

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0982563	(X3) Date Survey Completed 05/25/2018
Name of Provider or Supplier Cornerstone Pediatrics	Street Address, City, State 1055 Parkway Drive Suite A, Natchitoches, 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 Certification Survey was performed on May 25, 2018 at Cornerstone Pediatrics - CLIA #19D0982563 and was found in compliance with 42 CFR 493, Requirements for Laboratories. However, standard level deficiencies were cited.
D5207	<p>COMMUNICATIONS CFR(s): 493.1234</p> <p>The laboratory must have a system in place 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.</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 identifies 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. 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 2 on May 25, 2018 confirmed the laboratory failed to have a complete policy and procedure manual.</p>
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>

This STANDARD is not met as evidenced by:
Based on review of laboratory policy and procedure manual, and interview with personnel, the laboratory failed to establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to establish written policies and procedures that include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel involved in any phase of 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. Interview with personnel 2 on May 25, 2018 confirmed the laboratory failed to have a complete policy and procedure manual.

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 record review 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 did not have detailed instructions for: Proficiency Testing (PT): a) Ordering and ensuring that you are enrolled for Proficiency Testing. b) What to do when you receive samples from the PT Provider. c) How to handle the samples; who will test, when to test, how do you assure no inter and intra laboratory communication takes place d) How to record results to send into the PT Provider to be scored. e) What records to maintain. f) How to evaluate when you receive your scores from the PT Provider. g) What steps to take if corrective action is needed. h) What steps are required when the laboratory has their first and second two (2) out of three (3) failures. Policies and Procedures addressing the current Hematology Analyzer; Horiba Micros 60 Hematology Analyzer and not the Hematology Analyzer no longer in use: Abbott Cell Dyn 1700 Hematology Analyzer. Description of the course of action to take if the Horiba Micros 60 Hematology Analyzer becomes inoperable. Personnel Competency to include written policies and procedures that 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: and that assessments are to be performed semi

annually the first year and annually thereafter. Complaint Policies and Procedures Communication Policies and Procedures 2. Interview with personnel 2 on May 25, 2018 confirmed the policy and procedure manual was incomplete

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other 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 laboratory personnel, the laboratory failed to ensure that ABX Minoclar is not used beyond their expiration dates. Findings: 1. Observation by the surveyors during the tour of the laboratory on May 25, 2018 revealed the following expired items in place for patient testing: ABX Minoclar - lot number 160607L, with an expiration date of 2017-06-07. 2. Interview with personnel 2 on May 25, 2018 confirmed by observation the items cited were expired and in place for patient testing.

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 personnel, the Laboratory Director failed to ensure that the laboratory had a complete policy and procedure manual. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory did not have detailed instructions for: Proficiency Testing (PT): a) Ordering and ensuring that you are enrolled for Proficiency Testing. b) What to do when you receive samples from the PT Provider. c) How to handle the samples; who will test, when to test, how do you assure no inter and intra laboratory communication takes place d) How to record results to send into the PT Provider to be scored. e) What records to maintain. f) How to evaluate when you receive your scores from the PT Provider. g) What steps to take if corrective action is needed. h) What steps are required when the laboratory has their first and second two (2) out of three (3) failures. Policies and Procedures addressing the current Hematology Analyzer; Horiba Micros 60 Hematology Analyzer and not the Hematology Analyzer no longer in use: Abbott Cell Dyn 1700 Hematology Analyzer. Description of the course of action to take if the Horiba Micros 60 Hematology Analyzer becomes inoperable. Personnel Competency to include written policies and procedures that 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: and that assessments are to be performed semi annually the first year and annually thereafter. Complaint Policies and Procedures Communication Policies and Procedures 2. Interview with personnel 2 on May 25, 2018 confirmed the policy and procedure manual was incomplete

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to provide written job descriptions for all Laboratory Personnel. Findings: 1. Review of FORM 209 provided to the surveyor on May 8, 2018 revealed the laboratory failed to have written job descriptions for the following personnel: a) Clinical Consultant b) Testing Personnel 2. Interview with Personnel 2 on May 25, 2018 confirmed the laboratory failed to have written job descriptions for all Laboratory Personnel.

D6054

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 annually, after the first year.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Technical Consultant failed to evaluate and document the performance of individuals annually, for one (1) of three (3) personnel reviewed. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory had written personnel policies and procedures for personnel competency that state the laboratory is to document competency/evaluation of new personnel for orientation (when hired), twice the first year (6 months and annual) then annually thereafter. 2. Review of Personnel 2 Personnel Records revealed the laboratory failed to include documentation of annual competency /evaluations. 3. Interview with Personnel 2 on May 25, 2018 confirmed the laboratory did not perform an annual evaluation for her.