

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2134248	(X3) Date Survey Completed 11/03/2022
Name of Provider or Supplier Naspac 1, Llc Blackwood	Street Address, City, State 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to enroll in an approved PT program for routine chemistry tests from 9/19/19 to the date of survey. the finding includes: 1. The laboratory was enrolled in two out of three events for Creatine and Potential of Hydrogen (pH) with the College of American Pathologists (CAP). 2. The TP confirmed on 11/3/22 at 1:00 pm the laboratory was not enrolled in three PT testing events for the above mentioned analytes.</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of</p>

accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records, Observation in the analyzer and interview with the Testing Personnel (TP), the laboratory failed to take Corrective Action (CA) when controls were out of range for Toxicology tests performed on the Indiko Plus analyzer from June 2022 to the date of survey. The findings include: 1. A review of the QC records for MAS DOA Total 4 control failed for negative Buprenorphine as follows: 6/6/22, 6/11/22, 6/14/22, 6/17/22, 6/20/22, 6/29/22, 9/9/22, 9/12/22, 9/19/22, 9/21/22, 10/14/22, 10/17/22, 10/18/22, 10/26/22. 2. The laboratory did not have corrective action for the above mentioned QC failures. 3. Approximately 60 patients were fun and reported per day. 4. The TP confirmed on 11/3/22 at 1:30 pm that corrective action on failed QC was not performed and documented.

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 Testing Personnel (TP) 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 9/19/22 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 TP confirmed on 11/3/22 at 1:45 pm that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on an office review of the laboratory's performance in Proficiency Testing (PT) surveys, the laboratory director failed to provide appropriate direction to the laboratory personnel to ensure that the PT surveys are performed satisfactorily and compliance with the CLIA regulations are maintained.