

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0982563	(X3) Date Survey Completed 08/31/2022
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 Recertification survey was performed on August 31, 2022 at Cornerstone Pediatrics, CLIA ID # 19D0982563. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on observation during the laboratory tour, review of the laboratory policy and calibration records as well as interview with personnel, the laboratory failed to retain calibration documentation for the Horiba ABX Micros 60 hematology analyzer in 2021. Findings: 1. Observation by surveyor during the laboratory tour on August 31, 2022 at 1:00 pm revealed the laboratory utilized the Horiba ABX Micros 60 Hematology analyzer for Complete Blood Count (CBC) testing. 2. Review of the laboratory's policy for Hematology calibration revealed the laboratory performs calibrations for the Horiba ABX Micros 60 Hematology analyzer every six (6) months per manufacturer requirements. 3. Review of the laboratory's hematology calibration records for 2020, 2021, and 2022 revealed the laboratory did not retain the documentation of calibration for the following two (2) of four (4) events in 2021: a) May 2021 b) November 2021 4. In interview on August 31, 2022 at 2:50 pm, Testing Personnel 1 stated that the field service representative performs the hematology calibrations but she could not find the documentation to support the calibrations. Testing Personnel 1 confirmed the laboratory did not have calibration documentation for the identified events.</p>

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 by surveyor and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed and retained documentation of test methods as required. Refer to D3031.