Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D2204188	07/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Horizon Health - Williamsburg	114 North Second Street, Williamsburg, KY	

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
D0000	A Recertification Survey was initiated on 07/12/2023 and concluded on 07/12/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on facility policy review, observation and interview, the laboratory failed to follow their written policies for collecting and labeling 1 of 1 urine samples for urine toxicology testing. Findings included: Review of Section B (f) of the "Specimen Collection" policy and procedure, signed by the Laboratory Director (LD) on 11/24 /2020, revealed the policy stated the following: "Once the urine sample is determined acceptable, the sample is properly labeled by hand or by barcode with the minimum of two identifiers: i. Patient's name ii. Accession number of the barcode iii. Date of Birth iv. Last digits of the social security number or MRN" On 07/12/2023 at 9:50 AM, the Testing Personnel (TP) was observed processing a patient urine sample for toxicology analysis. It was noted that the urine collection cup was unlabeled. During an interview on 07/12/2023 at 10:00 AM, the TP confirmed she did not label the urine sample collection cup as required.
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 facility policy review, review of the package insert, observation and interview, the laboratory failed to properly label 2 of 2 quality control (QC) materials for the toxicology analyzer with expiration dates. Findings included: Review of a "Toxicology Quality Control" policy, signed by the Laboratory Director (LD) on 11/24 /2020, for both the Level 1 and 2 Urine Toxicology Controls, revealed the policy stated, "Once opened, it is stable for 30 days". Review of a package insert dated 05/24 /2021 for the UTAK (manufacturer of Quality Controls) DAU Level 1 and 2 Urine Toxicology Control revealed the package insert stated, "All analytes are stable for 30 days once product is reconstituted." The Drugs of Abuse Urine (DAU) Level 1 lot number D2509 and 2 lot number D2510 Urine Toxicology Controls currently in use were examined. It was observed at 11:00 AM on 07/12/2023 that they were not labeled with an open vial stability expiration date. During an interview on 07/12/2023 at 11:15 AM, the Testing Personnel (TP) revealed she did not label the control vials with the expiration date once reconstituted as required.