "Refrigerate-Do Not Freeze!" 2. Review of Cerilliant manufacturer's instructions for Codeine-6-beta-D-glucuronide showed, "Refrigerate." 3. Observation of the laboratory freezer showed one vial of Cerilliant Oxymorphone-D3-3-beta-D-glucuronide and one vial of Codeine-6-beta-D-glucuronide available for use. 4. Review of patient testing volumes showed the laboratory performs 93,590 toxicology tests annually. 5. Interview with TS #2 on April 14, 2022, at 11:00 am confirmed the laboratory failed to properly store internal standards per the manufacturer's instructions.</p>
<p>D5415</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, and interview with testing personnel (TP), open and expiration dates failed to be written on a bottle of Acetone Optima Lot 163970 1L reagent, used for toxicology testing. The laboratory performs approximately 93,590 toxicology tests annually. Findings: 1. An observation on April 14, 2022, at 11:15 am, revealed the open date and expiration date were not written on one of one bottle of Acetone Optima Lot 163970 1L. 2. In an interview on April 14, 2022 at approximately 11:15 am, TP #2 confirmed that the open date and expiration date were not written on the bottle of Acetone Optima Lot 163970 1L.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</p>

CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on direct observation and interview with technical supervisor (TS), the laboratory failed to ensure that the polypropylene glycol (PPG) reagent used for toxicology testing was not used past the expiration date. The laboratory performs approximately 93,590 toxicology tests annually. Findings: 1. Direct observation of the chemistry laboratory refrigerator revealed polypropylene glycol (PPG) reagent lot number A9352 with an expiration date of October 20, 2021. The date of the survey was April 14, 2022. 2. Interview with the TS #2 on April 14, 2022 at 11:15 am confirmed the PPG reagent was expired.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on record review and interview with the technical supervisor (TS), the laboratory did not establish a maintenance protocol for the SciexMD 4500 LC-MS/MS test system. The laboratory performs approximately 93,590 toxicology tests annually. Findings: 1. A record review of the laboratory procedures revealed the laboratory failed to document and have a protocol for maintenance activities for the SciexMD 4500 LC-MS/MS test system. 2. In an interview on April 14, 2022 at approximately 12:00 pm, the TS #2 confirmed the laboratory failed to document and have a protocol for maintenance activities for the SciexMD 4500 LC-MS/MS test system.

D5435

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on observation of 17 of 17 pipettes in use for chemistry testing, review of maintenance documentation and equipment maintenance policy PCS 005, and interview with the general supervisor (GS) and testing personnel (TP), the laboratory failed to define and perform a function check protocol to verify the accuracy of 14 of 17 pipettes for 2020 and 13 of 17 pipettes for 2021. Findings: 1. Observation of the chemistry area revealed 17 pipettes in use for chemistry testing. 2. No documentation was found to show the laboratory defined and performed a function check to verify the accuracy of 14 of 17 pipettes for 2020 and 13 of 17 pipettes for 2021. 3. Review of the equipment maintenance policy PCS 005 revealed "to perform annually." 4. The laboratory performed 155,859 chemistry tests annually. 5. Interview with the GS and TP #1 on April 14, 2022 at 11:30 am confirmed, that the laboratory failed to verify the accuracy of 14 of 17 pipettes for 2020 and 13 of 17 pipettes for 2021.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
Based on record review and interview with the technical supervisor (TS), the laboratory did not establish calibration, calibration verification procedures, and logs for the calibration for the SciexMD 4500 instrument. The laboratory performs approximately 93,590 toxicology tests annually. Findings: 1. A record review of the laboratory procedures revealed the laboratory failed to establish calibration, calibration verification procedures, and documentation logs for the calibration of the SciexMD 4500 triple quadrupole instrument. 2. 4500 Series of Instruments System User Guide states, "In general, for triple quadrupole systems, calibration and resolution is satisfactory for three to six months unless the system loses vacuum." "If the system loses vacuum, then check the calibration and resolution before using the system." 3. Record review revealed the laboratory failed to document when the SciexMD 4500 instrument lost vacuum or when the calibration and resolution was checked. 4. In an interview on April 14, 2022 at approximately 12:00 pm, the TS #2 confirmed the laboratory failed to establish procedures for calibration, calibration verification, and documentation logs for the calibration for the SciexMD 4500 triple quadrupole instrument. PPG calibration scans are not kept.

D6084

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(2)

The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards.

This STANDARD is not met as evidenced by:
Based on direct observation, record review and interview with the technical supervisor (TS) the laboratory failed to provide a fume hood for testing personnel handling toxic chemicals. The laboratory performs approximately 93,590 Toxicology tests annually. Findings: 1. Record review of Form FSC007-E Needle Rinse Preparation showed that acetonitrile and methanol is used in the preparation of the needle rinse. 2. An observation on April 14,2022 at approximately 1:40 pm, revealed the lab failed to have a fume hood for testing and reagent preparation. 3. In an interview on April 14,2022 at approximately 1:40 pm, the TS #2 confirmed that the lab does not have a fume hood and the needle rinse is prepared with acetonitrile and methanol on the open bench.

D6096

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(7)

The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified.

This STANDARD is not met as evidenced by:
Based on a review of the Dimension EXL manufacturer's System Operator's Guide, humidity temperature documentation, and interview with the general supervisor (GS), the laboratory director failed to ensure remedial actions were taken for unacceptable humidity ranges. Findings: 1. Review of the Dimension EXL System Operator's Guide, for performance specifications revealed relative humidity must be maintained at greater than or equal to 20 percent and less than or equal to 80 percent. 2. Review of the humidity log showed that for 8 of 21 days in January 2022, 16 of 20 days in February 2022, 5 of 23 days in March 2022, and 8 of 10 days in April 2022, the humidity fell outside of the acceptable range of 20 to 80 percent humidity. 3. The laboratory failed to document corrective actions for unacceptable humidity ranges. 4. Review of patient testing volumes showed the laboratory performs 155,859 chemistry tests annually. 5. Interview with the GS on April 14, 2022 at 3:00 pm confirmed the laboratory director failed to ensure remedial actions were documented and taken for unacceptable humidity ranges.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:
Based on a review of personnel competency documentation and interview with the general supervisor (GS), the LD failed to ensure competency for two of three technical supervisors (TS), one of one general supervisor (GS), and one of four testing

personnel (TP) for 2020 and 2021. Findings: 1. Review of 2020 and 2021 personnel competency documentation revealed the laboratory failed to perform competency assessments for TP #1, TS #1, 2, and GS #1 for 2020, 2021. 2. Interview with the GS on April 14, 2022, at 10:00 am confirmed the LD failed to ensure competency for two of three TS, one of one GS, and one of four testing personnel (TP) for 2020 and 2021.