

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0483827	(X3) Date Survey Completed 03/01/2022
Name of Provider or Supplier Freestone Medical Center	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	Based on a proficiency testing desk review survey performed on March 1, 2022, the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES : D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high 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: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute comparative evaluation records, the laboratory failed to achieve successful</p>

	<p>performance in two of two consecutive testing events for the specialty Immunohematology for the analyte Compatibility Testing, resulting in unsuccessful performance. Refer to D2181.</p>
D2181	<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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the American Proficiency Institute (API) Comparative Evaluations, the laboratory failed to attain a score of at least 80 percent for the analyte Compatibility Testing in two of two consecutive testing events in 2021. The findings included: 1. Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the American Proficiency Institute (API) Comparative Evaluations, the laboratory received the following unsatisfactory scores (satisfactory is 100%) for the analyte Compatibility Testing in the specialty of Immunohematology in two of two consecutive events: 2021 API 2nd event 60% 2021 API 3rd event 60%</p>
D6076	<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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing records, the Laboratory Director failed to ensure successful participation in a HHS approved proficiency testing program for analyte Compatibility Testing in Immunohematology. Refer to D6016.</p>
D6089	<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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute (API) Comparative Evaluations, the Laboratory Director failed to ensure successful participation in a HHS approved proficiency testing program for analyte Compatibility Testing in the specialty of Immunohematology for two of two events in 2021. Refer to D2181.</p>