Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2269784	08/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Choices Center For Reproductive Health	600 Giant City Rd, Carbondale, IL	

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	An initial certification survey was completed on 08/20/2024. It was determined that Immediate Jeopardy (IJ) existed for the following condition level deficiencies: 42 C.F.R 493.801 - Condition: Enrollment and testing of proficiency samples 42 C.F.R 493.1217 - Condition: Immunohematology 42 C.F.R 493.1403 - Condition: Laboratory Director 42 C.F.R 493.1409 - Condition: Technical Consultant
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the federal Casper report 0096D, laboratory proficiency testing (PT) records, lack of documentation, and interview with the laboratory representative; the laboratory failed to enroll in approved Health and Human Services (HHS) proficiency testing (PT) challenges for Rhesus (Rh) factor testing from the beginning of patient testing, 05/01/2023, through the date the surveyors were on site, 08/14 /2024, for the specialty of immunohematology. Findings include: 1. Review of laboratory PT records revealed that the laboratory failed to enroll in testing for the analyte Rhesus (Rh) factor from the beginning of patient testing, 05/01/2023, through the date the surveyors were on site, 08/14/2024, for the specialty of immunohematology. 2. Interview with the laboratory representative on 08/14/2024, at 11:21 am, confirmed no enrollment in an approved HHS PT program.

D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the federal Casper report 0096D, laboratory proficiency testing (PT) records, laboratory records, policy and procedure manuals, manufacturer's package insert, patient test reports, direct observation lack of documentation, and interview with the laboratory representative, the laboratory failed to establish and follow written policies and procedures to assess testing personnel and technical consultant competencies (See D5209); establish and follow written policies and procedures for monitoring, assessing, and correcting problems (See D5291); outline all components of test procedure (See D5403); have policy and procedure manuals reviewed, approved, signed, and dated by the current laboratory director (See D5407); demonstrate it can obtain performance specifications (See D5421); ensure negative and positive control materials were tested each day of testing (See D5449); and perform testing as outlined by the manufacturer for Rhesus (Rh) factor testing in the specialty of immunohematology (See D5551).
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: a) Based on review of laboratory policy and procedure manuals, lack of documentation, and interview with the laboratory representative; the laboratory failed to establish and follow written policies and procedures to assess testing personnel (TP) competency for two of two TP performing Rhesus (Rh) factor testing in the specialty of immunohematology. Findings include: 1. Review of the laboratory policy and procedure manuals found no policy / procedure in place used to monitor TP competency. 2. Review of laboratory competency assessment records showed the laboratory failed to assess competency for two of two TP. 3. Interview with the laboratory representative on 08/14/2024, at 11:41 am, confirmed the above findings. b) Based on review of laboratory policy and procedure manuals, lack of documentation, and interview with the laboratory representative; the laboratory failed to establish and follow written policies and procedures to assess technical consultant (TC) competency for one of one TC overseeing Rhesus (Rh) factor testing in the specialty of immunohematology. Findings include: 1. Review of the laboratory policy and procedure manuals found no policy / procedure in place used to monitor TC competency. 2. Review of laboratory competency assessment records showed the laboratory failed to assess competency for one of one TC. 3. Interview with the laboratory representative on 08/14/2024, at 11:41 am, confirmed the above findings.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manuals, lack of documentation, and interview with the laboratory representative; the laboratory failed to establish and follow written policies and procedures for monitoring, assessing, and correcting problems in the specialty of immunohematology. Findings Include: 1. Review of laboratory policy and procedure manuals revealed no documentation of a written quality assessment plan was available. 2. Interview with the laboratory representative on 08/14/2024, at 1:20 pm, confirmed no written quality assessment plan had been established.
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 review of the laboratory's policy and procedure manuals and interview with the laboratory representative; the laboratory failed to outline all components of test procedure for Rhesus (Rh) factor testing in the specialty of immunohematology. Findings Include: 1. Review of the policy and procedure manual identified the procedure, "DOCTOR'S KIT DKS RhD-25", which failed to have the following required components for Rhesus (Rh) factor testing on the ELDONCARD: a. Control procedures. b. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. c. Pertinent literature references. d. The laboratory's system for entering results in the patient record and reporting patient results. e. Description of the course of action to take if a test system becomes inoperable. 2. Interview with the laboratory representative on 08/14/2024, at 12:09 pm, confirmed the laboratory failed to outline all components of the test procedure.

