

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0046398	(X3) Date Survey Completed 08/05/2025
Name of Provider or Supplier Salem Memorial District Hospital	Street Address, City, State 35629 Hwy 72, Salem, MO	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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:</p> <p>This STANDARD is not met as evidenced by: Based on review of Triage quality control (QC) logs, lack of quality control package inserts, and interview with the technical consultant (TC) #1, the laboratory failed to retain QC package inserts for January 2025 to date August 5, 2025. Findings: 1. Review of Triage QC logs showed the laboratory used Triage Total 5 Control 1 and 2 for analytes: CKMB and troponin. 2. Lack of QC package inserts showed the laboratory failed to retain QC package inserts for January 2025 to date August 5, 2025. 3. Interview with the TC #1 on August 5, 2025, at 11:00 AM, confirmed the laboratory failed to retain Triage QC package inserts.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedures, Vitros 5600 chemistry analyzer quality control results, Vitros 5600 chemistry analyzer corrective action QC log and interview</p>

with the technical consultant (TC) #1, the laboratory failed to follow the established quality control procedure for thyroid stimulating hormone (TSH) for 1 of 21 patient testing days in 2025. Findings: 1. Review of the laboratory procedure "SMH-LAB-POL-031 Chemistry Quality Control" states "Document all corrective action on the log sheet, including any reference numbers from technical support, and leave for Lab Leadership to review." 2. Review of Vitros 5600 chemistry analyzer QC showed TSH immunoassay level 3 (IM3) QC was unacceptable on August 5, 2025. 3. Review of Vitros 5600 corrective action QC log from August 5, 2025, showed no corrective action documented. 4. Interview with the TC #1 on August 5, 2025, at 11:30 AM confirmed the laboratory failed to follow the established QC procedure for TSH.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(g)

(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

This STANDARD is not met as evidenced by:
Based on review of the Ortho Diagnostics Vitros 5600 chemistry analyzer quality control (QC) records, and interview with the technical consultant (TC) #1, the laboratory failed to document how criteria was established for acceptability of control materials providing quantitative results for 35 of 35 analytes. Findings: 1. Review of the Ortho Diagnostics Vitros 5600 chemistry analyzer QC records showed the laboratory used assayed and unassayed QC. The laboratory could not show how they established, documented, and defined statistical parameter criteria (mean and standard deviations) for acceptability of quantitative QC for the analytes albumin, alkaline phosphatase, ALT, AST, direct bilirubin, total bilirubin, calcium, chloride, HDL cholesterol, carbon dioxide, creatine phosphokinase, glucose, iron, lactic acid, LDL cholesterol, lipase, magnesium, phosphorus, potassium, sodium, total iron binding capacity (TIBC), total protein, triglyceride, blood urea nitrogen, uric acid, ethanol, beta HCG, thyroid stimulating hormone (TSH), free T4, free T3, acetaminophen, salicylate, troponin I, b-type natriuretic peptide (BNP) and vancomycin. 2. Interview with the TC #1 on August 5, 2025 at 1:00 PM confirmed the laboratory failed to establish criteria for acceptability of control materials providing quantitative results.

D6007

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(1)

(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on review of blood bank testing records, and interview with the technical consultant (TC) #1, the laboratory director failed to ensure that blood bank testing performed provided quality laboratory services for emergency release of blood on January 15, 2024. Findings: 1. Review of blood bank testing records showed emergency release request for patient #1, packed red blood cells unit #W045123355863 and packed red blood cells unit # W045123135569 were released and transfused on January 15, 2024. 2. Review of blood bank testing records showed worksheet from reference testing facility for patient #1, packed red blood cells unit # 359863 and packed red blood cells unit # 135569 were crossmatched on January 15, 2024. 3. Review of blood bank testing records showed no corrective action for the packed red blood cells unit number discrepancy. 4. Interview with the TC #1 on August 5, 2025, at 10:30 AM confirmed the laboratory director failed to ensure that blood bank testing performed provided quality laboratory services.