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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>05D0682666 | <b>(X3) Date Survey Completed</b><br><br>07/16/2021 |
| <b>Name of Provider or Supplier</b><br><br>Hrc Fertility - Pasadena  | <b>Street Address, City, State</b><br><br>333 S Arroyo Pkwy, Pasadena, 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>   |
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| <b>D2000</b>              | <p><b>ENROLLMENT AND TESTING OF SAMPLES</b><br/>CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on a review of the CMS Casper report 096 and the lack of documentation related to proficiency testing (PT) program and an interview with the Technical Consultant (TC), it was determined that the laboratory failed to enroll in proficiency testing (PT) for Cycle 1 of 2020. The laboratory inspection occurred on 7/16/21 between 11 a.m. and 2 p.m. Findings include: 1. The Casper 096 report for the Cycle 1 2020 was reviewed, and there were no entries for any of the CMS specialties, including Bacteriology (110), General Immunology (220), Endocrinology (330), Toxicology (340), Hematology (400) and ABO and Rh type (510). 2. The TC indicated that they utilized the College of American Pathology (CAP) proficiency testing during the time periods of 2019 and 2020. 3. There were no CAP results for Cycle 1 2020 for any analytes. 4. At approximately 12:00 p.m. on 7/16/21, the TC affirmed that they did not enroll with CAP for Cycle 1 proficiency testing. 5. The estimated annual test volumes submitted on the CMS-116 report were: - Microbiology 3,000 - Immunology 16,500 - Chemistry 32,300 - Hematology 19,600 - ABO and Rh 4,000</p> |
| <b>D6015</b>              | <b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  |

CFR(s): 493.1407(e)(4)

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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on a review of the CMS Casper report 096 and the lack of documentation related to proficiency testing (PT) program and an interview with the Technical Consultant (TC), it was determined that the laboratory failed to enroll in proficiency testing (PT) for Cycle 1 of 2020. The laboratory inspection occurred on 7/16/21 between 11 a.m. and 2 p.m. Findings include: 1. The laboratory director did not ensure that the laboratory was enrolled in an HHS approved proficiency program for each testing cycle. 2. See D 2000.