

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0404769	(X3) Date Survey Completed 05/12/2022
Name of Provider or Supplier Mankato Clinic	Street Address, City, State 1230 East Main Street, Mankato, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to enroll in an HHS approved proficiency testing program as required under 493.801 for testing performed under the subspecialty of Virology. Findings are as follows: The laboratory failed to enroll in an HHS approved proficiency testing program for SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus testing performed using the SARS-CoV-2/Flu/RSV cartridge on the Cepheid GeneXpert. Failure to enroll in an HHS approved proficiency program as required under 493.801 constitutes Condition level non-compliance. .</p>
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by:</p>

. Based on document review and interview with laboratory personnel, the laboratory failed to ensure proficiency testing (PT) samples from four of four Blood Cell Identification PT events from 2021 through early-2022 and two of two Clinical Microscopy PT events from 2021 were tested consistent with the number of times the laboratory routinely tested patient specimens. Findings are as follows: 1. The laboratory performed microscopic examinations for Blood Cell Identification, Urine Sediment, Vaginal Wet Prep, Fern, KOH Prep, Nasal Smear, Pinworm Prep, Stool Leukocytes, and Spermatozoa as confirmed by the General Supervisor (GS)) during a tour of the laboratory at 1:05 p.m. on 05/11/22. 2. The laboratory performed PT in 2021 and 2022 using the College of American Pathologists (CAP) proficiency testing provider. 3. The Proficiency Testing Procedure found in the QA Manual indicated PT samples would be tested in the same manner as patient specimens. 4. The Blood Cell Identification (BCP) PT samples were tested by multiple testing personnel (TP) and Technical Supervisors (TS) for four of four PT events reviewed from 2021 through early-2022 as indicated on attestation statements and survey result forms. See below. 2021 KP-A Samples: BCP-01 through BCP-06 Tested by: TS1, TS2, TC3, TP1, TP2, TP3, TP5, former TP KB 2021 KP-B Samples: BCP-06 through BCP-10 Tested by: TS2, TS3, TS4, TP1, TP2, TP3, TP4, TP5 2021 KP-C Samples: BCP-11 through BCP-16 Tested by: TS2, TS3, TS4, TP1, TP2, TP3, TP4, TP5 2022 KP-A Samples: BCP-01 through BCP-06 Tested by: TS1, TS2, TC4, TP1, TP2, TP3, TP4, TP5, TP8 5. The Clinical Microscopy samples were tested by multiple TP's and TS's for two of two PT events reviewed from 2021 as indicated on attestation statements and survey result forms. See below. 2021 CM-A Samples: CMP-04 through CMP-06, CMMP-26, USP-01 through USP-03 Tested by: TS1, TS2, TS3, TS4, TP1, TP2, TP3, TP4, TP8, former TP's KB and TB Samples:CMMP-20 through CMMP-25 Tested by: TS1, TS2, TS3, TS4 TP1, TP3, TP4, TP8, former TP KB 2021 CM-B Samples: CMP-13 through CMP-15, CMMP-30 through CMMP-35, CMMP-36, USP-04 through USP-06 Tested by: TS1, TS2, TP1, TP2, TP3, TP4, TP5, TP8, former TP TB CMP - Urine Sediment CMMP - Vaginal Wet Prep, Fern, KOH Prep, Nasal Smear, Pinworm Prep, Stool Leukocytes, Spermatozoa USP - Urine Sediment 5. In an interview at 11:15 a.m. on 05/12/22, the GS confirmed the above finding. .

D5213

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:
 . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of three non-graded proficiency testing (PT) results from a regulated Specialty when the PT program did not obtain the agreement required for scoring in 2021. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 1:05 p.m. on 05/11/22. 2. The laboratory performed PT using the College of American Pathologists (CAP) PT provider. 3. The Evaluation of Proficiency Testing Results procedure found in the QA Manual included direction to evaluate non-graded PT results. 4. One Bacterial Identification - Urine Culture result from the first 2021 Routine Microbiology Combination PT event was not graded by CAP due to non-consensus. See below. 2021 RMC-A Sample UC-02 Two Antimicrobial Susceptibility results from the first 2021 Routine Microbiology Combination PT event were not

graded by CAP due to non-consensus. See below. 2021 RMC-A Sample UC-1 for Cefotaxime Sample UC-1 for Ceftazidime 5. The CAP PT report included a participant summary for evaluation of non-graded test results. The participant summary for the 2021 RMC-A event was not present in laboratory records. An evaluation of the non-graded results was not found in laboratory records. The laboratory was unable to provide an evaluation of the non-graded results upon request. 6. In an interview at 11:10 a.m. on 05/12/22, the GS confirmed the above finding. .

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to evaluate the relationship between test results obtained from two Hematology analyzers, two microprobe DNA processors, and five molecular instruments at least twice annually 2021. Findings are as follows: 1. The laboratory performed Hematology, Bacteriology, Mycology, Parasitology, and Virology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 1:05 p. m. on 05/11/22. 2. The following instruments were observed as present and available for use during the tour: One Sysmex DxH 600 hematology analyzer and one Sysmex DxH 520 hematology analyzer The DxH600 was used as the primary Hematology analyzer and the DxH 520 was used as a back up analyzer in 2021 Two identical BD Affirm VPIII Microbial Identification systems Both systems were used for Vaginal DNA Probe testing in 2021. Six identical Meridian Bioscience Revogene molecular instruments Three Revogene instruments were used for Group A Streptococcus testing only. Three were used for Group A Streptococcus, Group B Streptococcus, and Clostridioides difficile testing. In 2021, five Revogenes were in use. 4. A twice annual process for comparison of test results obtained from multiple instruments was not established in the laboratory's procedure manuals. 5. Comparison of test results obtained from multiple instruments was not found in laboratory records from 2021. The laboratory was unable to provide documentation of test comparisons upon request. 6. In an interview at 2:00 p.m. on 05/12/22, the GS confirmed the above finding.