

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0483827	<b>(X3) Date Survey Completed</b>  12/02/2020
<b>Name of Provider or Supplier</b>  Freestone Medical Center	<b>Street Address, City, State</b>  125 Newman St, Fairfield, 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 Center of Medicare Services (CMS) national database and verified with the American Proficiency Institute (API). The facility was found to be out of compliance with the conditions of participation for the CLIA program. The following Conditions of Participation were found to be out of compliance: 493.803 Successful participation (proficiency testing) .
<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 review of an Individual Laboratory Profile (CASPER Report 0155D) dated 10-27-2020, online access to proficiency testing (PT) results provided by the</p>

American Proficiency Institute (API), verified by telephone on 12-01-2020, the laboratory failed to successfully participate in an approved PT program for the specialty of immunohematology in the third testing event of 2019 and the first testing event of 2020. Refer to D 2163. .

**D2153**

**ABO GROUP AND D(RHO) TYPING**  
CFR(s): 493.859(a)

Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

. Based on review of an Individual Laboratory Profile dated 10-27-2020, confirmed by API PT results, the laboratory failed to achieve acceptable performance in ABO Group and D (Rho) testing in 2019 and 2020 in the specialty of immunohematology. Findings: 1. Review of API testing records showed the following overall scores for the third testing event of 2019 and the first testing event of 2020: Testing event: 2019 3rd Analyte: D (Rho) Sample Reported Expected Score RED-11 Rh neg Rh neg Acceptable RED-12 Rh pos Rh pos Acceptable RED-13 Rh neg Rh neg Acceptable RED-14 Rh pos Rh pos Acceptable RED-15 Rh neg Rh pos Unacceptable Testing event: 2020 1st Analyte: ABO Group Sample Reported Expected Score RED-01 Grp AB Grp AB Acceptable RED-02 Grp B Grp B Acceptable RED-03 Grp A Grp A Acceptable RED-04 Grp AB Grp O Unacceptable RED-05 Grp B Grp B Acceptable Analyte: D (Rho) Sample Reported Expected Score RED-01 Rh neg Rh neg Acceptable RED-02 Rh pos Rh pos Acceptable RED-03 Rh neg Rh neg Acceptable RED-04 Rh pos Rh neg Unacceptable RED-05 Rh pos Rh pos Acceptable 2. API PT results were confirmed with API tech support via telephone on 12-01-2020. .

**D2163**

**ABO GROUP AND D(RHO) TYPING**  
CFR(s): 493.859(g)

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.

This STANDARD is not met as evidenced by:

. Based on review of an Individual Laboratory Profile dated 10-27-2020, confirmed by API PT results, the laboratory failed to achieve satisfactory performance for two consecutive testing events in 2019 and 2020 in the specialty of immunohematology. Findings: 1. Review of the Individual Laboratory Profile report showed the following overall scores for the third testing event of 2019 and the first testing event of 2020: Specialty: Immunohematology Testing Event 2019 3rd ABO Group 100% D (Rho) Type 80% Overall score: 90% (Unsatisfactory) Specialty: Immunohematology Testing Event 2020 1st ABO Group 80% D (Rho) Type 80% Overall score: 80% (Unsatisfactory)