Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2176921	12/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Southwest Transplant Alliance	8190 Manderville Ln, Dallas, TX	

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 entrance conference was held with the laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 42 CFR 493.1240 Pre-Analytic Systems 493.1403 Laboratory Director, (moderate complexity) 493.1409 Technical Consultant, (moderate complexity) 493.1441 Laboratory Director, (high complexity) 493.1447 Technical Supervisor, (high complexity) The laboratory's failure to be in compliance with these regulations was found to pose IMMEDIATE JEOPARDY to the patients served by the laboratory. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.

	This STANDARD is not met as evidenced by: Based on review of laboratory policy, Centers for Medicare and Medicaid (CMS)-209 form, College of American Pathologists (CAP) Proficiency Testing (PT) records, and staff interview, the laboratory failed to test proficiency testing samples in the same manner as it tests patient specimens for 3 of 3 testing events in 2021 (Chemistry A, B, C events). Findings included: 1. Review of the laboratory policy titled "Internal and External Proficiency Testing" stated the following: "5.2 Performing Proficiency Testing ... 5.2.2 bLIS entry for Accessioning and test-scheduling. 5.2.2.1 External Proficiency samples must be accessioned and tested with the laboratory's workload by personnel who routinely perform the testing, using the laboratory's routine testing methods." 2. Review of the CMS 209 form revealed 7 Testing Persons (TP-1 through TP-7) performed moderate complexity chemistry and hematology testing. 3. Review of the Chemistry proficiency testing records from 2021 (Chemistry A, B and C events) revealed TP-1, TP-2, TP-3, TP-4, TP-5, TP-6, TP-7 failed to participate in 3 of 3 proficiency testing events. Note: Proficiency testing was performed by a testing person who was no longer employed with the facility at the time of the survey. The laboratory failed to ensure proficiency testing samples were tested in the same manner as patient samples and rotated amongst the routine testing personnel. 4. During an interview on 12/14/2021 at 12:07 pm in the conference room, the Technical Consultant, after review of the proficiency testing records, confirmed the above findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: I. Based on review of laboratory policy, College of American Pathologists (CAP) proficiency testing (PT) records and confirmed in interview, the laboratory failed to review and evaluate the results obtained on proficiency testing for nucleic acid testing results for 1 of 3 events in 2021 (NAT-C 2021) and 1 of 2 events in 2021 (G-B 2021) for syphilis serology. Findings included: 1. Review of the laboratory's PT policy revealed: "5.4 Evaluating External Proficiency Testing ... 5.4.1.4 All external proficiency testing must have a Laboratory Director review." 2. Review of CAP PT records for 2021 revealed the laboratory did not ensure the laboratory director documented their review/evaluation of nucleic acid testing and syphilis serology PT results, as follows: NAT-C 2021 Nucleic Acid Testing PT final report was not signed. G-B 2021 Syphilis Serology PT final report was not signed. 3. The laboratory was asked to provide documentation of the review of the results. No documentation was provided. 4. During an interview on 12/14/2021 at 12:07 pm, the Technical Consultant confirmed the above findings. 44278 II. Based on review of laboratory policy, College of American Pathologists (CAP) proficiency testing (PT) records, and confirmed in interview, the laboratory director failed to review and evaluate the results obtained on proficiency testing (PT) for Hematology Auto Differential results for 1 of 3 events in 2021 (Event C). Findings Included: 1. Review of laboratory policy titled, "Internal and External Proficiency Testing" (Reviewed by the Laboratory Director on 06/08/2020) stated the following: ".. 5.4 Evaluating Proficiency Testing 5.4.1.4 All external proficiency testing must have a Laboratory Director review." 2.

