Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0409775	06/18/2026
Name of Provider or Supplier	**Street Address, City, State**	
Nemhs Trinity Hospital Lab	315 Knapp St, Wolf Point, MT	

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 Montana CLIA Program conducted a recertification survey ending on June 18, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and was found to be in compliance with condition-level CLIA requirements. However, the following standard-level deficiencies were identified during the survey.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on a microbiology record review and interview with Technical Supervisor (TS1), the laboratory failed to retain two years of patients' BD BACTEC blood culture test records from June 17, 2024 to May 5, 2026. Findings: 1. A review of patient result reports (25 065 0430 dated March 6, 2025, and 25 055 6113 dated February 24, 2025) and related microbiology records showed that no BD BACTEC FX blood culture patient test records had been retained. 2. An interview with TS1 on June 17, 2026, at 4:30 PM confirmed the BD BACTEC FX only retained patients records through May 5, 2026, and that earlier records had not been retained. 3. A review of the test volume sheet revealed 903 patient blood cultures were performed between June 17, 2025, to June 17, 2026 (12 months).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks

	may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on microbiology record review and interview with Technical Supervisor (TS1), the laboratory failed to follow its procedure to report positive BD BBL Taxo P Disc test results as presumptive or perform a definitive identification test for Streptococcus pneumoniae for 11 of 12 patients' blood cultures tested from January 1, 2024, to June 18, 2026. Findings: 1. A review of patient result report (25 065 0430) showed the final report was issued as "Streptococcus pneumoniae isolated". A review of the patient's microbiology test records confirmed a positive BD BBL Taxo P Disc test was performed and no additional definitive identification test for Streptococcus pneumoniae was performed. 2. A review of the laboratory's procedure "Staff Micro - Presumptive Identification of S. Pneumoniae Using The BD P Disk" states "BD BBL Taxo P Disc tests are presumptive" and "Positive results should be followed with more specific tests". The laboratory did not follow the procedure when reporting positive P Disc results. 3. An interview with TS1 on June 18, 2026, at 8:00 AM confirmed the laboratory did not follow its procedure and reported 11 of 12 patient blood cultures definitively as Streptococcus pneumoniae based solely on the presumptive P Disc test result from January 1, 2024, to June 18, 2026.