

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0894713	(X3) Date Survey Completed 05/14/2025
Name of Provider or Supplier Rnj Services Inc	Street Address, City, State 35-37 Progress St, Edison, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records, Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to follow its policies for assessing the competency of Testing Personnel (TP) from 1/1/24 to 5/14/25. The findings include: 1. There was no documented evidence CA was performed on TP # 1 in calendar year 2024. 2. The LD confirmed on 5/14/25 at 2:30 pm, the laboratory failed to follow its policies for assessing the competency of TP in calendar year 2024.</p>
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 (PT) records and interview with the Laboratory Director (LD), it was revealed that the laboratory failed to review PT performance codes "See note [42]" (No credit assigned due to absence of response) results obtained for PT performed with the College of American Pathologists (CAP) for Immunnoglobulin E, event K-A 2024 Ligand-General. The findings include: 1. K-A 2024 Ligand-General samples K-01,02,03,04,05 had coded results for see note 42</p>

which were not evaluated. 2. The LD confirmed on 5/13/25 at 11:00 am, the laboratory did not evaluate coded results for PT results obtained for the above mentioned PT event.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on surveyor review of the Proficiency Testing (PT) records and interview with the LD, the laboratory failed to verify the accuracy of all not graded results for PT events for Antibiotic Resistance Genes (ABR) performed on the Quantstudio 12K Flex RTPCR with the American Proficiency Institute (API) from 1/1/23 to 12/31/24. The findings include: 1. Review of ABR PT records revealed the laboratory received not graded results from API due to "no appropriate peer group." 2. There was no documented evidence the laboratory evaluated all not graded results for ABR PT events 1, 2, and 3 in calendar years 2023 and 2024. 3. The LD confirmed on 5/14/25 at 1:20 pm, the laboratory failed to verify the accuracy of all not graded PT scores from API.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM), Proficiency Testing (PT) records and interview with the Laboratory Director (LD)), the laboratory failed to verify the accuracy and reliability of Urinary Tract Infection (UTI) testing performed on the Quantstudio 12k Flex from 1/1/23 to 12/31/24. The finding includes: 1. Surveyor review of PT records revealed all organisms tested by the laboratory were not included in PT events 1, 2 and 3 in 2023 and 2024 performed with the American Proficiency Institute (API). 2. The following organisms were not verified for accuracy twice annually on the Quantstudio 12k Flex analyzer: a) Actinobaculumchaalii b) Alloscardovia omnicolens c) Candida auris d) Corynebacterium reigelii e) Enterobacter Aerogenes f) Pantoea Agglomerans g) Viridians Strep Group 3. The LD confirmed 5/14/25 at 1:10 pm, the laboratory did not verify the accuracy of all oragnsims performed on the Quantstudio 12k Flex.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or

examining specimens.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM), the lack of Quality Control Records (QCR) and interview with the General Supervisor (GS), the laboratory failed to follow the PM for "Quality Control protocol" and "Evaluation Of Quality Control Results" from 4/29/19 to 5/13/25. The findings include: 1. The PM stated "Quality Control protocol", "5. If control results and/or instrument checks are not within acceptable limits, the corrective action taken should be fully documented by the technologist after following standard protocols for the instrument and method. The supervisor or designee will be notified of any unacceptable control or patient result as well as any instrument/equipment problem and corrective action taken." a) There was no documented corrective action for any subspecialty when QC failed and was rerun. 2. The PM stated "Quality Control protocol", "6. The supervisor or designee will review all Quality Control (QC) data, instrument function check and temperature charts on a daily and weekly bases" a) There was no documented evidence that QC data was reviewed weekly. 3. The PM stated "Quality Control protocol", "8. New lots must be tested in parallel with the old lot for 2-3 days before being placed in service" a) There was no documented evidence the above mentioned procedure was performed. 4. The PM stated "Evaluation Of Quality Control Results" "Print out monthly L-J reports to be reviewed by the director" a) There was no documented evidence the above mentioned procedure was performed. 5. The GS confirmed on 5/13/25 at 12:30 pm that the laboratory did not follow the PM.

