

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1050083	(X3) Date Survey Completed 01/22/2018
Name of Provider or Supplier Ochsner Lsu Health Regional Urology	Street Address, City, State 255 W Bert Kouns Industrial Loop, Shreveport, 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 performed at Regional Urology - CLIA 19D1050083 on January 22, 2018. Regional Urology was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic Systems 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing; Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories Performing Moderate Complexity Testing; Technical Consultant
D5205	<p>COMPLAINT INVESTIGATIONS CFR(s): 493.1233</p> <p>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel the laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory did not have a written policy and procedure for addressing complaints and problems reported to the laboratory. The policy should include a detailed procedure on how to address, document and handle complaints or problems reported to the laboratory. 2. Interview with Personnel 1 and 2 on January 22, 2018 revealed they were unaware of all the policies and procedures that were required. Personnel 1 and 2 confirmed the laboratory did not have a complete policy and procedure manual.</p>
D5207	<p>COMMUNICATIONS CFR(s): 493.1234</p> <p>The laboratory must have a system in place to identify and document problems that</p>

occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel the laboratory failed to have a system in place to ensure that it documents all problems reported to the laboratory. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to have written policies and procedure to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. 2. Interview with Personnel 1 and 2 on January 22, 2018 revealed she was unaware of all the policies and procedures that were required. Personnel 1 and 2 confirmed the laboratory failed to have a complete policy and procedure manual.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL

CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the laboratory failed to follow manufacturer requirements for centrifugation of BD Vacutainer Rapid Serum tubes. Findings: 1. Observation by surveyors during laboratory tour on January 22, 2018 revealed the laboratory utilizes an Eppendorf 5804 centrifuge set for three (3) minutes at 4000 RCFs (14580 RPMs) in their Chemistry section. 2. Further observation by surveyors during laboratory tour on January 22, 2018 revealed the laboratory utilizes the BD Vacutainer Rapid Serum (RST) collection tubes. 3. Review of the BD vacutainer Rapid Serum Tube (RST) package insert revealed the following centrifugation recommendation: Rapid Serum Tubes at 4000 RPMs (301 RCFs) for three (3) minutes. 4. In interview on January 22, 2018, Personnel 2 stated she was unaware the Eppendorf 5804 centrifuge requirements did not meet the manufacturer's requirements for centrifugation of the BD Vacutainer Rapid Serum collection tubes.

D5400

ANALYTIC SYSTEMS

CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on observation, record review, and interview with personnel, the laboratory

failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish their own means and ranges for Quality Control (QC) for Hematology testing as required by the manufacturer. Refer to D5469 I. 3. The laboratory failed to establish their own means and ranges for Quality Control (QC) for Immunology testing as required by the manufacturer. Refer to D5469 II. 4. The laboratory's Quality Assurance monitors failed to identify and correct quality issues in Analytic Systems. Refer to D5791.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks 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 review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory failed to have policies and procedures for: a) Performance Specifications to include: * Detailed policies and procedures for testing personnel that instructed testing personnel what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. * Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges and analytical sensitivity and specificity. * Policies and procedures for when data from the studies for precision, accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. b) Addressing Flag issues on Complete Blood Cell counts (CBC) performed on the Medonic Hematology Analyzer and the Beckman Coulter Access 2 Immunology analyzer to include: *Flags and/or Abnormalities *Steps to meet the manufacturer's guidelines *Steps to take when the manufacturer refers to laboratory protocol, and *Laboratory protocol c)Proficiency Testing to include: *one (1) of two (2) and two (2) of three (3) failures for Proficiency Testing results 2. Interview with Personnel 2 on January 22, 2018 stated she was unaware of the policies needed and confirmed the laboratory did not have a complete policy and procedure manual.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials

