

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2075588	(X3) Date Survey Completed 06/24/2021
Name of Provider or Supplier Regional Urology	Street Address, City, State 201 Mcmillan Street, West Monroe, 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	An Initial survey was performed on June 24, 2021 at Regional Urology, LLC, CLIA ID # 19D2075588. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to address competency for Technical Consultant were complete. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did have a policy which includes competency assessment criteria; however, the policy did not include the frequency of performance assessment for personnel serving as Technical Consultant. 2. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed that Personnel 3 serves as Technical Consultant. 3. Review of personnel records for Personnel 3 revealed the Laboratory Director did perform a competency assessment for the duties as Technical Consultant. 4. In interview on June 24, 2021 at 3:08 pm, Personnel 1 confirmed the laboratory did not include the frequency at which the Technical Consultant has a competency assessment performed.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks</p>

may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to establish complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have written a policy and procedure to include: a) Twice a year verification for accuracy of the FastPack IP - Qualigen analyzers to include frequency, acceptability criteria, and corrective action plan. 2. In interview on June 24, 2021 at 3:08 pm, Personnel 1 confirmed the laboratory did not include the identified policy in the laboratory's manual.

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 by surveyor, review of manufacturer's temperature requirements, and interview with personnel, the laboratory failed to monitor the room temperature where supplies are stored per manufacturer requirements. Findings: 1. Observation by surveyor during the laboratory tour on June 24, 2021 at 1:04 pm revealed the laboratory did not monitor the room temperature of the phlebotomy room where the following supplies were stored: a) BD Vacutainer K2 EDTA tubes: * Lot 0044155 Expiration 6/30/21 * Lot 0345777 Expiration 4/30/22 b) BD Vacutainer Lithium Heparin tubes: * Lot 0227258 Expiration 12/31/21 * Lot 1014126 Expiration 5/31/22 * Lot 0345793 Expiration 4/30/22 c) BD Vacutainer Serum Separator Tubes (SST): * Lot 0245941 Expiration 8/31/21 2. Review of the manufacturer's storage requirements for the above supplies revealed the following: 4 - 25 degrees celsius. 3. In interview on June 24, 2021 at 3:08 pm, Personnel 1 confirmed the laboratory did not monitor the room temperature of the phlebotomy room.

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, manufacturer instructions, temperature /humidity logs, and interview with personnel, the laboratory failed to perform and document corrective actions when the room temperature and humidity was not maintained within acceptable range for twenty three (23) of ninety seven (97) days

reviewed. Findings: 1. Review of the policy "Laboratory Temperature Monitoring, Recording and Corrective Action" revealed under "Corrective Action for Units Alarming Temperatures Outside of Range" the following guidelines: a) If the temperature is 1-2 degrees celsius outside of the acceptable range: * Attempt to increase or decrease temperature, whichever applicable, by adjusting the thermostat on the unit * Monitor temperature for 30-45 minutes to interpret new settings * If after 45 minutes the temperature has not changed, refer to the next step b) If the unit temperature is 3 degrees celsius or greater outside of the acceptable range or has malfunctioned and is suspected or confirmed that the unit is non-operational, promptly transfer all products to a similar, working, monitored unit in the department c) Notify the maintenance department for repair of the unit d) Once the unit has been repaired, it should be monitored for a period of time to determine if the unit is once again operational e) Document all corrective action taken to resolve the problem on the temperature corrective action form and refer to supervisor for final review. 2. Review of the Laboratory Temperature Chart revealed the following acceptable ranges: a) Room Temperature: 18 - 25 degrees celsius b) Humidity: 30 - 80 % 3. Review of the laboratory's temperature charts for January 2021 through May 2021 revealed the room temperature and humidity was documented outside of acceptable limits without corrective actions performed for the following twenty three (23) days: a) January 4, 2021: documented room temperature 27.8 degrees celsius b) January 6, 2021: documented room humidity 29 % c) January 7, 2021: documented room humidity 29 % d) January 8, 2021: documented room humidity 29% e) January 12, 2021: documented room humidity 25% f) January 13, 2021: documented room humidity 26% g) January 14, 2021: documentd room humidity 26% h) January 15, 2021: documented room humidity 25% i) January 19, 2021: documented room humidity 24% j) January 26, 2021: documented room temperature 25.5 degrades celsius k) January 29, 2021: documented room humidity 28% l) February 1, 2021: documented room temperature 28.0 degrees celsius m) February 1, 2021: documented room humidity 28% n) February 2, 2021: documented room humidty 27% o) February 3, 2021: documented room humidity 26% p) February 4, 2021: documented room humidity 26% q) February 8, 2021: documented room temperature 28.2 degrees celsius r) February 8, 2021: documented room humidity 28% s) February 12, 2021: documented room humidity 27% t) February 23, 2021: documented room humidty 25% u) February 24, 2021: documented room humidity 25% v) March 5, 2021: documented room humidity 29% w) March 8, 2021: documented room temperature 27.8 degrees celsius x) March 8, 2021: documented room humidity 27% y) March 9, 2021: documented room humidity 26% z) April 19, 2021: documented room temperature 25.6 degrees celsius 4. In interview on June 24, 2021 at 3:08 pm, Personnel 1 stated the laboratory opened in January 2021 and they were having trouble controlling the temperature and humidity in the facility but has since regulated things to acceptable ranges. Personnel 1 confirmed the laboratory did not perform corrective action for the identified dates.

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.

	<p>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 performed test methods as required. Findings: 1. The laboratory failed to monitor the room temperature where supplies are stored per manufacturer requirements. Refer to D5413. 2. The laboratory failed to perform and document corrective actions when the room temperature and humidity was not maintained within acceptable range for twenty three (23) of ninety seven (97) days reviewed. Refer to D5785.</p>
<p>D6030</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established and maintained. Findings: 1. The laboratory failed to ensure written policies and procedures to address competency for Technical Consultant were complete. Refer to D5209.</p>
<p>D6031</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</p> <p>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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure an approved policy and procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish complete policies and procedures. Refer to D5401.</p>
<p>D6036</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the</p>

laboratory.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to monitor the room temperature where supplies are stored per manufacturer requirements. Refer to D5413. 2. The laboratory failed to perform and document corrective actions when the room temperature and humidity was not maintained within acceptable range for twenty three (23) of ninety seven (97) days reviewed. Refer to D5785.