

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2142104	(X3) Date Survey Completed 08/10/2022
Name of Provider or Supplier Innovative Laboratories	Street Address, City, State 6911 Laurel Bowie Rd Suite 212b, Bowie, MD	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory failed to sign and retain the attestation statements documenting that PT samples were tested in the same manner as patient specimens in four of four testing events. Findings: 1. Records from four PT events (2020 2nd, 2021 1st, 2021 2nd, and 2022 1st) were reviewed. 2. The signed attestation statements documenting that PT samples were tested in the same manner as patient specimens were missing from all four PT events. 3. During the survey on 08/10/2022 at 12:45 PM, the TC confirmed that PT records were missing the attestation statements signed by the testing person and the laboratory director or designee.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have</p>

deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with the technical consultant (TC), the laboratory failed to ensure that quality control materials were not used past their expiration date for urine drug screen testing. Findings: 1. Bottles of the following calibrators and controls were found opened in the refrigerator during the on-site survey conducted on 08/10/2022: a. Siemens Syva Emit Calibrator/Control Level 1, catalog number 9A528UL-P3, expiration date 06/02/2022 b. Siemens Syva Emit Calibrator/Control Level 3, catalog number 9A568UL-P3, expiration date 03/02/2022 c. Bio-Rad S1E low opiate, liquichek urine toxicology control, lot number 71930, expiration date 07/31/2022 2. The instrument printouts did not contain the lot number and expiration dates for the controls or calibrators used for each batch of testing and there was no reagent log or inventory list that documented the lot numbers, expiration dates, and dates in use for the reagents, calibrators and quality control materials. 3. During the survey on 08/10/2022 at 11:00 AM, the TC confirmed that the laboratory does not keep a record of lot numbers and expiration dates and does not track which lot number is in use at any given time to ensure that reagents, calibrators, and quality control materials are not used past their expiration dates.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of records and interview with the technical consultant (TC), the laboratory failed to ensure that all quality assurance (QA) records were reviewed and that monthly reviews were performed in a timely manner to ensure that potential problems could be identified and corrective actions implemented in a timely manner for urine drug screen testing. Findings: 1. The TC stated that the testing person would scan and email the temperature logs, instrument maintenance logs, monthly patient chart audits and instrument reports for the quality control and calibration results to the TC for review at the end of every month. 2. Each month the records were printed by the TC and attached to a cover sheet that contained any notes and the signature and date of review. 3. Monthly QA packets from 01/2021 - 07/2022 were reviewed, with the exception of 02/2022 when patient testing was not performed, for a total of 18 months. 4. Of the 18 months reviewed, records for 10/2021 were missing, five months were missing the temperature logs (01/2021, 02/2021, 04/2021, 12/2021, and 05/2022), four months were missing the instrument maintenance logs (01/2021, 11/2021, 12/2021, and 01/2022), and eight months were missing the "QA Req Review Monthly Chart Audit" (11/2021, 12/2021, 01/2022, 03/2022, 04/2022, 05/2022, 06/2022 and 07/2022). 5. The QA packets for the months of 11/2021 - 04/2021 were all reviewed on 05/23/2022. 6. During the survey on 08/10/2022 at 12:45 PM, the TC confirmed that the monthly QA packets that were reviewed did not always contain all QA documents and that the months of 11/2021 - 03/2022 were not reviewed in a timely manner to ensure that any potential problems were identified and corrective actions implemented in a timely manner.

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 review of final test reports and interview with the testing person (TP) and technical consultant (TC), the laboratory failed to include two patient identifiers on the final test report for positive patient identification for urine drug screen testing. Findings: 1. Final test reports from 03/2022 and 06/2022 were reviewed. 2. For patient identification the test reports had three lines labeled "PID", "Patient First Name", and "Patient Last Name." 3. Reports from 03/2022 had the patients' birth date entered in the line labeled "PID" as a second form of patient identification. Reports from 06/2022 only contained the patients' first and last name and no additional unique patient identifiers. 4. The new TP stated they began testing patient specimens around the end of 04/2022 and were not aware that the patients' birthdate was to be entered into line labeled "PID." There was no procedure that detailed how to create and print a patient final report. 5. During the survey on 08/10/2022 at 12:45 PM, the TC confirmed that the new TP had not been trained to input the patients' birthdate into the line labeled "PID" as a second patient identifier.