

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0893300	(X3) Date Survey Completed 02/12/2019
Name of Provider or Supplier Center For Pediatric And Adolescent Medicine,The	Street Address, City, State 604 North Acadia Road Suite 200, 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 performed at The Center for Pediatric & Adolescent Medicine-CLIA ID # 19D0893300 on February 12, 2019. The Center for Pediatric & Adoloscent Medicine 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 493.1421 CONDITION: Laboratories performing moderate complexity testing; Testing Personnel
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 Clinical Consultant and Technical Consultants were complete. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the following personnel serve as Clinical Consultant and/or Technical Consultant: a) Clinical Consultant: Personnel 2 b) Technical Consultants: Personnel 2 and Personnel 3 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not include a policy related to competency assessment criteria or frequency for personnel serving as Clinical and Technical Consultants. 3. Review of personnel records revealed the laboratory did not perform competency assessments for the duties of Clinical Consultant or Technical Consultant. 4. In interview on February 12, 2019, Personnel 3 stated she did not have a competency assessment performed by the Laboratory Director for her duties as Technical Consultant. Personnel 3 stated she was hired January 2019 and in the facility's probationary period. Personnel 3 further stated the laboratory did not have a policy for competency assessment for personnel serving as Clinical and Technical</p>

	<p>Consultants. Personnel 3 confirmed the laboratory did not have documentation of performance of competency assessment for Personnel 2's duties as Clinical and Technical Consultant.</p>
<p>D5221</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to perform an assessment for unsatisfactory Hematology proficiency test (PT) results. Findings: 1. Review of the laboratory's 2017 and 2018 American Proficiency Institute (API) PT results revealed the laboratory received the following "unacceptable" results for three (3) events: 2017 3rd Event: Sample HEM-15 for Platelet Count, API grade: "unacceptable"-80% 2018 1st Event: Sample HEM-02 for RDW, API grade: "unacceptable"-80% 2018 2nd Event: Sample HEM-10 for RDW, API grade: "unacceptable"-80% 2. Review of the laboratory's PT records revealed the laboratory did not perform assessments for the "unacceptable" by API PT results. 3. In interview on February 12, 2019, Personnel 4 stated for the identified PT results she thought nothing further needed to be done since the scores were 80%. Personnel 4 further stated she was unaware any score below 100 % needed to be investigated.</p>
<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to monitor the temperature of the closet where laboratory reagents are stored per manufacturer requirements. Findings: 1. Observation by surveyor during the laboratory tour on February 12, 2019 revealed the following reagents were stored outside of the main laboratory in a closet without temperature monitoring: a) Cell Dyn Emerald Cleaner, Lot # 7746, Quantity: one (1) bottle b) Cell Dyn Emerald Diluent, Quantity: (1) box c) Cell Dyn, CN-Free Lyse, Lot #770, Quantity: one (1) bottle 2. Review of the manufacturer's requirements for the identified items revealed a temperature requirement of 4-35 degrees Celsius. 3. In interview on February 12, 2019 at 10:00 am, Personnel 4 stated the laboratory does not monitor the temperature of the storage closet where the identified items were stored.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other</p>

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:

Based on observation and interview with personnel, the laboratory failed to ensure reagents have not exceeded their expiration date. Findings: 1. Observation by surveyor during the laboratory tour on February 12, 2019 revealed the following expired items located in the laboratory's Kenmore refrigerator: a) Hemotrol Level 1, Lot #63165, Expiration date: 2018-04, Quantity: one (1) box b) Hemotrol Level 2, Lot # 63666, Expiration date: 2018-04, Quantity: one (1) box c) Hemotrol Level 3, Lot # 62067, Expiration date: 2018-01, Quantity: one (1) box 2. In interview on February 12, 2019 at 10:00 pm, Personnel 4 stated she was unaware the identified items had expired. Personnel 4 further stated the identified items were unused.

