Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0306825	01/21/2026
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 a recertification survey completed on January 21, 2026, the laboratory was found out of compliance with the following conditions: 493.1210 Condition: Routine chemistry. 493.1217 Condition: Immunohematology.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on laboratory observation, a review of the manufacturer's package inserts, a review of test validation records, a review of the laboratory's quality control records, a review of the laboratory procedure manual, final patient test reports, electronic mail communications, and staff interview, the laboratory failed to ensure the procedure for the Abbott i-STAT High Sensitivity Troponin I (i-STAT hs-TnI) included the normal (reference) range (Refer to D5403 Citation One), failed to verify the normal/reference range for the i-STAT hs-TnI (Refer to D5421), failed to perform quality control (QC) for the creatinine analyte at least every eight hours according to the manufacturer's requirements (Refer to D5445), and the laboratory failed to follow the procedure for calculation of QC ranges for the albumin analyte (Refer to D5469).
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 a review of the laboratory's procedure manual, a review of the laboratory's form for recording transfusion medicine testing and patient test records, the laboratory's quality assessment documents for transfusion medicine, a review of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (FORM CMS-116)and staff interview, the laboratory failed to have a procedure that required a second verification of patient ABO group/Rh type (ABO /Rh) prior to the transfusion of blood products for patients without an established history (Refer to D5403 Citation Two), and the laboratory failed to identify and correct problems with transfusion medicine testing, including recording of results, failed quality control, undocumented quality control, and missing documentation of function checks in 2024 and 2025 (Refer to D5793 Citation One).
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: CITATION ONE: Based on a review of the laboratory procedure manual, lack of documentation, staff interview, and review of an electronic mail communication, annual urine microscopy competency assessment was not performed in 2024 for three of three established testing personnel reviewed. This was cited on the previous survey, and compliance was not maintained. The findings include: 1. The laboratory policy titled "Competency Evaluation" stated the following: "A skill competency assessment must be performed twice during the employee's initial year of employment of all technical staff and annually thereafter to ensure staff have adequate training and orientation to perform skills/procedures and test competently." 2. Urine microscopy competency assessment was not documented in 2024 for three of the three established testing personnel reviewed (testing personnel numbers one, four, and six). 3. During an interview on 01/20/26 at 10:45 a.m., the general supervisor/technical consultant stated that she accidentally left urine microscopy off the 2024 competency assessment forms when making changes. This confirmed the survey findings. 4. In an electronic mail communication received on 01/26/26 at 10:40 a.m., the general supervisor /technical consultant stated that approximately 948 urine microscopics were performed in 2024 during the time when competency assessments were not performed. CITATION TWO: Based on observation of the laboratory, a review of the laboratory's competency assessment records, and staff interview, the laboratory failed to have a process in place to document separate testing personnel competencies for the ABO group, Rh type, and compatibility testing performed using the tube method and the Ortho Gel method used for performing antibody screening. The findings include: 1. Observation of the transfusion medicine testing area of the laboratory on 01/20/26 at 8:40 a.m. revealed the laboratory performed ABO group, Rh type, and compatibility testing using the tube method, and antibody screening using the Ortho gel method. 2. A review of the laboratory's 2024 and 2025 testing personnel competency assessment records and forms revealed that separate competencies were not documented for the ABO group, Rh type, and compatibility testing performed using the tube method, and the antibody screen performed using the Ortho gel method. 3. The general supervisor/technical consultant confirmed the survey findings

