

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0682666	(X3) Date Survey Completed 04/25/2019
Name of Provider or Supplier Hrc Fertility - Pasadena	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2075	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on reviews second quarter (Q2-2017) of the College of the American Pathologists (CAP) proficiency testing performance evaluation records, random patient sampling test results, and interview with the technical consultant, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Rubella Antibody, IgG analyte. The findings included: a. Q1-2017, CAP reported a score of 60% for Rubella Antibody, IgG analyte. b. For seven (7) out of seven (7) random patient sampling test results reviewed covering period from 7/6/2017 to 8/29/2017, the laboratory analyzed and reported Rubella Antibody, IgG analyte approximately during the time the laboratory received the failed proficiency testing score. c. The technical consultant confirmed (4/25/2019, 1430) that the laboratory received that above unsatisfactory proficiency testing score.</p>
D2098	<p>ENDOCRINOLOGY CFR(s): 493.843(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on reviews first quarter (Q1-2017) of the College of the American Pathologists (CAP) proficiency testing performance evaluation records, random patient sampling test results, and interview with the technical consultant, it was determined that the</p>

	<p>laboratory failed to attain a score of at least 80 percent of acceptable responses for Human Chorionic Gonadotropin (HCG) analyte. The findings included: a. Q1-2017, CAP reported a score of 0% for HCG analyte. b. For four (4) out of four (4) random patient sampling test results reviewed covering period from 5/4/2017 to 6/7/2017, the laboratory analyzed and reported HCG analyte approximately during the time the laboratory received the failed proficiency testing score. c. The technical consultant confirmed (4/25/2019, 1430) that the laboratory received that above unsatisfactory proficiency testing score.</p>
<p>D5217</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on reviews and the lack of documentation of the laboratory's 2018, and 2019 verification of accuracy twice a year records, random patient sampling test results, and interview with the technical consultant the laboratory failed to perform verification of accuracy twice a year for Retrograde Urine Sperm Analysis. The finding included: a. Based on reviews and the lack of documentation for verification of accuracy two times per year, random patient sampling test results reviewed covering period from 10/5/2017 to 9/3/2018, the laboratory analyzed and reported Retrograde Urine Sperm Analysis analyte even though there was no verification of accuracy performed. b. The technical consultant confirmed (4/25/2019, 1430) that the laboratory failed to perform verification of accuracy two times per year for the above analyte.</p>
<p>D5473</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review s and the lack of documentation for HEMA 3 stain set used for microscopic evaluation for Semen Morphology its stain reactivity, and interview with the technical supervisor, it was determined that the laboratory failed to each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. The findings included: a. Based on reviews and the lack of documentation for the HEMA 3 stain reactivity, the laboratory failed to document stain reactivity whenever it is being used. b. For eight (8) out of eight (8) random patient test results reviewed covering period from 1/21/2019 to 4/15/2019, the laboratory lacked the documentation for HEMA3 stain reactivity whenever the stain is used for manual white blood cell count differential. c. The technical supervisor confirmed (4/25/2019, 1430) that the laboratory failed to document HEMA 3 stain kit for its reactivity whenever it is being used.</p>
<p>D6019</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES</p>

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

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)(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 reviews of the College of American Pathologists (CAP) proficiency performance evaluation records, random patient sampling test results, and interview with the technical consultant/technical supervisor, 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 D 2075, D 2098, and D5217.