

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0698438	(X3) Date Survey Completed 06/16/2021
Name of Provider or Supplier Women's Health Specialists	Street Address, City, State 1469 Humboldt Rd, Ste 200, Chico, 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 proficiency testing reports for events Q2-2018 and Q2-2020 from CMS (Individual Laboratory Profile report 155, CLIA) and AAB (American Association of Bioanalysts), laboratory proficiency testing records, and patients test records; observation of Immucor Rh Typing test kits, and interview with laboratory personnel on June 16, 2021, at 1pm, it was determined the laboratory demonstrated unsatisfactory testing for Rh Typing by failing to obtain correct results for each individual proficiency test sample. Findings included: 1. The laboratory reported incorrect Negative results (*) for proficiency testing, as follows: a. Event Q2- 2018; 1 incorrect Sample ID Lab result AAB result 5 Negative *..... Positive b. Event Q2 - 2020, 2 incorrect Sample ID Lab result AAB result 7 Negative *.... Positive 9 Negative *.... Positive 2. Laboratory personnel affirmed (6/16/21 @ 1pm) the aforementioned incorrect individual laboratory results. 3. Test records documented Rh Typings were performed and reported as Negative during the timeframes of May - October 2018 and 2020, as follows: Date Patient # ----- 5/02/18 1 6/13/18 3 7/03/18 5 8/31/18 2 9/20/18 1 10/29/18 1 5/04/20 4 6/05/20 3 7/01/20 6 8/12 /20 5 9/02/20 2 4. The reliability and quality of Rh Typing performed in 2018 and 2020 could not be assured when proficiency testing failed to demonstrate satisfactory testing for individual samples. Based on the stated annual test volume of 276 (CMS116, 6/16/21), the laboratory performed approximately 49 Rh Typings each month' .</p>
D2154	ABO GROUP AND D(RHO) TYPING

CFR(s): 493.859(b)

Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing reports of overall scores for events Q2-2018 and Q2-2020 from CMS (Individual Profile report 155, CLIA) and AAB (American Association of Bioanalysts), laboratory proficiency testing records, and patients test records; observation of Immucor Rh Typing test kits, and interview with laboratory personnel on June 16, 2021, at 1pm, it was determined the laboratory demonstrated unsatisfactory testing for Rh Typing by failing to attain overall event scores of 100%. Findings included: 1. AAB and CMS reported the laboratory failed to attain overall event scores of 100%: a. Event Overall Score

----- Q2 - 2018.....80% Q2 - 2020 60% 2.

Laboratory personnel affirmed (6/16/21 @ 1pm) the aforementioned overall event scores; and thus the failures to attain 100% as required by CMS/CLIA. 3. The reliability and quality of Rh Typing performed in 2018 and 2020 could not be assured when proficiency testing failed to demonstrate overall satisfactory testing. Based on the estimated annual test volume (CMS116, 6/16/21), the laboratory reported approximately 49 Rh Typings each month, including the following: Date Patient #
----- 5/02/18 1 6/13/18 3 7/03/18 5 8/31/18 2 9/20/18 1 10/29/18
1 5/04/20 4 6/05/20 3 7/01/20 6 8/12/20 5 9/02/20 2 .

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:

Based on the findings of June 16, 2021, at 1PM and deficiencies cited, the Laboratory Director, as Technical Consultant, is herein cited for deficient practice at providing technical and scientific oversight of the laboratory. Findings included: 1. The Laboratory Director/ Technical Consultant was deficient in providing technical oversight to ensure each individual proficiency test for Rh Typing was correct. a. For event Q2 - 2020 proficiency testing, the incorrect result reported for sample #9 was neither identified nor addressed. 2. The Laboratory Director/ Technical Consultant was deficient in providing technical oversight to ensure the overall score for each proficiency testing event for Rh Typing was 100%. 3. See D2153 and D2154.