

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0459634	(X3) Date Survey Completed 05/13/2019
Name of Provider or Supplier Thibodaux Regional Urology Clinic	Street Address, City, State 506 North Acadia Rd, Thibodaux, LA	
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	A Recertification Survey was conducted on May 13, 2019 at Thibodaux Urological Specialists-CLIA # 19D0459634. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure proficiency testing samples were tested in the same manner as patient samples. Findings: 1. Observation by surveyor during laboratory tour on May 12, 2019 revealed the laboratory utilizes the following two (2) Qualigen Fast Pack IP analyzers for Prostate Specific Antigen (PSA) testing: Serial Number 0065 Serial Number 1144 2. Further observation by surveyor revealed the laboratory tests patient samples one time on one analyzer. 3. Review of the laboratory's American Proficiency Institute (API) proficiency test records for 2018 and 2019 revealed the laboratory tested the three (3) samples issued for each event on both Qualigen analyzers. The laboratory reported the results from Serial Number 0065 for the events reviewed. 4. In interview on May 12, 2019 at 11:00 am, Personnel 2 stated the laboratory tested the proficiency samples on both Qualigen analyzers to check the accuracy of the second</p>

analyzer (Serial Number 1144). Personnel 2 confirmed the laboratory did not test the proficiency samples in the same manner as patients.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the laboratory failed to monitor the room temperature where blood collection supplies are stored per manufacturer requirements. Findings: 1. Observation by surveyor during the laboratory tour on May 12, 2019 revealed the laboratory did not monitor the room temperature where blood collection takes place and the following collection supplies are stored: a) BD Vacutainer SST blood collection tubes, Lot # 83479863, Quantity: approximately eighty (80) tubes b) BD Vacutainer SST blood collection tubes, Lot # 8340642, Quantity: approximately fifty five (55) tubes c) BD Vacutainer SST blood collection tubes, Lot # 9030868, Quantity: 300 tubes d) BD Vacutainer SST blood collection tubes, Lot # 9043944, Quantity: 100 tubes e) BD Vacutainer K2EDTA blood collection tubes, Lot # 8215728, Quantity: 100 tubes f) BD Vacutainer K2EDTA blood collection tubes, Lot # 8099821, Quantity: approximately fifteen (15) tubes g) BD Vacutainer Lithium Heparin blood collection tubes, Lot # 8276651, Quantity: approximately seventy six (76) tubes 2. Review of the BD Vacutainer manufacturer requirements revealed the following temperature requirement: 4-25 degrees Celsius. 3. In interview on May 12, 2019 at 9:55 am, Personnel 2 stated the laboratory did not monitor the blood collection area where the identified supplies are stored.

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:

*** Repeat Deficiency from survey conducted on September 11, 2017 *** Based on observation and interview with personnel, the laboratory failed to ensure supplies have not exceeded their expiration date. Findings: 1. Observation by surveyor during laboratory tour on May 13, 2019 revealed the following expired item: a) BBL Culture Swab Collection and Transport System, Lot # 172275009, Expiration Date: 2019-04-30, Quantity: one (1) swab 2. In interview on May 13, 2019, Personnel 2 confirmed the identified item was expired.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(iii)

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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required for accurate and reliable results. Findings: 1. The laboratory failed to monitor the room temperature where blood collection supplies are stored per manufacturer requirements. Refer to D5413. 2. The laboratory failed to ensure supplies have not exceeded their expiration date. Refer to D5417.

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 record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D2006.