

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D0894713	<b>(X3) Date Survey Completed</b> 04/29/2019
<b>Name of Provider or Supplier</b> Rnj Services Inc	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to retain Activated Partial Thromboplastin Time QC printouts for the month of January 2019. The LD confirmed on 4/29/19 at 11:30 am that QC printouts were not available for review.</p>
<b>D5309</b>	<p><b>TEST REQUEST</b> CFR(s): 493.1241(e)</p> <p>If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.</p> <p>This STANDARD is not met as evidenced by: Based on review of data entry audit trail in the computer, test requisitions and interview with the Owner, the laboratory failed to ensure that information from the patients' requisitions were transcribed accurately into the laboratory information system from 4/15/15 to the date of the survey. The findings include: 1. Accessioning Procedure stated 'Accuracy of the accessioning has to be double checked by the different accessionist at the end of shift' but there was no documentation to substantiate the procedure was followed. 2. The Plan of Correction (POC) of 4/15/15 stated 'Day time accessionist reviews all of the requisitions for accuracy' but there was</p>

	<p>no documented evidence . 3. The POC of 6/14/17 stated 'The laboratory will implement manual data entry verification process' and the laboratory director and quality system manager will monitor the effectiveness but it was not done. 4. The owner confirmed on 4/25/19 at 1:00 pm that the laboratory did not ensure information was transcribed accurately. NOTE: This is the repeat citation in last two surveys.</p>
<p><b>D5401</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to follow their Quality Assessment (QA) procedure from 6/14/17 to the date of a the survey. The findings include: 1 The QA procedure stated: a. The laboratory will use a tracer form to audit the laboratory. b. The laboratory reviews 12 patient results daily 2. There was no documented evidence the laboratory followed the QA procedures mentioned above. 3. The LD confirmed on 4/29/19 at 1:20 pm that the laboratory did not follow the QA procedure.</p>
<p><b>D5411</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Reagent Package Insert (RPI) and interview with the Owner, the laboratory failed to follow RPI instructions for Total Immunoglobulin E (TIE) test performed on the Adiva Centaur XP analyzer for maintaining specimen integrity from March 2019 to the date of survey. The findings include: 1. The RPI stated "Storage: 3 days at 2-8 degrees Celsius or 6 months at -20 degrees Celsius" but the laboratory did not ensure that TIE specimens were frozen when assayed after 3 days. 2. The laboratory batch specimens for TIE. Specimens for TIE were run Tuesdays and Thursdays. 3. Specimens received on Friday were run four days after collection and were not frozen. 4. Approximately 5 patients run and reported. 4. The Owner confirmed on 4/29/19 at 11:00 am that RPI instruction was not followed.</p>
<p><b>D5415</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> 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>

This STANDARD is not met as evidenced by:  
Based on surveyor review of Manufactures Package Insert, observation of the Quality Control (QC) material, and interview with the Testing Personnel (TP), the laboratory failed to put new expiration dates on Urinalysis Sediment Controls from May 2018 to the date of survey. The findings include. 1. The MPI for UP II Controls stated that QC material for Urine Particle test expires 30 days after opening if stored at 2 to 8 degrees Celsius. 2. The TP was not aware that QC material expired 30 days after opening. 3. The TP#3 on CMS form 209 confirmed on 4/29/19 /19 at 11:00 am the laboratory failed to put new expiration dates on the control material.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on lack of Performance Specification (PS) records and interview with the Laboratory Director (LD), the laboratory failed to ensure that PS procedures for Dehydroepiandrosterone sulfate and Antistreptolysin O were performed on the Siemens Advia Centaur XP and Vista Dimensions respectively from September 2017 to the date of survey. The LD confirmed on 4/25/19 at 11:15 am that PS were not performed.

**D5469**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (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 Laboratory Director (LD), the laboratory failed to verify that the assayed QC materials were within the acceptable ranges before they were put into use for tests

performed on the Adiva Centaur XP, 2 Vistas, and Sysmex XT 4000i from 6/14/17 to the date of survey. The LD confirmed on 4/29/19 at 1:00 pm that the laboratory did not verify QC materials.

**D5807**

**TEST REPORT**  
CFR(s): 493.1291(d)

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.

This STANDARD is not met as evidenced by:  
Based on surveyor review of Final Report, Performance Specification (PS) records and interview with the Laboratory Director (LD), the laboratory failed to have an accurate patient reference range for Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) from 6/11/18 to the date of survey. The findings include: 1. The PS records had PT range of 9.5 - 12.1 but the FR had 9.8 - 12.0 which was previous analyzer range. 2. The PS records of APTT had 23.90 - 30.70 but the FR had 24.7 - 33.7 which did not have a source for range. 3. The LD confirmed on 4.29.19 at 11:00 am that FR did not have accurate reference range.

**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:  
a) Based on surveyor review of the Performance Specification (PS) records and interview with the Laboratory Director (LD) the Laboratory Director (LD) failed to ensure that PS were adequate to perform Urine Sediment tests on the Sysmex UF-1000i from May 2018 to the date of survey. The findings include: 1. Method comparisons were not comparable. One was done by a manual method and the thereon by two stains of Urine flow cytometry with fluorescent dye method. 2. The method comparison for bacteria had a 50% disagreement percentage. 3. The LD confirmed on 4/24/2019 at 11:00 am the laboratory did not ensure PS were adequate. b) Based on surveyor review of the PS records and interview with the LD, the LD failed to ensure that PS were adequate to perform Special Chemistry tests on the Siemens Adiva Centaur XP from September 2017 to the date of survey. The findings include: 1. Linearity was not completed for Sex Hormone Binding Globulin, Testosterone II, and N-terminal-pro-BNP. 2. The LD confirmed on 4/25/2019 at 11:00 am the laboratory did not ensure PS were adequate.