	Review of College of American Pathologists (CAP) proficiency testing (PT) records revealed the laboratory director failed to document review of the following proficiency testing events: FH2-C 2021 Hematology Auto Differential FH2 3. During an interview on 12/14/2021 at 02:25 p.m. with the Technical Supervisor (TS-1) in the facility conference room, after review of proficiency testing records, TS-1 confirmed the above findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of laboratory policy, College of American Pathologists (CAP) proficiency testing (PT) records, CAP codes instructions, and confirmed in staff interview, the laboratory failed to document a self-grade of Molecular SARS-COV-2 analytes (unregulated) not evaluated or scored by the PT company for 1 of 1 events in 2021 (COV2-A 2021). Findings included: 1. Review of the laboratory policy titled "Internal and External Proficiency Testing" stated the following: "5.4 Evaluating Proficiency Testing 5.4.1 Evaluating External Proficiency Testing 5.4.1.1 Acceptance criteria will be determined by the individual institution. Some analytes are not regulated and thus not graded. However, these results are analyzed and evaluated by STA. 5.4.1.2 A review is performed for items that are not graded due to non-consensus, lab submitting results after the due date, failure to submit the results, or error in completing the form." 2. Review of the CAP code instructions "Actions Laboratories Should Take when a PT Result is Not Graded" revealed the following: Code: "26" Exception Reason Code Description: "Educational Challenge" Action Required: "Review participant summary for comparative results and document performance accordingly. Evaluation criteria are not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation." 2. Review of the CAP Sperm Morphology & Motility Online PT records for event SPCD-B 2020 revealed the laboratory failed to verify and document accuracy of results obtained for that event as follows: Method: N 1 Ct Value BD MAX Specimen: COV2-2; Result: 33.50 P; Grade: See Note [26] Specimen: COV2-3; Result: 32.80 P; Grade: See Note [26] Method: N 2 Ct Value BD MAX Specimen: COV2-2; Result: 33.90 P; Grade: See Note [26] Specimen: COV2-3; Result: 324.60 P; Grade: See Note [26] Review of the CAP "Original Evaluation" form stated: "[26] = Educational challenge" "P = Based on peer group statistics" 3. The laboratory was asked to provide documentation of the review of the results. No documentation was provided. 4. During an interview on 12 /14/2021 at 12:07 pm, the Technical Consultant confirmed the above findings.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493.

	1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policies, laboratory's specimen collection table, laboratory records, patient test records, and staff interview, the laboratory failed to meet the requirements for preanalytic systems, as evidenced by: 1. The laboratory failed to include patient preparation, specimen collection, specimen storage and preservation, specimen acceptability and rejection criteria in the specimen collection table provided to their clients. Refer to D5311, I. 2. The laboratory failed to ensure patient lactate specimens were collected in sodium fluoride /potassium oxalate collection tubes followed by immediate chilling as required by manufacturer's instructions for 15 of 15 patients in 2021 (November-December random sampling) and failed to ensure specimens were received and processed within 15 minutes as required by manufacturer's instructions for 7 of 15 patients in 2021 (November-December random sampling). Refer to D5311, II.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on review of manufacturer's instructions, laboratory policy, laboratory's specimen collection table, and staff interview, the laboratory failed to include patient preparation, specimen collection, specimen storage and preservation, specimen acceptability and rejection criteria in the specimen collection table provided to their clients. Findings included: 1. Review of the manufacture's package insert for lactate revealed: "Specimen Collection and Handling: Collection of a satisfactory specimen for lactate analysis requires special procedures to prevent changes in lactate while and after the specimen is drawn. The patient should be fasting and at complete rest. Blood is best collected without stasis in a container of sodium fluoride/potassium oxalate, followed by immediate chilling of the specimen and separation of the cells within 15 minutes... Avoid hemolysis. Keep sample on ice and analyze promptly. If testing cannot be performed immediately refrigerate the separated plasma sample for up to 24 hours or freeze it for up to 1 month ... Heparinized plasma is not recommended. Higher results will be obtained due to the absence of antiglycolytic agent in the collection tubes. Blood collection tubes containing sodium iodoacetate may be used for the LA method." 