D5415

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

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on surveyor observation of Quality Control (QC) material in use, review of the Control Kits Manufacturers Package Insert (MPI) and interview with the General supervisors (GS), the laboratory failed to put open and expiration dates on QC material used for Routine Chemistry, Immunology Endocrinology, Virology and Toxicology tests from 4/29/19 to 5/14/25. The findings include: 1. The expiration date of the QC material shortens once opened. 2. The laboratory had no open and expiration dates on the following QC material: a) Imunalysis Mult-Drug low control set 1 lot E55140 b) Imunalysis Mult-Drug low control set 2 lot E55142 c) Buprenorphine Urine High control Lot E54601 d) Buprenorphine Urine Low control Lot E54600 e) cTHC urine High control Lot E55109 f) EDDP Specific Urine High control Lot E54817 g) cTHC Urine Low control Lot E55108 h) EDDP Specific Urine Low control Lot E54816 i) Tosoh Hemoglobin A1c controls Level 1 and 2 Lot 7153 j) Liquid Assayed Multiquel Lot 45960 k) Liquichek Immunology Control Lot 85750 l) Liquichek Immunoassay Plus Control Lot 100390 2. The GS confirmed on 5/14/25 at 11:45 am, the laboratory failed to put open and expiration dates on the QC material.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

A) Based on surveyor review of the Quality Control (QC) Records and interview with the General Supervisor (GS), the laboratory used expired QC material for Amphetamine testing from 4/10/25 to 5/14/25. The findings include: 1. QC material expiration date changes once opened. 2. HEIA Amphetamine Urine QC material was stable for 30 days after opening. 3. HEIA Amphetamine Urine low QC material lot # E54620 expired 4/10/25. 4. HEIA Amphetamine Urine High QC material lot # E54621 expired 4/10/25. 5. Approximately 60 patients were run per day. 6. The GS confirmed on 5/14/25 at 11:00 am that the laboratory used expired QC material. 48354 B) Based on surveyor review of Performance Specifications for the Diasorin XL 5835, and interview with the Laboratory Director (LD), the laboratory used expired calibration material for the validation of the Diasorin XL 5835 from 4/26/22 to 5/14/25. The finding includes: 1. The validation for the Diasorin XL 5835 was performed on 4/26/22. 2. Assay COV2TG kit lot # 2897 expired on 3/9/22. 3. Assay LYT kit lot # 4803 expired on 4/4/22. 4. The LD confirmed on 5/14/25 at 11:30 am, the laboratory used expired calibration material during the validation of the Diasorin XL 5835.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(g)

(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

This STANDARD is not met as evidenced by:

A) Based on surveyor review of the Manufacturer Package Insert (MPI) Lack of Quality Control (QC) records and interview with the General Supervisor (GS), the laboratory failed to perform and document a positive and negative control for Toxicology testing performed on the ImmTox 270 analyzer each day of patient testing in April 2025. The findings include: 1. There was no documented evidence the QC was run for Toxicology testing performed on the ImmTox 270 analyzer on 4/11/25 and 4/16/25. 2. Approximately 120 patients were run and reported. 3. The GS confirmed on 5/14/25 at 12:10 PM the laboratory did not perform and document quality control on each of patient testing. 48354 B) Based on the lack of Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to perform and document QC for Manual Urine Microscopic (MUM) tests on each day of patient testing from 1/24/25 to 3/14/25. The finding includes: 1. There was no documented evidence laboratory personnel performed and documented QC for MUM tests on each day of patient testing. 2. The LD confirmed on 3/14/25 at 1:30 pm, the laboratory did not perform and document QC for MUM tests. C) Based on the lack of Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to perform and document QC for Manual Differential (MD) tests using the Automated Hematek Stainer on each day of patient testing from 8 /10/24 to 3/14/25. The finding includes: 1. There was no documented evidence

laboratory personnel performed and documented QC for MD tests on each day of patient testing. 2. The LD confirmed on 3/14/25 at 1:35 pm, the laboratory did not perform and document QC for MD tests.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

This STANDARD is not met as evidenced by:

Based on the lack of Quality Control Verification (QCV) records and interview with the Laboratory Director (LD), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment used on the Vitros XT 7600, Abbot Immtox 270, Tosoh G8 and IMMULITE 2000 xpi from 4/29/19 to 5/13/25. The finding includes: 1. There were no QCV records available for review for the above mentioned analyzers. 2. The LD confirmed on 5/13/25 at 12:20 pm, the assayed values of QC material were not verified before being put into use.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on surveyor review of Quality Control (QC) records and interview with the General Supervisor (GS), the laboratory failed to document corrective action when QC failed for routine Chemistry run on the Vitro XT 7600 in July 2024. the findings include: 1. QC level 1 was run for Sodium (Na) as follows: a) Twice on 7/15/24. b) Three times on 7/22/24, 7/24/25 and 7/26/24. c) Four times on 7/25/24. 2. QC level 2 was run for Sodium (Na) as follows: a) Twice on 7/12/24, 7/15/24, 7/19/24 and 7/26/24. b) Three times on 7/22/24, 7/23/24 and 7/24/24. c) Four times on 7/25/24. 3. There was no documented evidence corrective action was taken for the above mentioned QC runs. 4. The GS confirmed on 5/14/25 at 11:15 am that corrective action was not documented.

