

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2064026	<b>(X3) Date Survey Completed</b>  02/25/2022
<b>Name of Provider or Supplier</b>  Huntington Reproductive Center Medical Group	<b>Street Address, City, State</b>  8112 Milliken Ave Ste 101-1, Rancho Cucamonga, 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>D5217</b>	<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 observation of the laboratory operations, review of the laboratory's proficiency testing result reports, and interview with the laboratory personnel, it was determined that the laboratory failed to verify the accuracy of the semen analyses testing procedures that is not listed in subpart I of 42 CFR part 493, at least twice annually. The findings were as followed: a. The laboratory performed semen analysis and reported the patient test results including but not limited to the following tests: Sperm Motility, Sperm Count and Sperm Morphology in semen analysis procedure, which is not listed in the subpart I of 42 CFR part 493. b. At least twice annually, the laboratory must perform evaluation of proficiency testing performance and verify the accuracy of the testing results. c. To meet the requirements for the evaluation of proficiency testing performance, the laboratory elected to enroll a proficiency testing program, Andrology &amp; Embryology, offered by the American Association of Bioanalysts (AAB), d. The laboratory attained scores of 50% for Sperm Motility in S2 2020 and S1 2021 PT events, which were unsatisfactory analyte performance for the testing events. e. The laboratory reported Sperm Motility included in semen analysis for approximately 100 patient samples monthly. f. The laboratory personnel affirmed (2/25/2022 @ 11 AM) that the laboratory attained scores of 50 % for Sperm Motility in S2 2020 and S1 2021 AAB Andrology &amp; Embryology PT events which were unsatisfactory analyte performance for the testing events.</p>
<b>D6016</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</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 and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on observation of the laboratory operations, review of the laboratory's proficiency testing result reports, and interview with the laboratory personnel, it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required under Subpart H of 42 CFR part 493. The findings were as followed: a. The laboratory failed to ensure that the proficiency testing samples were tested as required under Subpart H of 42 CFR part 493. b. The laboratory performed semen analyses and reported the test result including but not limited to the following tests: Sperm Motility, Sperm Count and Sperm Morphology in a semen analysis procedure, which is not listed in the subpart I of 42 CFR part 493. c. To meet the requirements for the evaluation of proficiency testing performance, the laboratory elected to enroll the proficiency testing program, Andrology & Embryology, offered by the American Association of Bioanalysts (AAB), see D-5217,