Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0503581	12/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Sths Clinics Fm Edinburg Yarritu	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 laboratory was found out of compliance with the CLIA regulations. The condition not met was: D6033 - 42 C.F.R. 493.1409 Condition: technical consultant
D2123	HEMATOLOGY CFR(s): 493.851(c) 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: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2023 and staff interview, the laboratory failed to have documentation of participating in 2 of 3 events. The findings included: 1. A review of the laboratory's American Proficiency Institute's hematology proficiency testing records from 2023 determined the laboratory failed to participate in 2 of 3 events. They were: 2023 Event 2 2023 Event 3 2. The laboratory was asked to provide documentation of participating in the required proficiency testing. No documentation was provided. 3. The laboratory ceased hematology testing at the end of June 2023, but failed to notify the proficiency testing agency or the inspecting agency. 4. The practice manager confirmed the findings in an interview conducted on 12/20/2023 at 1000 hours in the conference room.
D5441	CONTROL PROCEDURES

	CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's hematology quality control records from January 2023 to June 2023, and staff interview, the facility failed to have documentation of monitoring quality control values over time for 2 of 6 months. The findings included: 1. A review of the laboratory's hematology quality control records from January 2023 to June 2023 determined the facility printed monthly levey-jennings charts to assess quality control results over time to detect shifts and trends. Further review identified 2 of 6 months where the charts were not reviewed. They were: May 2023 June 2023 2. The laboratory was asked to provide documentation of the charts being reviewed to determine if shifts or trends were occurring. No documentation was provided. 3. The practice manager confirmed the findings in an interview conducted on 12/20/2023 at 1215 hours in the conference room.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assurance report from March 2023, review of patient test records from March 31, 2023, and staff interview, it was revealed the laboratory failed to have documentation of corrective actions for 6 of 6 patients tested when the laboratory's quality control plan was not followed. The findings included: 1. A review of the laboratory's quality assurance report from March 2023 revealed: "On 3 /31/2023 (6) samples were ran before controls were ran. The regulations required to run and evaluate controls before any patient testing is done. This is to ensure that the unit is working properly. Please recall the patient results reported, notify the provider of this error so he can do follow ups, and keep records of the patients affected and their follow ups." 2. A review of the patient test records identified the followings 5 samples tested on 03/31/2023 prior to quality control testing being performed: Sequence number: 66 Identification number: 030741 Sequence number: 67 Identification number: none Sequence number: 69 Identification number: none Sequence number: 70 Identification number: none Sequence number: 71 Identification number: 012655 3. The laboratory was asked to provide documentation of performing

	the corrective actions stated in its monthly report. No documentation was provided. 4. The practice manager confirmed the findings in an interview conducted 12/20/2023 at 1200 hours in the conference room.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan, review of the laboratory's quality assessment records from January 2023 to November 2023, and staff interview, the laboratory failed to have documentation of the monthly review of records for 7 of 11 months. The findings included: 1. A review of the laboratory's quality assessment plan (approved by the laboratory director on 5/1/2014) under the section titled "Quality Assurance Review" revealed: "Our laboratory uses this quality assurance program to improve the laboratory services we provide to our physicians and patients. We will performed a quality review at least monthly and review the results with the laboratory director or technical consultant for their approval." 2. A review of the laboratory quality assessment records from January 2023 to November 2023 identified the laboratory failed to have documentation of performing the review for 7 of 11 months. The months without documentation of review were: May June July August September October November 3. The laboratory was asked to provide documentation of missing quality assessment records. No documentation was provided. 4. The practice manager confirmed the findings during an interview on 12/20/2023 at 1215 hours in the conference room. She stated the monthly reviews had not been done since the technical consultant had left the organization.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, and staff interview, it was determined the laboratory failed to have a qualified technical consultant (refer to D6035).
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of

	osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, and staff interview, it was determined the laboratory failed to have a qualified technical consultant in place since May 2023. The findings included: 1. A review of the laboratory's submitted Form CMS 209 showed the laboratory identified 1 technical consultant. 2. An interview with the practice manager on 12/20/2023 revealed the identified technical consultant left the organization in May 2023. She stated the facility had not found a qualified technical consultant since the previous one left. This confirmed the findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, the laboratory failed to have documentation of the technical consultant performing 5 of 5 annual reviews. The findings included: 1. A review of the laboratory's personnel records identified the laboratory failed to have documentation of the technical consultant performing 5 of 5 required annual reviews. The missing review were: a)

	Testing personnel number 1 Missing: May 2022 May 2023 b) Testing personnel number 2 Missing: December 2022 c) Testing personnel number 3 Missing: January 2022 January 2023 2. The laboratory was asked to provide documentation of the missing annual competency assessments. No documentation was provided. 3. The practice manager confirmed the findings in an interview conducted on 12/20/2023 at 0915 hours in the conference room.