	during an interview on 01/20/26 at 10:45 a.m. CITATION THREE: Based on a review of the laboratory's personnel records, a review of the laboratory procedure manual, and staff interview, the laboratory policy for competency assessment was not in compliance with Subpart M when it did not require competency assessments for duties delegated by the laboratory director. The findings include: 1. A review of the laboratory's personnel records revealed the following: Technical consultant duties were delegated to two persons. General supervisor duties were delegated to one person. Competency assessment was not documented in 2024, 2025, or 2026 for either of the two persons to whom duties were delegated. 2. The laboratory policy titled "Competency Evaluation" did not include a requirement for competency assessment for delegated laboratory director duties (technical consultant, general supervisor). 3. The general supervisor confirmed the survey findings during an interview on 01/20/26 at 1:30 p.m.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on laboratory observation, review of the laboratory procedure manual, review of calibration verification documents, review of patient activity reports, and staff interview, the laboratory failed to follow the procedure for performing calibration verification at least every six months in 2024 and 2025 for chemistry and toxicology analytes performed on the Beckman Coulter DxC 700 AU. The findings include: 1. Laboratory observation on 01/20/26 at 8:40 a.m. revealed the Beckman Coulter DxC 700 AU used for patient testing for chemistry and toxicology analytes. 2. The laboratory's procedure titled "Calibration Verification" stated that calibration verification would be performed for analytes on the Beckman Coulter DxC 700 AU for tests with less than three calibration points at least every six months. 3. A review of the laboratory's calibration verification records revealed the following: The calibration verification, due 03/08/24, was not performed until 09/24/24 for the Triglyceride analyte. The calibration verification for the Ethyl Alcohol and Ammonia analytes, due 09/05/24, was not performed until 03/28/25. The calibration verification, due 09/18/24, was not performed until 09/08/25, for the High-Density Lipoprotein Cholesterol analyte. The calibration verification, due 03/24/25, was not performed until 09/8/25, for the Carbon Dioxide, Creatinine, Direct Bilirubin, Total Bilirubin, and Total Protein analytes. The calibration verification, due 03/24/25, was not performed until 06/09/25, for the Albumin, Blood Urea Nitrogen, Calcium, Carbon Dioxide, Chloride, Cholesterol, Glucose, Lactic Acid, Magnesium, Phosphorus, Potassium, Sodium and Triglyceride analytes. 4. A random review of patient activity reports revealed the following: During the calibration verification gap from 03/08/24 to 09/24/24, approximately 23 Triglyceride results were reported. During the calibration verification gap from 09/05/2024 to 03/28/25, approximately 38 Ammonia results were reported. During the calibration verification gap from 03/24/25 to 06/09 /25, approximately 714 Albumin results were reported. During the calibration verification gap from 03/24/25 to 09/8/25, approximately 1,845 creatinine and 1,786 Total Protein results were reported. 5. The general supervisor/technical consultant confirmed the survey findings during an interview on 01/21/26 at 5:00 p.m.

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: CITATION ONE Based on a review of the laboratory procedure manual and staff interview, the procedure for the Abbott i-STAT High Sensitivity Troponin I (i-STAT hs-TnI) did not include the normal (reference) range. This was cited on the previous survey, and compliance was not maintained. The findings include: 1. The laboratory procedure for the Abbott i-STAT hs-TnI did not include the normal/reference range. The procedure was approved for use by the laboratory director on 10/21/25. 2. The general supervisor/technical consultant confirmed the survey findings during an interview on 01/20/26 at 2:00 p.m. CITATION TWO Based on a review of the laboratory's procedure manual, a review of the laboratory's Ortho Transfusion Service Testing Record, and a staff interview, the laboratory procedure failed to require that the recheck of the patient's ABO/Rh be performed prior to the transfusion of blood products for patients with no prior historic record with four patients identified from 2024 and 2025 that lacked documentation of ABO/Rh retype prior to the transfusion of blood products. The findings include: 1. The laboratory's procedure titled "ABO RH Tube" stated the following in the procedure notes: "When a patient does not have a previous ABO/Rh history (within the last 12 months) on file, the initial blood type result must be rechecked by a tech who did not perform the work-up." The policy did not require that the recheck of the blood type was performed prior to the issue of blood products for transfusion. 