Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0306825	12/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Shamrock Community Hospital, Inc	5001 East Main St, Erin, TN	

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	During an initial survey the laboratory was found out of compliance with the following condition: 493.1250 Condition: Analytic systems
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: Based on review of the laboratory procedure manual, the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), lack of documentation, and staff interview, the laboratory failed to follow its' own policies for testing personnel training and evaluation of competency for eight of eight testing personnel in 2023. The findings include: 1. Review of the laboratory's policy titled "QUALITY ASSURANCE (QA) FOR THE LABORATORY under the section for new employees revealed that new employees would be trained for each section they work, and that performance would be review at 90 days, six months and then annually. The policy titled "Competency Evaluation" revealed that "each individual's performance in the laboratory will be evaluated at orientation, at 6 months, and yearly thereafter." "Prior to implementation of new equipment or procedures - orientation, inservice and competency must be performed prior to test performance by technical staff." 2. Review of the FORM CMS 209 revealed eight testing personnel who perform patient testing. 3. There was no documentation of laboratory training /assessment of competency for testing personnel as follows: Testing person number one: Urine microscopic, manual differential, ABO, Rh, Antibody Screen, Compatibility testing, mono test, wet prep. Testing person number two: Beckman Coulter AU and Beckman Coulter Access chemistry instruments, urine microscopic, testing performed on the Abbott i-STAT instrument (blood gas and troponin I), and

	wet prep. Testing person number three: Triage meter for performance of D-Dimer, urine microscopic, manual differential, Beckman Coulter DxH complete blood count instrument, wet prep, and Sysmex CA 600 for performance of Prothrombin Time (PT) and activated Partial Thromboplastin Time (PTT). Testing person number four: Triage meter for performance of D-Dimer, urine microscopic, Beckman Coulter DxH complete blood count instrument, manual differential, Abbott i-STAT for performance of arterial blood gas and troponin I, mono test, Sysmex CA 600 for performance of PT and PTT, and serum pregnancy test on the ICON test kit. Testing person number five: Beckman Coulter DxH complete blood count instrument, urine microscopic, manual differential, Abbott i-STAT instrument for performance of blood gas and troponin I, mono test, wet prep, serum pregnancy test on the ICON test kit. Testing person number six: Triage meter for performance of D-Dimer, urine microscopic, Beckman Coulter DxH complete blood count instrument, manual differential, transfusion medicine testing to include ABO, Rh, antibody screen and compatibility testing, Abbott i-STAT for performance of arterial blood gas and troponin I, wet prep, and Sysmex CA 600 for performance of PT and PTT. Testing person number seven: Triage meter for performance of D-Dimer, Beckman Coulter AU and Access 2 chemistry instruments, Beckman Coulter DxH complete blood count instrument, urine microscopic, manual differential, Abbott i-STAT instrument for performance of blood gas and troponin I, wet prep, and Sysmex CA 600 for performance of PT and PTT. Testing person number eight: Beckman Coulter AU and Access 2 chemistry instruments, Beckman Coulter DxH complete blood count instrument, Abbott i-STAT instrument for performance of blood gas and troponin I and wet prep. 4. Interview with the general supervisor on 12/11/23 at 4 pm confirmed the laboratory failed to follow its' own policy for testing personnel training and competency assessment for all eight personnel who perform patient testing.
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 laboratory observations, review of laboratory procedures, patient test reports, manufacturer instructions for use, quality control records, patient test logs, lack of documentation, staff interview and electronic communications, the laboratory failed to maintain compliance with analytic systems when it failed to have a complete procedure manual for performance of hematology testing on the Beckman Coulter DxH 690T (Refer to D5403), failed to ensure the procedure for the Beckman Coulter DxH 690T hematology instrument was approved by the laboratory director before use (Refer to D5407), failed to perform Mean Normal Patient Prothrombin Time for the current lot of Innovin (Refer to D5411), failed to verify the performance of the moderately complex Respiratory Syncytial Virus (RSV) performed on the Quidel Sophia 2 (Refer to D5421-Citation One), failed to verify the performance specifications of the cardiac Troponin I performed on the i-STAT instrument (Refer to D5421-Citation Two), failed to establish performance specifications for RSV test performed on patients outside the manufacturer specified age groups (Refer to

