Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0464361	02/01/2024
Name of Provider or Supplier	**Street Address, City, State**	
Jackson Parish Hospital	165 Beech Springs Rd, Jonesboro, LA	

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 Validation Survey was conducted on January 29, 2024 through February 2, 2024 at Jackson Parish Hospital - CLIA # 19D0464361. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's CMS 209 form (Laboratory Personnel Report), policies, and personnel records, as well as interview with laboratory personnel, the laboratory failed to follow their competency assessment policy for six (6) of seven (7) Technical Consultants. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the laboratory listed the following personnel as Technical Consultants: Personnel 1 Personnel 2 Personnel 3 Personnel 4 Personnel 7 Personnel 8 Personnel 11 2. Review of the laboratory's "Testing Personnel Competency Assessment Schedule" policy revealed the following: - The TC is assessed for competency once per employment or when deemed necessary by the Laboratory Medical Director. 3. Review of personnel records revealed Technical Consultant competency assessment was not performed for the following personnel: Personnel 1 Personnel 2 Personnel 3 Personnel 4 Personnel 7 Personnel 8 4. In interview on January 30, 2024 at 10:29 a.m., the Laboratory Manager confirmed the laboratory did not have documentation of Technical Consultant competency assessments for the personnel identified above. II. Based on review of the laboratory's CMS 209 form (Laboratory Personnel Report), policies, and personnel records, as well as interview with laboratory personnel, the laboratory failed to follow their

	competency assessment policy for two (2) of three (3) General Supervisors. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the laboratory listed the following personnel as General Supervisors: Personnel 5 Personnel 9 Personnel 10 2. Review of the laboratory's "Testing Personnel Competency Assessment Schedule" policy revealed the following: - The GS will be assessed for competency once per employment or when deemed necessary by the Laboratory Medical Director. 3. Review of personnel records revealed General Supervisor competency assessments were not performed for the following pesonnel: Personnel 5 Personnel 10 4. In interview on January 30, 2024 at 10:29 a.m., the Laboratory Manager confirmed the laboratory did not have documentation of General Supervisor competency assessments for the personnel identified above.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's policies and quality control records, as well as interview with personnel, the laboratory failed to ensure the chemistry procedure manual contained quality control acceptability criteria for chemistry testing. Findings: 1. Observation by surveyors during the laboratory tour on January 29, 2024 at 1:41 p.m. revealed the laboratory utilized a Siemens Dimension EXL with LM for the chemistry testing. 2. Review of the "Quality Control" chemistry policy approved by the Laboratory Director February 15, 2023 revealed the following: - "Control values must be within 2SD. - If QC does not test within the specified range, refer to the "Quality Control Failure Troubleshooting Flow Chart" to determine the proper action required." 3. Further review of the laboratory's policies revealed a chemistry policy "Quality Control" approved by the Laboratory Director February 23, 2022. This policy was behind the policy indicated above which stated "Control values must be within 2SD; however, it is acceptable for one level to be within 3SD but not for two consecutive QC runs." 4. In interview on January 30, 2024 at 11:23 a.m., General Supervisor 1 stated quality control was acceptable if one (1) level was within the acceptable range and one (1) level was outside of the acceptable range 2 SD but within 3SD for one day. She also stated the policy signed in 2023 was never put into practice and was added in error to the policy manual and the policy approved in 2022

	was the policy in use by the laboratory. She confirmed the 2023 version of the quality control policy did not match the current practice.
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 observation by surveyors, review of manufacturer's instrument manual, donor questionnaires, normal patient mean study and interview with personnel, the laboratory failed to utilize acceptable normal donors per manufacturer requirements for Prothrombin Time (PT) normal mean studies. Findings: 1. Observation by the surveyor during the laboratory tour on January 29, 2024 at 2:19 pm revealed the laboratory utilizes the Sysmex CA-600 coagulation analyzer for Prothrombin Time (PT) and International Normalized Ratio (INR) patient testing. 2. Review of the Siemens Sysmex CA-600 analyzer manual under "Verification of Reference Interval" revealed the following criteria for inclusion of "normal donors" to include, but not limited to: "healthy population (no known pathological condition; no pre-surgical or hospitalized patients") and individuals not taking "any medications, including aspirin.": 3. Review of the laboratory's "Selection of Individuals for Reference Range Studies" revealed the following: * Do you consider yourself to be healthy? _____ * Have you recently been ill? _____ When _____ * Are you taking any prescribed or over the counter medications, including aspirin? _____ * Please list of all medications _____ * Do you have a medical condition that requires ongoing treatment by a physician? _____ 4. Review of the laboratory's normal donor mean PT study (performed on 12/20/2023) and donor questionnaires for Innovin Lot 564607 Expiration 11/24/2024 revealed the laboratory utilized the following eleven (11) of twenty one (21) unacceptable donors: * Donor 10-24-1973: No response provided: Do you have a medical condition that requires ongoing treatment by a physician? * Donor 2-28-76: No response provided: Do you consider yourself to be healthy? Have you recently been ill? Do you have a medical condition that requires ongoing treatment by a physician? * Donor 29192: No response provided: Do you consider yourself to be healthy? Have you recently been ill? Do you have a medical condition that requires ongoing treatment by a physician? * Donor 2-13-1962: No response provided: Do you have a medical condition that requires ongoing treatment by a physician? * Donor 6-29-1954: No reponse provided: Do you consider yourself to be healthy? Have you recently been ill? Do you have a medical condition that requires ongoing treatment by a physician? * Donor 121963: No response provided: Do you consider yourself to be healthy? Have you recently been ill? Do you have a medical condition that requires ongoing treatment by a physician? * Donor 082960: No response provided: Do you consider yourself to be healthy? Have you recently been ill? Are you taking any prescribed or over the counter medications, including aspirin? Do you have a medical condition that requires ongoing treatment by a physician? * Donor 042358: No response provided: Do you consider yourself to be healthy? Have you recently been ill? Are you taking any prescribed or over the counter medications, including aspirin? Do you have a medical condition that requires ongoing treatment by a physician? * Donor 11-13-1951: No response provided: Do you consider yourself to be healthy? Have you recently been

