

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2014717	(X3) Date Survey Completed 08/27/2018
Name of Provider or Supplier Star Laboratory Corporation	Street Address, City, State 125 Fleming Street, Piscataway, 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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing records and interview with the Technical Supervisor (TS), the laboratory failed to evaluate coded results obtained in 1-2018 event with the American Proficiency Institute (API). The finding includes: 1) The laboratory did not evaluate Not Graded 2 (lack of consensus) results for UDS-Opiates for sample # 2. 2) The TS confirmed on 8/27/18 at 11:50 am that the laboratory failed to evaluate coded result.</p>
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 tests from March 2018 to the date of the survey. The TS confirmed on 8/27/18 at 11:10 am the laboratory did not use different lot numbers.</p>

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Final Report (FR) and interview with the Technical Supervisor (TS), the laboratory failed to report Urine Drug test results accurately from initiation of testing to the date of survey. The findings include: 1. The cut off limits were reported as a range for Alpha-Hydroxyalprazolam and Oxazepam. 2. The laboratory performed non Food and Drug Administration cleared tests and there was no statement stating "The performance characteristics of this test were determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration" on FR. 3. The FR stated "Drug Screening (UD) results are presumptive only and associated numerical values are not to be used for quantitation" but numerical values are not reported for UD. 4. The FR stated "For drug confirmation and quantitation it is recommended to perform GC-MS or LC-MS but the laboratory performed and reported LC-MS results. 5. The TS confirmed on 8/28 /18 at 1:30 pm that Urine Drug tests were not reported accurately.

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 Technical Supervisor (TS) the Laboratory Director failed to ensure that PS were adequate to perform Urine Toxicology tests on the Shimadzu LCMS 8045 from July 2018 to the date of survey. The findings include: 1. An accuracy study was not performed. 2. There was no explanation of how the precision study was performed. 3. There was no source available for cut off points. 4. There was no documented evidence of a signed and dated summary of acceptance of PS. 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 hydrolysis control did not include validation of: a. Optimal Enzyme Concentration b. Temperature of the Heat Block c. Time on the Heat Block d. Temperature of the Incubator e. Time in the Incubator 7. There was no criteria to review chromatography. 8. There was no criteria for manual integration. 09. The TS confirmed on 8/27/18 at 3: 10 pm that the LD did not ensure the PS were adequate.

D6171

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Personnel Files and interview with the Technical Supervisor (TS), the Testing Personnel (TP) was not qualified to perform high complexity Urine Drug testing performed on MGC 240 analyzers from July 2018 to the date of survey. The TS confirmed on 8/27/18 at 11:00 am that the TP was not qualified.