Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2105179	07/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Specialty Laboratories	13530 Michigan Ave Suite Ll1, Dearborn, MI	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: . Based on record review, observation, and interview with the General Supervisor (GS), the laboratory failed to follow its policy to ensure positive patient identification for urine specimens collected for quantitative urine toxicology testing for 12 of 38 patient urine specimens present in the laboratory's refrigerator. Findings include: 1. A review of the laboratory's "Laboratory Sample Collection" policy on 7/13/22 revealed a section stating, "The specimen(s) are labeled to assure optimum patient specimen positive identification. Pre-analytic (pre-testing) phase. the specimens are labeled as follows: 1. Patient name and date of birth. 2. Time and date of collection." 2. A review of the laboratory's "Specimen Collection Procedure" on 7/13/22 revealed a section stating, "With a permanent marker write patient name and date of birth on the specimen cup." 3. The surveyor observed 38 urine specimens in the laboratory's Turbo Air refrigerator on 7/13/22 during a tour of the laboratory at 9:55 am. A total of 12 specimens did not meet the laboratory's policy and procedure requirements: a. 6/23/22 i. Three patients were missing the date of birth on the specimen. b. 6/20/22, one patient specimen had a name and date of birth written on the cup and a sticker for a patient with a different name and date of birth on the lid of the cup. c. 6/16/22, one patient had the incorrect date of birth. The year "89" was written on the cup and "1984" was on the specimen's sticker. d. 6/15/22, one patient was missing the date of birth on the specimen. e. 6/14/22 i. One patient had a discrepancy between the last name written on the cup and the specimen sticker on the cup. ii. One patient was missing the date of birth on the specimen. f. 6/10/22 i. Three patients were missing the

	date of birth on the specimen. ii. One patient had the incorrect date of birth. The year "96" was written on the cup and "1969" was on the specimen's sticker. 4. The surveyor requested corrective action documentation for the specimens not labeled according to policy on 7/13/22 at 10:38 am and it was not made available. 5. An interview on 7/13/22 at 2:47 pm with the GS confirmed the laboratory had not followed its specimen labeling policy.
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: . A. Based on record review and interview with the General Supervisor (GS), the laboratory failed to verify the accuracy of its toxicology testing at least twice annually for 2 (July 2020 to July 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's test menu and the laboratory's twice annual verification documentation on 7/13/22 revealed a lack of documentation that the following analytes had been assessed at least twice annually from July 2020 to July 2022: a. Cotinine b. Naloxone c. Naltrexone d. Flurazepam e. Midazolam f. Triazolam g. MDEA h. Amobarbital i. Ritalinic acid j. Sufentanil 2. An interview on 7/13/22 at 2: 47 pm with the GS confirmed the laboratory had not verified the accuracy of the analytes listed above for two years. B. Based on record review and interview with the General Supervisor (GS), the laboratory failed to verify the accuracy of its quantitative urine toxicology testing for its analytes using the College of American Pathologists (CAP) UT proficiency testing events for 2 (July 2020 to July 2022) of 2 years. Findings include: 1. A review of the laboratory's CAP UT proficiency testing events from July 2020 to July 2022 revealed the proficiency testing events assessed qualitative results and did not assess the laboratory's ability to produce accurate quantitative urine toxicology results. 2. A review of the laboratory's test menu, verification of accuracy documentation, and the analytes assessed using the CAP UT event revealed the following analytes did not have quantitative accuracy assessed: a. Dihyrocodeine b. Flunitrazepam c. Ketamine d. Cyclobenzaprine e. Zolpidem f. Butabarbital g. Methylphenidate h. Phentermine i. Amitriptyline j. Despramine k. Nortriptyline l. Imipramine m. Trazadone 3. An interview on 7/13/22 at 2:47 pm with the GS confirmed the CAP UT proficiency testing events did not assess the laboratory's ability to produce accurate quantitative urine toxicology results.
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 observation, record review, and interview with the General Supervisor (GS), the laboratory failed to ensure reagents and control materials were labeled with

	the expiration date for 9 containers observed in the laboratory. Findings include: 1. The surveyor observed the following reagents and control materials during a tour of the laboratory on 7/13/22 at 9:55 am that did not contain an expiration date or had an expiration date to reflect the control materials stability once opened: a. A brown bottle labeled with "HPLC water 7/6/22 NA" b. A brown bottle labeled with "Methanol 7/6 /22" c. A conical tube "MeOH Methanol" d. BioRad Immunoassay Plus control lot 85271 with the open date of 7/1/22 e. BioRad Immunoassay Plus control lot 85273 with the open date of 7/1/22 f. BioRad Specialty Immunoassay control lot 64913 with no open date g. BioRad Specialty Immunoassay control lot 64911 with no open date 2. A review of the laboratory's "General Quality Control" policy on 7/13/22 revealed a section titled "Labels" stating, "Reagents, Probes, antibodies, and chemicals are clearly labeled with content and quantity, concentration, storage, requirement, date prepared with technologist ID#, and expiration dates. Reagents will be assigned an expiration date based on known stability, frequency of use, storage conditions, and risk of contamination." 3. A review of the laboratory's "Lyphochek Specialty Immunoassay Control with Procalcitonin and Intact PTH" quality control manufacturer information revealed a section stating, "30 day open-vial stability at 2-8 degrees C." indicating the need to update the expiration date once the vials had been opened. 4. An interview on 7/13/22 at 12:29 pm with the GS confirmed the reagents and control materials listed above were not labeled with the expiration dates according to policy. ***This is a repeated deficiency from the 8/20/18 and the 3/29/21 recertification surveys***