

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0463303	<b>(X3) Date Survey Completed</b>  04/16/2026
<b>Name of Provider or Supplier</b>  North Caddo Medical Center	<b>Street Address, City, State</b>  715 S Pine, Vivian, 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 North Caddo Medical Center, CLIA ID 19D0463303, on April 13, 2026 through April 16, 2026. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 review of laboratory policy and personnel records as well as interview with personnel, the laboratory failed to follow their established competency assessment policy for one (1) of thirteen (13) testing personnel reviewed. Findings: 1. Review of the laboratory's "Competency Evaluation for Personnel Performing Clinical Testing" revealed "Newly hired personnel or a current staff member who is learning a procedure for the first time must demonstrate competency in accordance with the following schedule: 1. Initial training and competency must be documented prior to the reporting of any patient results; 2. Six months following the initial competency; 3. Twelve months following the initial competency; 4. Annually thereafter". 2. Review of the laboratory's personnel records revealed the laboratory did not document competency assessment for the following one (1) of thirteen (13) testing personnel within the established schedule: a) Testing Personnel 3 - Initial 10/13/2023; 6 month 05/11/2024; Annual 5/7/2025 3. In interview on April 13, 2026 at 01:15 pm, General Supervisor 2 confirmed the competency assessment for Testing Personnel 3 was not performed as required by laboratory policy.</p>
<b>D5403</b>	<b>PROCEDURE MANUAL</b>

CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

I. Based on observation by surveyor, review of laboratory policy, blood bank circular charts and interview with personnel, the laboratory failed to follow their established policy for documenting deviations of the acceptable range for the blood bank circular charts reviewed in 2025 and 2026. Findings: 1. Observation by surveyor during the laboratory tour on April 16, 2026 at 930 am revealed the laboratory utilizes the following refrigerator and freezer to monitor blood bank products: a) Helmer Freezer (Fresh Frozen Plasma) b) Helmer Refrigerator (Packed Red Blood Cells) 2. Review of the laboratory's blood bank policy under "Blood Bank Refrigerators/Freezers Maintenance" revealed "Document on chart any excursions from the acceptable range, e.g. replacing inventory, cleaning, alarm checks, etc". 3. Review of the laboratory's blood bank circular charts from 2025 and 2026 revealed the laboratory did not document deviations of temperatures for the following five (5) of sixty six (66) weeks reviewed: a) Helmer Freezer circular charts \* Week of February 19, 2025 through February 26, 2025 \* Week of May 14, 2025 through May 21, 2025 \* Week of August 27, 2025 through September 3, 2025 \* Week of January 7, 2026 through January 14, 2026 \* Week of February 11, 2026 through February 18, 2026 b) Helmer Refrigerator circular charts \* Week of February 19, 2025 through February 26, 2025 \* Week of May 14, 2025 through May 21, 2025 \* Week of August 27, 2025 through September 3, 2025 \* Week of January 7, 2026 through January 14, 2026 \* Week of February 11, 2026 through February 18, 2026 4. In interview on April 15, 2026 at 10:45 am, the Technical Consultant confirmed the laboratory did not follow the policy for documentation of circular charts for the identified weeks. II. Based on observation by surveyor, review of laboratory policy and quality control records as well as interview with personnel, the laboratory failed to follow their established quality control (QC) policy for the specialty of Hematology. Findings: 1. Observation during the laboratory tour on April 16, 2026 at 10:00 am revealed the laboratory utilizes the Cell-Dyn Ruby Hematology analyzer for Complete Blood Count (CBC) patient testing. 2. Review of the laboratory's "Cell-Dyn 26 Hematology Controls" policy under Quality Control revealed "The three levels of quality control material are to be analyzed every 24 hours of patient testing in the open mode and in closed mode is used for patient

	<p>testing". 3. Further review of the laboratory's quality control policy revealed the laboratory utilizes the Cell-Dyn 26 controls which includes low, normal and high levels. 3. Review of the laboratory's quality control records revealed the laboratory did not perform the normal control on July 17, 2025. 4. In interview on April 15, 2026 at 03:15 pm, the Technical Consultant stated the QC was not identified with Quality Assurance (QA) review. The Technical Consultant confirmed the normal QC level was not performed on the identified date per laboratory policy.</p>
<p><b>D5417</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy and blood bank reagent logs as well as interview with personnel, the laboratory failed to ensure blood bank reagents were not utilized past their expiration dates for two (2) of eighty seven (87) weeks reviewed. Findings: 1. Review of the laboratory's "Blood Bank" policy revealed "Document Lot # and Expiration Date on QC record EACH WEEK directly from the vials/saline bottle". 2. Review of the laboratory's blood bank reagent logs from August 2024 through March 2026 revealed the following expired reagents were utilized for the following two (2) of eighty seven (87) weeks reviewed: a) Week of October 14, 2024 through October 20, 2024 * Immucor Poly AHG - Lot 702030; Expiration 10/08/24 b) Week of December 16, 2025 through December 22, 2024 * Ortho Confidence 1 Cells - Lot CNF370; Expiration 12/10/24 * Ortho Confidence 2 Cells - Lot CNF370; Expiration 12/10/24 * Ortho Confidence Antiserum - Lot CNF370; Expiration 12/10/24 3. In interview on April 15, 2026 at 10:00 am, the Technical Consultant stated the laboratory started reviewing the blood bank log more thoroughly in 2025 and 2026. The Technical Consultant confirmed the identified weeks had documentation of expired blood bank reagents documented.</p>
<p><b>D6014</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(3)(iii)</p> <p>(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory policy and records, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5417.</p>
<p><b>D6030</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(12)</p> <p>(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</p>

	<p>necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, personnel records and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.</p>
<p><b>D6031</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(13)</p> <p>(e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's policy, records and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to follow their established policy for documenting deviations of the acceptable range for the blood bank circular charts reviewed in 2025 and 2026. Refer to D5403 I. 2. The laboratory failed to follow their established quality control (QC) policy for the specialty of Hematology. Refer to D5403 II.</p>
<p><b>D6036</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy and records and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to follow their established policy for documenting deviations of the acceptable range for the blood bank circular charts reviewed in 2025 and 2026. Refer to D5403 I. 2. The laboratory failed to follow their established quality control (QC) policy for the specialty of Hematology. Refer to D5403 II. 3. The laboratory failed to ensure blood bank reagents were not utilized past their expiration dates for two (2) of eighty seven (87) weeks reviewed. Refer to D5417.</p>
<p><b>D6046</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--</p>

This STANDARD is not met as evidenced by:  
Based on review of laboratory policy, personnel records and interview with personnel,  
the Technical Consultant failed to perform complete competency assessment  
procedures. Refer to D5209.