Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2077019	(X3) Date Survey Completed 10/17/2023
Name of Provider or Supplier Naspac 1, Llc - Hainesport	**Street Address, City, State** 404 Creek Crossing Blvd, Hainesport, 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 the lack of raw data print-out work records (WR) from the Thermo Fisher Scientific Indiko Plus analyzer and surveyor interview with the Testing Personnel #1 (TP #1) on the CMS-209 provided at the time of the survey, the laboratory failed to maintain analyzer WR's for patient's and Quality Control (QC) for routine chemistry and toxicology tests performed on the Thermo Fisher Scientific Indiko Plus analyzer from 10/21/21 to the date of the survey. The finding includes: 1. The TP #1 stated, "The WR's for patient's and QC are saved in the analyzer and Laboratory Information System (LIS)". 2. The laboratory ran and reported approximately 470,000 patients from 10/21/21 to the date of the survey. 3. The TP #1 confirmed on 10/17/23 at 2:00 pm that the laboratory did not maintain the analyzer WR's for patient's and QC.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with Testing Personnel #1 (TP #1) on the CMS-209 provided at the time of the survey, the

	laboratory failed to establish a written procedure for how and when to verify the electronic data transfer from the Thermo Fisher Scientific Indiko Plus analyzer to the Laboratory Information System (LIS) from 10/21/21 to the date of survey. The TP #1 confirmed on 10/17/23 at 1:00 pm that the laboratory did not have the procedure mentioned above.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel #1 (TP #1) on the CMS-209 provided at the time of the survey, the laboratory failed to establish a back-up plan including storage, sending out and/or running by other methods in case the instrument and/or equipment become inoperable, reagents are not available or any other emergency situation occurs where testing cannot be performed from 10/21/21 to the date of survey. The TP #1 confirmed on 10 /17/23 at 12:50 pm that the laboratory did not have the procedure mentioned above.