

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2122735	(X3) Date Survey Completed 06/21/2023
Name of Provider or Supplier Acorn To Oak Pediatrics	Street Address, City, State 1025 Hwy 80 E, Haughton, 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 June 21, 2023 at Acorn to Oaks Pediatrics, CLIA ID # 19D2122735. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation by surveyor and interview with personnel, the laboratory failed to ensure supplies did not exceed expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on June 21, 2023 at 2:40 pm revealed the following expired items: eSwab Collection & Preservation of Aerobic, Anaerobic, & Fastidious Bacteria Lot N2009550; Expiration 05/31/2023; Quantity: 32 swabs 2. In interview on June 21, 2023 at 3:00 pm, Personnel 2 confirmed the identified supplies exceeded the expiration date.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyors, review of maintenance records, and interview</p>

with laboratory personnel, the laboratory failed to ensure the weekly and monthly maintenance on the Beckman Coulter DxH 500 was performed as required by the manufacturer. Findings: 1. Observation by surveyor during the laboratory tour June 21, 2023 at 2:40 pm revealed laboratory utilized a Beckman Coulter DxH 500 analyzer for Complete Blood Count (CBC) testing in the specialty of Hematology. 2. Review of the maintenance log for the Beckman Coulter DxH 500 hematology analyzer revealed the following weekly and monthly maintenance to be performed: a) Weekly: * Reviewed Levey Jennings * Problems, shifts, trends noted with Levey Jennings b) Monthly: * EyeWash Check * DxH 500 Bleach cycle (performed monthly or every 1,000 cycles) 3. Review of the maintenance records for the Beckman Coulter DxH 500 analyzer from January 2022 through April 2023 revealed the laboratory did not perform the following maintenance: a) Weekly: January 27, 2023 b) Monthly Bleach cycle: * September 2022 * November 2022 * February 2023 * March 2023 * April 2023 4. In interview on June 21, 2023 at 4:15 pm, Personnel 2 stated the monthly bleach cycle is performed every 1,000 cycles instead of monthly but she did not document maintenance forms as needed. Personnel 2 confirmed the identified maintenance was not performed as required.

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, review of laboratory policy and records along with interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to ensure supplies did not exceed expiration dates. Refer to D5417.

D6023

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(6)

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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:
Based on review of laboratory policy and records as well as interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Findings: 1. The laboratory failed to ensure the weekly and monthly maintenance on the Beckman Coulter DxH 500 was performed as required by the manufacturer. Refer to D5429.