Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0046398	10/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Salem Memorial District Hospital	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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records for 2020 and 2021 and interview with technical supervisor (TS) #2 the laboratory failed to have the laboratory director's attestation documentation for five of the eight PT testing events for 2021. Findings: 1. Review of PT records for 2021 revealed the laboratory could not provide attestation records for the laboratory director to show routine integration of samples into the patient workload for 2021 Microbiology events 2 and 3, 2021 Chemistry Core events 2 and 3, and 2021 Hematology /Coagulation 2nd event. 2. Interview with TS #2 on October 19, 2021 at 1:30 PM confirmed the laboratory could not provide PT attestation records for laboratory director for 2021 Microbiology events 2 and 3, 2021 Chemistry Core events 2 and 3, and 2021 Hematology /Coagulation event 2.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of procedures and interview with the technical supervisor (TS) #2,

	the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated correct problems. Findings: 1. Review of procedures showed a lack of quality assessment (QA) policies or procedures for an ongoing mechanism to monitor, assess, and, when indicated correct problems. 2. Interview with the TS #2 on October 19, 2021 at 2:00 PM confirmed the laboratory failed to establish written QA policies or procedures.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of Ortho Diagnostics Vitros 5600 quality control (QC) records, review of Sysmex CA-600 QC records, review of Sysmex CA-600 analyzer, review of mini-ised QC, Tosoh G8 QC, Biofire QC, gram stain QC, review of manufacturer's instructions, and interviews, the laboratory failed to meet the condition of analytic systems. The laboratory failed to address ABO/Rh units (Refer to D5401); failed to ensure approved procedures available (Refer to D5407); failed to follow manufacturer's instructions for storage (Refer to D5411); failed to label microbiology staining material (Refer to D5415); failed to discard expired reagents (Refer to D5417); failed to ensure accuracy of pipettes in use (Refer to D5435); failed to perform calibration verification at least every six months (Refer to D5439); failed to follow EPOC IQCP (Refer to D5445); failed to perform two controls each day of patient testing for mini-iSED (Refer to D5447); failed to perform a positive and negative control each day of patient testing (Refer to D5449); failed to establish criteria for acceptability of control materials providing quantitative results (Refer to D5469); failed to perform gram stain QC weekly (Refer to D5503); failed to include two levels of control material each 8 hours of operation for PT (Refer to D5545); failed to provide a procedure to check patient history (Refer to 5551); failed to perform and document first quarter 2021 refrigerator blood bank alarm check (Refer to D5555); and the laboratory failed to establish criteria for acceptable differences between instruments/methodologies performing the same test (Refer to D5575).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 review of immunohematology procedures and interview with technical supervisor (TS) #2, the laboratory failed to provide a procedure for ABO/Rh specifications for transfusion. Findings: 1. Review of "Immunoglobulin crossmatch

	using MTS anti IgG Cards" showed no indication of actions to be taken if unable to provide type specific and Rh specific units for transfusion. 2. Review of immunohematology records showed a blood type B positive patient was transfused on: August 14, 2021 patient was transfused with two units of B positive blood August 17, 2021 patient was transfused with one unit of O positive blood October 16, 2021 patient was transfused with two units of B positive blood October 17, 2021 patient was transfused with one unit of O positive blood 3. Interview with TS #2 on October 19, 2021 at 10:30 AM confirmed that the immunohematology procedures did not address which ABO/Rh units should be used if unable to provide type specific and Rh specific units.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory procedures and interview with the technical supervisor (TS) #2, the laboratory director (LD) failed to ensure procedures and changes to procedures be approved, signed, and dated by the current laboratory director before use. Findings: 1. Review of hematology, chemistry, and immunohematology procedures revealed the current LD did not approve, sign, and date the procedures. 2. Interview with the TS #2 on October 19, 2021 at 2:00 PM confirmed the current LD did not approve, sign, and date laboratory procedures before use. The current LD assumed responsibilities on July 14, 2011.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, room temperature logs, documentation of chemistry refrigerators temperatures, observation of quality control (QC) material stored in the refrigerators, and interview with the technical supervisor #2 , the laboratory failed to follow the manufacturer's instructions for storage of control materials for 56 of the 291 testing days from January 1, 2021 through October 19, 2021 and did not perform daily humidity checks for 2019, 2020 and to date October 19, 2021 to ensure instrument was within manufacturer's specifications for humidity requirements. Findings: 1. Review of the manufacturer's quality control instructions for Citrol 1 and 3 indicated storage temperature between 2 degrees celsius (C) to 8 degrees C. 2. Review of the laboratory's temperature chart showed a defined acceptable range of 2 degrees C to 8 degrees C. For 56 of the 291 testing days the laboratory failed to meet the manufacturer's required 2 degrees C to 8 degree C temperature range. 3. Review of the laboratory records showed no documentation of laboratory's humidity for 2019, 2020 and to date October 19, 2021. The manufacturer's requirements for the Sysmex XN-550 for operation of the instrument