2. Review of the laboratory's policy for lactate revealed: "SPECIMEN COLLECTION AND HANDLING Collection of a satisfactory specimen for lactate analysis requires special procedures to prevent changes in lactate while and after the specimen is drawn. The patient should be fasting and at complete rest. Blood is best collected without stasis in a container of sodium fluoride/potassium oxalate, followed by immediate chilling of the specimen and separation of the cells within 15 minutes... Avoid hemolysis. Keep sample on ice and analyze promptly. If testing cannot be performed immediately refrigerate the separated plasma sample for up to 24 hours or freeze it for up to 1 month ... Heparinized plasma is not

recommended. Higher results will be obtained due to the absence of antiglycolytic agent in the collection tubes. Blood collection tubes containing sodium iodoacetate may be used for the LA method." 3. Review of the laboratory's specimen collection table revealed: Lab: CMP, BMP, Mg, Phos, Amylase, Lipase Tube Color: Green Tube Additive: Lithium Heparin Lab: CBC Tube Color: Purple Tube Additive: K EDTA Lab: PT/PTT/INR Tube Color: Blue Tube Additive: Sodium Citrate Lab: Type and Screen Tube Color: Pink Tube Additive: K EDTA Lab: Cardiac Enzymes Tube Color: Green Tube Additive: Lithium Heparin Lab: UA Tube Color: Cup Tube Additive: N /A The specimen collection table provided to clients failed to include patient preparation, specimen collection, specimen storage and preservation, specimen acceptability and rejection for lactate specimens. 3. During an interview on 12/16 /2021 at 2:50 pm, laboratory representatives were asked why lacte was not listed on the specimen collection table and if lactate was collected on ice. The General Supervisor-1 stated that lactate specimens were part of the CMP panel. The Technical Consultant stated that lactate specimens were collected in green sodium heparin tubes and were not collected on ice. During an interview on 12/16/2021 at 2:53 pm, the Clinical Practice Nurse Manager stated that lactate specimens were not collected on ice because the specimen tubes were transported to the laboratory immediately. These statements confirmed the above findings. Word Key: CMP- complete metabolic panel BMP- basic metabolic panel Mg- magnesium Phos- phosphate CBC- complete blood count K EDTA- ethylenediaminetetraacetic acid PT- prothrombin time PTT- partial thromboplastin time INR- International Normalized Ratio UA- urinalysis II. Based on laboratory policy, manufacturer's instructions, laboratory records, patient test records, and staff interview, the laboratory failed to ensure patient lactate specimens were collected in sodium fluoride/potassium oxalate collection tubes followed by immediate chilling as required by manufacturer's instructions for 15 of 15 patients in 2021 (November-December random sampling) and failed to ensure specimens were received and processed within 15 minutes as required by manufacturer's instructions for 7 of 15 patients in 2021 (November-December random sampling). Findings: 1. Review of the laboratory's policy for lactate revealed: "SPECIMEN COLLECTION AND HANDLING Collection of a satisfactory specimen for lactate analysis requires special procedures to prevent changes in lactate while and after the specimen is drawn. The patient should be fasting and at complete rest. Blood is best collected without stasis in a container of sodium fluoride/potassium oxalate, followed by immediate chilling of the specimen and separation of the cells within 15 minutes... Avoid hemolysis. Keep sample on ice and analyze promptly. If testing cannot be performed immediately refrigerate the separated plasma sample for up to 24 hours or freeze it for up to 1 month ... Heparinized plasma is not recommended. Higher results will be obtained due to the absence of antiglycolytic agent in the collection tubes. Blood collection tubes containing sodium iodoacetate may be used for the LA method." 2. Review of the manufacture's package insert for lactate revealed: "Specimen Collection and Handling: Collection of a satisfactory specimen for lactate analysis requires special procedures to prevent changes in lactate while and after the specimen is drawn. The patient should be fasting and at complete rest. Blood is best collected without stasis in a container of sodium fluoride/potassium oxalate, followed by immediate chilling of the specimen and separation of the cells within 15 minutes ... Avoid hemolysis. Keep sample on ice and analyze promptly. If testing cannot be performed immediately refrigerate the separated plasma sample for up to 24 hours or freeze it for up to 1 month... Heparinized plasma is not recommended. Higher results will be obtained due to the absence of antiglycolytic agent in the collection tubes. Blood collection tubes containing sodium iodoacetate may be used for the LA method." 3. Review of laboratory records revealed documentation of electronic mail dated 12/30/2020 from the Technical Consultant to the Clinical Practice Nurse

