

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0885144	(X3) Date Survey Completed 05/23/2018
Name of Provider or Supplier Stockton Pregnancy Control Med Clinic	Street Address, City, State 3209 N California St, Stockton, CA	
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
D2153	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(a)</p> <p>Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing (PT) results reports, and interview with the laboratory staff, ten (10) random patient test reports reviewed from 02/02/2017 to 04/19/2018, it was determined that the laboratory failed to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory performed Rh (D) type and is enrolled in ACP Medical Laboratory Evaluation proficiency testing (PT) program (Subspecialty:ABO/RHO). b. The laboratory attained a score of 60% for Rh (D) in the 2rd PT event 2017 which was unsatisfactory analyte performance. Sample# Your Result Acceptable Response BB-6 Rh Pos Rh Pos BB-7 Rh Pos Rh Pos BB-8 Rh Pos Rh Neg BB-9 Rh Neg Rh Pos BB-10 Rh Neg Rh Neg c. The laboratory staff affirmed on 05/29/2018 (survey date) that the laboratory failed to attain a score of at least 100 percent of acceptable responses for each analyte or test in the testing event. d. The laboratory's testing declaration estimates the annual volume of Rh typing performed and reported at 3,000 tests.</p>
D6019	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) proficiency testing performance summary reports, and interview with the testing personnel, it was determined that the laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. See D2153.