

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2139067	(X3) Date Survey Completed 06/28/2023
Name of Provider or Supplier Naspac - Nj, Pllc (Wg)	Street Address, City, State 2325 Maryland Ave, Willow Grove, PA	
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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor record review (Application for Exception to Section 5.22(f)) and interview with testing personnel #1 (TP) and TP #2, the laboratory failed to ensure that the State of Pennsylvania (PA) regulations were met regarding having a supervisor on site during all normal scheduled working hours in which tests are being performed. Findings Include: 1. The PA regulations (5.23 (b)(1)) states: "A general supervisor who meets all the requirements of subsection (a)(1), (2) or (3) and is on the laboratory premises during all normal scheduled working hours in which tests are being performed." 2 . Review of the application for Exception to Section 5.22 (f) form signed by the laboratory director (LD) on 04/26/2021 states: " the laboratory director will appoint a qualified general supervisor for each laboratory who will be on-site to oversee laboratory operations during all hours in which testing is being performed and who will review quality control records on a weekly basis". 3. On the day of the survey, 06/28/2023 at 12:30 pm, during an interview, TP #1 and TP #2 stated that the laboratory did not have a qualified supervisor onsite for every hour of patient testing as required by the State of PA.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with Testing Personnel #1 (TP) and TP #2, the laboratory failed to ensure that the verifications of accuracy for urine creatinine, pH, and specific gravity examinations were performed at least twice annually, as required for tests not included in subpart I from 04/06/2021 to the date of the survey. Findings include: 1. On the day of the survey, 06/28/2023 at 11:32 am, the laboratory could not provide documentation that the verification of accuracy for urine creatinine, pH, and specific gravity examinations were performed on Thermo Fisher Indiko Plus analyzer at least twice annually from 04/06/2021 to the date of the survey. 2. TP #1 and TP #2 confirmed the findings above on 06/28/2023 around 12:30 pm.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on review of the Pennsylvania Department of Health (PA DOH) proficiency testing (PT) records and interview with testing personnel #1 (TP) and TP #2, the laboratory director (LD) failed to ensure that 2 of 3 PA DOH PT events for drugs of abuse testing were reviewed by they appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action in 2022. Findings include: 1. On the date of the survey, 06/28/2023 at 10:26 am, the laboratory could not provide documentation that the following 2 of 3 PA DOH PT results were reviewed and assessed by the LD for drugs of abuse tesing in 2022: - Event 2 in 2022 for Drugs of Abuse from the State of Pennsylvania - Event 3 in 2022 for Drugs of Abuse from the State of Pennsylvania 2. TP #1 and #2 confirmed the findings above on 06/28/2023 around 11:30 am.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on review of Quality Assessment (QA) records and interview with testing personnel #1 (TP) and TP #2, the laboratory director failed to ensure quality assessment (QA) programs were maintained and documented to assure the quality of laboratory services provided for 4 of 4 quarters in 2021 and 1 of 2 quarters in 2023. Findings include: 1. On the day of survey, 06/28/2023 at 10:28 am, the laboratory

could not provide documentation of their quality assessment activities performed for 4 of 4 quarters in 2021 and 1 of 2 quarters in 2023. 3. TP #1 and TP #2 confirmed the findings above on 06/28/2023 around 12:30 pm.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the laboratory personnel report (CMS-209), personnel credentials, competency assessment (CA) records, and interview with testing personnel #1 (TP) and TP#2, the technical consultant (TC) failed to evaluate the competency of 4 of 4 testing personnel (TP) that performed toxicology and chemistry testing in 2021, and 2022. Findings include: 1. On the day of the survey, 6/28/2023 at 10:02 am, record review revealed the TC failed to perform CA assessments on the following TP that performed drug screen analysis on the Thermo Fisher Indiko Plus analyzer in 2021 and 2022: - 3 of 4 TP in 2021 (CMS 209 personnel #2, #3, #4) - 3 of 4 TP in 2022 (CMS 209 personnel #2, #3, #4) 2. Further review of CA records and interview with TP #1 and TP #2 on 06/28/2023 at 10:02 am, revealed that TP #2 performed the competency assessments for 1 of 4 TP (CMS 209 TP #1) that performed drug screen analysis on the Thermo Fisher Indiko Plus analyzer in 2022 and 2023 3. Review of personnel credentials provided on the date of the survey, revealed TP #1 has a high school diploma, which does not meet the minimum educational qualifications (493.1411) to perform technical consultant responsibilities for moderate complexity testing in toxicology and chemistry. 4. TP #1 and TP #2 confirmed the findings above on 06/28/2023 around 12:30 pm.