

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2077019	(X3) Date Survey Completed 01/29/2019
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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing records and interview with the Testing Personnel (TP), the laboratory failed to evaluate coded results obtained for Toxicology proficiency testing performed with the American Proficiency Institute (API) in the 1st 2018 event. The finding includes: 1. The laboratory did not evaluate code 2 "Not Graded" for USD Opiates - No Consensus - event 1, 2018. 2. The TP #1 listed on CMS form 209 confirmed on 1/29/19 at 10:30 am that the laboratory failed to evaluate coded results.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to establish a procedure to verify new QC material used in Toxicology tests before use</p>

from 2/23/17 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 1/29/19 at 10:00 am the laboratory did not have a procedure to verify new Toxicology QC.