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:

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 surveyor during laboratory tour on February 12, 2019 revealed the laboratory utilizes the Emerald Cell Dyn instrument with Cell-Dyn 18 Plus Controls for Complete Blood Count (CBC) testing. 2. Review of the Cell-Dyn 18 Plus Control package insert under "Performance Characteristics" section revealed the following: "The recovery ranges are intended to reflect inter-laboratory and inter-instrument variability; thus they are wider than the +/- 2 SD QC range for one instrument. Always perform quality control according to good laboratory practice, laboratory director's requirements, and any regulatory or accreditation requirements." 3. Review of the laboratory's "Quality Control Policy-Cell Dyn Emerald" revealed the following: Effective January 16, 2019: a) "Prior to implementation of a new lot of quality control, testing personnel will verify the accuracy of said lot and run it concurrently along with the current lot that is being used." b) "To prevent a quality control range that may be too narrow, our policy is to use the ranges as established by the manufacturer's package insert. The quality control will be closely monitored on a consistent basis as well as alongside a peer-review program to allow our laboratory to compare its performance with that of other laboratories." 4. Review of the laboratory's quality control records for December 2017, October 2018, and January 2019 revealed the laboratory utilized the

manufacturer's ranges of wider than 2 standard deviations (SD) for the following lot numbers put in use: a) Cell Dyn 18 Plus Low Control: Lot # L9014 b) Cell Dyn 18 Plus Normal Control: Lot # N9014 c) Cell Dyn 18 Plus High Control: Lot # H9014 5. In interview on February 12, 2019 at 10:20 am, Personnel 3 stated prior to January 2019, the laboratory established their own QC means and ranges. 6. In further interview on February 12, 2019 at 10:50 am, Personnel 3 and Personnel 4 stated the laboratory had issues with the established ranges being too tight with frequent repeats of QC material. Personnel 3 stated the Laboratory Director approved the laboratory utilizing the manufacturer's ranges and implemented a new quality control policy effective January 2019.

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, 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 the laboratory personnel were performing test methods as required for accurate and reliable results. Refer to D6014. 2. 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. 3. The Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Refer to D6020. 4. The Laboratory Director failed to ensure testing personnel performing moderate complexity testing met educational requirements. Refer to D6029. 5. The Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D6030.

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 temperature of the closet where laboratory reagents are stored per manufacturer requirements. Refer to D5413. 2. The laboratory failed to ensure reagents have not exceeded their expiration date. Refer to D5417.

<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(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;</p> <p>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 D5221.</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 director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Refer to D5469.</p>
<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</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)(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure testing personnel performing moderate complexity testing met educational requirements. Refer to D6065.</p>
<p>D6030</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES</p>

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 were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. The laboratory failed to ensure written policies and procedures to address competency for Clinical Consultant and Technical Consultants were complete. Refer to D5209. 2. The Technical Consultant(s) failed to evaluate and document the performance of individuals at least semi-annually during the first year for one (1) of three (3) testing personnel reviewed. Refer to D6053.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Technical Consultant(s) failed to evaluate and document the performance of individuals at least semi-annually during the first year for one (1) of three (3) testing personnel reviewed. Findings: 1. Review of personnel records for Personnel 5 revealed no documentation of performance of semi-annual competency evaluation, due September 2018. 2. In interview on February 12, 2019, Personnel 4 stated the laboratory could not find documentation of a semi-annual competency evaluation for Personnel 5.

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

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.

This CONDITION is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to provide documentation to ensure all testing personnel met education requirements. Refer to D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor 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 record review and interview with personnel, the laboratory failed to provide documentation that one (1) of three (3) testing personnel reviewed met the educational qualifications for performing moderate complexity testing. Findings: 1. Review of personnel records on February 12, 2019 revealed the laboratory failed to maintain documentation of at least a High School Diploma or equivalent for the following personnel: Personnel 5 2. In interview on February 12, 2019, Personnel 4 confirmed the laboratory did not maintain documentation of education for Personnel 5.