

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0503581	(X3) Date Survey Completed 01/12/2022
Name of Provider or Supplier Sths Clinics Fm Edinburg Yarritu	Street Address, City, State 1200 S 10th Street, Edinburg, 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 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 493.1403 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: Based on review of the laboratory's American Proficiency Institute proficiency testing (PT) records and confirmed in interview of laboratory personnel, the laboratory had not successfully participated in a proficiency testing program approved by HHS, for</p>

	<p>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 hematology for the analyte White Blood Cell Differential (WBC). See D2130</p>
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute proficiency testing (PT) records and confirmed in interview of laboratory personnel, the laboratory failed to attain a score of at least 80% acceptable responses for each analyte in the subspecialty of hematology for the analyte White Blood Cell Differential (WBC). The findings included: 1. API 2021 - 1st event the laboratory received an unsatisfactory score of 67% for WBC Differential. 2. API 2021 - 3rd event the laboratory received an unsatisfactory score of 73% for WBC Differential. 3. The findings were confirmed in interview with the technical consultant on January 12, 2022 at 13:30 hours in the conference room.</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive 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 laboratory's American Proficiency Institute proficiency testing (PT) records and confirmed in interview of laboratory personnel, the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two consecutive testing events or two out of three consecutive testing events in the specialty of Hematology. Two out of three unsatisfactory scores results in unsuccessful PT performance. The findings included: 1. API 2021 - 1st event the laboratory received an unsatisfactory score of 67% for WBC Differential. 2. API 2021 - 3rd event the laboratory received an unsatisfactory score of 73% for WBC Differential. 3. The findings were confirmed in interview with the technical consultant on January 12, 2022 at 13:30 hours in the conference room. Key: WBC - white blood cell</p>
D6000	<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:</p>

Based on review of the laboratory's proficiency testing records and confirmed in interview of laboratory personnel, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016

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 review of the laboratory's proficiency testing records and confirmed in interview of laboratory personnel, 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 D2130