2. A review of the laboratory's Ortho Transfusion Service Testing Record, used to record patient testing, revealed that the second verification of the ABO/Rh was not performed prior to the transfusion of blood products for the following patients: Patient identification number (PID) 72614 (08/27 /24)- Documented as no history. One unit of packed red cells was issued for transfusion on 08/27/24 at 22:23, patient retype performed on 08/28/24. PID 306967 (03/10/25)--- Documented as no history. Two units of packed red cells were issued for transfusion on 03/11/25 at 22:45 and 03/11/25 at 02:35, prior to the retype performed on 03/11/25. According to the label on the blood bank log, the retype was performed on the same sample used for the original testing. PID 406690 (05/07/25)-Documented as no history, retype needed. Two units of packed red cells were issued for transfusion

	on 05/07/25 at 01:50, and 04:05, prior to the patient retype performed on 05/08/25. The Transfusion Service Testing Record did not indicate whether the retype was performed on the same sample or a different sample. PID 305631 (05/09/25)- Documented as no history. Two units of packed red cells were issued on 05/09/25 at 18:54 and 20:47. There was no indication on the Transfusion Service Testing Record whether the retype was performed on the same sample, a different sample, or the time of testing. 3. The general supervisor/technical consultant confirmed the survey findings during an interview on 01/21/26 at 5:00 p.m.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 laboratory observation, a review of the laboratory procedure manual, a review of the manufacturer's package insert, a review of test validation records, a review of final patient test report, staff interview and electronic mail (email) communication, the laboratory failed to verify the normal (reference) range for the Abbott i-STAT High Sensitivity Troponin-I assay (i-STAT hs-TnI) with two patients reported since testing began. This was cited on the previous survey, and compliance was not maintained. The findings include: 1. Laboratory observation on 01/20/26 at 8: 40 a.m. revealed the Abbott i-STAT instrument used for performing patient testing for the High Sensitivity Troponin-I assay. During the tour, the general supervisor stated that the instrument was used as a backup to the primary test method performed on the Beckman Coulter Access 2 instrument. 2. The laboratory policy titled "New Test Validation and Implementation" stated: "Before a test procedure is put into place in the laboratory, validation studies must be performed to ensure the methodology is correct and results for patients are correct." 3. The manufacturer's package insert for the Abbott i-STAT hs-TnI stated the 99th percentile of the upper reference limit (normal range) as follows: "Female 13 ng/L, Male 28 ng/L, Overall 21 ng/L." 4. A review of the validation records for the i-STAT hs-TnI assay revealed no documentation of a dedicated study to verify the normal reference interval. The checklist used to ensure the validations were complete had "previously performed" written by the "Reference Range Validation (normal range study)" section. The checklist was signed by both the general supervisor/technical consultant and the laboratory director. 5. The final patient test report for patient identification number 71235 (female patient) (reported on 01/15/26) revealed a reference range of 2.9 - 27 ng /L. 6. The general supervisor/technical consultant stated the following during an interview on 01/20/26 at 2 p.m.: The laboratory did not perform a dedicated normal (reference range) study for the Abbott i-STAT hs-TnI. The hs-TnI assay normal range had already been validated on the Beckman Coulter Access 2 instrument (primary method). The laboratory used the same upper limit range for the Abbott i-STAT hs-TnI as used for the primary test method. This confirmed the survey findings. 7. The general supervisor/technical consultant stated via email communication received on 01 /28/26 at 10:04 a.m. that the first patient was reported on 11/11/25 (patient

	identification number 312609) using the Abbot i-STAT hs-TnI method. A total of two patients had been reported since testing began (patient 312609 and patient 71235). Word Key: ng/L=nanograms/liter