having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

I. Based on observation, record review, and interview with personnel, the laboratory failed to establish their own means and ranges for Quality Control (QC) for Hematology testing as required by the manufacturer. Findings: 1. Observation by surveyors during laboratory tour on January 22, 2018 revealed the laboratory utilizes the Medonics-M Hematology analyzer for Complete Blood Count (CBC) testing. 2. Further observation revealed the laboratory utilizes the Boule Con-Diff Tri-Level for Quality Control (QC) on the Medonic-M Hematology analyzer. 3. Review of the Boule Con-Diff Tri-Level package insert revealed "Individual laboratories should expect better precision than that shown in the expected range column". 4. Review of QC records revealed the laboratory utilized the manufacturer's ranges for the following two (2) lots: a) October 2017 (Lot: Low-2170831, Normal-2170832, High-2170833) b) December 2017 (Lot: Low-2171121, Normal-2171122, High-2171123) 5. In interview on January 22, 2018 at 230pm, Personnel 2 stated the laboratory utilized the manufacturer's ranges for Hematology QC and confirmed they did not establish their own means and ranges. II. Based on observation, record review, and interview with personnel, the laboratory failed to establish their own means and ranges for Quality Control (QC) for Immunology testing as required by the manufacturer. Findings: 1. Observation by surveyors during laboratory tour on January 22, 2018 revealed the laboratory utilizes the Beckman Coulter Access 2 for Immunology testing. ****NOTE**** Immunology testing to include: Prostate-Specific Antigen (PSA), Free Prostate-Specific Antigen (FPSA), and Testosterone 2. Further observation revealed the laboratory utilizes the Biorad Liquichek Immunoassay Plus Quality Control (QC) for Immunology testing. 3. Review of the Biorad Liquichek Immunoassay Plus Control package insert revealed "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control". 4. Review of QC records revealed the laboratory utilized the manufacturer's ranges for the following two (2) lots: a) Lot: Level 1-40891, Level 2-40892, Level 3-40893 b) Lot: Level 1-40931, Level 2-40932, Level 3-40933 put in use August 2017 5. In interview with Personnel 2 on January 22, 2018 at 230pm, she stated the laboratory utilized the manufacturer's ranges for Immunology QC. Personnel 2 confirmed the laboratory did not establish their own means and ranges.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues in Analytic Systems. Findings: 1. A review of patient test records and quality control records indicated problems found in the analytic systems as follows: a) The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and

	<p>procedures. Refer to D5401. b) The laboratory failed to establish their own means and ranges for Quality Control (QC) for Hematology testing as required by the manufacturer. Refer to D5469 I. c) The laboratory failed to establish their own means and ranges for Quality Control (QC) for Immunology testing as required by the manufacturer. Refer to D5469 II. 2. The laboratory had a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory; however, the monitors failed to identify the deficiencies identified. 3. Interview with Personnel 2 on January 22, 2018 confirmed the laboratory failed to identify the deficiencies cited above.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Refer to D6014. 2. The Laboratory Director failed to ensure that quality control programs were established to assure the quality of laboratory testing. Refer to D6020. 3. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D6021. 4. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6031</p>
<p>D6014</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Refer to D5311.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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</p>

director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that quality control programs were established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to establish their own means and ranges for Quality Control (QC) for Hematology testing as required by the manufacturer. Refer to D5469 I. 2. The laboratory failed to establish their own means and ranges for Quality Control (QC) for Immunology testing as required by the manufacturer. Refer to D5469 II. 3. The laboratory failed to take corrective action when quality control (QC) values were unacceptable for Immunology testing. Refer to D5783.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to 5791.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

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;

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. The laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Refer to D5205. 2. The laboratory failed to have a system in place to ensure that it documents all problems reported to the laboratory. Refer to D5207. 3. The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5401.

<p>D6033</p>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight for the laboratory. Findings: 1. The Technical Consultant failed to provide technical and scientific oversight for the laboratory. Refer to 6036. 2. The Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D6042.</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 laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Refer to D5205. 2. The laboratory failed to have a system in place to ensure that it documents all problems reported to the laboratory. Refer to D5207. 3. The laboratory failed to follow manufacturer requirements for centrifugation of BD Vacutainer Rapid Serum tubes. Refer to D5311. 4. The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. D5401.</p>
<p>D6042</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)</p> <p>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to establish their own means and ranges for Quality Control (QC) for Hematology testing as required by the manufacturer. Refer to D5469 I. 2. The laboratory failed to establish their own means and ranges for Quality Control (QC) for Immunology testing as required by the manufacturer. Refer to D5469 II.</p>