D5783

CORRECTIVE ACTIONS

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

(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 the General Supervisor (GS), the laboratory failed to take Corrective Action (CA) when controls were out of range for Toxicology tests performed on the ImmTox 270 from April 2025 to 5/14/25. The findings include: 1. A review of the QC records for Toxicology negative controls failed Buprenorphine as follows: 4/10/25, 4/14/25 and 4/15/25. 2. A review of the QC records for Toxicology negative control failed Oxycodone on 5/7/25 3. The laboratory did not have corrective action for the above mentioned QC failures. 4. Approximately 60 patients were run and reported per day. 5. The GS confirmed on 5/14/25 at 1:30 pm that corrective action on failed QC was not performed and documented.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1299(a)

(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 Procedure Manual (PM), Final Report (FR) and interview with the Laboratory Owner (LO), the laboratory failed to have an ongoing mechanism to monitor the accuracy of calculated test results for the Laboratory Information System (LIS) to the Electronic Medical Records (EMR) from 4/29/19 to 5/14/25. The findings include: 1. The laboratory did not have procedures to monitor the accuracy of calculated test results for the LIS to the EMR. 2. The LO confirmed on 5/14/25 at 12:00 pm that the laboratory failed to have an ongoing mechanism to monitor the accuracy calculated test results.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on an interview with the Laboratory Director (LD), the LD failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from 4/29/19 to

	<p>5/14/25. 1. The LD failed to ensure that PS procedures performed for testing performed on the Vitro XT 7600 analyzer were adequate: Cross refer 6086. 2. The LD failed to ensure that the laboratory maintained the Quality Control (QC) program: Cross refer 6093. 3. The LD failed to ensure that all necessary remedial actions are documented whenever significant deviations from the laboratory 's established performance characteristics are identified: Cross refer 6096.</p>
<p>D6086</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <p>(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Laboratory Director (LD) failed to ensure that PS procedures performed for chemistry testing performed on the Vitro XT 7600 analyzer were adequate from 9/26/23 to 5/13/25. The findings include: 1. There was no documented evidence that a normal patient range study was performed prior to the start of patient testing. 2. The LD confirmed on 5/13/25 at 11:15 am that PS records were not adequate.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p> <p>This STANDARD is not met as evidenced by: A) Based on surveyor review of the Quality Control (QC) records and interview with the General Supervisor (GS), the Laboratory Director failed to ensure that the laboratory maintained the QC program from 4/29/19 to 5/14/25. The findings include: 1.The laboratory failed to follow the Procedure Manual for "Quality Control protocol" and "Evaluation Of Quality Control Results": Cross refer 5401. 2. The laboratory failed to perform and document a positive and negative control for Toxicology testing: Cross refer 5449. 3. The laboratory failed to verify commercially assayed QC material with each new lot and/or shipment used on the Vitros XT 7600, Abbot Immtox 270, Tosoh G8 and IMMULITE 2000 xpi: Cross refer 5469. 48354 B) Based on survey review of the Procedure Manual (PM) and interview with the Laboratory Director (LD), the LD failed to ensure the quality control program was established to assure the quality of laboratory services using the Beyond Care Quality Control Monitor (BCQM) from 2/1/23 to 5/14/25. The finding includes: 1. The laboratory could not provide approved procedures for reviewing Quality Control (QC) using the Sysmex BCQM. 2. There was no documented evidence Continuous Calibration Verification Certificates were reviewed for the Sysmex analyzer. 3. There was documented evidence Insight reports were reviewed for the Sysmex analyzer. 4. The LD confirmed on 3/14/25 at 11:00 am, the QC program for the laboratory using the BCQM was not established.</p>
<p>D6096</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES</p>

CFR(s): 493.1445(e)(7)

(e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and

This STANDARD is not met as evidenced by:

The laboratory Director failed to ensure that all necessary remedial actions are documented whenever significant deviations from the laboratory 's established performance characteristics are identified from to 5/14/25. 1. The laboratory failed to document Corrective Action (CA) when Quality Control (QC) failed for routine Chemistry: Cross refer 5781. 2. The laboratory failed to take CA when QC was out of range for Toxicology tests: Cross refer 5783.