D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manuals, lack of documentation, and interview with the laboratory representative; the laboratory failed to have policy and procedure manuals reviewed, approved, signed, and dated by the current laboratory director (as noted on the CMS-209 Laboratory Personnel Form) for the specialty of immunohematology. Findings include: 1. Review of laboratory policy and procedure manuals revealed no laboratory director (LD) approval, including signature and date, by the current LD for the procedure, "DOCTOR'S KIT DKS RhD-25" for ELDONCARD Rhesus (Rh) factor testing. 2. Interview with the laboratory representative on 08/14/2024, at 12:09 pm, confirmed the LD had not signed or dated the procedure relating to immunohematology testing.
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 review of the laboratory records, lack of documentation, patient test reports, and interview with the laboratory representative; the laboratory failed to demonstrate it can obtain performance specifications for the "DOCTOR'S KIT DKS RhD-25" EldonCard immunohematology Rhesus (Rh) factor test prior to the start of patient testing on 05/01/2023. Findings Include: 1. Review of laboratory records for immunohematology Rh testing found no verification study for immunohematology Rh factor testing was completed for the "DOCTOR'S KIT DKS RhD-25" EldonCard testing kit. 2. A review of 21 of 21 patient test reports confirmed Rh factor patient testing had been conducted at the laboratory under the specialty of immunohematology: Patient #: Report Date: 64262 05/01/2023 64214 05/01/2023 63892 05/22/2023 64628 05/22/2023 65410 06/29/2023 66400 08/28/2023 66738 09/05/2023 60997 09/12/2023 68613 01/25/2024 69325 02/29/2024 69181 04/16/2024 70130 05/08/2024 70053 05/21/2024 56046 06/04/2024 70686 06/11/2024 70703 06/20/2024 70506 07/02/2024 71034 07/02/2024 71147 07/11/2024 68886 08/09/2024 71731 08/10/2024 3. Interview with the representative at 1:20 pm, on 08/14/2024, confirmed that no verification of performance for immunohematology testing had been completed at the laboratory which started Rh factor patient testing 05/01/2023.
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 review of patient test reports, laboratory quality control (QC) records, lack of documentation, laboratory policy and procedure manuals, manufacturer's package insert, and interview with the laboratory representative; the laboratory failed to ensure negative and positive control materials were tested each day of testing for Rhesus (Rh) factor in the specialty of immunohematology prior to reporting patient test results. Findings include: 1. Review of the laboratory's policy and procedure manual found the document, "QUALITY CONTROL METHODS ELDONCARD BLOOD TYPING", which indicated: "While a control panel is built into each Eldoncard test, the following methods can be used as external controls. 1. Test with a known Rh factor donor whole blood sample. 2. Test using the standard forward typing method using Ortho Anti-A, Anti-B or Anti-D sera. Anti-D would be required for Rh only test cards .... 3. Test with Ortho Surgiscreen 8% or 10% whole blood control (external) ....." 2. Review of 21 of 21 patient test reports and lack of QC documentation confirmed the laboratory failed to run QC on the date patient testing was performed. Patient #: Report Date: 64262 05/01/2023 64214 05/01/2023 63892 05/22/2023 64628 05/22/2023 65410 06/29/2023 66400 08/28/2023 66738 09/05/2023 60997 09/12 /2023 68613 01/25/2024 69325 02/29/2024 69181 04/16/2024 70130 05/08/2024 70053 05/21/2024 56046 06/04/2024 70686 06/11/2024 70703 06/20/2024 70506 07 /02/2024 71034 07/02/2024 71147 07/11/2024 68886 08/09/2024 71731 08/10/2024 3. During the survey on 08/14/2024, at 11:47 am, the laboratory representative confirmed that external QC was not performed for Rh factor testing.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: a) Based on review of manufacturer's package insert, lack of documentation, direct observation, and interview with the laboratory representative; the laboratory failed to document the open and modified expiration dates as required by the product manufacturer. Findings include: 1. Review of the manufacturer's package insert, "DOCTOR'S KIT DKS RhD-25", indicated, "Storage and Stability: The EldonCards are placed in an EldonBag. An EldonBag is opened by cutting at the indicated line on the label, so that it can be re-sealed with the zipper. When opening the bag for the first

