Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0046398	10/30/2023
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
D0000	A recertification and complaint survey was completed on October 30, 2023. It was determined that Immediate Jeopardy (IJ) existed for the following condition level deficiencies: 42 C.F.R. 493.1250 Condition: Analytic Systems 42 C.F.R. 493.1441 Condition: Laboratory Director 42 C.F.R. 493.1487 Condition: Testing Personnel
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 laboratory procedures, observation of laboratory counters during the laboratory tour, observation of the Labconco fume hood, review of the waived Abbott Afinion hemoglobin A1c manufacturer's instructions, Abbott Afinion hemoglobin A1c quality control (QC) records, review of the waived Cobas Liat manufacturer's instructions, Cobas Liat QC records, review of Ortho Diagnostics Vitros 5600 QC records, review of STAGO Satellite coagulation analyzer QC, review of patient results, observation of laboratory analyzers, lack of instrument comparisons, and interviews with laboratory personnel, the laboratory failed to meet the condition of analytic systems. The laboratory failed to ensure a written procedure is available for the Ortho Diagnostics Vitros 5600 chemistry analyzer (Refer to D5401); the laboratory failed to ensure laboratory reagents were not used when they had exceeded their expiration date (Refer to D5417); the laboratory failed to ensure the fume hood was ventilated (Refer to D5435); the laboratory failed to perform two control materials of different concentrations each day of patient testing for hemoglobin A1c

	testing (Refer to D5447); the laboratory failed to perform a negative and positive control each day of patient testing on the Cobas Liat test systems (Refer to D5449); the laboratory failed to establish criteria for acceptability of control materials providing quantitative results for 36 of 36 analytes performed on the Ortho Diagnostics Vitros 5600 (Refer to D5469); the laboratory failed to ensure QC was acceptable before reporting patients results for uric acid for 7 of 60 testing days (Refer to D5481); the laboratory failed to include two levels of control material each 8 hours operation for prothrombin time (PT), partial thromboplastin time (PTT), and fibrinogen for 40 of 40 testing days (Refer to D5545); and the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results using different instruments in 2022 and to date October 24, 2023 (Refer to D5775).
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 laboratory procedures and interview with the technical supervisor (TS) #2, the laboratory failed to ensure a written procedure is available for the Ortho Diagnostics Vitros 5600 chemistry analyzer. Findings: 1. Review of laboratory procedures showed no procedure for the Ortho Diagnostics Vitros 5600 chemistry analyzer. 2. Interview with the TS #2 on October 24, 2023 at 3:30 PM confirmed the laboratory failed to ensure a written procedure for the Ortho Diagnostics Vitros 5600 chemistry analyzer is available.
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 observation of laboratory counters during the laboratory tour, and interview with the technical supervisor (TS) #2, the laboratory failed to ensure laboratory reagents were not used when they had exceeded their expiration date. Findings: 1. Observation of laboratory counters during the laboratory tour showed one opened bottle of Covid-19 Ag Reagent lot# 102594818, expiration April 30, 2023 still in use and one opened bottle of Propper Seracult lot# 20002, expiration August 2023 still in use. 2. Interview with the TS #2 on October 24, 2023 at 3:30 PM confirmed the laboratory failed to ensure laboratory reagents were not used when they had exceeded their expiration date.
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 the Labconco fume hood and interview with technical supervisor (TS) #2, the laboratory failed to ensure the fume hood was ventilated. Findings: 1. Observation of the Labconco fume hood showed no proper ventilation. Confidential interview stated, "The hood has not been hooked up since it was moved". 2. Observation of the Labconco fume hood showed Seracult fecal occult blood kits, O & P collection containers, and one bottle of Covid-19 Ag Reagent in use under hood. 3. Interview with TS #2 on October 24, 2023 at 2:00 PM confirmed the laboratory failed to ensure the fume hood was ventilated.
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 the waived Abbott Afinion hemoglobin A1c manufacturer's instructions, January 2023 to date October 24, 2023 quality control (QC) records, and interview with the technical supervisor (TS) #2, the laboratory failed to perform two control materials of different concentrations each day of patient testing for 289 of 297 days. Findings: 1. Review of the waived Abbott Afinion hemoglobin A1c manufacturer's instructions states "Controls should be analyzed: with each new shipment, with each new lot, when training new operators and at least every 30 days." 2. Review of Afinion hemoglobin A1c QC records showed the laboratory failed to follow manufacturer's instructions for performing QC at least every 30 days and when training new operators. Failure to follow manufacturer's instructions for waived testing changes the complexity of Afinion hemoglobin A1c testing from waived to high complexity. 3. Review of Afinion hemoglobin A1c QC records showed no QC was performed for 289 days from January 1, 2023 to October 24, 2023. The laboratory has performed 1749 hemoglobin A1c's patient tests. 4. Interview with the TS #2 on October 24, 2023 at 2:30 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: Based on observation of the Roche Cobas Liat test systems, review of the waived Cobas Liat for SARS-CoV-2, influenza A/B, and strep A manufacturer's instructions, January 2023 to date October 24, 2023 quality control (QC) records, and interview with the technical supervisor (TS) #2, the laboratory failed to perform a negative and positive control each day of patient testing for 297 of 297 days. Findings: 1. Observation of the Roche Cobas Liat test systems showed 3 analyzers performing SARS-CoV-2, influenza A/B, and strep A. 2. Review of the waived Cobas Liat for SARS-CoV-2, influenza A/B, strep A manufacturer's instructions states "Before using a new lot of Cobas SARS-CoV-2 & influenza A/B assay tubes a Lot Validation procedure must be performed on the Cobas Liat. The procedure includes running a Negative Control sample and a Positive Control sample." 3. Review of Cobas Liat for SARS-CoV-2, influenza A/B, strep A QC records showed the laboratory failed to follow manufacturer's instructions for new lots. Failure to follow manufacturer's instructions for waived testing changes the complexity of the Cobas Liat testing system from waived to high complexity. 4. Review of Cobas Liat for SARS-CoV-2, influenza A/B, strep A QC showed no documentation of QC from January 1, 2023 to October 24, 2023. The laboratory has performed 1616 patient tests on the Cobas Liat test systems. 5. Interview with the TS #2 on October 24, 2023 at 2:30 PM confirmed the laboratory failed to perform a negative and positive control each day of patient 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 March 8, 2023 to August 21, 2023 Ortho Diagnostics Vitros 5600 quality control (QC) records, and interview with the technical supervisor (TS) #2, the laboratory failed to establish criteria for acceptability of control materials providing quantitative results for 36 of 36 analytes. 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 for the analytes: ethanol, beta-human chorionic gonadotropin, sodium, potassium, chloride, carbon dioxide, creatinine, glucose, urea