	specifies humidity range between 20-85 percent. 4. Interview with the TS #2 on October 19, 2021 at 10:30 AM confirmed the laboratory failed to properly monitor the chemistry refrigerators and store QC materials and supplies per manufacturer's instructions and failed to monitor humidity to ensure the operation of the Sysmex XN-550 was performed within the manufacturer's specified humidity range.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the microbiology staining areas and interview with the technical supervisor (TS) #2, the laboratory failed to label four of four coplin jars used for gram staining. Findings: 1. Observation of the microbiology staining areas showed four coplin jars of liquid material with no identifying label. 2. Interview with the TS #2 on October 19, 2021 at 10:00 A.M. confirmed the laboratory failed to identify liquid material in four coplin jars.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observations during the laboratory tour, and interview with technical supervisor (TS) #2, the laboratory failed to discard expired reagents. Findings: 1. Observation of expired reagents and available for use during the laboratory tour were: BD BBL Stacker Plates used for plating microbiology organisms, Lot #1146173, Expiration date: September 23, 2021 Triage Total 5 control 1 used for d-dimer and troponin tests controls, Lot # C3653AN, Expiration date: May 21, 2021 Two bottles of Fisherbrand crystal violet stain used for gram staining, Lot # 530710, Expiration date: September 2021 2. Interview with TS #2 on October 19, 2021 at 9:30 AM confirmed the laboratory failed to properly monitor expiration dates of BBL Stacker plates, controls and reagents available for use.
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 of laboratory pipettes, the lack of function check documentation and interview with the technical supervisor (TS) #2, the laboratory failed to perform and document a function check to verify the accuracy of two mechanical pipettes. Findings: 1. Observation of laboratory pipettes revealed two pipettes were not evaulated in 2021 to verify the accuracy of the dispensed volumes. Thermoscientific finnpipette F2 verification was due on July 7, 2021 and ID Tipmaster Pipette verification was due on August 1, 2021. 2. The laboratory did not have documentation that two pipettes were evaluated in 2021 to verify the accuracy of the dispensed volumes. 3. Interview with the TS #2 on October 19, 2021 at 11:30 AM confirmed the laboratory failed to ensure the accuracy of the pipettes in use for testing.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of 2019/2020 and to date October 19, 2021 calibration verification for the Ortho Vitros 5600 chemistry analyzer, EPOC blood gas analyzer and interview with the technical supervisor (TS) #2, the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range. Findings: 1. Review of Vitros 5600 calibration records for 2019, 2020 and to date October 19, 2021 showed no calibration every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for the analytes: albumin, alcohol, alkaline phosphatase, alanine aminotransferase, ammonia, amylase, asparate aminotransferase, vitamin B12, blood urea nitrogen, calcium, cholesterol, creatine kinase, chloride, creatinine, total bilirubin, high density lipoprotein, potassium, lactic