	time, record the date in the frame provided on the label. After removal of cards, close the zipper carefully. Cards kept in properly closed EldonBags are stable for 6 months after the first opening, if the desiccant sachet is still present, and if the EldonBag is not opened more than 50 times.... EldonCards that have been out of their EldonBag for more than 30 minutes should be used within the same day." 2. Upon of tour of the laboratory on 08/14/2024, at 12:10 pm, direct observation revealed no open or modified expiration date on the opened EldonBag. 3. Upon of tour of the laboratory on 08/14/2024, at 12:10 pm, direct observation revealed an unused EldonCard outside of the EldonBag, with no date indicating when it was removed from the EldonBag. 4. During the survey on 08/14/2024, at 1:20 pm, the laboratory representative confirmed the above findings. b) Based on review of laboratory records, manufacturer's package insert, lack of documentation, and interview with the laboratory representative; the laboratory failed to perform QC measures as outlined by the manufacturer for Rhesus (Rh) factor testing in the specialty of immunohematology. Findings include: 1. Review of the manufacturer's package insert, "DOCTOR'S KIT DKS RhD-25", indicated for external controls, under "Quality Control", "Upon receipt of a shipment of kits, check for possible damage during transportation and ensure the quality of the kits by testing with red cells with and without the RhD antigen ...." 2. Review of the manufacturer's package insert, "DOCTOR'S KIT DKS RhD-25", indicated for internal controls, under "How to read the results", "If a positive reaction is observed in the Control field, the test result is invalid and the examination has to be repeated ...." 3. Review of laboratory records revealed no external or internal QC documentation. 4. During the survey on 08/14/2024, at 11:47 am, the laboratory representative confirmed that external QC was not being performed and internal QC was not being documented.
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: Based on review of laboratory policy and procedure manuals, laboratory records, proficiency testing (PT) records, manufacturer's package insert, patient test reports, direct observation, lack of documentation, and interview with the laboratory representative, the laboratory director failed to ensure the facility is operating properly; failed to ensure verification procedures were performed to determine the performance characteristics of the Rhesus (Rh) factor testing method prior to patient testing (See D6013); failed to ensure laboratory testing personnel were performing the test methods as required for accurate and reliable results (See D6014); failed to ensure successful participation in a Health and Human Services (HHS) approved proficiency testing (PT) program for the specialty of immunohematology resulting in the laboratory's unsuccessful PT enrollment (See D6015); failed to ensure quality control programs were maintained to assure the quality of laboratory services provided (See D6020); failed to ensure establishment and follow written policies and procedures for monitoring, assessing, and correcting problems including pre-analytic, analytic, and post-analytic phases of testing in the specialty of immunohematology (See D6021); failed to ensure two of two testing personnel (TP) performing EldonCard Rhesus (Rh) factor testing received the appropriate training for the type and complexity of testing performed and have demonstrated that they can perform all testing operations reliably

	to provide and report accurate results (See D6029); failed to ensure policies and procedures are established and followed for monitoring testing personnel who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain competency to perform test procedures proficiently (See D6030); failed to provide an approved procedure manual outlining all aspects of immunohematology testing performed by the laboratory (See D6031); and failed to identify the responsibilities and duties of two of two testing personnel (TP) and one of one technical consultant (TC) engaged in all phases of immunohematology testing (See D6032).
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 review of the laboratory records, lack of documentation, patient test reports, and interview with the laboratory representative; the laboratory director failed to ensure verification procedures were performed to determine the performance characteristics of the Rhesus (Rh) factor testing method prior to patient testing. See D5421.
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 policy and procedure manuals, laboratory records, manufacturer's package insert, direct observation, lack of documentation, and interview with the laboratory representative; the laboratory director failed to ensure laboratory testing personnel were performing the test methods as required for accurate and reliable results. Findings include: 1. The laboratory director failed to establish and follow written policies and procedures to assess testing personnel and technical consultant competency. See D5209. 2. The laboratory director failed to ensure all components of the testing procedure for Rhesus (Rh) factor testing were outlined. See D5403. 3. The laboratory director failed to ensure control procedures were performed and documented for Rh factor testing. See D5449. 4. The laboratory director failed to ensure that testing personnel were following manufacturers' instructions for use for Rh factor testing. See D5551.

D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, manufacturer's package insert, lack of documentation, and interview with the laboratory representative; the laboratory director failed to ensure the laboratory enrolled in an approved proficiency testing (PT) program for Rhesus (Rh) factor testing in the specialty of immunohematology. See D2000.
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 review of laboratory policies and procedures, laboratory records, manufacturer's package insert, lack of documentation, and interview with the laboratory representative; the laboratory director failed to ensure quality control programs were maintained to assure the quality of laboratory services provided. Findings include: 1. The laboratory director failed to ensure negative and positive control materials were tested each day of testing for Rhesus (Rh) factor in the specialty of immunohematology prior to reporting patient test results. See D5449. 2. The laboratory director failed to ensure quality control was being performed as directed by the manufacturer's package insert. See D5551.
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 review of laboratory policy and procedure manuals, lack of documentation,

	and interview with the laboratory representative; the laboratory director failed to ensure establishment and follow written policies and procedures for monitoring, assessing, and correcting problems including pre-analytic, analytic, and post-analytic phases of testing in the specialty of immunohematology. See D5291.
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 review of laboratory records, lack of documentation, CMS-209 (Laboratory Personnel Report), and interview with the laboratory representative; the laboratory director failed to ensure two of two testing personnel (TP) performing EldonCard Rhesus (Rh) factor testing received the appropriate training for the type and complexity of testing performed and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. Findings Include: 1. Review of the laboratory personnel report (CMS-209) identified two new TP, TP #1 and TP #2, performing EldonCard Rh factor testing. 2. Review of laboratory records revealed no training or competency documentation. 3. On survey date 08/14/2024, at 11:16 am, the laboratory representative confirmed that no initial training or competency documentation for two of two new TP were available for review.
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 review of laboratory policy and procedure manuals, the CMS-209 (Laboratory Personnel Report) form, competency records, lack of documentation, and interviews with the laboratory representative; the laboratory director failed to ensure policies and procedures are established and followed for monitoring testing personnel

