

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2265294	(X3) Date Survey Completed 09/19/2024
Name of Provider or Supplier Red River Women's Clinic	Street Address, City, State 302 Hwy 75 N, Suite 108, Moorhead, MN	
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	The Red River Women's Clinic laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on September 19, 2024. The following standard-level deficiencies were cited: 493.1254 Maintenance and function checks - (a)(2) and (b)(2) .
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document function checks (calibration) for 2 of 2 digital thermometers in 2024. Findings are as follows: 1. The laboratory performed Rhesus (Rh) typing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:00 a.m. on 09/19/24. 2. The following digital thermometers were observed as in use during the tour: ML traceable thermometer Serial #: 221203375 Calibration Expiration Date: 01/31/24 Location: Refrigerator Use: Rh quality control material and patient specimen storage temperature monitoring Marketlab thermometer and hygrometer Serial #: 221551149 Calibration Expiration Date: 05/31/24 Location: Countertop Use: Daily room temperature and humidity monitoring 3. Function check documentation for this equipment was not found in laboratory records. The laboratory was unable to provide current certificates of calibration or function check documentation for the equipment upon request. 4. A procedure defining equipment</p>

function check activities and frequency was not found during review of laboratory policies and procedures. See D5435 5. In an interview at 10:05 a.m. and 11:30 a.m. on 09/19/24, TP1 confirmed the above finding. .

D5435

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to establish a function check procedure and perform function checks for general laboratory equipment . Findings are as follows: 1. The laboratory performed Rhesus (Rh) typing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:00 a.m. on 09/19/24. 2. The following ONiLAB mechanical pipettes were observed as present and available for use during the tour: Serial # YE224AX0255086 Type: Single channel, 5-50 ul Serial # YE224AX0255090 Type: Single channel, 5-50 ul The calibration date found on the manufacturer certificates was 05/22/22 for both pipettes. The manufacturer's operator's manual did not provide calibration frequency requirements. 3. Function check documentation for this equipment was not found in laboratory records. The laboratory was unable to provide function check documentation for the equipment upon request. 4. Function check requirements for laboratory equipment were not included in the CLIA Notebook policies and procedures found in the CLIA Log manual. 5. In an interview at 10:10 a.m. on 09/19/24, TP1 confirmed the above finding. .