	ill? Do you have a medical condition that requires ongoing treatment by a physician? * Donor 11-24-1988: No response provided: Do you consider yourself to be healthy? Have you recently been ill? Are you taking any prescribed or over the counter medications, including aspirin? Do you have a medical condition that requires ongoing treatment by a physician? * Donor 4-12-1971: No response provided: Are you taking any prescribed or over the counter medications, including aspirin? Do you have a medical condition that requires ongoing treatment by a physician? 5. In interview on January 31, 2024 at 9:49 am, Testing Personnel 5 confirmed the laboratory utlilized unacceptable donors for the normal mean PT study.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's temperature records, and interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for one (1) of (4) four areas in the laboratory where supplies are stored. Findings: 1. Observation by surveyors during the laboratory tour on January 29, 2024 at 1:41 p.m. revealed the laboratory stored the following supplies in a room where Microbiology testing is performed: a) Cepheid Xpert CT/NG - storage requirements 2 - 28 degrees Celsius b) Cepheid Xpert Xpress Strep A - storage requirements 2 - 28 degrees Celsius c) Cepheid Xpert TV - storage requirements 2 - 28 degrees Celsius d) Cepheid Xpert C. difficile/Epi - storage requirements 2 - 28 degrees Celsius e) Cepheid Xpert Xpress CoV-2/Flu/RSV - storage requirements 2 - 28 degrees Celsius f) Greiner Bio-one K2EDTA - storage requirements 4 - 25 degrees Celsius g) Greiner Bio-one Lithium Heparin - storage requirements 4 - 25 degrees Celsius h) Greiner Bio-one Serum Clot Activator - storage requirements 4 - 25 degrees Celsius i) Greiner Bio-one MiniCollect Tube Lithium Heparin - storage requirements 4 - 25 degrees Celsius j) Eswab LQ Amies - storage requirements 5 - 25 degrees Celsius 2. Review of the laboratory's "GeneXpert System Maintenance Log" records for January 2023 through October 2023 revealed the laboratory defined the acceptable room temperature limits as 15 - 30 degrees Celsius. 3. In interview on January 31, 2023 at 3:30 p.m., the Laboratory Manager confirmed the laboratory's acceptable room temperature limits in the Microbiology room exceeded the manufacturers' acceptable room temperature limits for supplies stored there.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on observation by surveyors, review of laboratory's maintenance records and interview with personnel, the laboratory failed to ensure the monthly maintenance on the Sysmex CA 600 coagulation analyzer was performed as required by the manufacturer for two (2) of twenty four (24) months reviewed in 2022 and 2023. Findings: 1. Direct observation by surveyors during the laboratory tour on January 29, 2024 at 2:19 pm revealed the laboratory utilizes the Sysmex CA 600 series analyzer for the following testing in coagulation: Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), and D Dimer 2. Review of the laboratory's Sysmex CA 600 maintenance checklist revealed the laboratory performs the following monthly maintenance: a) Replace reagent bottle 3. Further review of the maintenance checklists from January 2022 through December 2023 revealed the laboratory did not perform the monthly maintenance for the following two (2) of twenty four (24) months reviewed: a) April 2022 b) June 2023 4. In interview on January 31, 2024 at 1: 08 pm, Testing Personnel 5 confirmed the monthly maintenance was not performed as required for the identified months.
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 observation, review of the laboratory's policies and maintenance records, and interview with personnel, the laboratory failed to perform and document quarterly maintenance on the Thermo Scientific CW3 Cell Washer as required by the laboratory for three (3) of three (3) quarters reviewed. Findings: 1. Observation by surveyors during the laboratory tour on January 29, 2024 at 1:41 p.m. revealed the laboratory utilized one (1) Thermo Scientific CW3 Cell Washer. 2. Review of the laboratory's Blood Bank policy "Scheduled QC and Maintenance" revealed the following required quarterly maintenance: - Check timers and RPM on cell washer and record (performed by contracted Biomed) 3. Review of the laboratory's maintenance logs revealed the following: - 3 month: Check RPM Check spin time 4. Review of the 2023 maintenance records for the Thermo Scientific CW3 Cell Washer revealed documentation of the RPM check, but not the spin time for the following months: - March 2023 - June 2023 - September 2023 5. In interview on January 30, 2024 at 4:12 p.m., the Laboratory Manager confirmed the maintenance identified above was not performed.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems

	quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on direct observation, record review, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. The laboratory failed to ensure the chemistry procedure manual contained quality control acceptability criteria for chemistry testing. Refer to D5403. 2. The laboratory failed to utilize acceptable normal donors per manufacturer requirements for Prothrombin Time (PT) normal mean studies. Refer to D5411. 3. The laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for one (1) of (4) four areas in the laboratory where supplies are stored. Refer to D5413. 4. The laboratory failed to ensure the monthly maintenance on the Sysmex CA 600 coagulation analyzer was performed as required by the manufacturer for two (2) of twenty four (24) months reviewed in 2022 and 2023. Refer to D5429. 5. The laboratory failed to perform and document quarterly maintenance on the Thermo Scientific CW3 Cell Washer as required by the laboratory for three (3) of three (3) quarters reviewed. Refer to D5433.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) 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. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 form (Laboratory Personnel Report) and personnel records as well as interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of Technical Consultant to six (6) of seven (7) personnel serving as Technical Consultants. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the following personnel were listed as Technical Consultants: Personnel 1 Personnel 2 Personnel 3 Personnel 4 Personnel 7 Personnel 8 Personnel 11 2. Review of personnel records revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of Technical Consultant to the following personnel: Personnel 1 Personnel 2 Personnel 3 Personnel 4 Personnel 7 Personnel 8 3. In interview on January 30, 2024 at 10:29 a.m., the Laboratory Manager confirmed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of Technical Consultant to the personnel identified above.
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 review of laboratory maintenance records and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to utilize acceptable normal donors per manufacturer requirements for Prothrombin Time (PT) normal mean studies. Refer to D5411. 2. The laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for one (1) of (4) four areas in the laboratory where supplies are stored. Refer to D5413.
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 review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D5793.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) 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 laboratory policy, maintenance records and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Findings: 1. The laboratory failed to ensure the monthly maintenance on the Sysmex CA 600 coagulation analyzer was performed as required by the manufacturer for two (2) of twenty four (24) months reviewed in 2022 and 2023. Refer to D5429.
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 and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The laboratory failed to follow their competency assessment policy for six (6) of seven (7) Technical Consultants. Refer to D5209 I. 2. The Technical Consultants failed to perform annual competencies in 2022 and 2023 for eleven (11) of twenty five (25) testing personnel reviewed. Refer to D6046.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory maintenance records and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to utilize acceptable normal donors per manufacturer requirements for Prothrombin Time (PT) normal mean studies. Refer to D5411. 2. The laboratory failed to ensure the monthly maintenance on the Sysmex CA 600 coagulation analyzer was performed as required by the manufacturer for two (2) of twenty four (24) months reviewed in 2022 and 2023. Refer to D5429.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)

