

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0940439	<b>(X3) Date Survey Completed</b>  12/30/2020
<b>Name of Provider or Supplier</b>  Cooper Institute Reproductive Laboratory	<b>Street Address, City, State</b>  7500 Beechnut St, # 308, 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>	<p>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: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D2017 - 42 C.F.R. 493.807 (a) - Reinstatement After Failure D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;</p>
<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:</p>

Based on a review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the American Association of Bioanalysts (AAB) proficiency testing records from 2018-2020, it was determined the laboratory has not successfully participated in a proficiency testing program, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the specialty of chemistry for the analyte Human chorionic gonadotropin (hCG).

**D2017**

**REINSTATEMENT OF NONWAIVED LABORATORIES**  
CFR(s): 493.807(a)(b)

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.

This CONDITION is not met as evidenced by:

Based on a review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the American Association of Bioanalysts (AAB) proficiency testing records from 2019-2020, it was revealed the laboratory had not successfully participated in proficiency testing for the satisfactory performance in the specialty of Endocrinology for the analyte Human chorionic gonadotropin (hCG) for 3 of 3 consecutive testing events in 2020. Three out of three overall testing event scores of unsatisfactory performance results in unsuccessful PT performance. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "0" for subspecialty of Endocrinology for the 2020 AAB Chemistry 1st, 2nd, and 3rd events. 2. A proficiency desk review of the AAB proficiency testing records from 2019-2020 confirmed that the laboratory received an Endocrinology score of 0% for the 2020 AAB Chemistry 1st, 2nd, and 3rd events. 3. The laboratory must demonstrate sustained satisfactory performance ( $\geq 80\%$ ) on two consecutive testing events for reinstatement.

**D2098**

**ENDOCRINOLOGY**  
CFR(s): 493.843(a)

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.

This STANDARD is not met as evidenced by:

Based on a review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the American Association of Bioanalysts (AAB) proficiency testing records from 2019-2020, it was revealed the laboratory failed to

achieve satisfactory performance (80% or greater) for the Human chorionic gonadotropin (hCG) analyte in 3 of 3 consecutive testing events. Findings were: 1. A review of the CMS (Center for Medicare Services) national database from 2020 revealed the laboratory received a score of '0' for HCG for 3 of 3 events. 2020 AAB 1st event 2020 AAB 2nd event 2020 AAB 3rd event 2. A proficiency desk review of the AAB proficiency testing records from 2019-2020 confirmed the laboratory received a score of '0' for hCG for 3 of 3 events. 2020 AAB 1st event 2020 AAB 2nd event 2020 AAB 3rd event

**D2099**

**ENDOCRINOLOGY**  
CFR(s): 493.843(b)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:  
Based on a review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the American Association of Bioanalysts (AAB) proficiency testing records from 2019-2020, it was revealed that the laboratory failed to attain an overall testing event score of at least 80 % for 3 of 3 Endocrinology events which constitutes unsatisfactory performance. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "0" for Endocrinology on the 1st, 2nd, and 3rd events of 2020 for this facility. 2. A proficiency desk review of AAB proficiency testing records for 2019-2020 revealed the facility to attain an overall testing event score of at least 80 % for 3 of 3 Endocrinology events in 2020. 2020 AAB 1st event - 0% 2020 AAB 2nd event - 0% 2020 AAB 3rd event - 0%

**D2100**

**ENDOCRINOLOGY**  
CFR(s): 493.843(c)

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.

This STANDARD is not met as evidenced by:  
Based on a review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the American Association of Bioanalysts (AAB) proficiency testing records from 2019 - 2020, it was revealed that the laboratory failed to participate in the 1st, 2nd, and 3rd endocrinology events of 2020. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "0" for the subspecialty of endocrinology on the 1st, 2nd and 3rd events of 2020 for this facility. 2. A review of AAB proficiency test records revealed the laboratory received a 0% for the subspecialty of endocrinology for the 1st, 2nd, and 3rd events in 2020 for

	<p>"Failure to Participate." The PT summary was rated by the provider as unsatisfactory performance for all analytes for testing events 2020-1; 2020-2; and 2020-3 endocrinology.</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 review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the American Association of Bioanalysts (AAB) proficiency testing records from 2019-2020, it was revealed the laboratory failed to achieve satisfactory performance (80% or greater) for the HCG (Human chorionic gonadotropin) analyte in 3 of 3 consecutive testing events in 2020. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "0" in 3 of 3 consecutive testing events for the HCG analyte in 2020. 2020 AAB 1st Chemistry event 2020 AAB 2nd Chemistry event 2020 AAB 3rd Chemistry event 2. A proficiency desk review of the AAB proficiency testing records from 2019-2020 confirmed that the laboratory received an endocrinology score of 0% in 3 of 3 consecutive testing events for the HCG analyte in 2020. 2020 AAB 1st Chemistry event 2020 AAB 2nd Chemistry event 2020 AAB 3rd Chemistry event</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 review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the American Association of Bioanalysts (AAB) proficiency testing records from 2019-2020, it was revealed the laboratory failed to achieve an overall testing event score of satisfactory performance (80% or greater) for 3 of 3 consecutive testing events for the subspecialty of Endocrinology in 2020. Three out of three overall testing event scores of unsatisfactory performance results in unsuccessful PT performance. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "0" for subspecialty of Endocrinology for the 2020 AAB Chemistry 1st, 2nd, and 3rd events. 2. A proficiency desk review of the AAB proficiency testing records from 2019-2020 confirmed that the laboratory received an Endocrinology score of 0% for the 2020 AAB Chemistry 1st, 2nd, and 3rd events.</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</p>

with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on a desk review of laboratory proficiency testing performance it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Findings were: 1. A review of the laboratory proficiency testing results revealed that the laboratory director failed to ensure that the laboratory participated successfully. (refer to D6016) By not providing overall management and direction of the laboratory, the laboratory director could not ensure the accuracy or reliability of all laboratory services provided by the facility.

**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 results it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in an approved proficiency testing program. (refer to D2108, D2107)