Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D1079580	**(X3) Date Survey Completed** 05/13/2019
Name of Provider or Supplier Statmed Quick Quality Clinic At North Pinellas	**Street Address, City, State** 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 05/13/19. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D6063-Laboratory Testing Personnel 493.1421
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 record review and interview with Testing Person #B the laboratory failed to establish their own QC (quality control) target values for each new lot number for 2 out of 2 years (2017-2019) reviewed for the CBC (Complete Blood Count) analyzer. Findings Included: Review of the CBC controls manufacturer's instructions (Revision 13) revealed that "Assay means are not intended for use as analyzer QC file target values. For effective QC, each laboratory should set its own target values. Sysmex recommends that laboratories establish their own QC target values for each new lot number by collecting at least 10 data points per control level over 5 days." Review of

	QC records for the CBC analyzer revealed no lot to lot comparisons performed. Interview on 05/13/19 at 3:50 PM with Testing Person #B, confirmed that the laboratory had not performed lot to lot comparison when a new lot was opened.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review and interview with Testing Person #B the laboratory failed to verify the education of 3 (#C, #E, and #G) out of 8 (#A, #B, #C, #D, #E, #G, #H, and #I) Testing Personnel reviewed (See D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review and interview with Testing Person #B the laboratory failed to verify the education of 3 (#C, #E, and #G) out of 8 (#A, #B, #C, #D, #E, #G, #H, and #I) Testing Personnel reviewed. Findings Included: Review of the CMS 209, Laboratory Personnel Report, signed by the Laboratory Director on 05/03/19 revealed Employee #C, #E, and #G held the position of Testing Personnel (TP) for moderate complexity. Review of personnel files revealed no documentation of education for Testing Person #C, #E, and #G. Interview on 05/13/19 at 4:30 PM with Testing Person #B, confirmed that the laboratory only had licenses, but not proof of education.