

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 48D0693849	(X3) Date Survey Completed 09/21/2021
Name of Provider or Supplier St Thomas Clinical Reference Laboratory	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted at St. Thomas Clinical reference laboratory on September 20 -21, 2020 by the CMS New York CLIA Branch Location federal surveyor. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the technical supervisor the laboratory failed to label reagents with preparation and expiration dates in the chemistry sections of the laboratory. Findings include: On 09/20/21 at approximately 11:00am a tour of the chemistry section of the laboratory revealed the reagents were not labeled with an open date/ expiration dates. The surveyor requested reagent logs for reagents loaded to the Centaur XP, the laboratory testing personnel stated "We dont have a reagent log and we don't label expiration dates on the reagents, we just put them on the machine, we change the reagents based on the reservoir level". During an exit interview on 09 /21/2021 at approximately 2:30 PM with the technical supervisor confirmed the laboratory did not label reagents with open/ expiration dates.</p>
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation and interview with the technical supervisor the laboratory failed to discard reagents that exceeded their expiration date. Findings include: On 09/20/21 at approximately 11:00am during a tour of the chemistry section of the laboratory the surveyor observed two of the following reagents in use on the Centaur XP chemistry instrument: Acid Reagent expiration date 06-30-2021 Base Reagent expiration date 06-30-2021 During an exit interview on 09/21/2021 at approximately 2:30 PM ,the technical supervisor confirmed the laboratory used expired reagents on the Centaur XP chemistry instrument.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on observation and interview with the technical supervisor the laboratory failed perform preventative maintenance on the Centaur XP as defined by the manufacturer . Findings include: On 09/20/21 at approximately 11:00am, a tour of the chemistry section of the laboratory revealed the lack of daily maintenance procedures performed on Centaur XP included the following: Daily cleaning procedure was not performed for three months from the date of the survey last performed 06/16/2021. Cleaning Solution replacement was not performed for three months from the date of the survey last performed 06/22/2021 During an exit interview on 09/21/2021 at approximately 2: 30 PM with the technical supervisor confirmed the laboratory did not perform the preventative maintenance as defined by the Centaur XP manufacturer.