

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2149272	(X3) Date Survey Completed 11/20/2018
Name of Provider or Supplier Med Screen Laboratories	Street Address, City, State 992 Clifton Avenue, Clifton, 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
D5467	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(g)</p> <p>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-- When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual, Calibrators, Controls and interview with the Technical Supervisor (TS), the laboratory failed to use different lot numbers of calibrators to make the calibrator and control for Urine Toxicology confirmation tests from July 2018 to the date of the survey. The TS confirmed on 11 /20/18 at 11:40 am the laboratory did not use different lot numbers.</p>
D6086	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Technical Supervisor (TS) the Laboratory Director (LD) failed to ensure that PS were adequate to perform Urine Toxicology confirmation tests on the Shimadzu LCM-8060 from July 2018 to the date of survey. The findings include: 1. There was no validation performed to establish the expiration date of reagents,</p>

working solutions, Internal Standard, controls and calibrators used. 2. The validation of the hydrolysis control did not include validation of: a. Optimal Enzyme Concentration b. Temperature of the Heat Block c. Time on the Heat Block 3. Sample stability studies were not adequate. 4. The TS confirmed on 11/20/18 at 1:40 pm the laboratory did not ensure PS were adequate.