

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D2138868	<b>(X3) Date Survey Completed</b> 07/16/2024
<b>Name of Provider or Supplier</b> Naspac1, Llc - Cherry Hill	<b>Street Address, City, State</b> 1601 Kings Highway North, Cherry Hill, NJ	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with the General Supervisor (GS), the laboratory failed to follow the PM for "5. Quality Control (QC) Data" from 6/2/22 to the date of the survey. The findings include: 1. The PM stated "5.3 All QC Data will be maintained and monitored by the designees to include", "5.3.1 Monthly reports on results", "5.3.2 Identification of upward or downward trends". 2. There was no documented evidence that the aforementioned procedures were performed. 3. The GS confirmed on 7/16/24 at 12:00pm the laboratory did not follow the PM.</p>
<b>D5469</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>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</p>

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 General supervisor (GS), the laboratory failed to to verify QC material with each new lot and/or shipment of QC for urine toxicology tests performed on the AB Sciex 4500 and 4000 from 6/2/22 to the date of survey. The GS confirmed on 7/16/24 at 12:20 pm that the QC material was not verified before putting in use.

**D5775**

COMPARISON OF TEST RESULTS  
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Laboratory Records and interview with the General Supervisor (GS), the laboratory failed to perform and document correlation studies for Toxicology test performed on the AB Sciex 4000 and 4500 analyzers twice per year from 6/2/22 to the date of the survey. The GS confirmed on 7/16/24 at 12:20 pm that the laboratory did not do correlation studies.