	acid, lipase, magnesium, sodium, phosphorous, total protein, triglyceride, uric acid, glucose, acetaminophen, salicylate, valproic acid, vancomycin, beta human chorionic gonadotropin, direct bilirubin, carbon dioxide, low density lipoprotein, creatine kinase MB, digoxin, free T3, Free T4, gentamicin, gamma-glutamyl transferase, total iron binding capacity, lithium, pro bnp, prostate specific antigen, thyroid stimulating hormone, troponin, vitamin D3, and phenytoin. 2. Review of the EPOC blood gas analyzer calibration records for 2019, 2020 and to date October 19, 2021 showed no calibration every six months that included at least a minimal value, a mid-point, and a maximum value near the upper limit to verify the laboratory's reportable range for the analytes: sodium, potassium, calcium, glucose, creatinine, chloride, lactate, pH, pCO2, and pO2. 3. Interview with TS #2 on October 19, 2021 at 2:30 PM confirmed the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range on the Ortho Vitros 5600 chemistry analyzer and the EPOC blood gas analyzer.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. This STANDARD is not met as evidenced by: Based on review of the EPOC blood gas individualized quality control plan (IQCP), 2019, 2020 and to date October 19, 2021 EPOC quality control (QC) and interview with the technical supervisor (TS) #2, the laboratory failed to follow the EPOC IQCP for 30 of 33 months. Findings: 1. Review of the EPOC IQCP states "We have determined that the manufacturer's QC protocol in addition to every 30 day and new lot/new shipment QC requirements are sufficient for this test system". 2. Review of the EPOC QC showed lack of QC documentation for 2019, 2020 and January, February, March, April, June, and August 2021 for the analytes: sodium, potassium, calcium, glucose, creatinine, chloride, lactate, pH, pCO2, pO2 and hematocrit. 3. Interview with the TS #2 on October 19, 2021 at 3:30 PM confirmed the laboratory failed to follow the EPOC IQCP for QC requirements.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on review of mini-iSED quality control (QC) and interview with the technical supervisor (TS) #2, the laboratory failed to perform two control materials of different concentrations each day of patient testing. Findings: 1. Review of mini-iSED QC showed on October 7, 2021 a patient erythrocyte sedimentation rate (ESR) was performed and no QC was documented. 2. Interview with the TS #2 on October 19, 2021 at 3:00 PM confirmed the laboratory failed to perform two control materials of different concentrations each day of patient testing.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Review of the BioFire respiratory panel 2.1 quality control (QC) and interview with the technical supervisor (TS) #2, the laboratory failed to include a negative and positive control material each day of patient testing. Findings: 1. Review of Biofire Respiratory panel 2.1 which includes adenovirus coronavirus 229E, coronavirus HKU1, coronavirus NL63, coronavirus OC43, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), human metapneumovirus, human rhinovirus /enterovirus, influenza A, influenza B, parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, respiratory syncytial virus, bordetella parapertussis, bordetella pertussis chlamydia pneumoniae and mycoplasma pneumoniae showed a negative and positive control were not performed each day of patient testing. Since patient testing started on March 15, 2021, 185 patients results have been reported. 2. Interview with the TS #2 on October 19, 2021 at 2:00 PM confirmed the laboratory failed to perform a negative and a positive control material each day for the BioFire respiratory panel 2.1 testing.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) 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-- Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Ortho Diagnostics Vitros 5600 quality control (QC) records,

	Sysmex CA 600 QC records, the lack of documentation for the parameters of acceptable QC and interview with the technical supervisor (TS) #2, the laboratory failed to establish criteria for acceptability of control materials providing quantitative results. Findings: 1. Review of the Ortho Diagnostics Vitros 5600 QC records showed the laboratory did not establish and define statistical parameter criteria (mean and standard deviations) for acceptability of quantitative QC results reported on the chemistry analyzer for the analytes: albumin, alcohol, alkaline phosphatase, alanine aminotransferase, ammonia, amylase, asparate aminotransferase, vitamin B12, blood urea nitrogen, calcium, cholesterol, creatine kinase, chloride, creatinine, total bilirubin, high density lipoprotein, potassium, lactic acid, lipase, magnesium, sodium, phosphorous, total protein, triglyceride, uric acid, glucose, acetaminophen, salicylate, valproic acid, vancomycin, beta human chorionic gonadotropin, direct bilirubin, carbon dioxide, low density lipoprotein, creatine kinase MB, digoxin, free T3, Free T4, gentamicin, gamma-glutamyl transferase, total iron binding capacity, lithium, pro bnp, prostate specific antigen, thyroid stimulating hormone, troponin, vitamin D3, and phenytoin. 2. Review of the Sysmex CA 600 QC records showed the laboratory did not establish and define statistical parameter criteria (mean and standard deviations) for acceptability of quantitative QC results reported on the coagulation analyzer for the analytes: prothrombin time and partial thromboplastin time. 3. Interview with the TS #2 on October 19, 2021 at 3:00 PM confirmed the laboratory failed to establish criteria for acceptability of control materials providing quantitative results.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: Based on review of "Gram Stain Procedure", gram stain quality control (QC) and interview with the technical supervisor (TS) #2, the laboratory failed to perform gram stain QC each week. Findings: 1. Review of "Gram Stain Procedure" states "Quality Control: Weekly and upon opening a new bottle of stain". 2. Review of gram stain QC showed no QC was performed the week of December 12, 2020 and the week of July 12, 2021. 3. Interview with TS #2 on October 19, 2021 at 3:30 PM confirmed the laboratory failed to perform gram stain QC weekly.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of "coagulation" procedure, coagulation quality control (QC) and interview with technical supervisor (TS) #2, the laboratory failed to include two levels of control material each 8 hours operation for prothrombin time (PT) and partial thromboplastin time (PTT) from January 2020 to date October 19, 2021. Findings: 1. Review of "coagulation" procedure states "Both controls should be tested at the

