

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1079580	<b>(X3) Date Survey Completed</b>  11/27/2023
<b>Name of Provider or Supplier</b>  Statmed Quick Quality Clinic At North Pinellas	<b>Street Address, City, State</b>  27001 Us Hwy 19 N Ste 1033b, Clearwater, FL	
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>D0000</b>	An announced onsite CLIA recertification survey was conducted at Statmed Quick Quality at North Pinellas on 11/27/23. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D2007</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the Laboratory Personnel Report, the laboratory procedure manual, proficiency testing (PT) records and staff interview, the laboratory failed to have three (#D, #E, #F) of four testing personnel (#C - #F) rotate through performance of PT in the specialty of Chemistry Core for six out of six events (2022 1st, 2nd, 3rd and 2023 1st, 2nd, and 3rd) and Hematology/Coagulation for 4 out of 4 events (2022 1st, 2nd and 2023 1st and 2nd) for 2 out of 2 years reviewed (2022-2023). Findings included: Record review of the CMS 209 form, Laboratory Personnel Report, signed by the Laboratory Director on 11/25/2023 showed the laboratory had 4 testing personnel (#C, #D, #E, and #F). Record review of the Laboratory Proficiency Testing procedure (signed by the Laboratory Director on 10/06/21) revealed "The Proficiency Testing event should be assigned to the testing personnel, rotating personnel to assess competency." Review of the PT records from American Proficiency Institute (API) showed all PT attestation forms were signed by Testing Person #C as the "Person Performing Test" for Chemistry Core for 2022 1st, 2nd, 3rd and 2023 1st, 2nd, and 3rd events and Hematology/Coagulation for 2022 1st, 2nd and 2023 1st and 2nd events. No attestation forms for Testing Person #D, #E, and #F were present. On 11/27</p>

/23 at 11:00 AM, the Technical Consultant confirmed that the laboratory had not been rotating testing personnel to perform Chemistry Core and Hematology/Coagulation proficiency testing.