

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2279981	<b>(X3) Date Survey Completed</b> 09/21/2023
<b>Name of Provider or Supplier</b> Houston Ivf - Woodlands	<b>Street Address, City, State</b> 1001 Medical Plaza Dr Ste 290, The Woodlands, TX	
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>D0000</b>	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
<b>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's records from April 2023 and staff interview, the laboratory failed to have documentation of verification studies (accuracy, precision, and reportable range) for one of one hematology test - Semen analysis. Findings include: 1. A review of the laboratory's records revealed the laboratory started semen analysis (count, motility, and morphology) testing in April 2023. 2. Further review of the laboratory's records revealed the laboratory failed to have documentation of the verification studies (accuracy, precision, and reportable range) for semen analysis testing. 3. An interview with the clinical lab manager on 9/21/23 at 9:45 a.m. in the conference room, after review of the records, confirmed the above findings.</p>
<b>D5433</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially</p>

available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies, maintenance records for 2023, and staff interview, the laboratory failed to have documentation of performing the required cleaning and clarity check on the Makler counter chamber for 12 of 12 days of patient testing between April 21, 2023 and June 26, 2023. Findings include: 1. A review of the laboratory's policy titled 'Semen Analysis' revealed the following: "The Makler is washed, rinsed, and dried following use. Lines on the chamber are observed for clarity and absence of scratches." 2. A review of the laboratory's maintenance records for 2022 revealed the laboratory failed to have documentation of performing the cleaning and clarity check on the Makler counter chamber for the following 12 patient testing days: 4/21/23 5/2/23 5/4/23 5/5/23 5/18/23 5/19/23 6/5/23 6/8/23 6/15/23 6/19/23 6/23/23 6/26/23 3. An interview with the clinical lab manager on 9/21/23 at 9:50 a.m. in the conference room, after review of the records, confirmed the above findings.