	initiation of each testing day, upon reagent changes, with each calibration, and at least once every 8-hour shift on each day of testing". 2. Review of PT and PTT quality control showed two levels of QC was not performed every 8 hours of operation from February 2020 to October 2020, and December 2020 through April/July/August 2021. During this time 2718 PT patients were tested and 720 PTT patients were tested. 3. Review of PT and PTT QC showed no documentation of QC for January and November 2020, May, June, September and to date October 19, 2021. 4. Interview with TS #2 on October 19, 2021 at 3:00 PM confirmed the laboratory failed to perform two levels of PT and PTT QC each 8 hours of operation.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of blood bank procedures and interview with the technical supervisor (TS) #2, the laboratory failed to provide a procedure for checking patient history. Findings: 1. Review of blood bank procedures showed no procedure for checking patient history prior to performing blood bank procedures. 2. Interview with the TS #2 on October 19, 2021 at 2:00 PM confirmed the laboratory failed to provide a blood bank procedure for checking patient history.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the blood bank procedure manual, blood bank refrigerator alarm checks for 2019, 2020 and to date October 19, 2021 and interview with the technical supervisor (TS) #2, the laboratory failed to perform and document quarterly refrigerator alarm inspections. Findings: 1. The blood bank procedure manual states," High and low temperature checks of the blood bank alarm will be performed quarterly." 2. Review of blood bank refrigerator alarm checks revealed the laboratory

	did not have documentation for first quarter 2021 alarm check. 3. Interview with the TS #2 on October 19, 2021 at 11:45 AM confirmed, the laboratory failed to perform and document first quarter 2021 refrigerator blood bank alarm check.
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 review of blood gas, hematology and chemistry instrument records for 2020-2021 and and interview with the technical supervisor (TS) #2, the laboratory failed to evaluate and define the relationship between instruments/ methodologies performing the same tests. Findings: 1. Review of blood gas instrument records revealed the laboratory performs pH, pO2, pCO2 on the Gem Premier 4000 and the Siemens EPOC. The instrument comparison records failed to show how the laboratory defined limits of acceptability and evaluate the variance between instruments/methodologies performing the same tests. 2. Review of Siemens EPOC records and Sysmex XN-550 records revealed the laboratory performs hematocrit on both instruments. The instrument comparison records failed to show how the laboratory defined limits of acceptability and evaluate the variance between instruments/methodologies performing the same tests. 3. Review of the Siemens EPOC records and Vitros 560 records revealed the laboratory performs sodium (NA), potassium (K), calcium (CA) , glucose, creatinine, and lactate on both instruments. The instrument comparison records failed to show how the laboratory defined limits of acceptability and evaluate the variance between instruments/methodologies performing the same tests. 4. Interview with the TS #2 on October 19, 2021 at 11:30 AM confirmed, the laboratory failed to establish criteria for acceptable differences between instruments /methodologies performing the same tests.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the verification procedures, quality assessment program, testing personnel training, procedure manuals, proficiency testing records and interviews, the laboratory director failed to ensure that verification procedures used are adequate (Refer to D6086); failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training (Refer to D6087, D6102); failed to ensure quality assessment programs were established to assure the quality of laboratory services and to identify failures in quality as they occur (Refer to D6094); failed to ensure the establishment and maintenance of acceptable levels of analytical performance (Refer to D6095).

