

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2207753	(X3) Date Survey Completed 12/21/2022
Name of Provider or Supplier Ochsner Lsu Health Shreveport Ambulatory Care	Street Address, City, State 1602 Kings Highway, 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 Validation survey was performed at Ochsner LSU Health Shreveport Ambulatory Care Clinic, CLIA # 19D2207753, on December 21, 2022. Ochsner LSU Health Shreveport Ambulatory Care Clinic was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories performing moderate complexity testing; Technical Consultant 42 CFR 493.1421 CONDITION: Laboratories performing moderate complexity testing; Testing Personnel
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, proficiency testing records and interview with personnel, the laboratory failed to retain proficiency testing records for one (1) of five (5) events reviewed for 2021 and 2022. Findings: 1. Review of the laboratory's "POC Proficiency Testing Surveys" policy revealed the following: a) Under "Preparation and Performing Procedure" - "The testing personnel sign the Attestation form acknowledging participation in the survey meeting COM. 01400 PT Attestation Statement. The area and individual who performed the test may be noted on the answer form. The POCT technologist generally will sign the testing personnel area." b) Under "POCT Supervisory Personnel" - "The Attestation statement is signed by the laboratory director or qualified designee and all individuals involved in the testing process fulfilling COM.01400." 2. Review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records for 2021 and 2022 revealed the laboratory did not retain the following attestation statement for one (1) of five (5) events reviewed: a) CAP AQI - A 2022 Critical Care Aqueous Blood Gas 3. In interview on December 21, 2022 at 11:00 am, Technical Consultant 1</p>

confirmed the laboratory did not have the attestation statement for the identified PT event.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's CMS 209 (Laboratory Personnel Report) form, policy and procedures, personnel records, and interview with personnel, the laboratory failed to perform competency assessments as required for eleven (11) of fourteen (14) testing personnel who perform point of care moderate complexity testing. Findings: 1. Review of the CMS 209 form provided to surveyor revealed the laboratory employed the following fourteen (14) testing personnel who performs point of care moderate complexity testing in the specialty of Chemistry: a) Personnel 1 b) Personnel 2 c) Personnel 3 d) Personnel 7 e) Personnel 8 f) Personnel 9 g) Personnel 11 h) Personnel 12 i) Personnel 13 j) Personnel 14 k) Personnel 15 l) Personnel 16 m) Personnel 17 n) Personnel 18 2. Review of the laboratory's "Training, Competency, and Performance Assessment of Laboratory Personnel Policy" revealed the following: "For nonwaived testing, competency must be assessed at the following frequency: * During the first year of an individual's duties, competency must be assessed at least semiannually. * After an individual has performed his/her duties for one year, competency must be assessed at least annually. * Retraining and reassessment of competency must also occur when problems are identified with an individual's performance." 3. Review of personnel records from 2021 and 2022 revealed the laboratory did not have documentation of initial, 6 month, or annual competency assessments for the following eleven (11) of fourteen (14) testing personnel: a) Personnel 7 b) Personnel 8 c) Personnel 9 d) Personnel 11 e) Personnel 12 f) Personnel 13 g) Personnel 14 h) Personnel 15 i) Personnel 16 j) Personnel 17 k) Personnel 18 4. In interview on December 21, 2022 at 11:00 am, Technical Consultant 1 confirmed the laboratory did not perform competency assessments for the identified testing personnel.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:

Based on observation by surveyors, review of laboratory policy and records, 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 proficiency samples were tested as required by qualified testing personnel. Refer to D6016. 2. The Laboratory Director failed to ensure the laboratory employed testing personnel that met the licensure and educational requirements. Refer to D6028. 3. The Laboratory Director failed to ensure testing personnel had appropriate training documentation prior to patient testing. Refer to D6029. 4. The

Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6030.

