

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0934736	(X3) Date Survey Completed 02/27/2023
Name of Provider or Supplier Ncmc Plain Dealing Medical Clinic	Street Address, City, State 112 North Forrest Street, Plain Dealing, 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 February 27, 2023 at North Caddo Medical Center Plain Dealing Clinic, CLIA ID # 19D0934736. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, temperature records and interview with personnel, the laboratory failed to document corrective actions for unacceptable freezer temperatures in 2022 and 2023 as required by laboratory policy. Findings: 1.</p>

Review of the laboratory's policy under "Specific Preventative Maintenance Activities" revealed "Temperature readings of refrigerators, freezers, and on-board instrument temperature monitors are read once daily. Out of range temperature should be recognized and responded to with documented corrective action". 2. Review of the laboratory's temperature logs for 2022 and 2023 revealed the laboratory freezer temperature has an acceptable range of -10 degrees celsius to -25 degrees celsius. 3. Further review of the laboratory's temperature logs for 2022 and 2023 revealed the laboratory did not document corrective actions for the following sixty one (61) days of fourteen (14) months reviewed: a) December 2022 * December 1, 2022 - temperature documented as eleven (11) degrees celsius * December 2, 2022 - temperature documented as eleven (11) degrees celsius * December 5, 2022 - temperature documented as eleven (11) degrees celsius * December 6, 2022 - temperature documented as eleven (11) degrees celsius * December 7, 2022 - temperature documented as eleven (11) degrees celsius * December 8, 2022 - temperature documented as eleven (11) degrees celsius * December 9, 2022 - temperature documented as eleven (11) degrees celsius * December 12, 2022 - temperature documented as eleven (11) degrees celsius * December 13, 2022 - temperature documented as eleven (11) degrees celsius * December 14, 2022 - temperature documented as eleven (11) degrees celsius * December 15, 2022 - temperature documented as eleven (11) degrees celsius * December 16, 2022 - temperature documented as eleven (11) degrees celsius * December 19, 2022 - temperature documented as eleven (11) degrees celsius * December 20, 2022 - temperature documented as eleven (11) degrees celsius * December 21, 2022 - temperature documented as eleven (11) degrees celsius * December 22, 2022 - temperature documented as eleven (11) degrees celsius * December 27, 2022 - temperature documented as eleven (11) degrees celsius * December 28, 2022 - temperature documented as eleven (11) degrees celsius * December 29, 2022 - temperature documented as eleven (11) degrees celsius * December 30, 2022 - temperature documented as eleven (11) degrees celsius * December 31, 2022 - temperature documented as eleven (11) degrees celsius b) January 2023 * January 3, 2023 - temperature documented as eleven (11) degrees celsius * January 4, 2023 - temperature documented as eleven (11) degrees celsius * January 5, 2023 - temperature documented as eleven (11) degrees celsius * January 6, 2023 - temperature documented as eleven (11) degrees celsius * January 9, 2023 - temperature documented as eleven (11) degrees celsius * January 10, 2023 - temperature documented as eleven (11) degrees celsius * January 11, 2023 - temperature documented as eleven (11) degrees celsius * January 12, 2023 - temperature documented as eleven (11) degrees celsius * January 13, 2023 - temperature documented as eleven (11) degrees celsius * January 16, 2023 - temperature documented as eleven (11) degrees celsius * January 17, 2023 - temperature documented as eleven (11) degrees celsius * January 18, 2023 - temperature documented as eleven (11) degrees celsius * January 19, 2023 - temperature documented as eleven (11) degrees celsius * January 20, 2023 - temperature documented as eleven (11) degrees celsius * January 23, 2023 - temperature documented as eleven (11) degrees celsius * January 24, 2023 - temperature documented as eleven (11) degrees celsius * January 25, 2023 - temperature documented as eleven (11) degrees celsius * January 26, 2023 - temperature documented as eleven (11) degrees celsius * January 27, 2023 - temperature documented as eleven (11) degrees celsius * January 30, 2023 - temperature documented as eleven (11) degrees celsius * January 31, 2023 - temperature documented as eleven (11) degrees celsius c) February 2023 * February 1, 2023 - temperature documented as eleven (11) degrees celsius * February 2, 2023 - temperature documented as eleven (11) degrees celsius * February 3, 2023 -

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 temperature documented as eleven (11) degrees celsius * February 27, 2023 -
 temperature documented as eleven (11) degrees celsius 4. In interview on February 27, 2023 at 2:03 pm, Testing Personnel 2 stated that she did not think to put the negative sign in front of the temperature documented. Testing Personnel 2 confirmed the laboratory did not document corrective action for the identified days above.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory temperature records and interview with personnel, the laboratory failed to establish complete procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5403.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
 Based on review of laboratory records, and interview with personnel, the Laboratory Director failed to ensure that a complete quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D5791.

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 review of laboratory policy and procedure manual and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.