

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0999095	<b>(X3) Date Survey Completed</b>  05/19/2022
<b>Name of Provider or Supplier</b>  Houston Ivf DbA Ccrm Houston	<b>Street Address, City, State</b>  929 Gessner Rd, Suite 2300, Houston, 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>	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing company. The facility was found to be out of compliance with the conditions of participation of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.803 D2016 Condition: Successful participation [proficiency testing] 493.1403 D6000 Condition: Laboratories performing moderate complexity testing; laboratory director
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a desk review of proficiency testing records obtained from the CMS (Center</p>

	<p>for Medicare Services) national database and verified with the proficiency testing company, American Association of Bioanalysts (AAB), it was determined the laboratory had not successfully participated in a proficiency testing program approved by CMS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the sub-specialty of Endocrinology. Refer to D2100 and D2108.</p>
<p><b>D2098</b></p>	<p><b>ENDOCRINOLOGY</b> 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 a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Association of Bioanalysts (AAB) proficiency test results, it was revealed the laboratory failed to achieve satisfactory performance of at least 80% for 3 of 3 analytes in the sub-specialty of Endocrinology. Findings included: Event Analyte Score Ch21Q3 TSH 0.0** Ch22Q1 TSH 0.0NR Ch22Q1 HCG 0.0NR Ch22Q1 FT4 0.0NR Legend: TSH = Thyroid Stimulating Hormone HCG = Human Chorionic Gonadotropin FT4 = Thyroxine, Free ** = Out of grading range or incorrect response NR = Not received</p>
<p><b>D2099</b></p>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Association of Bioanalysts (AAB) proficiency test results, it was revealed the laboratory failed to achieve an overall testing event score of at least 80% in the sub-specialty of Endocrinology. Findings included: Event Sub-specialty Score Ch21Q3 66.7 Ch22Q1 0.0</p>
<p><b>D2100</b></p>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p>

	<p>This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Association of Bioanalysts (AAB) proficiency test results, it was revealed the laboratory failed to participate in a testing event resulting in an unsatisfactory performance and results with a score of 0 for the first testing event of 2022 in the sub-specialty of Endocrinology. Findings included: Event Sub-specialty Score Ch22Q1 0.0</p>
<p><b>D2107</b></p>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Association of Bioanalysts (AAB) proficiency test results, it was revealed the laboratory failed to achieve satisfactory performance with scores of at least 80% for the same analyte in 2 out of 3 consecutive testing events in sub-specialty of Endocrinology for the analyte TSH (Thyroid Stimulating Hormone). Findings include: TSH: Event Ch21Q3 - unacceptable score of 0.0 Event Ch22Q1 - unacceptable score of 0.0</p>
<p><b>D2108</b></p>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Association of Bioanalysts (AAB) proficiency test results, it was revealed the laboratory failed to achieve an overall testing event score of at least 80% in 2 out of 3 consecutive testing events in the sub-specialty of Endocrinology. Findings included: Event Sub-specialty Score Ch21Q3 66.7 Ch22Q1 0.0</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by:</p>

Based on a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Association of Bioanalysts (AAB) proficiency test results, it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

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

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 a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Association of Bioanalysts (AAB) proficiency test results, it was revealed the laboratory director failed to ensure successful participation in a CMS-approved proficiency testing program. Refer to D2098, D2099, D2100, D2107 and D2108.