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 review of the CMS-209 (Laboratory Personnel Report), personnel records, proficiency testing records and interview with personnel, the Laboratory Director failed to ensure proficiency samples were tested as required by qualified testing personnel. Findings: 1. Review of the CMS 209 personnel form provided to surveyor revealed the laboratory employs the following fourteen testing personnel for moderate complexity testing in the specialty of Chemistry: * Personnel 1 * Personnel 2 * Personnel 3 * Personnel 7 * Personnel 8 * Personnel 9 * Personnel 11 * Personnel 12 * Personnel 13 * Personnel 14 * Personnel 15 * Personnel 16 * Personnel 17 * Personnel 18 2. Review of the laboratory's personnel records revealed the laboratory did not have documentation to support the state licensure and/or education requirements for the following fourteen (14) of fourteen (14) testing personnel: * Personnel 1 - no education documented * Personnel 2 - no education documented * Personnel 3 no education documented * Personnel 7 - no state licensure and education documented * Personnel 8 - no state licensure and education documented * Personnel 9 - no state licensure and education documented * Personnel 11 - no state licensure and education documented * Personnel 12 - no state licensure and education documented * Personnel 13 - no state licensure and education documented * Personnel 14 - no state licensure and education documented * Personnel 15 - no state licensure and education documented * Personnel 16 - no state licensure and education documented * Personnel 17 - no state licensure and education documented * Personnel 18 - no state licensure and education documented 3. Review of the laboratory's CAP proficiency testing records for 2021 and 2022 revealed the following proficiency testing samples were performed by testing personnel who did not meet the licensure and/or education requirements for four (4) of five (5) events reviewed: a) CAP AQI - B 2021 Critical Care Aqueous Blood Gas * Personnel 17 performed samples 06 and 09 * Personnel 18 performed samples 07 and 08 b) CAP AQI - C 2021 Critical Care Aqueous Blood Gas * Personnel 16 performed samples 11 and 12 * Personnel 17 performed samples 13 and 15 * Personnel 15 performed samples 14 c) CAP AQI - B 2022 Critical Care Aqueous Blood Gas * Personnel 13 performed samples 06, 07, and 08 * Personnel 14 performed samples 09 and 10 d) CAP AQI - C 2022 Critical Care Aqueous Blood Gas * Five (5) different Testing Personnel signed attestation statement; however, the testing personnel did not identify the samples which they tested 4. In interview on December 21, 2022 at 11:00 am, Technical Consultant 1 confirmed the above identified proficiency testing events were tested by unqualified testing personnel.

D6028

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(10)

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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, personnel records and interview with personnel, the Laboratory Director failed to ensure the laboratory employed testing personnel that met the licensure and educational requirements. Findings: 1. The laboratory failed to ensure testing personnel met the state of Louisiana licensure requirement for eleven (11) of fourteen (14) testing personnel reviewed. Refer to D6064. 2. The laboratory failed to provide documentation that fourteen (14) of fourteen (14) testing personnel reviewed met the educational qualifications for performing moderate complexity testing. Refer to D6065.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's CMS-209 (Laboratory Personnel Report), personnel records and interview with personnel, the Laboratory Director failed to ensure testing personnel had appropriate training documentation prior to patient testing. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) revealed the following testing personnel performs moderate complexity testing in the specialty of Chemistry: * Personnel 1 * Personnel 2 * Personnel 3 2. Review of the personnel records from 2021 and 2022 revealed the Laboratory Director did not review the initial training for the following three (3) of three (3) testing personnel: a) Personnel 1 - initial training performed 10/04/2022 b) Personnel 2 - initial training performed 02/23/2021 c) Personnel 3 - initial training performed 08/09/2022 3. In interview on December 21, 2022 at 11:00 am, Technical Consultant 1 confirmed the initial training for the above identified testing personnel was not reviewed by the Laboratory Director.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

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;

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The laboratory failed to perform competency assessments as required for eleven (11) of fourteen (14) testing personnel who perform point of care moderate complexity testing. Refer to D5209. 2. The Technical Consultants failed to evaluate competency annually for thirteen (13) of fourteen (14) testing personnel reviewed. Refer to D6046.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

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.