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the manufacturer's package insert for the creatinine reagent, a review of the laboratory's quality control records, and staff interview, the laboratory failed to perform quality control (QC) for the creatinine analyte at least every eight hours according to the manufacturer's requirements in 2024 and 2025, with approximately 7,399 patient creatinine tests reported in 2024 and 2025. The findings include: 1. Laboratory observation on 01/20/26 at 8:40 a.m. revealed the Beckman Coulter DxC 700 AU used for patient testing for chemistry and toxicology analytes. 2. The Beckman Coulter DxC 700 AU creatinine instructions for use stated: "Run QC at a minimum of every 8 hours." 3. Creatinine QC was not performed every eight hours as required by the manufacturer in December 2025. 4. The technical consultant confirmed the survey findings via phone on 01/28/26 at 2:00 p.m. 5. An electronic mail communication received from the technical consultant on 01/29/26 at 11:31 a.m. revealed the following: The creatinine QC had not been performed according to manufacturer requirements since September 2023. Approximately 3,618 creatinine tests were reported in 2024, and 3,781 were reported in 2025.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the laboratory procedure manual, a review of quality control (QC) records, a review of patient test report, staff interview

	and electronic mail communication, the laboratory failed to follow the procedure for calculation of QC ranges for the albumin analyte for QC lot 46021, with approximately 2,965 patients reported during the use of the control, spanning from 02 /21/25 to the survey date. This was cited on the previous survey, and compliance was not maintained. The findings include: 1. Laboratory observation on 01/20/26 at 8:40 a. m. revealed the Beckman Coulter DxC 700 AU used for patient testing for chemistry and toxicology analytes. 2. The laboratory procedure titled "Quality Control Plan" stated that "Biorad assayed controls have provided ranges on package insert. The package insert notes that the ranges are based on a 3SD span, unless otherwise noted. A 2SD range will need to be calculated and used as the target range." "Mean and ranges will be updated in analyzer and any LIS system that quality control is monitored within." 3. A review of the laboratory's QC records for the albumin analyte revealed the following: Lot number 46021 (Level One) was used in December 2025 for performing chemistry QC. The manufacturer's package insert for lot 46021 stated a QC range of 1.89-2.82 mg/dL, which represented a 3SD range. Based on the laboratory procedure, the calculated 2SD range for lot 46021 (level one) for albumin was 1.95- 2.57 mg/dL. The albumin QC range programmed in the Beckman Coulter DxC 700 AU chemistry instrument was a target mean of 2.26 with a 1SD of 0.76 for level one, resulting in a 2SD range of .74 to 3.78 mg/dL. The albumin QC range programmed in the LIS for level one was 0.7 to 3.8 mg/dL. 4. A review of a patient test report revealed that albumin was reported on patient identification number 39871 on 12/02/25 during the period when the Level One QC range for albumin was not calculated according to policy. 5. The technical consultant confirmed the survey findings during an interview on 01/21/26 at 5:00 p.m. 6. The technical consultant stated via electronic mail communication received on 01/28/26 at 10:09 a.m. that lot 46021 was put into use on 02/21/2025, with approximately 2,965 patient albumin tests reported during the time frame when the incorrect SD was used. Word Key: LIS=Laboratory Information System mg/dL=Milligrams per deciliter SD=Standard Deviation
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: CITATION ONE: Based on a review of the laboratory procedure manual, thelaboratory's transfusion medicine test records, quality control and maintenance records, patient test records, the laboratory's quality assessment documentation for transfusion medicine, a review of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (FORM CMS-116), and staff interview, the laboratory failed to identify and correct problems with transfusion medicine testing, including recording of results, failed quality control, undocumented quality control, and missing documentation of function checks in 2024 and 2025. 1. A review of the laboratory's policy titled "Quality Assurance Plan - Laboratory Services" revealed that the laboratory would monitor pre-analytic, analytic, and post-analytic phases of testing. It also stated that the laboratory would actively search for mistakes and investigate their causes. "A summary is completed monthly for the

