

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2151446	<b>(X3) Date Survey Completed</b>  03/12/2025
<b>Name of Provider or Supplier</b>  Md Matt	<b>Street Address, City, State</b>  10220 S Dolfields Rd #106, Owings Mills, MD	
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>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the testing person (TP) and laboratory director (LD), the laboratory's procedure manual did not include instructions for receiving and labeling the patient specimen containers for toxicology screening. Findings: 1. On 03/12/2025 at 11:56 PM the TP stated that three barcoded stickers were printed for each patient specimen and affixed to the lid and side of the urine cup and to the tube that was placed into the toxicology analyzer. 2. During the exit interview on 03/12/2025 at 12:25 PM, the LD confirmed that the procedure manual did not include instructions for receiving and labeling patient specimens for toxicology screening.</p>
<b>D5415</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p>

This STANDARD is not met as evidenced by:  
Based on observation, review of quality control (QC) open vial stability, and interview with the laboratory director (LD), the laboratory failed to label the toxicology QC vials with the opened expiration date. Findings: 1. The "Indiko Plus Quality Control Information" document stated that the drugs of abuse (DOAT) QC had a 30-day open vial stability. 2. The QC vials for DOAT 2, 3, 4, and 5 were labeled with the opened dates of 03/11/2025, 02/23/2025, 02/13/2025, and 02/18/2025, respectively, but not the updated expiration date of 30 days beyond their opened date. 3. During the exit interview on 03/12/2025 at 12:25 PM, the LD confirmed that DOAT QC vials were not labeled with the opened vial expiration dates.

**D5417**

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

(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 review of the reagent on board stability and reagent logs, and interview with the laboratory director (LD), the laboratory failed to document the buprenorphine reagent reconstituted expiration date on the reagent logs. Findings: 1. The "Indiko Plus Reagent Information" document stated that the Buprenorphine II reagent had a 60-day stability from the time of reconstitution. 2. The laboratory reconstituted the reagent on the date put into use. 3. The "CEDIA Buprenorphine II Reagent" log documented lot number 74998700 as put into use on 12/19/2024 with an expiration date of 08/31/2025. 4. During the exit interview on 03/12/2025 at 12:25 PM, the LD confirmed that the buprenorphine reagent log did not capture the updated expiration date of 60 days after reconstitution.

**D5807**

TEST REPORT  
CFR(s): 493.1291(d)

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:  
Based on review of a patient test report and interview with the laboratory director (LD), the final test report did not contain the normal range for oxidants. Findings: 1. The laboratory reported results for oxidants to determine specimen validity for urine toxicology screening specimens. 2. The final test report included the normal ranges for all the specimen validity analytes (creatinine, pH, and specific gravity) except for oxidants. 3. During the exit interview on 03/12/2025 at 12:25 PM, the LD confirmed that the final test report did not include the normal range for oxidants.