	(b) The technical consultant is responsible for-- (b)(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 the laboratory's CMS 209 form (Laboratory Personnel Report), competency assessment forms and interview with personnel, the Technical Consultants failed to perform annual competencies in 2022 and 2023 for eleven (11) of twenty five (25) testing personnel reviewed. Findings: 1. Review of the laboratory's CMS 209 form revealed the following seven (7) of twenty five (25) personnel serves as Technical Consultants: * Personnel 1 * Personnel 2 * Personnel 3 * Personnel 4 * Personnel 7 * Personnel 8 * Personnel 11 2. Review of the laboratory's "Personnel Competency Assessment Respiratory/Blood Gas" form revealed the Technical Consultant did not sign/date the form as the evaluator for the following eleven (11) of twenty five (25) testing personnel in 2022 and 2023: * Personnel 13 - 2022 annual competency 12/6/22; 2023 annual competency 11/14/23 * Personnel 15 - 2022 annual competency 12/12/22; 2023 annual competency 11/14/23 * Personnel 16 - 2022 annual competency 12/12/22; 2023 annual competency 11/14/23 * Personnel 17 - 2022 annual competency 12/12/22; 2023 annual competency 11/14/23 * Personnel 19 - 2022 annual competency 12/12/22; 2023 annual competency 11/14/23 * Personnel 20 - 2022 annual competency 12/12/22; 2023 annual competency 11/14/23 * Personne 21 - 2022 annual competency 12/16/22; 2023 annual competency 11/14/23 * Personnel 22 - 2022 annual competency 12/12/22; 2023 annual competency 11/14/23 * Personnel 23 - 2022 annual competency 12/12/22; 2023 annual competency 11/14 /23 * Personnel 24 - 2022 annual competency 12/1/22; 2023 annual competency 11/14 /23 * Personnel 25 - 2023 annual competency 9/28/23 3. In interview on January 29, 2024 at 4:26 pm, Testing Personnel 16 stated that she performed the direct observations for the identified testing personnel on the 2022 and 2023 competency assessments. Testing Personnel 16 confirmed the Technical Consultants did not perform the competencies for the identified personnel.
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 observation, review of maintenance logs, and interview with personnel, the Laboratory Director failed to ensure maintenance procedures were performed to ensure acceptable levels of test performance. Refer to D5433.
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 personnel records and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The laboratory failed to follow their competency assessment policy for two (2) of three (3) General Supervisors. Refer to D5209 II. 2. The General Supervisors failed to evaluate all criteria of competency for Immunohematology testing for five (5) of ten (10) testing personnel reviewed. Refer to D6151.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 (Laboratory Personnel Report) form, personnel records, and interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of General Supervisor to two (2) of three (3) personnel reviewed. Findings: 1. Review of the laboratory's CMS 209 form revealed the laboratory has three (3) personnel listed as General Supervisors. 2. Review of personnel records revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of General Supervisor to the following Personnel: Personnel 5 Personnel 10 3. In interview on January 30, 2024 at 10:29 a.m., the Laboratory Manager confirmed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of General Supervisor to the personnel identified above.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (3) The director or technical supervisor may delegate to the general supervisor the responsiblity for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel. This STANDARD is not met as evidenced by: Based on review of the Laboratory Personnel Report (CMS 209), personnel records, and interview with personnel, the General Supervisors failed to evaluate all criteria of competency for Immunohematology testing for five (5) of ten (10) testing personnel reviewed. Findings: 1. Review of the laboratory's Laboratory Personnel Report revealed the following personnel listed as General Supervisors: Personnel 5 Personnel 9 Personnel 10 2. Review of personnel records for 2022 and 2023 revealed the following personnel had some competency assessment criteria for high complexity testing in Immunohematology performed by personnel other than the General

	Supervisors: a) Personnel 1 - 2022 Immunohematology Competency Assessment - Personnel 7 evaluated the following: - Performs/documents quality controls - Completes blood bank log - Demonstrates proper platelet product handling - Thaws and documents FFP preparation - Completes component disposition records on log and in the Electronic Medical Record - Understands/performs external alarm checks, when applicable - Successful performance of ABO-Rh, Antibody Screen and Compatibility testing b) Personnel 5 - 2022 Immunohematology Competency Assessment - Personnel 7 evaluated the following: - Performs/documents quality controls - Completes blood bank log - Completes blood bank log - Blood storage requirements - Performs/documents maintenance - Demonstrates proper platelet product handling - Thaws and documents FFP preparation - Understands/performs external alarm checks, when applicable - Successful performance of ABO-Rh, Antibody Screen and Compatibility testing - Troubleshooting/evaluation of problem solving skills c) Personnel 8 - 2022 Immunohematology Competency Assessment - Personnel 3 evaluated the following: - Performs/documents maintenance - Successful performance of proficiency testing/blind sampling/patient testing d) Personnel 10 - 2022 Immunohematology Competency Assessment - Personnel 2 evaluated the following: - Completes blood bank log - Blood storage requirements - Performs /documents maintenance - Demonstrates proper platelet product handling - Thaws and documents FFP preparation - Completes component disposition records on log and in the Electronic Medical Record - Understands/performs external alarm checks, when applicable - Troubleshooting/evaluation of problem solving skills e) Personnel 6- 2023 Immunohematology Competency Assessment - Personnel 4 evaluated the following: - Performs/documents quality controls - Completes blood bank log - Completes blood bank log - Blood storage requirements - Performs/documents maintenance - Demonstrates proper platelet product handling - Thaws and documents FFP preparation - Understands/performs external alarm checks, when applicable - Successful performance of ABO-Rh, Antibody Screen and Compatibility testing 3. In interview on January 29, 2024 at 4:13 p.m., the Laboratory Manager confirmed the competency assessments identified above were not conducted by personnel identified by the laboratory as General Supervisors.