	nitrogen, creatine phosphokinase, total protein, albumin, calcium, direct bilirubin, total bilirubin, aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, triglyceride, high density lipoprotein, lipase, magnesium, phosphorus, iron, uric acid, lactic acid, total iron binding capacity, thyroid stimulating hormone, Free T4, Free T3, Acetaminophen, salicylate, troponin I, vancomycin, brain natriuretic peptide, and low-density lipoprotein. 2. The laboratory could not provide package inserts for control materials. The laboratory performs approximately 103,339 chemistry tests per year. 3. Interview with the TS #2 on October 24, 2024 at 3:00 PM confirmed the laboratory failed to establish criteria for acceptability of control materials providing quantitative results.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of August 24, 2023 to date October 24, 2023 Ortho Diagnostics Vitros 5600 chemistry analyzer quality control (QC) records and interview with the technical supervisor (TS) #2, the laboratory failed to ensure QC was acceptable before reporting patients results for the analyte uric acid for 7 of 60 testing days. Findings: 1. Review of the Ortho Diagnostics Vitros 5600 chemistry analyzer QC showed the analyte uric acid was not within acceptable limits for: level 1 control acceptable range 3.14-3.49 mg/dl: 10/6/23 3.57 mg/dl level 3 control acceptable range 9.33-10.15 mg /dl: 9/17/23 9.32 mg/dl 9/24/23 9.32 mg/dl 9/29/23 9.23 mg/dl 10/3/23 9.32 mg/dl 10/9 /23 9.21 mg/dl 10/23/23 9.31 mg/dl 2. Interview with the TS #2 on October 24, 2023 at 2:00 PM confirmed the laboratory failed to ensure QC was acceptable before reporting patient results for uric acid.
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 laboratory procedures, review of STAGO Satellite coagulation analyzer quality control (QC), review of patient results and interview with the technical supervisor (TS) #2, the laboratory failed to include two levels of control material each 8 hours operation for prothrombin time (PT), partial thromboplastin time (PTT), and fibrinogen for 40 of 40 days from August 23, 2023 to October 1, 2023. Findings: 1. Review of "Coag Controls (PT, PTT and Fib) and Neoplastine" procedure states "Two different levels of control should be used." 2. Review of STAGO Satellite coagulation analyzer QC showed no documented QC for 40 of 40 days from August 23, 2023 to October 1, 2023. 3. Review of patient results showed the laboratory performed 33 prothrombin time (PT), and 4 partial thromboplastin time (PTT) patient tests when QC was not documented. 4. Interview with the TS #2 on