Manager that stated: "Per our conversation please see the package insert statements below about heparin tubes in our testing ... For the lactic acid the heparin isn't the preferred tube type but the values we have obtained have been in normal ranges thus far. I am sending the package insert excerpt: Specimen Stability Collection of a satisfactory specimen for lactate analysis requires special procedures to prevent changes in lactate while and after the specimen is drawn. The patient should be fasting and at complete rest. Blood is best collected without stasis in a container of sodium fluoride/potassium oxalate, followed by immediate chilling of the specimen and separation of the cells within 15 minutes ... Avoid hemolysis. Keep sample on ice and analyze promptly. If testing cannot be performed immediately refrigerate the separated plasma sample for up to 24 hours or freeze it for up to 1 month... Heparinized plasma is not recommended. Higher results will be obtained due to the absence of antiglycolytic agent in the collection tubes. Blood collection tubes containing sodium iodoacetate may be used for the LA method." The laboratory did not ensure patient lactate specimens were collected in sodium fluoride/potassium oxalate collection tubes. 4. Review of patient test records revealed the laboratory did not ensure patient lactate specimens were collected in sodium fluoride/potassium oxalate collection tubes and chilled immediately as required by the manufacturer for the following patients in 2021 (random review): 11/26/2021 Accession ID: 40006139 12/03/2021 Accession IDs: 40006195, 40006194, 40006192 12/07/2021 Accession ID: 40006228, 40006241, 40006234 12/12/2021 Accession ID: 40006300 12/13/2021 Accession IDs: 40006307, 40006306, 40006302, 40006304 12/14/2021 Accession IDs: 40006335, 40006338 12/15/2021 Accession ID: 40006347 5. During an interview on 12/16/2021 at 2:50 pm, the Technical Consultant stated that lactate specimens were collected in green sodium heparin tubes and were not collected on ice. During an interview on 12/16/2021 at 2:53 pm, the Clinical Practice Nurse Manager stated that lactate specimens were not collected on ice because the specimen tubes were transported to the laboratory immediately. 6. Review of patient test records revealed the laboratory did not ensure patient lactate specimen's plasma were received and centrifuged within 15 minutes as required by the manufacturer for the following patients in 2021 (random review): Accession ID: 40006139 Collection date: 11/26 /2021, collection time: 21:07 hours, received time: 21:36 hours, analysis time: 21:46 hours, time elapsed from collection to receipt: 29 minutes Accession ID: 40006195 Collection date: 12/03/2021, collection time: 14:09 hours, received time: 14:39 hours, analysis time: 14:54 hours, time elapsed from collection to receipt: 30 minutes Accession ID: 40006194 Collection date: 12/03/2021, collection time: 10:30 hours, received time: 10:59 hours, analysis time: 11:14 hours, time elapsed from collection to receipt: 29 minutes Accession ID: 40006192 Collection date: 12/03/2021, collection time: 03:55 hours, received time: 04:15 hours, analysis time: 04:23 hours, time elapsed from collection to receipt: 20 minutes Accession ID: 40006300 Collection date: 12/12/2021, collection time: 19:40 hours, received time: 19:58 hours, analysis time: 20:38 hours, time elapsed from collection to receipt: 18 minutes Accession ID: 40006307 Collection date: 12/13/2021, collection time: 17:30 hours, received time: 17: 48 hours, analysis time: 18:13 hours, time elapsed from collection to receipt: 18 minutes Accession ID: 40006306 Collection date: 12/13/2021, collection time: 12:53 hours, received time: 13:09 hours, analysis time: 13:18 hours, time elapsed from collection to receipt: 16 minutes Accession ID: 40006335 Collection date: 12/14 /2021, collection time: 14:15 hours, received time: 15:04 hours, analysis time: 15:11 hours, time elapsed from collection to receipt: 49 minutes The laboratory failed to ensure patient lactate specimen's plasma were received and processed within 15 minutes as required by the manufacturer. There was no documentation of the specimens separated plasma being stored in the refrigerator if the specimens could not be tested immediately after centrifugation, as stated by the manufacturer. 7. Review of

	laboratory records revealed the laboratory had an annual test volume of 480 lactate specimens. 8. During the exit interview on 12/17/2021 at 2:00 pm, the Technical Consultant confirmed the above findings.
