

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2138868	(X3) Date Survey Completed 12/20/2019
Name of Provider or Supplier Naspac1, Llc - Cherry Hill	Street Address, City, State 1601 Kings Highway North, Cherry Hill, 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
D5305	<p>TEST REQUEST CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Test Requisitions (TR) and interview with the General Supervisor (GS), the laboratory failed to ensure that TR included all relevant and necessary information for accurate and reliable testing and reporting from March 2019 to the date of survey. The finding includes: 1. A review of 26 TR revealed 14 were missing specimen validation. 2. The GS confirmed on 12/20/19 at 12:50 pm that all relevant and necessary information was not on the TR.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,</p>

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:

a) Based on surveyor review of the Procedure Manual (PM), and interview with the General Supervisor (GS), the laboratory failed to have an accurate Quality Control Procedure for Toxicology tests run on the AB Sciex analyzer from March 2019 to the date of survey. The findings include: 1) The QC procedure SOP#425-001 found in the PM was written for Synergy Laboratories. 2) The PM stated "Urine test results are the only results that can be released greater than the linear range." 3) The GS confirmed on 12/20/19 at 11:05 am the laboratory failed to have an accurate QC procedure. b) Based on surveyor review of the PM and interview with the GS, the laboratory failed to have a procedure for validating reagents, mobile phases and standards used for Toxicology tests from March 2019 to the date of the survey. The GS confirmed 12/20 /19 at 11:00 am that the laboratory did not have the above mentioned procedures.

D5413

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)**

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM), Temperature Logs (TL) and interview with the General Supervisor (GS), the laboratory failed to define an acceptable Temperature Range (TR) for the refrigerator where reagents for Toxicology tests were stored from March 2019 to the date of survey. The findings include: 1. A review of the TL revealed an acceptable TR to be between 0 and 5 degrees Celsius (C) but the procedure manual stated TR must be between 2-8 C. 2. The Refrigerator was out of range 92 days out of 96 days from July thru December 2019. 3. Approximately 100 Toxicology tests were performed each day. 4. The GS confirmed on 12/20/19 at 9:30 am that the laboratory did not define an appropriate Refrigerator TR.

<p>D5415</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the Quality Control material and interview with the General Supervisor (GS), the laboratory failed to put lot numbers, prepared and expiration dates on all controls, calibrators, and internal standards used for urine Toxicology tests performed on the AB Sciex analyzer from March 2019 to the date of survey. The GS confirmed on 12/20/19 at 1:00 pm the laboratory failed to properly label the above mentioned material.</p>
<p>D5423</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specifications (PS) and interview with the General Supervisor (GS), the laboratory failed to have complete PS for Toxicology tests performed on the AB Sciex from March 2019 to the day of the survey. The findings include: 1. A review of the PS revealed the laboratory did not establish performance characteristics as follows: a. The validation of the hydrolysis control did not include validation of: i. Optimal Enzyme Concentration ii. Temperature of the Heat Block iii. Time on the Heat Block b. No source from Clinical Scientific Literature was available to support PS. c. Method comparison studies were not performed. d. Analytical Sensitivity was not established for all parameters at 20% per Clinical Scientific Literature. 2. The GS confirmed on 12/20/19 at 1:00 pm that the Laboratory Director did not ensure that PS were completed.</p>
<p>D5447</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different</p>

concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records and interview with the General Supervisor (GS), the laboratory failed to perform and document of two levels the Hydrolysis control on each day of patient testing for Toxicology tests from March 2019 to the date of the survey. 1. A review of the work records revealed the laboratory failed to document a Negative Hydrolysis control each day patient samples were run. 2. Approximately 100 patients were run per day 3. The GS confirmed on 12/20/19 at 1:30 pm that two levels of QC were not performed every day of patient testing.

D5467

CONTROL PROCEDURES

CFR(s): 493.1256(d)(9)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual, observation of Calibrators, Controls and interview with the General Supervisor (GS), the laboratory failed to prepare control and calibrator material from different lot numbers of standards for Urine Toxicology confirmation tests from March 2019 to the date of the survey. The GS confirmed 12/20/19 at 1:40 pm that the laboratory did not use different lot numbers to prepare calibrators and controls.

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(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 accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records and interview with General Supervisor (GS), the laboratory failed to take corrective action when controls were out of range for Toxicology Testing on the AB Sciex on 9/30/19. The findings include: 1. A review of the QC records revealed QC was out of range as stated below: a. Oxycodone - two out of four level 3 QC, and one out four level 2 QC. b. Noroxycodone - three out of three level 3 QC. c. Gabapentin - two out four level 2 QC. 2. Approximately 100 patients were run during the above mentioned time frame. 3. The GS confirmed on 12/20/19 at 12:50 pm that corrective action on failed QC was not performed.

D5805

TEST REPORT

CFR(s): 493.1291(c)

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.

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 report Toxicology tests results accurately from March 2019 to the date of survey. The finding includes: 1. The laboratory did not have the following statement on the FR "The performance characteristics of this test were determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration". 2. The GS confirmed on 12/20/19 at 11:45 am that Toxicology tests were not reported accurately.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Final Report (FR) and interview with the Technical Supervisor (TS), the laboratory failed to identify problems on the FR for Toxicology tests performed on the AB Sciex from March 2019 to the date of the survey. The findings include: 1. 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) cut off in the PM was 50 but on the FR it was 100. 2. The GS confirmed on 12/20/19 at 1:30 pm the the laboratory did not identify problems on the FR.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Performance Specification (PS) records and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to ensure that PS were adequate to perform toxicology tests on the AB Sciex analyzer from March 2019 to the date of survey. The findings include: 1. There was no evidence of LD review of PS. 2. The criteria for linearity stated "A calibration curve consisting of 6 calibration points at designated concentrations will be prepared five

times separately. The curve will be linear for weighted 1/X for all analytes. Acceptance: r2 value of >.98" but a review of the PS revealed: a. Midazolam Curve 4 r2 = .96 b. Curves 1,3,4 and 5 for Norbuprenorphine were not calculated. c. Cyclobenzaprine curve 3 and 4 r2 = .97 d. Methadone curve 3 r2 = .97 3. The stability study was not preformed past seven days. 4. The GS confirmed on 12/20/19 at 11:30 am the LD failed to ensure PS were adequate.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure 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 surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the Laboratory Director failed to ensure that the 2019 PT events A and B for toxicology performed with the College of American Pathologists were reviewed by appropriate staff. The GS confirmed on 12/20/19 at 11:45 am that the LD did not ensure all PT reports were reviewed by appropriate staff.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must 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 Records (PR) and interview with the General Supervisor (GS), the Laboratory Director failed to ensure that the education record for one of three testing personnel was available from March 2019 to the date of the survey. The GS confirmed on 12/20/19 at 10:00 am that all education records were not available.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual (PM) and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to establish a

Competency Assessment (CA) procedure with all the required elements for Testing Personnel from March 2019 to the date of survey. The GS confirmed on 12/20/19 at 10:00 am that a CA procedure was not established.

D6179

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1495(b)(5)

Each individual performing high complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, clinical consultant, or director.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Quality Control (QC) records and interview with the General Supervisor (GS), the Testing Personnel failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the AB Sciex analyzer from March 2019 to the date of the survey. The GS confirmed on 12/20/19 at 12:45 pm that trends and shifts were not reviewed.