	October 24, 2023 at 3:00 PM confirmed the laboratory failed to perform two levels of PT, PTT and fibrinogen QC each 8 hours of operation.
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 laboratory procedures, observation of laboratory analyzers, lack of instrument comparisons, and interview with the technical supervisor (TS) #2, the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results using different instruments in 2022 and to date October 24, 2023. Findings: 1. Review of the laboratory's "Instrument Correlations" procedure states "If the lab uses more than one instrument/method to test for a given analyte, the instrument/method must be checked against each other at least twice per year for correlation of results." 2. Observation of the laboratory analyzers showed an Abaxis Piccolo chemistry analyzer and an Ortho Diagnostics Vitros 5600 chemistry analyzer, both analyzers perform alanine transaminase (ALT), alkaline phosphatase, calcium, chloride, creatinine, glucose, potassium, sodium, total bilirubin, carbon dioxide (CO2), total protein, and blood urea nitrogen (BUN) testing. 3. Observation of the laboratory analyzers showed an Ortho Diagnostics Vitros 5600 chemistry analyzer and a Quidel Triage Meter Pro chemistry analyzer, both analyzers perform troponin testing. 4. Observation of the laboratory analyzers showed a BioFire FilmArray test system and three Roche Cobas Liat test systems, both test systems perform influenza A, influenza B and SARS CoV2 testing. 5. Lack of instrument comparisons showed the laboratory had no documentation to evaluate and define the relationship between the Abaxis Piccolo chemistry analyzer and Ortho Diagnostics Vitros 5600 chemistry analyzer, the Ortho Diagnostics Vitros 5600 chemistry analyzer and Quidel Triage Meter Pro chemistry analyzer or the BioFire FilmArray test system and Roche Cobas Liat test system twice a year in 2022 and to date October 24, 2023. 6. Interview with the TS #2 on October 24, 2023 at 10:00 AM, confirmed the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results using different instruments.
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 chemistry quality control (QC), coagulation QC, proficiency testing, initial training, performance evaluations, quality assessment program, and interviews, the laboratory director (LD) failed to provide overall management and direction of the laboratory. The LD failed to ensure an approved corrective action plan

	is followed when any PT result is found to be unacceptable or unsatisfactory (Refer to D6092); the LD failed to ensure the d-dimer quality control program was maintained (Refer to D6093); 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 (Refer to D6094); the LD failed to ensure establishment and maintenance of acceptable levels of QC were documented for 35 chemistry analytes (Refer to D6095); the LD failed to ensure that hemoglobin A1c test results are not reported until the system is functionaing properly (Refer to D6097); the LD failed to ensure all employees received appropriate training for the type and complexity of testing. (Refer to D6102); and LD failed to ensure the established competency policy was followed (Refer to D6103).
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on the review of the 2023 proficiency testing (PT) records, policy and interview with the technical supervisor (TS) #2, the laboratory director (LD) failed to ensure an approved corrective action plan is followed when any PT result is found to be unacceptable or unsatisfactory. Findings: 1. Review of 2023 hematology/coagulation first event PT record shows the laboratory obtained an unacceptable result for specimen PTI-02 analyte protime on the iStat coagulation analyzer. Result reported, 13.1. Result expected, 13.5 - 18.3. 2. Review of PT records showed, TS #2 documented "All results within acceptable allowed limits" on the American Proficiency Institute Performance Review and Corrective Action form. 3. Review of policy titled "Proficiency Testing" states: "Unacceptable results, unacceptable coded results (ie Educational Challenges), and results showing bias or trending results will be noted." 4. Interview with TS #2 on October 24, 2023 at 11:00 AM, confirmed the LD failed to ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 STAGO Satellite coagulation analyzer d-dimer quality control (QC), review of patient results and interview with technical supervisor (TS) #2, the laboratory director failed to ensure the d-dimer quality control program was maintained for 41 of 41 days from August 23, 2023 to October 2, 2023. Findings: 1. Review of STAGO Satellite coagulation analyzer d-dimer QC showed no documentation of d-dimer QC for 41 days from August 23, 2023 to October 2, 2023. 2. Review of patients results showed the laboratory performed 6 d-dimer patient tests

