

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2134248	(X3) Date Survey Completed 04/24/2018
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
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to maintain copies of all PT records for Urine Drug testing performed with the American Proficiency Institute (API) in the 2-2017. The finding includes: 1. The laboratory did not have the evaluation page for PT results in event 2-2017. 2. The GS confirmed on 4/24/18 at 10:00 am that all PT records were not maintained.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Maintenance Records (MR) and interview with the General Supervisor (GS), the laboratory failed to perform and document maintenance as specified by the manufacturer on the Thermo Fisher analyzer used in Urine Drug Screening Tests from January 2018 to the date of the survey. The findings include: 1. A review of the MR revealed maintenance was not performed as follows: a. Weekly maintenance was not performed in January, February, March and April 2018. b.</p>

	<p>Monthly maintenance was not performed in February and March 2018. 2. The GS confirmed on 4/24/18 at 10:15 am that maintenance as specified by the manufacturer was not performed.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the General Supervisor (GS), the laboratory failed to ensure that the Test Report Date (TRD) was indicated on the FR from August 2016 to the date of survey. The GS confirmed on 4/24/18 at 11:30 am that the TRD was not on the FR.</p>
<p>D5807</p>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Manufacturers Package Insert (MPI), Final Report (FR) and interview with the General Supervisor (GS), the laboratory failed to ensure the Normal Reference Interval (RI) was correct on the FR for Specific Gravity (SG) tests performed on the Thermo Fisher Indiko Plus from August 2016 to the date of the survey. The finding includes: 1. The upper limit of the RI for SG was 1.035 on the FR but the MPI limit was 1.030. 2. The GS confirmed on 4/24/18 at 11:45 am that the laboratory failed to have the correct RI on the FR.</p>
<p>D6013</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>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;</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor review of the Performance Specification (PS) records and interview with the General Supervisor (GS), the Laboratory Director failed to ensure that PS procedures performed on the Thermo Fisher Indiko Plus analyzer were adequate from August 2016 to the date of the survey. The finding includes: 1. A review of the Precision Statistics revealed that there was no indication if analyte had passed, failed, or was uncertain. 2. The GS confirmed on 4/24/18 at 10:30 am that PS were not reviewed.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on surveyor review of Personnel Files and interview with the General Supervisor (GS), the Laboratory Director failed to have education records for one out of two Testing Personnel (TP) from August 2016 to the date of the survey. The GS confirmed on 4/25/18 at 9:45 am that there was no education record for one out of two TP.