Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2134248	09/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Naspac 1, Llc Blackwood	160 Fries Mills Road, Blackwood, NJ	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Clinical consultant (CC) the laboratory failed to retain QC assay sheets for Toxicology tests run on the Indiko Plus analyzer from 11/3/22 to the date of the survey. The CC confirmed on 9/11/24 at 10:00 am that the QC assay sheets were not retained.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) procedure and interview with the Clinical Consultant (CC), the laboratory failed to to verify QC material with each new lot and/or shipment of QC for urine toxicology tests performed on the Indiko Plus from 11/3/22 to the date of survey. The GS confirmed on 9/11/24 at 10:20 am that the QC material was not verified before putting in use.
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 surveyor review of the Procedure Manual and interview with Clinical Consultant (CC) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 11/3/22 to the date of survey. The finding includes: 1. The laboratory failed to have a procedure to verify new lots of controls before they were put in use. 2. The CC confirmed on 9/11/24 at 11:40 am that the laboratory failed to have a procedure to verify new lots of controls before they were put in use.
D5807	TEST REPORT CFR(s): 493.1291(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 surveyor review of the Finial Report (FR), Manufactuers package inserters (MPI), and interview with the Cinical Concultant (CC), the laboratory failed to ensure that the Reference Interval (RI) was accurate for Fentanyl run on the Indoko Plus analuyzer form 11/3/22 to the date of survey. The finding includes; 1. The CC stated that RI's were taken from the Manufactuers reagent insert. 2. The RI on the FR for Fentanyl was >=100 ng/mL 3. The MPI stated the RI for Fentanyl was 2.0 ng/mL 4. The CC confirmed on 9/11/24 at 11:30 am that the laboratory failed to ensure the RI was accurate.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are

	adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Clinical Consultant (CC), the Laboratory Director (LD) failed to ensure that PS procedures for Toxicology tests performed on the Indiko Plus analyzer were adequate from 11/3/22 to the date of survey. The findings include: 1. There was no documented evidence that PS procedures were performed on Fentanyl. 2. The CC confirmed on 9/11/24 at 11:15 am that PS records were not adequate.