

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0940439	(X3) Date Survey Completed 10/29/2021
Name of Provider or Supplier Cooper Institute Reproductive Laboratory	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	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 Reinstatement After Failure D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;
D2016	<p>SUCCESSFUL PARTICIPATION 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 desk review of proficiency testing records obtained from the CMS (Center 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 HHS, 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 Endocrinology for the analyte Thyroxine (TY). (Refer to D2107)

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 desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the proficiency testing records from American Association of Bioanalysts (AAB), it was determined the laboratory had not successfully participated in proficiency testing for the analyte Thyroxine under the specialty of Endocrinology for 3 of 3 testing events and has not demonstrated sustained satisfactory performance on two consecutive proficiency events since the unsuccessful scores. Findings include: 1. Chemistry Q1 2021 first event the laboratory received an unsatisfactory score of 0% for the analyte Thyroxine 2. Chemistry Q2 2021 second event the laboratory received an unsatisfactory score of 0% for the analyte Thyroxine. * The 2021 first event and 2021 second event resulted in initial unsuccessful proficiency testing performance. 3. Chemistry Q3 2021 third event the laboratory received an unsatisfactory score of 0% for the analyte Thyroxine. * The 2021 third event constituted non-initial unsuccessful proficiency testing performance.

D2107

ENDOCRINOLOGY
CFR(s): 493.843(f)

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.

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 proficiency testing

	<p>records from American Association of Bioanalysts (AAB), it was revealed the laboratory failed to achieve satisfactory performance for the analyte Thyroxine for 3 of 3 events in 2021. Findings include: 1. A review of the laboratory's AAB proficiency test results revealed the laboratory received an unacceptable score of 0% for the analyte TY (Thyroxine) for the following 3 events: - Chemistry Q1 2021 first event - Chemistry Q2 2021 second event - Chemistry Q3 2021 third event</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR 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: 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)</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <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;</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 director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. (Refer to D2107)</p>