

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0921495	<b>(X3) Date Survey Completed</b>  03/28/2019
<b>Name of Provider or Supplier</b>  Huntington Reproductive Center A	<b>Street Address, City, State</b>  500 Superior Ave Ste 130, Newport Beach, 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>D5891</b>	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory 's patient test result reports, and interview with the testing personnel, it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the post-analytic system. The findings included: a. The laboratory performed semen analyses (SA) for its patients. b. The testing personnel performed the test and typed up the final SA reports. c. Review of the patient final SA reports, incorrect patient name with patient ID #822668 was noted when verified with the name appeared in the "Semen Collection Form" submitted by the patient. d. The laboratory performed SA in approximately 100 patient samples monthly. e. The testing personnel affirmed (3/28/19 @ 12:15 PM) that the patient name was typed incorrectly. f. The laboratory failed to follow its quality assessment policies and procedures to monitor and assess the accuracy of the laboratory test result reports.</p>
<b>D6094</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p>

This STANDARD is not met as evidenced by:

Based on review of the laboratory's final patient test result reports, and interview with the testing personnel, it was determined that the laboratory director failed to ensure that the quality assessment programs were maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: See D-5891