	while QC was not documented. 3. Interview with the TS #2 on October 24, 2023 at 3: 30 PM confirmed the laboratory director failed to ensure the d-dimer quality control program was maintained.
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, review of Stago Sta Satellite analyzer quality control (QC) procedure, Vitros 5600 analyzer QC procedure and interview with the technical supervisor (TS) #2, the laboratory director (LD) failed to ensure approved quality assessment programs were established to assure the quality of laboratory services and to identify failures in quality as they occur. Findings: 1. Review of laboratory procedures showed no approved quality assessment program. 2. Review of Stago Sta Satellite analyzer procedure showed no approved procedure for the acceptability of QC. 3. Review of Vitros 5600 chemistry analyzer procedure showed no approved procedure for the acceptability of QC. 2. Interview with the TS #2 on October 24, 2023, at 1:30 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 review of Vitros 5600 analyzer quality control (QC) from August 21, 2023 to date October 24, 2023 and interview with the technical supervisor (TS) #2, the laboratory director (LD) failed to ensure establishment and maintenance of acceptable levels of QC were documented for 35 of 35 analytes. Findings: 1. Review of Vitros 5600 analyzer QC showed the laboratory started using Bio-Rad Liquid uanssayed multiqual and Bio-Rad Liquichek Immunoassay Plus QC on 8/21/23. The laboratory could not provide established QC ranges for the analytes: ethanol, beta-human chorionic gonadotropin, sodium, potassium, chloride, carbon dioxide, glucose, urea nitrogen, creatine phosphokinase, total protein, albumin, calcium, direct bilirubin, total bilirubin, aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, triglyceride, high density lipoprotein, lipase, magnesium, phosphorus, iron, uric acid, lactic acid, total iron binding capacity, thyroid stimulating hormone, Free T4, Free T3, Acetaminophen, salicylate, troponin 1, vancomycin, brain natriuretic peptide, and low-density lipoprotein. 2. Interview with the TS #2 on October 24, 2023 at 2:00 PM confirmed the LD failed to ensure establishment and maintenance of acceptable levels of QC were documented for 35 chemistry analytes.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7)

	The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on review of the Abbott Afinion hemoglobin A1c quality control (QC) January 2023 to date October 24, 2023 quality control (QC), patient reports and interview with the technical supervisor (TS) #2, the laboratory director failed to ensure that hemoglobin A1c test results are not reported until the system is functioning properly. Findings: 1. Review of Afinion hemoglobin A1c QC showed a statement "unable to run QC for July 2023 due to running out of cartridges. New lot received & monthly QC performed on 8/4/23", testing personnel #2 signed the statement. 2. Review of July patient reports showed 175 Afinion hemoglobin A1c patients were reported. 3. Interview with the TS #2 on October 24, 2023 at 2:30 PM confirmed the laboratory director failed to ensure that hemoglobin A1c test results are not reported until the system is functionaing properly.
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 review of personnel records, Stago STA Satellite training documentation, and interview with the technical supervisor (TS) #2, the laboratory director (LD) failed to ensure all employees received appropriate training for the type and complexity of testing for two of eight testing personnel. Findings: 1. Review of personnel records showed TP #6 and TP #8 hire dates were July 31, 2023. 2. Training documentation showed the TS #2 signed the Stago STA Satellite training documentation sheet for TP #6 and TP #8 on July 25, 2023. 3. Interview with the TS #2 on October 24, 2023 at 11:00 AM, confirmed the LD failed to ensure all employees received appropriate training for the type and complexity of testing.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of policy, initial personnel competencies, and interview with the technical supervisor (TS) #2, the laboratory director (LD) failed to ensure established

	policies are followed to monitor individuals who conduct initial competencies. Findings: 1. Review of policy titled, "Delegation of Responsibility" states: "Employees with at least 1 year of experience in testing and other departmental tasks and duties may precept Initial Training of new employees." 2. Review of personnel competencies for TP #7 and TP #8 showed the preceptor performing the initial competency did not meet the required one year experience. 3. Interview with the TS #2 on October 24, 2023 at 11:00 AM, confirmed the LD failed to ensure the established competency policies are followed.
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 review of initial personnel competencies and confidential interviews with all testing personnel (TP), the technical supervisor (TS) failed to evaluate and document initial competency for three of eight TP. Findings: 1. Review of initial competencies showed the TS signed competency evaluations for eight TP. 2. Confidential interview on October 24, 2023, stated "never saw a competency and did not sign one." During training, the trainer "only verbally went over tests, no direct observation of testing." 3. Confidential interview on October 24, 2023, stated "had no training on the Liat." 4. Confidential Interview on October 17, 2023, stated "never had training completed before performing patient testing." 5. Interview with the TS #2 on October 24, 2023 at 11:00 AM, confirmed the TS #2 failed to evaluate and document initial competencies.
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 technical supervisor (TS) #2, the TS #2 failed to evaluate and document competency/performance for one of eight personnel annually the first year, 2023. Findings: 1. Review of personnel records revealed the laboratory did not have documentation to show TS #2 evaluated and documented annual competency for TP #4 for 2023. 2. Interview with the TS #2 on October 24, 2023 at 11:00 AM, confirmed the TS #2 failed to evaluate and document competency/performance annually the first year.
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, one of eight testing personnel (TP) did not meet the 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 review of academic credentials and interview with the technical supervisor (TS) #2, the laboratory failed to provide academic credentials to qualify one of eight testing personnel. Findings: 1. Review of academic credentials showed no academic credentials available for testing personnel (TP) #7. 2. Interview with the TS #2 on October 24, 2023 at 11:00 AM confirmed the laboratory failed to provide academic credentials to qualify one testing personnel.