Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0919706	08/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	1965 S Eagle Rd Ste 130, Meridian, ID	

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	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory technologist, the laboratory failed to retain calibration reports and data, as well as manufacturer quality control assay reference sheets for the Sysmex pocH-100i hematology analyzer since August 2017 and failed to retain the manufacturer's quality control assay reference sheets and calibration and calibration verification data print-outs from the Medience PathFast immunoassay analyzer since October 2017. Findings: 1. A review of the Sysmex hematology analyzer quality control records revealed the laboratory failed to retain the manufacturer's quality control assay reference sheets for 3 out of 3 levels of external liquid quality control materials and failed to retain calibration records and instrument data print-outs from the time of installation in August 2017 to May 2018. 2. A review of the PathFast analyzer quality control records revealed the laboratory failed to retain the manufacturer's quality control assay reference sheets for 2 out of 2 levels of external liquid quality control materials for troponin and 1 out of 2 levels of quality control materials for the D-dimer assay since July 2018, and failed to retain calibration and calibration verification data print-outs between November 2017 and August 2018. 2. An interview on August 30, 2018 at 1:30 PM, with the laboratory technologist, confirmed the testing personnel failed to retain all quality control assay sheets and calibration data for the hematology and PathFast analyzer from the time of installation in August 2017.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)

	All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and an interview with the laboratory technologist, the laboratory failed to document the evaluation of ungraded, unsatisfactory, and unacceptable PT results for hematology and chemistry analytes from the American Proficiency Institute (API) program 2018 events 2. Findings: 1. A review of PT results from API 2017 event 2, revealed the laboratory failed to document the review and corrective actions for unsatisfactory performance of urine sediment examination, unacceptable lymphocyte, neutrophil, white cell count, and ungraded results for the d-dimer analyte in event 2. 2. An interview on August 30, 2018 at 10:05 AM, with the laboratory technologist, confirmed the laboratory failed to document the evaluation and corrective action for ungraded and unacceptable results from API 2018 event 2.
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 record reviews, the laboratory failed to evaluate and monitor the overall quality of the analytic test systems and failed to correct and identify problems in the specialties of hematology and chemistry since the beginning of patient testing in October 2017. Refer to D541, D5433, D5437, D5439, D5481, and D5779.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory technologist, the laboratory failed to establish the reportable range or linearity and perform calibration for the Sysmex pocH-100i hematology analyzer at the time of installation in August 2017. Findings: 1. A review of the Sysmex pocH-100i hematology analyzer verification of performance records revealed the laboratory failed to establish the reportable range for the analyzer and failed to perform calibration before testing on

	patients in August 2017. 2. An interview on August 30, 2018 at 1:45 PM, with the laboratory technologist, confirmed the laboratory failed to perform the verification of performance activities prior to reporting patient test results.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) 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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory technologist, the laboratory failed to document all unscheduled maintenance activities and corrective actions for the Sysmex pocH-100i hematology analyzer and the Medience PathFast analyzer since August 2017. Findings: 1. A review of service reports and notes in the laboratory revealed the laboratory failed to document unscheduled troubleshooting and corrective action activities for maintenance performed on the analyzers in the lab from the time of installation in August 2017. 2. An interview on August 30, 2018 at 2: 30 PM, with the technical technologist, confirmed the laboratory testing personnel failed to document unscheduled maintenance activities on the hematology and the PathFast analyzers.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory technologist, the laboratory testing personnel failed to perform and document calibration procedures at least once every 6 months or for the Sysmex pocH-100i hematology analyzer used to since October 2017. Findings: 1. A record review of calibration reports for the Sysmex pocH-100i analyzer revealed the laboratory failed to perform and document calibration activities at least once every 6 months. 2. An interview on August 30, 2018, at 12:40 PM, with the laboratory technologist, confirmed the laboratory failed to perform, document, or retain calibration procedure activities.

