

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1039361	(X3) Date Survey Completed 12/18/2019
Name of Provider or Supplier Louisiana Extended Care Hospital Of Lafayette	Street Address, City, State 2810 Ambassador Caffery Pkwy, 6th Floor, Lafayette, 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 Louisiana Extended Care Hospital - CLIA # 19D1039361 on December 18, 2019. Louisiana Extended Care Hospital was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing, Laboratory Director
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure that proficiency testing (PT) documents were signed by the appropriate personnel. Findings: 1. Review of the laboratory's policy for Proficiency Testing (PT) revealed attestations must be signed by testing personnel and the laboratory director. 2. Review of the laboratory's PT records revealed the attestation statements for 2018 Routine Chemistry (1st, 2nd, and 3rd Events) and 2019 Routine Chemistry (1st, 2nd, and 3rd Events) were signed by the Testing Personnel only. The Laboratory Director did not sign all attestation documents. 3. In interview on December 18, 2019, the Laboratory</p>

Manager stated she was unaware that the Laboratory Director needed to sign all Proficiency Testing documents. The Laboratory Manager confirmed the attestation statements were not signed by the Laboratory Director for all six (6) PT events in 2018 and 2019.

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 record review and interview with personnel, the laboratory failed to establish complete competency policies for testing personnel. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. Further review of the laboratory's policy and procedure manual revealed how testing personnel competency will be assessed was not included. 3. In interview on December 18, 2019, the Laboratory Manager confirmed the laboratory's policy and procedure manual did not include competency assessment for testing personnel.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

I. Based on record review and interview with personnel, the laboratory failed to perform an assessment for unsatisfactory proficiency test (PT) results. Findings: 1. Review of the laboratory's 2018 and 2019 College of American Pathologists (CAP) PT results revealed the laboratory received the following "unsatisfactory" results: 2018 Routine Chemistry Event 2: Sample AQ-B 2018 Crit Care/Aqueous Blood Gas for PO2 - "unsatisfactory" 40% 2. Review of the laboratory's PT records revealed the laboratory did not perform an assessment for the identified unsatisfactory CAP PT result. 3. In interview on December 18, 2019 at 09:35 am, the Laboratory Manager stated the laboratory could not find documentation of assessment for the above PT results. II. Based on record review and interview with personnel, the laboratory failed to retain documentation to support proficiency testing results for the third event in 2018. Findings: 1. Review of the laboratory's 2018 College of American Pathologists (CAP) Proficiency Testing (PT) revealed the laboratory did have the proficiency testing evaluation and scores. 2. Further review of the laboratory's 2018 College of

	<p>American Pathologists (CAP) Proficiency Testing (PT) revealed the laboratory did not have the following documentation for Routine Chemistry AQ-B 2018 Crit Care /Aqueous Blood Gas Event 3: a) Attestation forms signed by the Laboratory Director and Testing Personnel b) Raw Data to support proficiency testing results 3. In interview on December 18, 2019 at 09:35 am, the Laboratory Manager stated she could not find the documentation for the above testing event.</p>
<p>D5401</p>	<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 may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish a laboratory policy and procedure manual. Findings: 1. Review of the laboratory's documents and records revealed the laboratory did not have written polices and procedures that included: a) Performance specification: detailed procedures for performing accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference range studies, acceptability criteria for studies, and actions to take when data from the studies fail to meet acceptability criteria b) Quality Control (QC): laboratory practices in place to include the QC material in use, frequency of testing QC, review of QC results, whether an Individualized Quality Control Plan (IQCP) was performed, and notification of personnel when changes occur with each QC specialty. 2. In interview on December 18, 2019 at 03:15 pm, the Laboratory Manager confirmed the above policies were not included in the laboratory policy and procedure manual.</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 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 all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D6018. 2. The Laboratory Director failed to ensure the laboratory followed the corrective action plan for unacceptable proficiency testing results. Refer to D6019. 3. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6030. 4. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.</p>
<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D2015.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory followed the corrective action plan for unacceptable proficiency testing results. Refer to D5221 I and II.

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 record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.

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. Refer to D5401.