

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2228682	(X3) Date Survey Completed 12/06/2021
Name of Provider or Supplier Statmed Quick Quality Clinic At North Pinellas Llc	Street Address, City, State 1714 Sw 17th Street, Ocala, 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
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview the laboratory failed to monitor the eyewash per their policy since received their eyewash on 10/19/2021 (See D3011).</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview the laboratory failed to follow manufacturer's instructions (MI) for Complete Blood Count (CBC) controls from 11/15/2021 to 11/30/2021. Findings Included: During a tour of the laboratory on 11/24</p>

/21 at 3:45 PM Low, Normal, and High CBC controls (Lot 1306) were observed with an open date of 11/10/2021. MI for the 3 levels of controls state "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8 C after being re-capped." Interview on 11/30/2021 at 1:31 PM the Office Manager confirmed that the controls with the open date of 11/10/2021 were still in use (20 days later).