	D5423), failed to ensure at two levels of controls were performed each day of patient testing for the cardiac Troponin I performed on the i-STAT instrument (Refer to D5447), failed to ensure two levels of quality control were performed for the qualitative serum pregnancy test for the ICON test kit (Refer to D5449-Citation number one), failed to ensure two levels of quality control were performed each day of patient testing for the non-waived RSV test performed on the Quidel Sophia 2 (Refer to D5449-Citation number two), failed to verify the quality control (QC) ranges that were in use for the Thyroid Stimulating Hormone (Refer to D5469), and failed to ensure an anti-human globulin (AHG) crossmatch was performed when the patient had a positive antibody screen (Refer to D5551).
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 of the laboratory, review of the laboratory procedure for the Beckman Coulter DxH 690T hematology instrument, and interview with the general supervisor, the laboratory procedure failed to include all procedure manual requirements and included instructions for testing not performed by the laboratory. The findings include: 1. Observation of the laboratory on 12/11/23 at 8:45 am revealed the Beckman Coulter DxH 690T in use for patient testing. During observation, the general supervisor stated the laboratory performs patient testing for Complete Blood Count with automated white blood cell differential (CBC w/diff) and reticulocyte count. The general supervisor further stated the laboratory does not perform body fluid testing on the DxH 690T. 2. Review of the laboratory procedure for the DxH 690T revealed the following that was not included in the procedure: Sample handling, specimen rejection, specimen storage stability, calibrator and control handling and storage, patient normal/reference ranges, quality control protocol and frequency, the system for entering patient results into the patient record, and the reportable range for the tests performed as validated. The laboratory procedure also included refences to body fluid analysis which were not performed by the laboratory. 3. Interview with the general supervisor on 12/12/23 at 5 pm confirmed the laboratory procedure for use of the DxH690T did not include required elements and included references to tests not performed by the laboratory.

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 observation of the laboratory, review of the laboratory procedure for the DxH 690T hematology instrument, procedures for the Beckman Coulter AU chemistry instrument, and interview with the general supervisor, the laboratory failed to ensure the procedures in use for testing performed on the Beckman Coulter DxH 690T and Beckman Coulter AU chemistry instrument were approved by the lab director. The findings include: 1. Observation of the laboratory on 12/11/23 at 8:45 am revealed the Beckman Coulter DxH 690T in use for patient testing for CBC w/diff and reticulocyte count and the Beckman Coulter AU instrument in use for performing chemistry assays. 2. Review of the laboratory procedure for the DxH 690T hematology instrument, and the procedures for use of the vancomycin, salicylate, digoxin, and acetaminophen tests performed on the Beckman Coulter AU instrument revealed no approval by the lab director. 3. Interview with the general supervisor on 12 /12/23 at 4:30 pm confirmed the laboratory failed to ensure the procedures for the use of the DxH 690T hematology instrument and procedures for tests performed on the Beckman Coulter AU chemistry instrument were approved by the laboratory director prior to patient testing.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and staff interview, the laboratory procedure for the Beckman Coulter DxH 690T did not include the date the procedure was placed into use. The findings include: 1. Review of the laboratory procedure for the Beckman Coulter DxH 690T hematology instrument revealed the procedure did not include the initial date of use. 2. Interview with the general supervisor on 12/12/23 at 5 pm confirmed the procedure for the DxH690T did not include the date the procedure was placed into use.
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 of the laboratory, review of the manufacturer package insert, lack of documentation, patient test results, staff interview and email communication,

