

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0540794	<b>(X3) Date Survey Completed</b> 03/26/2018
<b>Name of Provider or Supplier</b> Her Medical Clinic	<b>Street Address, City, State</b> 1414 S Grand Ave Ste 400, Los Angeles, CA	
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>D2153</b>	<p><b>ABO GROUP AND D(RHO) TYPING</b> 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 third quarter (Q3-2016) of the Medical Laboratory Evaluation (MLE) proficiency testing records, random patient sampling test results and interview with the testing personnel, 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. The findings included: a. Q3-2016, MLE reported an unsatisfactory proficiency testing results of 80% for ABO and Rh group test. b. For seven (7) out of seven (7) random patient sampling test results reviewed covering period from 12/30/2016 to 2 /14/2018, the laboratory analyzed and reported patient Rh group test results. c. The testing personnel affirmed (3/26/2018, 12N), that the laboratory received the above unsatisfactory proficiency testing score of 80% for ABO and Rh group.</p>
<b>D5411</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> 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 review of the manufacturer's product insert Anti-D (Monoclonal Blend)</p>

Gamma Clone (by Slide test), the lack of documentation of control performance, random patient sampling test results and interview with the testing personnel, it was determined that the laboratory failed to follow the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for Rh grouping. The findings included: a. The laboratory is using Anti-D (Monoclonal Blend) Gamma -clone by slide method to detect Rh groups. b. Based on the manufacturer's package insert instructions: "Red blood cells known to be D-positive and D-negative for use as controls." c. For seven (7) out of seven (7) random patient sampling test results reviewed covering period from 12/30/2016 to 2/14/2018, the laboratory analyzed and reported patient Rh group test results even though positive and negative controls were not performed. d. The Laboratory has no documentation of performing and following the above instructions for the controls. e. The testing personnel affirmed (3/26/2018, 12N), that the laboratory has no documentation of control performances for positive and negative controls.

**D5449**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on review of the manufacturer's product insert Anti-D (Monoclonal Blend) Gamma Clone (by Slide test), the lack of documentation of controls performance, random patient sampling test results and interview with the testing personnel, it was determined that the laboratory failed to at least once a day patient specimens are assayed or examined a qualitative procedure, to include a negative and positive control materials and must document all control procedures performed. The findings included: a. The laboratory is using Anti-D (Monoclonal Blend) Gamma -clone by slide method to detect Rh groups. b. Based on the manufacturer's package insert instructions: "Red blood cells known to be D-positive and D-negative for use as controls." c. For seven (7) out of seven (7) random patient sampling test results reviewed covering period from 12/30/2016 to 2/14/2018, the laboratory analyzed and reported patient Rh group test results even though positive and negative controls were not performed. d. The Laboratory has no documentation of performing and following the above instructions for the controls. e. The testing personnel affirmed (3/26/2018, 12N), that the laboratory has no documentation of control performances for positive and negative controls.

**D6022**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

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 and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:  
Based on review of the manufacturer's product insert Anti-D (Monoclonal Blend) Gamma Clone (by Slide test), (D 5411), the lack of documentation of control performance, (D 5449), random patient sampling test results and interview with the testing personnel, it was determined that the laboratory director failed to ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur