

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2013404	(X3) Date Survey Completed 11/13/2020
Name of Provider or Supplier Methodist Hospital For Surgery	Street Address, City, State 17101 Dallas Parkway, Addison, 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 CMS (Centers for Medicare and Medicaid Services) national database and verified with the proficiency testing company, American Proficiency Institute (API). 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 Successful participation in a proficiency testing program 493.1441 Laboratory Director, High Complexity
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, 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 Immunohematology/Compatibility Testing. Refer to D2181

D2173

COMPATIBILITY TESTING

CFR(s): 493.863(a)

Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:

Based on a review of Centers for Medicare and Medicaid (CMS) report 155 and American Proficiency Institute (API) proficiency testing records for 2019 and 2020, it was revealed the laboratory failed to attain an overall compatibility testing event score of at least 100% (2019-3rd Event and 2020-1st Event) for Immunohematology /Compatibility Testing which constitutes unsatisfactory performance. Findings included: 1. Review of the CMS 155 report revealed the following results: 2019 - 3rd Event laboratory received an overall unsatisfactory score 80% for Compatibility testing. 2020 - 1st Event laboratory received an overall unsatisfactory score of 0% for Compatibility testing. 2. Review of the laboratory's API proficiency testing records from 2019 and 2020 revealed the following results: API 2019 - 3rd Event laboratory received an overall unsatisfactory score 80% for Compatibility testing. API 2020 - 1st Event laboratory received an overall unsatisfactory score of 0% for Compatibility testing/Failure to participate.

D2174

COMPATIBILITY TESTING

CFR(s): 493.863(b)

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:

Review of the CMS report 155 and American Proficiency Institute (API) proficiency testing records found that the laboratory failed to participate in the 2020 1st Testing Event for Compatibility testing, resulting in a score of 0% constituting unsatisfactory performance. Findings included: 1. Review of the CMS 155 report revealed the following results: 2020 - 1st Event laboratory received an overall unsatisfactory score of 0% for Compatibility testing. 2. Review of the laboratory's API proficiency testing records from 2019 and 2020 revealed the following results: API 2020 - 1st Event laboratory received an overall unsatisfactory score of 0% for Compatibility testing

	<p>/Failure to participate. This failure to participate resulted in a score of 0% and unsatisfactory performance for the specialty of Immunohematology for Compatibility testing.</p>
<p>D2181</p>	<p>COMPATIBILITY TESTING CFR(s): 493.863(e)</p> <p>Failure to achieve an overall testing event score of satisfactory 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 report 155 and American Proficiency Institute (API) proficiency testing (PT) records from 2019 (1st, 2nd, and 3rd Events) and 2020 (1st and 2nd Events), it was revealed that the laboratory failed to achieve satisfactory performance (100%) for the same analyte in two consecutive testing events or two out of three consecutive testing events in the specialty for Immunohematology /Compatibility testing resulting in unsuccessful PT performance. Findings included: 1. Review of the CMS 155 report revealed the following results: 2019 - 3rd Event laboratory received an overall unsatisfactory score 80% for Compatibility testing. 2020 - 1st Event laboratory received an overall unsatisfactory score of 0% for Compatibility testing. 2. Review of the laboratory's API proficiency testing records from 2019 and 2020 revealed the following results: API 2019 - 3rd Event laboratory received an overall unsatisfactory score 80% for Compatibility testing. API 2020 - 1st Event laboratory received an overall unsatisfactory score of 0% for Compatibility testing/Failure to participate.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>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. Refer to D6089</p>
<p>D6089</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure 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 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 a HHS approved proficiency testing program. Refer to D2181.</p>