	the laboratory failed to perform the mean normal patient prothrombin time (PT) (MNPT) used in the calculation of the International Normalized Ratio (INR) for the current lot of PT reagent (Innovin) in use on the date of the onsite survey (12/11/23), with approximately 20 patients reported from 04/27/23 to 12/20/23. The findings include: 1. Observation of the laboratory on 12/11/23 at 8:45 am revealed the Siemens CA 600 coagulation instrument (serial number 11779) on the counter in use for performing patient testing for PT, calculated INR and activated Partial Thromboplastin Time (aPTT). The current lot number of Innovin in use for performing patient testing for PT/INR was 549795. 2. Review of the manufacturer package insert for the Innovin reagent revealed that the MNPT (used in the INR calculation) must be determined specifically for each lot. 3. There was no documentation that the mean normal patient determination had been performed for the current lot of Innovin (549795). 4. Review of patient test results revealed PT and calculated INR reported on 12/09/23 for patient 1004177. 5. Interview with the general supervisor on 12/13/23 at 6 pm confirmed the laboratory did not perform the MNPT for the current lot of Innovin. 6. Review of an email communication received from the laboratory supervisor on 12/20/23 at 12:37 pm revealed that approximately 20 patient PT/INR results had been reported from 04/27/23 (date laboratory changed from a certificate of accreditation to a certificate of compliance) to 12/20/23.
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: CITATION ONE: Based on observation of the laboratory, review of manufacturer package insert, reported patient results, patient test log, lack of documentation, staff interview and email communication, the laboratory failed verify the manufacturer performance specifications for use of the moderately complex Quidel Sophia 2 Respiratory Syncytial Virus (RSV) test prior to patient testing which began on 05/18/23 with eleven patients reported between the ages of seven and eighteen. The findings include: 1. Observation of the laboratory on December 11, 2023 at 8:45 am revealed the Quidel Sophia 2 instrument in use for performing patient testing for RSV. 2. Review of the manufacturer package insert revealed the RSV test performed on the Sophia 2 as moderately complex for patients seven to less than nineteen. 3. Review of patient id number 401144 revealed patient testing reported for RSV on 12/04/23. The age of the patient on the date of service was seven. 4. Review of the patient test logs for the Sophia 2 RSV revealed that patient testing began on 05/18/23. 5. There was no documentation of verification studies performed for use of the moderately complex RSV test. 6. Interview with the laboratory supervisor on 12/11/23 at 4:00 pm confirmed the laboratory failed to verify the performance specifications for the use of the moderately complex Sophia 2 RSV. 7. Email communication received on 12/27/23 at 8:24 am revealed that approximately eleven patients between the ages of seven and eighteen were reported from 05/18/23 to the date of the survey on 12/11/23. CITATION TWO: Based on observation of the laboratory, lack of documentation, a

	patient test report, staff interview and email communication, the laboratory failed to verify the performance specifications for use of the Cardiac Troponin-I (cTnI) performed on the i-STAT instrument prior to patient testing which began on 09/14/23 with seven patients reported from 09/14/23 to the date of the survey on 12/11/23. The findings include: 1. Observation of the laboratory on 12/11/23 at 8:45 am revealed an i-STAT instrument on the counter in use for moderately complex patient testing for blood gas analysis and cTNI. During observations, the supervisor stated the cTnI was used as a backup for their primary chemistry instrument. 2. There was no documentation of test performance verification for the cTnI. 3. Review of a final patient test report revealed reporting of cTnI performed on the i-STAT on 11/28/23 for patient 1003906. 4. Interview with the general supervisor on 12/11/23 at 4 pm confirmed the laboratory used the i-STAT to perform cTnI patient testing and that no verification of performance specifications were performed. 5. Review of an email communication received on 12/21/23 at 6:36 am revealed seven patient cTnI tests performed on the i-STAT were reported since patient testing began on 09/14/23.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer package insert, reported patient results, lack of documentation, staff interview and email communication, the laboratory failed to establish the performance specifications for the use of the Quidel Sophia 2 Respiratory Syncytial Virus (RSV) test in patients over the age of eighteen years, with seven patients over the age of eighteen tested and reported from the time testing began on 05/18/23 to the date of the onsite survey on 12 /11/23. The findings include: 1. Observation of the laboratory on December 11, 2023 at 8:45 am revealed the Quidel Sophia 2 instrument in use for performing patient testing for RSV. During observation, the general supervisor stated the laboratory performs RSV testing on the Sophia 2 on patients of all ages. 2. Review of the manufacturer package insert revealed the RSV test performed on the Sophia 2 was waived for patients under the age of seven, moderately complex for patients seven to less than nineteen years. The RSV test was not categorized for use in patients over the age of eighteen. 3. Review of patient sample number 40978 revealed patient testing performed and reported for RSV on 11/15/23. The age of the patient on the date of testing was 29. 4. There was no documentation that establishment studies had been performed for use of the Sophia 2 RSV test for patients over the age of eighteen. 5. Interview with the laboratory supervisor on 12/11/23 at 4 pm confirmed the laboratory failed to establish performance specifications for the use of the Sophia 2 RSV test on

