

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 46D2163989	<b>(X3) Date Survey Completed</b> 04/08/2022
<b>Name of Provider or Supplier</b> Flc Lab	<b>Street Address, City, State</b> 11978 S Redwood Rd, Riverton, UT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with Laboratory Directory (LD) and Testing Personnel (TP), the laboratory failed to enroll in an approved PT program for creatinine in the specialty of Routine Chemistry. The laboratory performs approximately 26,000 toxicology tests annually on the Thermo Scientific Indiko Plus Clinical Chemistry Analyzer. Findings include: 1. A review of the laboratory PT records for 2019, 2020, 2021, and 2022 revealed the laboratory failed to enroll in creatinine PT. 2. Interview with LD and TP on 04/08/2022, at 2:15 PM, confirmed the laboratory was not enrolled in creatinine PT.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p>

This STANDARD is not met as evidenced by:  
Based on a record review and an interview with the Laboratory Director (LD), the laboratory failed establish and follow policy or procedure to assess the competency of Testing Personnel (TP) for tests performed on the Thermo Scientific Indiko Plus Clinical Chemistry Analyzer and the position held by the Technical Consultant (TC). The laboratory performs approximately 26,000 toxicology test annually. Findings include: 1. A review of the laboratory procedures revealed the laboratory failed to have a policy or procedure to assess all six elements required for the competency assessment of one of one TP. 2. A review of the laboratory procedures revealed the laboratory failed to have a policy or procedure to assess based on the position responsibilities of one of one TC. 3. An interview on 04/08/2022, at 2:20 PM, with the LD, confirmed the laboratory failed to have a policy or procedure to assess the competency for TP and TC.

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:  
Based on record review and interview with the Laboratory Director (LD), the laboratory failed to establish a policy or procedure to verify the accuracy of the tests twice annually for twelve of twelve analytes. The laboratory performs approximately 26,000 toxicology tests annually on the Thermo Scientific Indiko Plus Clinical Chemistry Analyzer. Finding include: 1. A review of the laboratory procedures revealed the laboratory failed to have policy or procedure to verify twice annually the accuracy of the analytes amphetamine, barbiturate, benzodiazepine, buprenorphine, cannabinoids, methadone, opiate, oxycodone, pH detect, specific gravity, cocaine, and ecstasy. 2. An interview on 04/08/2022, at 2:15 PM, with LD, confirmed the laboratory failed to have a policy or procedure to verify the accuracy of the tests twice annually for amphetamine, barbiturate, benzodiazepine, buprenorphine, cannabinoids, methadone, opiate, oxycodone, pH detect, specific gravity, cocaine, and ecstasy.

**D5415**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:  
Based on record review, direct observation, and interview with the Technical Consultant (TC), written expiration dates were not on five of five buprenorphine calibrators. The laboratory performs approximately 26,000 toxicology tests annually on the Thermo Scientific Indiko Plus Clinical Chemistry Analyzer. Findings include: 1. Review of the laboratory document, "Fidelity Lab Solutions - Riverton, UT Indiko Plus Calibrator Information" revealed open buprenorphine calibrators are stable for 60 days. 2. Direct observation on 04/08/2022, at 3:20 PM, revealed the expiration dates

failed to be written on five of five buprenorphine calibrators. 3. In an interview on 04/08/2022 at 3:25 PM, with the TC, confirmed that expiration dates are not written on the controls.

**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:

Based on direct observation and interview with technical consultant (TC), the laboratory failed to ensure that the MAS DOA Total Controls used for toxicology testing were not used past their expiration date. The laboratory performs approximately 26,000 toxicology tests annually on the Thermo Scientific Indiko Plus Clinical Chemistry Analyzer. Findings include: 1. Direct observation of the toxicology laboratory refrigerator revealed MAS DOA Total Controls lot numbers DAT22032, DAT22033, DAT22034, and DAT22035 with an expiration date of 03-31-2022. The date of the survey was 04-08-2022. 2. Interview with the TC on April 08, 2022 at 3:45 PM confirmed the MAS DOA Total Controls were being utilized for patient testing past their expiration date.