

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0503581	<b>(X3) Date Survey Completed</b>  04/17/2018
<b>Name of Provider or Supplier</b>  Sths Clinics Fm Edinburg Yarritu	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, review of patient logs, and confirmed in interview of facility personnel, the laboratory failed to ensure expired items were not available for use in patient testing. The findings were: 1. Direct observation made in the laboratory on 04/17/2018 at 1615 hours in the laboratory revealed 1 opened vial of True Metrix blood glucose test strips. Lot Number: MU2395 Open Date: 10-17-2017 Quantity: 6 strips left in bottle 2. Review of manufacturer's instructions for True Metrix blood glucose test strips (R3TVHP03 Rev. 50) under, "Caring for Test Strips" stated, "Write the date opened on test strip vial label when removing first test strip. Discard all unused test strips in vial after</p>

either date printed next to EXP on the test strip vial label or 4 months after date opened, whichever comes first. Using test strips past these dates may cause inaccurate results." 3. Review of patient logs from February 17, 2017 (the open expiration date) to April 17, 2018 (the date of the onsite survey) revealed the laboratory tested the following patient when the blood glucose test strips were expired. Visit ID: 2018064 Result: 99 mg/dL 4. The laboratory was asked to provide documentation of following the manufacturer's instructions to ensure blood glucose test strips were not used after their expiration date. No documentation was provided. 5. An interview with the technical consultant on 04/17/2018 at 1645 hours in the office confirmed the findings. Key: mg/dL - milligrams per deciliter

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on random review of final patient reports and confirmed in interview of facility personnel, the laboratory failed to ensure the name and address of the laboratory location where send out tests were performed were included on final reports. The findings were: 1. Random chart review revealed the laboratory sends out specimens for chemistry testing to an outside laboratory. 2. Upon review of a final patient report performed on 03/09/2018 revealed the name and address of the facility where the test was performed was not included on the final report. (see patient alias report) 3. The laboratory was asked provide documentation that the name and address of the facility where the test was performed was included on the final patient report. No documentation was provided. 4. An interview with the laboratory director and the technical consultant on 04/17/2018 at 1545 hours in the laboratory confirmed the findings.