	who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain competency to perform test procedures proficiently. Refer to D5209 and 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 review of laboratory policy and procedure manuals, lack of documentation, and interview with laboratory representative; the laboratory director failed to provide an approved procedure manual outlining all aspects of immunohematology testing performed by the laboratory. See D5407.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, Laboratory Personnel Report (CMS-209), lack of documentation, and interview with the laboratory representative, the laboratory director failed to identify the responsibilities and duties of two of two testing personnel (TP) and one of one technical consultant (TC) engaged in all phases of immunohematology testing. Findings include: 1. Review of the Laboratory Personnel Report (CMS-209) form revealed two TP and one TC engaged in moderate complexity testing in the specialty of immunohematology, including Rhesus (Rh) factor testing. 2. Review of laboratory policies and procedures revealed a lack of documentation identifying the responsibilities and duties of two of two TP and one of one TC for the specialty of immunohematology. 3. Interview with the representative at 12:09 pm, on 08/14/2024, confirmed that there were no documents specifying the duties and responsibilities for each person engaged in testing process.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409

	The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory policy and procedure manuals, laboratory records, proficiency testing (PT) records, manufacturer's package insert, patient test reports, direct observation, lack of documentation, and interview with the laboratory representative, the technical consultant failed to ensure verification procedures were performed to determine the performance characteristics of the Rhesus (Rh) factor testing method prior to patient testing (See D6040); failed to ensure the laboratory enrolled in an approved proficiency testing (PT) program for Rhesus (Rh) factor testing in the specialty of immunohematology (See D6041); failed to ensure quality control programs were maintained to assure the quality of laboratory services provided (See D6042); failed to address training needs for two of two testing personnel (TP) performing Rhesus (Rh) factor testing (See D6045); failed to ensure two of two Rhesus (Rh) factor testing personal (TP) established and maintained their competency to perform and report testing in the specialty of immunohematology accurately and proficiently (See D6046).
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the laboratory records, lack of documentation, patient test reports, and interview with the laboratory representative; the technical consultant failed to ensure verification procedures were performed to determine the performance characteristics of the Rhesus (Rh) factor testing method prior to patient testing. See D5421.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, manufacturer's package insert, lack of documentation, and interview with the laboratory representative; the technical consultant failed to ensure the laboratory enrolled in an approved proficiency testing (PT) program for Rhesus (Rh) factor testing in the specialty of immunohematology. See D2000.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)

	(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, manufacturer's package insert, lack of documentation, and interview with the laboratory representative; the technical consultant failed to ensure quality control programs were maintained to assure the quality of laboratory services provided. Findings include: 1. The technical consultant failed to ensure negative and positive control materials were tested each day of testing for Rhesus (Rh) factor in the specialty of immunohematology prior to reporting patient test results. See D5449. 2. The technical consultant failed to ensure quality control was being performed as directed by the manufacturer's package insert. See D5551.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) 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; This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manuals, Laboratory Personnel Report (CMS-209) form, laboratory records, lack of documentation, and interview with the laboratory representative; the technical consultant failed to address training needs for two of two testing personnel (TP) performing Rhesus (Rh) factor testing in the specialty of immunohematology. Findings include: 1. Review of laboratory personnel records found TP #1 and #2, as identified on the CMS-209, were authorized to perform Rh factor testing in the specialty of immunohematology. 2. Review of training documentation found neither TP #1 nor TP #2 had documented training for Rh factor testing in the specialty of immunohematology. 3. Interview with the representative at 12:09 pm, on 08/14/2024, confirmed that there were no training documents available for review.
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 CMS-209 (Laboratory Personnel Report), laboratory competency records, lack of documentation, and interview with the laboratory representative; the technical consultant (TC) failed to ensure two of two Rhesus (Rh) factor testing

	personal (TP) established and maintained their competency to perform and report testing in the specialty of immunohematology accurately and proficiently. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) form found TP #1 and #2 were authorized to perform Rh factor testing in the specialty of immunohematology. 2. Review of the laboratory competency records revealed two TP, TP #1 and TP #2, failed to have competency assessments for EldonCard Rh factor testing. 3. Interview with the representative at 12:09 pm, on 08/14/2024, confirmed that there were no competency assessments available for review.