

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2062622	(X3) Date Survey Completed 07/09/2025
Name of Provider or Supplier Nshoa	Street Address, City, State 1500 Route 112 Building 1 1st Floor, Port Jefferson Station, NY	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's i-STAT policy and procedure manual as well as interview with the Quality Assurance Coordinator (QAC), the current Laboratory Director (LD) failed to approve, sign, and date the revised laboratory policy and procedure manual. FINDINGS: 1. There was no documented LD approval and date of approval of the i-STAT policy and procedure manual implemented March 21, 2025. 2. The QAC confirmed the findings on July 9, 2025, at approximately 10:30 A.M.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of analyzer patient test results as well as interview with the QAC, the</p>

laboratory failed to indicate test result positive patient identification including either patient's name and identification number or unique patient identifier. FINDINGS: 1. There was no documentation of patient name and unique identifier on the Siemens Clinitek Urine Analysis test result printouts. 2. Approximately three hundred patients were tested from 2023 through the survey date. 3. The QAC confirmed the findings on July 9, 2025, at approximately 11:00 A.M.

D5813

TEST REPORT
CFR(s): 493.1291(g)

(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

This STANDARD is not met as evidenced by:
Based on review of patient test logs, current Standard Operating Procedures (SOPs), as well as interview with the QAC, the laboratory failed to immediately alert the test provider when any test resulted in an alert value. FINDINGS: 1. There was no documentation of positive test results on the Abbott ID-Now COVID-19 patient test log. 2. This is contrary to the current, approved SOPs which instruct, "All positive patient results must be notified to doctor/nurse practitioner." 3. Approximately fifty COVID-19 patients tested positive from 2023 through the survey date. 4. The QAC confirmed the findings on July 9, 2025, at approximately 11:30 A.M.