

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1105941	(X3) Date Survey Completed 03/06/2019
Name of Provider or Supplier Cleanslate Centers	Street Address, City, State 59 Bobala Rd, Holyoke, MA	
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
D0000	A CLIA recertification survey was conducted for the CleanSlate Centers laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
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 procedure review and interview the laboratory failed to have a procedure manual which included the following: a) A review of the laboratory procedure titled for "Guidelines for accepting or rejecting patient results based on quality control results", revealed that the procedure did not include instructions for documenting</p>

	<p>remedial action and/or investigation regarding quality control failures. b) The technical consultant and general supervisor interviewed on 3/6/19 at 11:30 AM. confirmed that the procedure did not include the above stated information and that it had to be updated due to laboratory technologist failing to document remedial actions or investigation in response to quality control failures (refer to D6178). .</p>
<p>D5775</p>	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow their system that twice a year evaluated and defined the relationship between multiple analyzers performing the same type of testing as evidenced by the following: a) The laboratory performs urine drug screens on two chemistry analyzers (Beckman AU 2700 and AU 400). b) A review of the laboratory documentation for cross comparisons of the two analyzers revealed that the comparisons had been performed only once in 2018 (4/24 /18). c) The general supervisor confirmed in an interview on 3/6/19 at 11:11 AM that cross comparisons between the two analyzers had only been performed once during 2018. .</p>
<p>D6178</p>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(4)</p> <p>Each individual performing high complexity testing must follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, testing personnel failed to follow established procedures for documentation whenever test systems were not within the laboratory's established acceptable levels of performance as evidenced by the following: A review of quality control Levey Jennings charts and cumulative quality control for calendar year 2018 revealed that personnel were not documenting what remedial action or investigation in response to unacceptable quality control results for urine drug screens run on the Beckman AU 2700 and AU 400 chemistry analyzers (e.g., Alkaline Phosphatase for 12/12/18). Levey Jennings charts and cumulative quality control reviewed showed repeats of quality control until results were acceptable. However, there was no documentation of any remedial action or investigation documented anywhere in the laboratory's record system. b) Interview with the technical and general supervisor on 3/6/19 at 11:30 AM confirmed that personnel were supposed to be documenting remedial action in the comment section whenever quality control failures were investigated and resolved. They further stated that the staff had been in-serviced regarding quality control failure documentation. In addition, they admitted that the laboratory's quality control policy needed to be updated to reflect the laboratory's requirements for quality control failure documentation (refer to D5403).</p>