

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0457593	<b>(X3) Date Survey Completed</b>  02/11/2026
<b>Name of Provider or Supplier</b>  Pediatric Clinic - Westbank	<b>Street Address, City, State</b>  151 Ochsner Blvd, Suite F, Gretna, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Recertification survey was performed at Pediatric Clinic Westbank, CLIA ID 19D0457593, on February 11, 2026. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 by surveyor, review of manufacturers' storage requirements, and interview with personnel, the laboratory failed to monitor the room temperature of one (1) of one (1) storage rooms where laboratory supplies were stored. Findings: 1. Observation by surveyor during the laboratory tour on February 11, 2026 at 9:37 am revealed the following items were stored in a storage room without temperature monitoring: a) Abbott ID Now Strep A2 test kits b) Abbott ID Now RSV test kits c) Abbott ID Now Influenza A &amp; B test kits d) Coulter DxH Diluent e) Coulter DxH Cell Lyse f) Coulter DxH Cleaner 2. Review of the manufacturers' storage requirements revealed the following: a) Abbott ID Now test kits storage temperature of 2-30 degrees Celsius b) Coulter DxH Diluent storage temperature of 2-40 degrees Celsius c) Coulter DxH Cell Lyse storage temperature of 2-40 degrees Celsius d) Coulter DxH Cell Lyse storage temperature of 2-25 degrees Celsius e) Coulter DxH</p>

Cleaner storage temperature of 2-25 degrees Celsius 3. In interview on February 11, 2026 at 9:32 am, Medical Assistant 2 stated the room temperature of the storage room was not monitored.

**D5415**

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

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of the manufacturer's instructions, test menu, and interview with personnel, the laboratory failed to label in-use Complete Blood Count (CBC) controls with open expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on February 11, 2026 at 9:15 am revealed the following Coulter 6 Cell controls loaded in two instrument racks in the American BioTech Supply refrigerator were not labeled with the updated open expiration dates: Rack 1: Level 1 lot 123176280, Level 2 lot 133186280 and Level 3 lot 143196280; Rack 2: lot 123176300, Level 2 lot 133186300 and Level 3 lot 143196300. The tubes were labeled with an open date of February 9, 2026. 2. Review of the manufacturer's package insert for the Coulter 6 Cell controls revealed the controls open vial stability as sixteen days not to exceed eighteen events. 3. In interview on February 11, 2026 at 9:32 am, Medical Assistant 2 confirmed the identified controls were not labeled with open expiration dates. 4. Review of the laboratory's test menu revealed the laboratory performs 43,860 CBC tests annually.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of the laboratory's performance specification studies, and interview with personnel, the laboratory failed to have complete accuracy and precision studies for Complete Blood Count (CBC) testing. Findings: 1. Observation by surveyor during the laboratory tour on February 11, 2026 at 9:15 am revealed the laboratory utilizes the Beckman Coulter DxH 690T instrument for CBC testing. 2. Review of the laboratory's performance specification studies for CBC testing revealed the laboratory did not include complete precision studies and acceptability criteria for the accuracy study. 3. In interview on February 11, 2026 at 10:25 am, Medical Assistant 1 confirmed the laboratory did not include complete precision studies and acceptability criteria for the accuracy study .

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:

Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure performance specification studies were complete. Refer to D5421.

**D6014**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(3)(iii)

(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, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. 1. The laboratory failed to monitor the room temperature of one (1) of one (1) storage rooms where laboratory supplies were stored. Refer to D5413. 2. The laboratory failed to label in-use Complete Blood Count (CBC) controls with open expiration dates. Refer to D5415.