

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2215667	<b>(X3) Date Survey Completed</b>  12/11/2024
<b>Name of Provider or Supplier</b>  Usa Vascular Ctr Of New Jersey Llc - Orange	<b>Street Address, City, State</b>  272 Main Street, Orange, 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>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</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 Coordinator (LC) the laboratory lacked the work records for all American Proficiency Institute (API) PT events in the calendar years 2023 and 2024. The LC confirmed on 12/11/24 at 11:35 am work records were not available for all PT events in the calendar years 2023 and 2024.</p>
<b>D3009</b>	<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 review of the laboratories NJ State License, Proficiency Testing</p>

	<p>(PT) and interview with the State of New Jersey Proficiency Provider Program lead, the Laboratory Director (LD) failed to be in compliance with New Jersey Administrative code N.J.A.C. 8:44-2.5(b)3. The finding includes: 1. N.J.A.C. 8:44-2.5 (b)3. states Laboratories shall: iii. Maintain records of all proficiency testing results in surveys in which they participate and make such records, including results, interpretations and cumulative performance data routinely available to the Department of Health and Senior Services. 2. The LD failed to make PT Hematology and Routine Chemistry data routinely available to the Department of Health and Senior Services.</p>
<p><b>D3031</b></p>	<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 surveyor review of the Quality Control (QC) records, Work Records (WR) and interview with the Laboratory Coordinator (LC), the laboratory failed to retain all QC records and WR for tests performed on the iStat analyzer from 3/2/21 to the date of survey. The finding includes: 1. The instrument printouts for QC and patient WR where not available at the time of survey. 2. The LC confirmed on 12/11/24 at 11:00 am that the all QC and WR records were available at the time of survey.</p>
<p><b>D5215</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(b)(2)</p> <p>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).</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 Coordinator (LC), the laboratory failed to verify the accuracy of Hematology and Routine Chemistry PT results obtained in 2024 Chemistry - Core - 2nd event with the American Proficiency Institute (API). The findings include: 1. There was no evidence of the laboratory verified the accuracy of Hematology and Routine Chemistry analytes when the laboratory failed to submit PT results prior to the submission deadline. 2. The LC confirmed on 12/11/24 at 10:40 am the accuracy of PT results were not verified</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>

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Procedure Manual (PM), and interview with the Laboratory Coordinator (LC), the laboratory failed to follow all procedures for "Laboratory Quality Assurance Plan" "B. Quality Control (AC) Assesment" from 3/5 /21 to the date of survey. The findings include: 1. There the procedure "Laboratory Quality Assurance Plan" "B. Quality Control (AC) Assesment" stated "1. Quality Control records will be reviewed monthly by the laboratory director". 2. There was no documented evidence that the aforementioned procure was followed. 3. The LC confirmed on 12/11/24 at 10:30 am that the laboratory did not follow the PM.

**D5407**

PROCEDURE MANUAL  
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Individualized Quality Control Plan (IQCP) and interview with the Laboratory Coordinator (LC), the laboratory failed to have an approved, signed and dated IQCP procedures by the Laboratory Director (LD) and was not complete from 9/3/21 to the date of the survey. The findings include: 1. A review of the IQCP plan revealed that there was no evidence of review, approval or signature of the LD on the IQCP. 2. A Quality Assessment (QA) plan did not include frequency of review of QA. 3. The LC confirmed on 12/11/24 at 11:15 am that IQCP plan was not signed by LD and did not include frequency of review of QA.

**D5411**

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

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.

This STANDARD is not met as evidenced by:  
Based on surveyor review of analyzer Quality Control Records (QC), review of the Manufacturer QC Assayed Value Sheet (MQCAVS) and interview with the Laboratory Coordinator (LC), the laboratory failed to follow the MQCAVS for Hematology and routine chemistry testing performed on the iStat from 1/8/24 to the date of survey. The findings include: 1. The MQCAVS for level 1 lot #301168 did not match the QC records as follows: a) The MQCAVS had Chloride (CL) listed as 70-80 mmol/L the QC records had 69-79 mmol/L. b) The MQCAVS had Ionized calcium (iCA) listed as 0.78-0.94 mmol/L the QC records had 0.74-0.90 mmol/L. c) The MQCAVS had Creatine (creat) listed as 2.6-4.2 mmol/L the QC records had 2.7-4.3 mmol/L. d) The MQCAVS had Hematritc (Hct) listed as 19-25 mmol/L the QC records had 17-23 mmol/L. 2. The MQCAVS for level 3 lot #321171 did not match the QC records as follows: a) The MQCAVS had Sodium (NA) listed as 153-165 mmol/L the QC records had 156-161 mmol/L 3. The LC confirmed on 12/11/24 at 11:40 am, the laboratory failed to follow the MQCAVS .

**D5447**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different 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, Individual Quality Control Plan (IQCP) and interview with Laboratory Coordinator (LC), the laboratory failed to perform and document controls each month of patient testing for Hematology and Routine Chemistry tests performed on the iSTAT analyzer in June of 2024. The findings include: 1. The IQCP state QC will be run once a month.. 2. There was no documented evidence that QC was run in June 2024. 3. The LC confirmed on 12/11 /24 at 12:00 pm that QC was not done in June 2024.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(a)(c)

(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.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual and interview with Laboratory Coordinator (LC), the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 03/05/21 to 12/11/24. The finding includes: 1. The laboratory lacked a Quality Control Verification (QCV) procedure for all specialties performed by the laboratory. 2. The LC confirmed on 12/11/24 at 11:45 am that the laboratory failed to have a QCV procedure for all specialties.

**D5801**

**TEST REPORT**

CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Final Report (FR) Work Records (WR), Electronic Medical Records (EMR) and interview with the Laboratory Coordinator (LC) the

laboratory failed to ensure test results were reported accurately for Hemoglobin (Hb) testing into the EMR on 9/19/2022. The finding includes: 1. A review of eight EMR entries revealed one patient had results as follows: a) Hb on the WR was 13.3 g/dL but the FR had 15 g/dL. 2. The LC confirmed on 12/11/24 at 11:30 am that the laboratory did not ensure test results were accurately recorded in the EMR.

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) 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 the lack of Performance Specification (PS) records and interview with the Laboratory Coordinator (LC), the Laboratory Director (LD) failed to ensure that PS was performed on iStat analyzer from 3/5/21 to the date of survey. The LC confirmed on 12/11/24 at 10:35 am that PS was not performed.