	patients over the age of eighteen. 6. Email communication received on 12/20/23 at 9: 45 am revealed that seven patients over the age of eighteen were tested between 05/18 /23 (first date of testing) to the date of the onsite survey on 12/11/23.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, review of a patient test report, the quality control (QC) log for the Cardiac Troponin I (cTnI), and electronic communication, the laboratory failed to perform at least two levels of external QC for the cTnI performed on the i-STAT instrument each day of patient testing in 2023. The findings include: 1. Observation of the laboratory on 12/11 /23 at 8:45 am revealed the Abbott i-STAT in use for patient testing. During the laboratory tour the general supervisor stated the i-STAT was used for performing blood gas analysis and cTnI testing as a backup method to their chemistry platform. 2. Review of the laboratory procedure for the i-STAT troponin I revealed that external quality control would be performed with each lot change, each shipment and every 30 days. 3. Review of a patient test report revealed cTnI performed on the i-STAT reported on 09/12/23 for patient number 1002322. 4. Review of the i-STAT QC log for the Troponin I revealed no documentation that external quality control was performed on 09/12/23. 5. Communications via email with the general supervisor on 12/21/23 revealed the following: Communication at 6:36 am revealed that seven patient cTnI results from the i-STAT instrument had been reported since the first patient was performed. Communication at 8:11 am confirmed the laboratory did not perform at least two levels of external quality control each day of patient testing for the cTnI performed on the i-STAT instrument.
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: CITATION NUMBER ONE Based on observation of the laboratory, review of patient test reports, quality control logs, and electronic communication, the laboratory failed to perform negative and positive quality control (QC) each day of patient testing for the qualitative serum pregnancy test in 2023 with three patients reported since 05/23 /23. The findings include: 1. Observation of the laboratory on 12/11/23 at 8:45 am revealed patient testing for qualitative serum pregnancy test performed using the ICON test kit. During the tour the general supervisor stated that external QC is done

	with each new lot, shipment and every 30 days. 2. Review of patient test reports revealed patient testing for qualitative serum pregnancy reported on 11/12/23 (patient 401237). 3. Review of the QC log for the serum pregnancy test revealed no documentation of external QC performed on 11/12/23. 4. Email communication with the general supervisor on 12/21/23 at 6:36 am revealed a total of three qualitative serum pregnancy tests were reported from 05/23/23 to the date of the onsite survey on 12/11/23, without performance of daily external negative and positive QC. CITATION NUMBER TWO Based on observation of the laboratory, review of a patient test report, lack of documentation, and electronic communication, the laboratory failed to perform negative and positive QC each day of patient testing for the non-waived RSV test. The findings include: 1. Observation of the laboratory on 12 /11/23 at 8:45 am revealed non-waived qualitative testing for the RSV test using the Sophia 2 test kit and system. During the tour the general supervisor stated that external QC is done with each new lot, shipment and every 30 days. 2. Review of a patient test report revealed patient testing for RSV reported on 12/04/23 for patient number 401144. 3. There was no documentation that external negative and positive QC was performed on 12/04/23. 4. Communications via email with the general supervisor on 12/21/23 at 6:36 am confirmed the laboratory did not perform daily external negative and positive controls for the RSV test each day of patient testing.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of quality control records, review of the manufacturer package insert, review of a patient test result, and interview the laboratory supervisor, the laboratory failed to ensure quality control ranges were verified for the Thyroid Stimulating Hormone (TSH) analyte when placed into use on 09/16/23 until the date of the onsite survey completed on 12/13/23. The findings include: 1. Observation of the laboratory on 12/11/23 at 8:45 am revealed the Beckman Coulter Access 2 (serial #574038) in use for performing patient testing. The general supervisor stated the laboratory performs free thyroxine, thyroid stimulating hormone, quantitative human chorionic gonadotropin, troponin I and B-type natriuretic peptide on the instrument. 2. Review of the quality control records for the TSH analyte revealed the following: Biorad Liquichek Immunoassay Plus control lot numbers 85341 and 85342 in use. The manufacturer package insert had a target mean of 0.732 uIU/mL with a range of 0.631 - 0.833 for Level one. The range for level one as entered into the instrument was a target of 0.7 with a one SD of 0.35 resulting in a two SD QC range of 0 to 1.4 mIU/mL, and a 3SD range of -.35 to 1.75 mIU/mL. 3.

