Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2083671	11/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sunrise Clinical Laboratory	26-32 Ball Street, Irvington, NJ	

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
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 the Competency Assessment (CA) records, CA procedure and interview with the General Supervisor (GS), the laboratory failed to follow the CA procedure to perform a CA annually on five of five testing personnel and the General, Clinical and Technical Supervisor from June 2017 to the date of the survey. The GS confirmed on 11/14/18 at 10:35 am that CA procedure was not followed.
D5315	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS. This STANDARD is not met as evidenced by: Based on surveyor review of work records and interview with the General Supervisor (GS) the laboratory referred testing to a non-CLIA-certified laboratory from 10/6/16 to the date of survey. The finding includes. 1) The reader testing personnel #1 was performing statistical analysis for toxicology testing at a non-CLIA-certified laboratory. a) The GS stated, "Stephanie reads from home". 2) The GS confirmed on 11/14/18 at 2 pm that testing was referred to a non-CLIA-certified laboratory.

D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: a) Based on surveyor review of the Procedure Manual (PM) and interview with the General Supervisor (GS), the laboratory failed to follow the procedure for "Quality Assurance" from 10/6/16 to the date of survey. The findings include: 1. The PM stated monthly and quarterly QA tasks pages 8-11 in the PM are to be documented. 2. There was no documented evidence that the monthly and quarterly QA was being completed. 3. The GS confirmed on 11/14/18 at 11:50 am that the PM was not followed. b) Based on surveyor review of the PM and interview with the GS, the laboratory failed to follow the procedure for toxicology tests performed on the AU480 from July 2018 to the date of survey. The findings include: 1. The cut off value for Canabinoids in the PM was 50 ng/dL. The cut off value in the AU480 was 100 ng /mL. 2. The cut off value for Buprenorphine in the PM was 10 ng/mL. The cut off value in the AU480 was 50 ng/mL. 3. The GS confirmed on 11/14/18 at 12:00 pm that the PM was not followed. 35471 c) Based on surveyor review of the PM and interview with the GS, the laboratory failed to establish a procedures for Urine and Oral Fluid Toxicology from February 2017 to the date of survey. The findings include: 1. The laboratory failed to establish a procedure to verify new lots of reagents prior to patient testing. 2. The laboratory failed to establish a procedure to address carryover. 3. The GS confirmed on 11/14/18 at 2:40 pm that the laboratory did not establish the above procedures.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT 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: a) Based on surveyor review of the Quality Control (QC) Records and interview with the General Supervisor (GS), the laboratory used expired QC material for Ethanol (ETHNL) testing from 6/3/18 to 11/14/18. The findings include: 1. QC material expiration date changes once opened. 2. The laboratory was unaware that MAS Toxicology QC material was stable for 30 days after opening. 3. MAS Toxicology Level 4 Lot DAT19054A for high ETHNL QC opened 5/3/18 expired 6/3/18. 4. Approximately eleven thousand patients were run and reported after 6/3/18. b) Based on surveyor review of the QC Records and interview with the GS, the laboratory used expired QC material for ETHNL and Buprenorphine (BURPE) testing from 8/16/18 to 11/14/18. The findings include: 1. MAS Toxicology Level 1 Lot DAT19051A for low ETHNL and BURPE QC opened 7/16/18 expired 8/16/18. 5. MAS Toxicology Level 6 Lot DAT19056A for high BURPE QC opened 7/23/18 expired 8/23/18. 6. Approximately six thousand patients were run and reported after 8/16/18. 5. The GS confirmed on 11/14/18 at 11:00 am that the laboratory used expired QC material.

D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on surveyors review of Maintenance Records (MR) and interview with the General Supervisor (GS), the laboratory failed to document function checks for the pipettes and centrifuges used in Toxicology testing from 10/6/16 to the date of the survey. The finding includes: 1. The laboratory did not have documentation of Revolutions Per Minute (RPM's) and Timing on the centrifuges. 2. The laboratory did not have documented evidence of calibration for nine pipettes. 3. The GS confirmed on 11/14/18 at 11:45 am that the function checks above were not performed.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the General Supervisor (GS) the Laboratory Director (LD) failed to ensure that PS were adequate to perform Oral Fluid and Urine Toxicology (UT) tests on the Shimadzu and AB Sciex from February 2018 to the date of survey. The findings include: 1. The laboratory staff did not perform the UT verification. 2. There was no acceptable criteria for PS from clinical scientific literature. 3. There was no source available for cut off points. 4. The acceptance rate for Quality Control was 30%. 5. There was no validation performed to establish the expiration date of reagents, working solutions, Internal Standard, controls and calibrators used. 6. The validation of the UT hydrolysis control did not include validation of: a. Optimal Enzyme Concentration b. Temperature of the Heat Block c. Time on the Heat Block 7. There was no criteria to review chromatography of UT peaks. 8. There was no criteria for manual integration of UT peaks. 9. There were no UT correlation studies performed. 10. UT sample stability studies were not performed. 11. Verification of manufacturers instructions for Specimen Collection, handling and rejection were not performed. 12. The GS confirmed on 11/14/18 at 2:20 pm that the LD did not ensure the PS were adequate.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Records (PR) and interview with the General Supervisor (GS), The Laboratory Director failed to ensure that one of five Testing Personnel had appropriate education and training documented prior to patient testing on the date of survey. The GS confirmed on 11/14/18 at 10:20 am that education and training were not documented.