This CONDITION is not met as evidenced by:
Based on observation by surveyor, review of laboratory policies, personnel records, and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultants failed to evaluate competency annually for thirteen (13) of fourteen (14) testing personnel reviewed. Refer to D6046.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with personnel, the Technical Consultants failed to evaluate competency annually for thirteen (13) of fourteen (14) testing personnel reviewed. Findings: 1. Review of the personnel records for 2021 and 2022 revealed the laboratory did not have documentation of annual competency assessments for testing personnel performing point of care moderate complexity testing for the following thirteen (13) of fourteen (14) personnel reviewed: a) Personnel 1 b) Personnel 3 c) Personnel 7 d) Personnel 8 e) Personnel 9 f) Personnel 11 g) Personnel 12 h) Personnel 13 i) Personnel 14 j) Personnel 15 k) Personnel 16 l) Personnel 17 m) Personnel 18 2. In interview on December 21, 2022 at 11:00 am,

	<p>Technical Consultant 1 stated that she took over the technical consultant/point of care coordinator position in October 2022. Technical Consultant 1 further stated that she could not find all the documentation for competency assessments for the identified testing personnel. Technical Consultant 1 confirmed the laboratory did not perform annual competency assessments for testing personnel in 2021 and 2022.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of personnel records and interview with personnel, the laboratory failed to provide documentation to ensure all testing personnel met licensure and education requirements. Findings: 1. The laboratory failed to ensure testing personnel met the state of Louisiana licensure requirement for eleven (11) of fourteen (14) testing personnel reviewed. Refer to D6064. 2. The laboratory failed to provide documentation that fourteen (14) of fourteen (14) testing personnel reviewed met the educational qualifications for performing moderate complexity testing. Refer to D6065.</p>
<p>D6064</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a)</p> <p>Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS 209 (Laboratory Personnel Report), personnel records, and interview with personnel, the laboratory failed to ensure testing personnel met the state of Louisiana licensure requirement for eleven (11) of fourteen (14) testing personnel reviewed. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) revealed that the following testing personnel performs moderate complexity testing for the specialty of Chemistry: * Personnel 1 * Personnel 2 * Personnel 3 * Personnel 7 * Personnel 8 * Personnel 9 * Personnel 11 * Personnel 12 * Personnel 13 * Personnel 14 * Personnel 15 * Personnel 16 * Personnel 17 * Personnel 18 2. Review of personnel records revealed the laboratory did not include a state license covering moderate complexity testing issued by Louisiana State Board of Medical Examiners (LSBME) for the following eleven (11) of fourteen (14) testing personnel: * Personnel 7 * Personnel 8 * Personnel 9 * Personnel 11 * Personnel 12 * Personnel 13 * Personnel 14 * Personnel 15 * Personnel 16 * Personnel 17 * Personnel 18 3. In interview on December 21, 2021 at 11:00 am, Technical Consultant 1 confirmed the above identified testing personnel did not have a Louisiana State laboratory license to perform moderate complexity testing.</p>
<p>D6065</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor</p>

of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of the Laboratory Personnel Report (CMS 209), personnel records and interview with personnel, the laboratory failed to provide documentation that fourteen (14) of fourteen (14) testing personnel reviewed met the educational qualifications for performing moderate complexity testing. Findings: 1. Review of the CMS 209 form provided to surveyor and personnel records revealed the laboratory did not maintain documentation of at least a High School Diploma or equivalent for the following fourteen (14) of fourteen (14) testing personnel: a) Personnel 1 b) Personnel 2 c) Personnel 3 d) Personnel 7 e) Personnel 8 f) Personnel 9 g) Personnel 11 h) Personnel 12 i) Personnel 13 j) Personnel 14 k) Personnel 15 l) Personnel 16 m) Personnel 17 n) Personnel 18 2. In interview on December 2, 2022 at 11:00 am, Technical Consultant 1 confirmed the laboratory did not have documentation of education for the above identified Testing Personnel.