	Review of the manufacturer package insert revealed the following statement: "The mean values and corresponding +/- 3SD in the Assignment of Values Data Charts were derived from replicate analyses and are specific for this lot of product." 4. Review of a patient test report revealed patient testing for TSH performed on 11/28/23 on a date when the incorrect QC ranges were in use (patient sample number 82160). 5. Interview with the laboratory supervisor on 12/13/23 at 6 pm confirmed the laboratory failed to ensure quality control ranges entered for the TSH analyte were verified before placing into use with incorrect ranges in use for the TSH analyte on the date of the survey. Word Key: uIU/mL= milli-international units per milliliter SD= Standard Deviation
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's transfusion medicine records and interview with the general supervisor, the laboratory failed to ensure an anti-human globulin (AHG) crossmatch was performed when the patient had a positive antibody screen (one of one patients reviewed). The findings include: 1. Observation of the laboratory on 12/11/23 at 8:45 am revealed testing for transfusion medicine being performed using Ortho reagents. The general supervisor stated the laboratory performs patient testing for ABO, Rh, Antibody Screen, and Compatibility testing. She also stated the laboratory does not perform antibody identification or AHG crossmatches. 2. Review of the laboratory's transfusion medicine test log, reference laboratory reports, and patient transfusion records for patient medical record # 400774 / account # 1003138 revealed the following: A positive antibody screen on 10/23/23. The sample was sent to the laboratory's reference lab for identification. Antibody identification provided by the reference lab was anti-E. The transfusion records revealed two units of E-negative units (W0408 23 105383 and W0408 23 105381) were transfused on 10/23/23. There was no documentation that an anti-human globulin (AHG) crossmatch was performed by the reference laboratory. 3. Interview with the laboratory supervisor on 01/02/24 at 3:30 pm confirmed the laboratory failed to ensure an AHG crossmatch was performed when the patient antibody screen was positive on 10/23/23 for patient medical record #400774 / account#1003138.
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 observation of the laboratory, review of validation records for the Beckman Coulter DxH 690T hematology instrument, a patient test report, and staff interview, the lab director failed to review and approved the validations performed for the Beckman Coulter DxH 690T hematology instrument with patient testing being performed since 09/16/23. The findings include: 1. Observation of the laboratory on 12 /11/23 at 8:45 am revealed the Beckman Coulter DxH 690T in use for hematology patient testing to include CBC w/diff and reticulocyte count. 2. Review of the validations performed for the Beckman Coulter DxH 690T revealed the calibration, linearity, carryover, and reproducibility studies were not reviewed or approved by the lab director. 3. Review of the first patient reported from the DxH 690T revealed patient testing began on 09/16/23 (patient account number 1002405). 4. Interview with the general supervisor on 12/11/23 at 4 pm confirmed the lab director failed to review or approve the validations performed for the Beckman Coulter DxH 690T hematology instrument.
D6081	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(d) Each individual may direct no more than five laboratories. This STANDARD is not met as evidenced by: Based on review of the Aspen Web 116 database and interview with the laboratory director, the laboratory director failed to ensure he did not have directorship of more than five non-waived laboratories. The findings include: 1. Review of the Aspen Web 116 revealed the laboratory director had six non-waived laboratories listed under his directorship. 2. During a phone interview on 12/11/23 at 9:35 am the laboratory director stated that he used to direct one of the labs on the list, but had not directed the lab in about three to four years. He stated he would get that taken care of. This confirmed the survey findings.