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 a record review and an interview with the laboratory technologist, the laboratory failed to perform and document calibration verification procedures at least once every 6 months or for the Medience PathFast analyzer used to test cardiac markers and D-dimers since October 2017. Findings: 1. A record review of calibration verification reports for CK-MB, proBNP, D-dimer, and troponin performed on the Medience PathFast test system revealed the laboratory failed to perform and document calibration verifications at least once every 6 months. 2. An interview on August 30, 2018, at 11:30 AM, with the laboratory technologist, confirmed the laboratory failed to perform and document calibration verifications.
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 quality control record reviews and an interview with the laboratory technologist, the laboratory failed to meet the quality control requirements for D-dimer and troponin tests performed on the Medience PathFast chemistry analyzer prior to reporting patient results since July of 2018. Findings: 1. A review of quality control records and manufacturer assay sheets revealed the testing personnel failed to verify the acceptability of 2 out of 2 levels of external liquid quality control material for troponin and 1 out of 2 levels of external liquid quality control material for D-dimer. 2. An interview on August 30, 2018 at 11:45 AM, with the laboratory technologist, confirmed the laboratory testing personnel failed to verify the

	acceptability of quality control results prior to reporting patient troponin and D-dimer test results since July 2018.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on records review and an interview with the laboratory technologist, the laboratory testing personnel failed to perform and document corrective action procedures prior to reporting patient test results from a clotted or platelet-aggregated complete blood count specimen on July 6, 2018. Findings: 1. A review of instrument print-outs from patients on July 6, 2018, revealed a patient complete blood count showed decreased red blood cell indices and critical low platelet count of 39. A review of the final patient report revealed a corrected platelet count of 150 with no documentation of corrective actions. 2. An interview on August 30, 2018, at 2:45 PM, with the laboratory technologist, confirmed that the laboratory testing personnel failed to follow the procedure and document corrective actions prior to reporting patient test results.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a policy review and an interview with the laboratory technologist, the laboratory failed to establish and follow a system to monitor and correct problems in the analytic test systems since the opening of the laboratory in October 2017. Findings: 1. A record review of quality control, calibration, instrument installation verification activities, and patient report reviews revealed the laboratory failed to monitor the quality assessment activities for testing performed on the Sysmex pocH-100i and Medience PathFast to identify and correct problems in the analytic system. 2. An interview on August 30, 2018, at 3:00 PM, with the laboratory technologist, confirmed the laboratory failed to establish a system to monitor and identify all problems related to the analytic test systems.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units

	of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory technologist, the laboratory testing personnel failed to indicate the condition of a complete blood count (CBC) specimen for a patient test report on July 6, 2018. Findings: 1. A patient report review revealed the laboratory failed to indicate the condition of the unacceptable CBC specimen prior to reportingpatient results. 2. An interview on August 30, 2018, at 2:45 PM, with the laboratory technologist, confirmed that the laboratory testing personnel failed to follow the procedure and document the disposition of the patient's CBC specimen on the final report.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory technologist, the laboratory testing personnel failed to notify the referring provider of the error in reporting a complete blood count (CBC) specimen for an unacceptable patient sample collected on July 6, 2018. Findings: 1. A patient report review revealed the laboratory failed to notify the referring provider of the error in reporting a clotted or platelet-aggregated (CBC) patient specimen. 2. An interview on August 30, 2018, at 2:45 PM, with the laboratory technologist, confirmed that the laboratory testing personnel failed to notify the referring provider of the error in reporting the patient's unacceptable CBC specimen.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on a procedure review and an interview with the operation manager, the laboratory failed to establish and follow written procedures for a system to monitor and correct problems in the post-analytic system since the opening of the laboratory in October 2017. Findings: 1. A policy review revealed the laboratory failed to establish and follow a quality assessment procedure to identify and correct problems in the post-

	analytic system. 2. An interview on August 30, 2018, at 2:50 PM, with the laboratory technologist, confirmed the laboratory failed to establish a system to monitor and identify problems related to the post-analytic test system.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: The laboratory director failed to provide overall management and direction for the testing performed in the laboratorysince October 2017. Refer to D6004, D6013, D6014, D6019, D6020, D6021, D6022, D6029, and D6030.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record reviews, the laboratory director failed to fulfill his responsibility in providing overall operation and management of the laboratory since opening in October 2017. Findings: 1. A review of records for the laboratory revealed the laboratory director failed to ensure testing personnel were trained and competent to perform procedures in the laboratory and failed to monitor and oversee the general laboratory, analytic, and post-analytic systems.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) 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 a record review and an interview with the laboratory technologist, the