laboratory medical director to review for further action." 2. A review of the laboratory's transfusion medicine test records and quality control/maintenance records from April 2024 through December 2025 revealed the following: BB Log / Patient Testing / QC/Maintenance Records: 04/30/24--Unit retypes performed on five units (W0408 24 103021, W0408 24 103036, W0408 24 114347, W0408 24 103118, W0408 24 103131). 07/19/24 patient 38270- No recorded antibody screen on the Ortho Transfusion Service Testing Record. Two units of packed red cells were issued for transfusion. 05/06/25 patient 92058- The interpretation for the antibody screen was not recorded. 09/04/25 patient 404883-The ABO/Rh was not recorded for unit numbers W0408 25 104407, W0408 25 104408, W0408 25 104775. All three units were transfused to the patient. 09/05/25 patient 404883-The ABO/Rh was not recorded for unit number W0408 25 104782, the compatibility interpretation was not recorded. 09/18/25 patient 404883-Th ABO/Rh was not recorded for unit number W0408 25 104782, the compatibility interpretation was not recorded. The unit was issued to the patient. 11/03/25 patient 404883-The crossmatch interpretation was not recorded for unit numbers W0408 25 110002 and W0408 25 105389. 11/04/25 patient 404883 - The crossmatch interpretation was not recorded for unit numbers W0408 25 202686, W0408 25 105852. 12/16/25 The ABO interpretation was not recorded for unit number W0408 25 120064 (unit retype). 12/22/25 The antibody screen was not recorded for patient 312398 with three units of blood issued for transfusion. The crossmatch interpretation was not recorded for any of the three units. The blood transfusion record and the patient results in the laboratory electronic medical record recorded the antibody screen as negative and the units as compatible. QC and maintenance records: 04/30/24-Rh reaction for Confidence Cell 2 recorded as negative, the expected result was positive. 12/22/24- MTS centrifuge revolutions per minute was not documented. 01/21/25-Rh Control documented as 4+, expected result was negative. 2/7/25-Rh Control documented as 4+, expected result was negative. 3/18 /25-Rh control documented as 4+, expected result was negative. 4/27/25- Rh Control QC was not documented. 6/5/25- Anti-A and Anti-B QC for the Confidence Cell 1 was not performed. 12/22/25- Antibody screen QC was not performed. 2. A review of the laboratory's quality assessment documentation revealed that the log used to record results, the quality control and maintenance log, and all transfusion records had been reviewed by both the general supervisor and the laboratory director/technical supervisor. 3. The laboratory did not provide documentation of corrective action for the errors identified by the surveyor. 4. A review of the FORM CMS-116 revealed that the laboratory performs approximately 35 ABO/Rh and antibody screens per year and approximately 66 compatibility tests per year. 5. The general supervisor confirmed the survey findings during an interview on 01/21/26 at 5:00 p.m. CITATION TWO: Based on a review of the laboratory procedure manual, a review of laboratory quality control (QC) records, a review of QA records, and staff interview, the laboratory failed to identify problems with the lack of urine microscopic QC for one of thirty-one days in March 2025. The findings include: 1. A review of the laboratory's policy titled "Quality Assurance Plan - Laboratory Services" revealed that the laboratory would monitor pre-analytic, analytic, and post-analytic phases of testing. It also stated that the laboratory would actively search for mistakes and investigate their causes. "A summary is completed monthly for the laboratory medical director to review for further action." 2. A review of the Urinalysis Microscopic Quality Control Log revealed no documentation that urine microscopic quality control (QC) had been performed on 03/30/25 (one of thirty-one days in March 2025). The document was reviewed by the general supervisor/technical consultant on 04/04/25 with no documented corrective action. 3. The March 2025 monthly laboratory director summary did not indicate that any problems were identified or corrective action performed. 4. The general supervisor/technical consultant confirmed the survey

	findings during an interview on 01/21/26 at 11:40 a.m.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: The laboratory director failed to ensure that the normal range for the Abbott i-STAT hs-TnI was verified (Refer to D5421).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: The laboratory director failed to ensure that calibration verification was performed according to the laboratory procedure (Refer to D5401), failed to ensure that quality control was performed according to the manufacturer's instructions for the creatinine analyte (Refer to D5445), failed to ensure that the correct quality control ranges for the albumin analyte were used (Refer to D5469), failed to ensure that errors in transfusion medicine testing were identified (Refer to D5793 Citation One), and failed to ensure that errors in urine microscopy quality control performance were identified (Refer to D5793 Citation Two).