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: I. Based on review of Sysmex CA-620 coagulation analyzer manufacturer's instructions, reference interval study for PT (prothrombin time) and staff interview, the laboratory failed to follow manufacturer's instructions for establishing the reference interval (patient normal range) for PT reagent (Innovin) upon installation of the Sysmex CA-620 coagulation analyzer. Findings included: 1. The Sysmex CA-620 coagulation analyzer manufacturer's instructions (Installation Package Rev 2.1), stated the following: "V. Reference Interval: Verification of Reference Interval .... Requirements: Donors must be from a healthy population (no known pathological condition; no pre-surgical or hospitalized patients; Donors should not take any medications, including aspirin; Donors should span the adult range ...Testing should be performed over a period of several days and by different people, if possible, to allow for day to day variation; Samples should be drawn each testing day, following the established laboratory protocol for collection, storage, and processing; The test results from the donors should be analyzed statistically ..." NOTE: This form references CLSI document EP28-A3C: Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory: Approved Guideline, Third Addition, October 2010.1. 2. Review of records for Sysmex CA-620 coagulation analyzer (Serial Number : 24324) revealed it was validated in 01/2021. The current MNPT (mean normal prothrombin time) was based on the PT reagent, Innovin, with samples from First Baptist Hospital. (Unknown number of males and females and unknown if on any medications) The laboratory failed to establish the mean of the normal patient range with the normal individuals as required by the manufacturer which refers to a CLSI document (EP28-A3C). The laboratory did not include donors from their own population with documentation for ensuring individuals were normal. 3. During an interview on 12/15/2021 at 03:12 p.m. in the conference room, the Technical Supervisor confirmed the laboratory did not establish a normal patient range with normal individuals from their own population. II. Based on manufacturer's instructions and staff interview, the laboratory failed to follow manufacturer's instructions for operating environment for 2 of 2 EPOC analyzers. Findings Included: 1. Review of "EPOC Operator's Guide" (51012382 Rev.: 3) stated the following: "5.14 Operating Environment Relative Humidity The Reader must be used where the relative humidity is less than 85% at 30 degrees Celsius condensing." 2. During a tour of the facility on 12/14/2021 at 01:15 p.m., the inspector was escorted to the EPOC testing station. The Technical Supervisor was asked if the testing stations' environment was monitored. The supervisor stated it was not. This confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: I. Based on manufacturer's instructions, review of the laboratory's environmental monitoring records, and confirmed in staff interview, the laboratory failed to ensure room humidity ranges were within manufacturer's specifications for 107 of 144 readings in 2021 (12/2021). Findings included: 1. Review of the ADVIA 360 Hematology Operator's Guide revealed the following: "Appendix D: Specifications System Specifications ... Operating conditions ...Relative humidity: 45-85% non-condensing" 2. A review of the laboratory's environmental monitoring records from 12 /06/2021 revealed the laboratory had an established acceptable humidity range for the laboratory of 20-80%. The laboratory failed to ensure room humidity ranges were within manufacturer's specifications of 45-85%. 3. Further review of the laboratory's continuous environmental monitoring records revealed 107 of 144 readings when the humidity was out of the manufacture's acceptable range of 45-85% on 12/06/2021. The following is a random sampling of those readings: Time: 06:13 hours; humidity: 43.88% Time: 06:23 hours; humidity: 42.37% Time: 06:33 hours; humidity: 41.69% Time: 07:23 hours; humidity: 37.15% Time: 07:33 hours; humidity: 36.02% Time: 07: 43 hours; humidity: 35.36% Time: 08:03 hours; humidity: 33.84% Time: 08:23 hours; humidity: 32.5% Time: 08:33 hours; humidity: 31.67% Time: 09:03 hours; humidity: 30.43% Time: 09:53 hours; humidity: 28.66% Time: 10:03 hours; humidity: 28.22% Time: 10:13 hours; humidity: 28.07% Time: 10:53 hours; humidity: 26.92% Time: 13: 03 hours; humidity: 23.78% Time: 14:43 hours; humidity: 23% Time: 15:03 hours; humidity: 22.89% Time: 19:33 hours; humidity: 18.75% Time: 20:33 hours; humidity: 18.17% Time: 23:23 hours; humidity: 23.42% 4. During an interview on 12/16/2021 at 10:42 am, the Technical Consultant confirmed the above findings. II. Based on manufacturer's instructions, review of the laboratory's environmental monitoring records, and confirmed in staff interview, the laboratory failed to define a temperature range for the Dimension EXL chemistry analyzer, to ensure temperature did not exceed manufacturer instructions. Findings included: 1. Review of the Dimension EXL with LM/EXL 200 System Operator's Guide revealed the following: "Room Temperature Requirements ... Room temperature must be between 64F (18C) and 86F (30C), with a maximum fluctuation of 5F (2.8C) per hour." 2. A review of the laboratory's environmental monitoring records from 12/06/2021 revealed the laboratory had an established acceptable room temperature range for the laboratory of 15-30C The laboratory failed to define a temperature range to ensure temperatures did not exceed manufacturer's instructions of 18-30C for patient specimens tested on the Dimension EXL chemistry analyzer. 3. During an interview on 12/16/2021 at 10:42 am, the Technical Consultant confirmed the above findings.