D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of prothrombin time (PT) procedure, lack of innovin new lot number verification for patient normal values and interview with the technical supersvior (TS), the laboratory director (LD) failed to ensure the new lot number of innovin was verified prior to patient testing. Findings: 1. Review of PT procedure showed no procedure for when a new lot number of innovin is started. 2. Review of Sysmex CA 600 paperwork showed no documentation of lot Number 549780 being verified for patient normal values. 3. Interview with the TS #2 on October 19, 2021 at 3:00 PM confirmed the LD failed to ensure the new lot number of innovin was verified for patient normal values.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT), signed center for medicare services (CMS) agreement, immunohematology compatibility testing logs, and interview with the technical supervisor (TS) #2, the laboratory director (LD) failed to ensure laboratory personnel are performing the test methods as required for accurate and reliable results. Findings: 1. Review of PT results for 2020 and 2021 showed unsatisfactory immunohematology compatibility scores for three of five PT events. 2. The LD signed a CMS agreement on October 11, 2021 which stated "Salem Memorial District Hospital also agrees to the limitation of its CLIA certification for the analyte of Compatibility Testing due to unsuccessful participation in proficiency testing". 3. Review of immunohematology compatibility testing logs showed one patient was tested and three units of blood were transfused on October 16, 2021. 4. Interview with the TS #2 on October 19, 2021 at 12:15 PM confirmed the LD failed to ensure the agreement was followed and immunohematology compatibility testing was ceased.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures and interview with the technical supervisor (TS) #2, the laboratory director (LD) failed to ensure quality assessment programs were established to assure the quality of laboratory services and to identify

	failures in quality as they occur. Findings: 1. No quality assessment programs were available for review. 2. Interview with the TS #2 on October 19, 2021 at 2:00 PM confirmed the LD failed to ensure quality assessment programs were established to assure the quality of laboratory services and to identify failures in quality as they occur.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on lack of quality control procedures, review of Vitros 5600 chemistry analyzer quality control (QC), Sysmex CA 600 coagulation analyzer and interview with the technical supervisor (TS) #2, the LD failed to ensure the establishment and maintenance of acceptable levels of analytical performance. Findings: 1. Review of the QC procedures showed no criteria for acceptability of QC results. 2. Review of MAS Chemtrak H unassayed chemistry QC showed no establishment and documentation of acceptable levels of analytical performance for the analytes: albumin, alcohol, alkaline phosphatase, alanine aminotransferase, asparate aminotransferase, blood urea nitrogen, calcium, cholesterol, creatine kinase, chloride, creatinine, total bilirubin, high density lipoprotein, potassium, lactic acid, lipase, magnesium, sodium, phosphorous, total protein, triglyceride, uric acid, glucose, carbon dioxide, low density lipoprotein, gamma-glutamyl transferase, total iron binding capacity, and lithium. 3. Interview with TS #2 confirmed the laboratory used manufacturer's insert ranges for MAS Liquimmune liquid assayed immunoassay control. Review of MAS Liquimmune liquid assayed immunoassay control lot number 24091 manufacturer's insert showed analyte ranges as: free T4 2.01-3.02 Review of QC ranges in the CPSI (CPSI is where QC is accepted) LIS system showed analyte ranges as: free T4 2.00-3.04 4. Review of MAS Liquimmune liquid assayed immunoassay control lot number 24092 manufacturer's insert showed analyte ranges as: digoxin 1.49-2.23 PSA 1.41-2.91 Review of QC ranges in the CPSI LIS system showed analyte ranges as: digoxin 1.48-2.24 PSA 1.39-2.92 5. Review of MAS Liquimmune liquid assayed immunoassay control lot number 24093 manufacturer's insert showed analyte ranges as: digoxin 2.26-3.40 Review of QC ranges in the CPSI LIS system analyte ranges as: digoxin 2.25-3.41 6. Review of the Sysmex CA 600 analyzer showed a paper attached on the front of the analyzer stating "QCO3 PT 10.3-10.9 stop 10.1-11.1, QCO4 43.8-45.6 stop 42.7-49.7, QCO3 PTT 2.41-27.3 stop 23.3-28.1, QCO4 PTT 53.5-59.7 stop 51.9-61.3". The TS #2 did not have documentation or explanation on how the ranges on the front of the analyzer were established. 7. Interview with the TS #2 on October 19, 2021 at 12:15 PM confirmed the LD failed to ensure the establishment and maintenance of acceptable levels of analytical performance.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate

