

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  48D0693849	<b>(X3) Date Survey Completed</b>  05/15/2018
<b>Name of Provider or Supplier</b>  St Thomas Clinical Reference Laboratory	<b>Street Address, City, State</b>  Medical Art Complex Suite #9 Altona, St Thomas, VI	
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>D5305</b>	<p>TEST REQUEST CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.</p> <p>This STANDARD is not met as evidenced by: Based on review of records, observation, and interview with the laboratory owner, technical supervisor, and laboratory clerk, the laboratory failed to ensure that the date of collection and, if appropriate, the specimen collection was on the requisition and in SAIL, the Laboratory Information Systems (LIS). The findings include: 1. The test requisition did not include a data field for collection date and time. 2. On observation, SAIL LIS did not have a data field for collection date and time. 3. There was no documentation of collection date and time for Specimen 003137299 that had a request for stool occult blood.</p>
<b>D5313</b>	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)</p>

The laboratory must document the date and time it receives a specimen.

This STANDARD is not met as evidenced by:

Based on review of records, observation of SAIL (LIS) , and interview with the laboratory owner, technical supervisor, the laboratory failed to document the receipt date and time of specimens. The findings include: a. The registration print out of the LIS indicated order date and time. The laboratory owner stated the order date and time was the same as the receipt date and time of specimens that were collected and or drawn in the laboratory and specimens collected by patients themselves. b. There was no policy stating the the order date and time was equivalent to receipt date and time. b. SAIL, the LIS did not have a data field for receipt date and time. SAIL had data field for order date and time and report date and time.

**D6088**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(4)

The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on review of records and interview with and confirmation by the laboratory owner and technical supervisor, the laboratory failed to enroll in Proficiency testing Program for second event 2017. The owner stated the laboratory started to perform testing on February 2, 2017.