

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405305	(X3) Date Survey Completed 11/07/2024
Name of Provider or Supplier Murray County Medical Center	Street Address, City, State 2042 Juniper Avenue, Slayton, 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 Murray County Medical Center 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 completed on November 7, 2024. The following standard-level deficiencies were cited: 493.1256 Control procedures 493.1451 Technical supervisor responsibilities .
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</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 minimum quality control activities required for a Chemistry test system in 2022, 2023, and 2024. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 1:10 p.m. on 11/06/24. 2. A Profile-V MedtoxScan Drugs of Abuse Test System was observed as present and available for use during the tour. 3. The manufacturer required Quality Control (QC) testing with positive and negative control materials for new lots and shipments of Profile-V cartridge devices and weekly as defined in the manufacturer's Profile-V MedtoxScan Reader System Quick Reference Instructions proved by the laboratory. 4. QC testing using positive and negative control materials was required for new lots and shipments of test</p>

cartridges as established in the Medtox Individualized Quality Control Plan and the Drug Screening Procedure (Medtox) found in PolicyStat, the laboratory's policy management software. A requirement for weekly QC testing was not found in procedures reviewed on date of survey. 5. The laboratory performed QC testing with positive and negative control materials for new lots and shipments of Medtox test cartridges as indicated in laboratory QC records. Weekly QC testing documentation was not found. The laboratory was unable to provide weekly QC documentation for the time period under review, November 2022 through November 2024, upon request. 6. In an interview at 10:08 a.m. on 11/07/24, the GS confirmed the above finding and indicated Medtox system QC testing was only performed for new test cartridge lots and shipments. .

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the Technical Supervisor failed to ensure comprehensive competency assessments for four of four tenured testing personnel were performed and documented in 2023. Findings are as follows: 1. The laboratory performed Microbiology, Immunology, Chemistry, Hematology, and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 1:10 p.m. on 11/06/24. 2. The following non-waived test systems, analyzers, tests, and test kits were in use in 2023 as indicated by the GS during the tour: Quidel Solana molecular testing platform Ortho Vitros 5600 chemistry analyzer Radiometer ABL Flex blood gas analyzer Alere Triage Meter chemistry analyzer Alere Afinion2 chemistry analyzer Profile-V Medtoxscan chemistry analyzer Sysmex XN-550 hematology analyzer Sysmex CA-660 coagulation analyzer Alcor miniiSED ESR analyzer Grifols Immunohematology (IH) test system Microscopes and stains for microscopic examinations Manual differential Urine sediment KOH fungal exam Vaginal wet preparation Post vasectomy Serum hCG test kit 3. A competency assessment including all current laboratory tests was required annually for tenured testing personnel as established in the Competency Assessment procedure found in PolicyStat, the laboratory's policy management software. 4. Competency assessment forms implemented in 2023 did not include the following tests systems or tests as indicated below: Direct observation of test performance: Solana, ABL 90 Flex, Triage,Afinion2, Medtox, miniiSED, Grifols IH system Direct observation of equipment maintenance: Solana, ABL 90 Flex, Triage,Afinion2, Medtox, miniiSED, Grifols IH system Blind sample assessment or proficiency testing: ABL 90 Flex, Triage, Afinion2, Medtox, Grifols IH system Problem solving: Solana, ABL 90 Flex, Triage,Afinion2, Medtox, CA-660, miniiSED, Grifols IH system, Microscopic examinations 5. The laboratory was unable to provide additional competency assessment documentation upon request. 6. In an interview at 4:08 p.m. on 11/06/24, the GS confirmed the above finding. .