	results. This STANDARD is not met as evidenced by: Based on lack of testing personnel (TP) educational documents, competency assessment documentation for 2019-2021 and interview with the technical supervisor (TS) #2, the laboratory director failed to ensure that prior to testing patients' specimens, 9 of 23 personnel have the appropriate education and experience, received the appropriate training before performing patient testing and demonstrated that they can perform all testing operations reliably. Review of training records and competency records indicated 1 of 23 personnel did not have appropriate training to ensure all testing operations and results were reliably provided and reported accurately. Findings: 1. Review of personnel records showed the laboratory could not provide appropriate educational documentation for nine personnel listed on the CMS 209. Educational records were missing for TP #3, TP #5, TP #8, TP #9, TP #10, TP#11, TP #12, TP #13 and TP #14. 2. Review of competency assessment documentation showed that TP #1 lacked documentation of appropriate training prior to testing patient specimens. 3. Interview with the TS #2 on October 19, 2021 at 12:00 PM confirmed the laboratory director failed to ensure all testing personnel had appropriate education and received appropriate training prior to testing patient specimens.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of chemistry quality control (QC), hematology QC, laboratory temperature and humidity records and 2019/2020/2021 personnel performance evaluations, the technical supervisors (TS) failed to fulfill the technical supervisor responsibilities. TS #2 failed to establish the parameters for acceptable levels of analytic performance and ensure that these levels are maintained throughout the entire testing process (Refer to D6117); and failed to document two semi annual and six annual competency evaluations for 2019/2020/2021 (Refer to D6127 and 6128).
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of Tosoh package insert for hemoglobin A1c, Tosoh analyzer quality control (QC), Sysmex CA 600 coagulation analyzer QC, Vitros 5600 chemistry analyzer and interview with the technical supervisor (TS) #2, the technical supervisor

	failed to establish a quality control program, the parameters for acceptable levels of analytic performance and ensure that these levels are maintained throughout the testing process. Findings: 1. Review of Tosoh package insert for hemoglobin A1C lot # 7103 showed ranges for level 1: 4.9-6.0 and level 2: 10.2-12.4. Interview with the TS #2 confirmed the laboratory used the package insert QC values. 2. Review of Tosoh QC log for hemoglobin A1C showed lot # 7103, QC ranges handwritten on the top of log as follows: normal control range 5.3-6.5, abnormal control range 10.4-12.2. 3. Review of the Sysmex CA 600 coagulation analyzer for prothrombin time (PT) and partial thromboplastin time (PTT) showed the TS #2 could not access QC in analyzer. Interview with TS #2 confirmed he had not been trained on that aspect of the instrument. No QC could be accessed in the analyzer from September 1, 2021 to date October 19, 2021. 4. Review of Vitros 5600 Chemistry analyzer showed TS #2 could not access QC or calibrations from analyzer. 5. Interview with the TS #2 on October 19, 2021 at 1:00 PM confirmed the TS #2 failed to establish a quality control program, the parameters for acceptable levels of analytic performance and ensure that these levels are maintained throughout the testing process.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of performance evaluations and interview with the technical supervisor (TS) #2, TS #1 and TS #2 failed to evaluate and document performance evaluations at least semiannually during the first year for 2 of 23 testing personnel (TP). Findings: 1. Lack of performance evaluations showed no semiannual performance evaluations were documented during the first year of patient testing for TP #1 and TP #12. 2. Interview with the TS #2 on October 19, 2021 at 2:00 PM confirmed the technical supervisors did not evaluate and document the semiannual performance evaluation for TP #1 and TP #12.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the technical supervisor (TS) #2, the TS failed to evaluate and document competency/performance for 6 of 23 testing personnel (TP) at least annually during 2019, 2020 and to date October 19, 2021. Findings: 1. Review of personnel records revealed the laboratory did not have documentation to show the TS evaluated and documented annual competency for TP #2, TP #3, TP #4, TP #6, TP #7, TP#11 performing patient testing during 2019, 2020 and to date October 19, 2021. 2. Interview with TS #2 on October 19, 2021 at 2:00

	PM confirmed the laboratory lacked documentation of competency/performance evaluations to ensure competency/performance were conducted at least annually.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of personnel records and interview with the technical supervisor (TS) #2 confirmed 9 of 23 testing personnel did not have academic qualifications required to perform high complexity testing (Refer to D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2) (ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b) (4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard

	laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on the lack of academic credentials and interview with the technical supervisor (TS) #2, the laboratory failed to provide academic credentials to qualify 9 of 23 testing personnel. Findings: 1. The laboratory could not provide documentation (academic credentials) to show testing persons: TP #3, TP#5 , TP#8, TP #9, TP #10, TP #11, TP #12, TP #13, TP #14 were qualified to perform high complexity testing. 2. Interview with the TS #2 on October 19, 2021 at 1:00 PM confirmed the documents needed to qualify the testing persons: TP #3, TP #5, TP #8, TP #9, TP #10, TP #11, TP #12, TP #13, TP #14 were not available for review.