	laboratory director failed to ensure all verification procedures for the Sysmex pocH-100i hematology analyzer met the performance specifications for the laboratory from the time of installation in August 2017. Findings: 1. A record review of the Sysmex accuracy and precision data revealed the laboratory director failed to verify the test system met all verification procedures and met the laboratory's performance criteria since the installation in August 2017. 2. An interview on August 30, 2018, at 12:40 PM, with the laboratory technologist, confirmed the laboratory director failed to ensure the hematology test system met all verification activities.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a record review, the laboratory director failed to ensure the testing personnel are performing test procedures for the Sysmex pocH-100i hematology analyzer and the Medience PathFast test system as required to report accurate and reliable patient test results. Findings: 1. A review of quality control records and manufacturer assay sheets revealed the testing personnel failed to verify the acceptability of 2 out of 2 levels of external liquid quality control material for troponin and 1 out of 2 levels of external liquid quality control material for D-dimer. 2. A patient report review revealed the laboratory failed to indicate the condition of the unacceptable complete blood count specimen prior to reporting patient results.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on a record review, the laboratory director failed to ensure the corrective action plans are followed during the review of proficiency testing results from American Proficiency Institute (API) for unsatisfactory or unacceptable test results. Findings: A review of the procedure manual revealed the laboratory technologists failed to follow the written procedure for documenting corrective actions and problems in proficiency testing.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record reviews and interviews with the laboratory technologists, the laboratory director failed to ensure the quality control program for the laboratory meets the CLIA requirements since the time of opening in October 2017. Findings: 1. A review of quality control records and manufacturer assay sheets revealed the testing personnel failed to verify the acceptability of 2 out of 2 levels of external liquid quality control material for troponin and 1 out of 2 levels of external liquid quality control material for D-dimer. 2. A record review of calibration verification reports for the Medience PathFast test system revealed the laboratory failed to perform and document calibration verifications for CK-MB, proBNP, and D-dimer assays. 3. A record review of calibration reports for the Sysmex pocH-100i analyzer revealed the laboratory failed to perform and document calibration activities at least once every 6 months.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record reviews, the laboratory director failed to ensure the quality assessment for the laboratory was established and monitored to identify errors and correct problems for all phases of testing in the laboratory since the opening in October 2017. Findings: 1. A policy review revealed the laboratory failed to establish and follow a quality assessment procedure to identify and correct problems in the post-analytic system. 2. A record review of quality control, calibration, instrument installation verification activities, and patient report reviews revealed the laboratory failed to monitor the quality assessment activities for testing performed on the Sysmex pocH-100i and Medience PathFast to identify and correct problems in the analytic system.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs

	are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record reviews, the laboratory director failed to identify errors in the test systems and failed to identify error in patient reporting from the records reviewed in July 2018. Findings: 1. A patient report review revealed the laboratory failed to notify the referring provider of an error in reporting a clotted or platelet-aggregated complete blood count for a patient specimen. 2. A record review of quality control and manufacturer assay sheets revealed the laboratory director failed to identify errors in the quality control requirements for D-dimer and troponin assays.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) 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 record reviews and an interview with the laboratory technologist, the laboratory director failed to ensure all testing personnel are trained and demonstrate competency prior to testing patient samples since October 2017. Findings: 1. A review of training records for 2 out of 2 testing personnel revealed the laboratory director failed to document training for the hematology test system and the general laboratory procedures prior to testing patient samples. 2. A review of competency assessment documents revealed the laboratory director, who is also the technical consultant, failed to perform competency assessments on 2 out of 2 testing personnel since October 2017. 3. A review of a patient's report on July 6, 2018 revealed the laboratory technologist failed to follow the laboratory procedure for a clotted hematology specimen by not performing corrective actions, rejecting specimen, or reporting the specimen according to procedures. 4. An interview on August 30, 2018, at 2:50 PM, with the laboratory technologist, confirmed the laboratory failed to document training and competency on the testing personnel.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) 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 record review, the laboratory director failed to ensure that policies and procedures are followed for monitoring the competency of testing personnel, ensure testing personnel are following laboratory procedures, and reporting patient results proficiently since the opening of the laboratory in October 2017. Findings: 1. A record review of a final patient report and instrument data revealed the testing personnel failed to follow the procedure for a clotted or a platelet-aggregated complete blood count test. 2. A record review of the laboratory policies and procedures for test system calibration and quality control performance revealed the testing personnel failed to follow the procedures for performance and documentation. 3. A record review of the laboratory policy for record retention revealed the testing personnel failed to follow the policy for retaining manufacturer assay reference sheets and instrument data printouts. 4. A personnel record review revealed the laboratory director failed to ensure testing personnel are appropriately trained and competent to perform tests before reporting patient results.