Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1079580	10/02/2025
Name of Provider or Supplier	**Street Address, City, State**	
Statmed Quick Quality Clinic At North Pinellas	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted at Statmed Quick Quality Clinic at North Pinellas on 10/02/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D2000 493.801 Condition: Enrollment and Testing of Proficiency Samples D6000 493.1403 Condition: Moderate Complexity Laboratory Director
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and interview, the Hematology proficiency samples failed to be examined or tested by personnel who routinely perform the testing in the laboratory from 2nd 2024 Hematology event to 2nd 2025 Hematology event. (See D2007)
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) 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.

	This STANDARD is not met as evidenced by: Based on record review and interview, the Hematology proficiency samples failed to be examined or tested by personnel who routinely perform the testing in the laboratory from 2nd 2024 Hematology event to 2nd 2025 Hematology event. This is a repeat citation from the 11/27/2023 recertification survey. Findings included: 1. The CMS-209 Laboratory Personnel Report signed by the Laboratory Director on 10/2 /2025 listed four Testing Personnel (TP-A, TP-B, TP-C, and TP-D). 2. The accepted Plan of Correction signed by the Laboratory Director on 12/12/2023 for the recertification survey conducted 11/27/2023 stated the Technical Consultant (TC) would be the responsible person to ensure proficiency samples would be rotated and /or assigned with a correction date of 12/15/2023. 3. The Attestation Statement for 2nd 2024 Hematology event to 2nd 2025 Hematology event documented only TP-A performed the proficiency testing. The first event of 2024 was performed by staff no longer employed by the laboratory. 4. The TC on 10/2/2025 at 11:36 a.m. confirmed although TP-A was the primary testing personnel the TP-B, TP-C, and TP-D routinely performed patient testing.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure Hematology proficiency samples were examined or tested by personnel who routinely performed the testing in the laboratory from 2nd 2024 Hematology event to 2nd 2025 Hematology event. (See D6016), the Laboratory Director failed to document being onsite at least every six months with evidence of performing activities that were part of the laboratory director responsibilities from 2/1/2025 to 10/2/2025. (See D6005), and the Laboratory Director failed to ensure that one (TP-D) of four (TP-A,TP-B, TP-C, and TP-D) Testing Personnel had documentation of demonstrating that they could perform all testing operations reliably to provide and report accurate results, prior to testing patients' specimens. (D6029)
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to document being onsite at least every six months with evidence of performing activities that were

	part of the laboratory director responsibilities from 2/1/2025 to 10/2/2025. Findings included: 1. Review of the Laboratory Director on-site review documented the only onsite Laboratory Director visit was performed on 2/1/2025. The review was a checklist which did not document when he signed in, who he interacted with, or what activities were performed. 2. The Technical Consultant on 10/2/2025 at 1:20 p.m. confirmed the only onsite Laboratory Director visit was performed on 2/1/2025. The review was a checklist which did not document when he signed in, who he interacted with, or what activities were performed.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure the Hematology proficiency samples were examined or tested by personnel who routinely perform the testing in the laboratory from 2nd 2024 Hematology event to 2nd 2025 Hematology event. (See D2007)
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that one (TP-D) of four (TP-A,TP-B, TP-C, and TP-D) Testing Personnel had documentation of demonstrating that they could perform all testing operations reliably to provide and report accurate results, prior to testing patients' specimens. Findings included: 1. The CMS-209 Laboratory Personnel Report signed and dated by the Laboratory Director on 10/2/2025 listed four Testing Personnel (TP-A,TP-B, TP-C, and TP-D). The Technical Consultant (TC) stated on 10/2/2025 at 10:48 a.m. that TP-D started at the laboratory on 5/27/2025. 2. TP-D's employee records did not include documentation of evaluation of performance to test and report accurate results, prior to testing patients' specimens. 3. The TC confirmed on 10/2/2025 at 10:48 a.m., there was no documentation for TP-D of evaluation to perform patient testing. 4. Review of patient chemistry and hematology records documented TP-D performed chemistry testing on 6/4/2025 and hematology testing on 5/21/2025. The TC documented evaluation of TP-D on 10/1/2025.