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:
I. Based on review of verification studies for Dimension EXL chemistry analyzer, laboratory records, and confirmed in interview, the laboratory failed to ensure the reportable range for chemistry analytes were verified by the laboratory's studies. Findings included: 1. According to verification studies, the laboratory added the Dimension EXL chemistry analyzer to their test menu on 01/2021. 2. A review of verification studies for the Dimension EXL chemistry analyzer revealed the laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies for chemistry analytes as required by 493.1253 as follows (random sampling of analytes): Reportable range from verification study Amylase: 0.33-740.667 U/L Manufacturer's reportable range: Amylase: 0.000-734.000 U/L Laboratory reportable range: Amylase: 0.00-650 U/L The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. Reportable range from verification study AST: 1.00-958.333 U/L Manufacturer's reportable range: AST: 0.000-1000.000 U/L Laboratory reportable range: AST: 0.00-1000.00 U/L The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. Reportable range from verification study Calcium: 1.967-14.067 mg/dL Manufacturer's reportable range: Calcium: 1.500- 13.900 mg/dL Laboratory reportable range: Calcium: 5.00-15.00 mg/dL The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. Reportable range from verification study Chloride: 55.00-180.67 mmol/L Manufacturer's reportable range: Chloride: 55.00-179.00 mmol/L Laboratory reportable range: Chloride: 50.0-200.0 mmol/L The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. Reportable range from verification study CKMB: 0.067-322.900 ng/mL Manufacturer's reportable range: CKMB: 0.000-330.000 ng/mL Laboratory reportable range: CKMB: 0.50-300.00 ng/mL The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. Reportable range from verification study Carbon Dioxide: 0.00-44.07 mmHg Manufacturer's reportable range: Carbon Dioxide: 0.00-46.00 mmHg Laboratory reportable range: Carbon Dioxide: 5.0-45.0 mmHg The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. Reportable range from verification study GGT: 6.000-708.000 U/L Manufacturer's reportable range: GGT: 0.000-703.000 U/L Laboratory reportable range: GGT: 0.00-800.00 U/L The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. 3. Review of laboratory records revealed the following annual laboratory test volumes: 254 amylase tests 480 AST tests 480 calcium tests 481 chloride tests 301 CKMB tests 478 Carbon Dioxide tests 12 GGT tests 4. During an interview on 12/15/2021 at 11:28 am, the Technical Consultant confirmed the above findings. Word Key: AST- aspartate aminotransferase CKMB-creatinine kinase-MB GGT- gamma glutamyl transferase II. Based on review of verification studies for ADVIA 360 hematology analyzer, laboratory records, and confirmed in interview, the laboratory failed to ensure the reportable range for hematology analytes were verified by the laboratory's studies. Findings included: 1. According to verification studies, the laboratory added the ADVIA 360 hematology

	analyzer to their test menu on 01/2021. 2. A review of verification studies for the ADVIA 360 chemistry analyzer revealed the laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies for hematology analytes as required by 493.1253 as follows: Reportable range from verification study WBC: 0.45-106.56 10^3/uL Manufacturer's reportable range: WBC: 0.0-85 10^3/uL Laboratory reportable range: WBC: 0.0-85 10^3/uL The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. Reportable range from verification study HGB: 0.9-23.8 g/dL Manufacturer's reportable range: HGB: 1.0-25.0 g/dL Laboratory reportable range: HGB: 1.0-25.0 g/dL The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. Reportable range from verification study RBC: 0.25-8.63 10^6/uL Manufacturer's reportable range: RBC: 0.00-8.00 10^6/uL Laboratory reportable range: RBC: 0.00-8.00 10^6/uL The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. Reportable range from verification study PLT: 14-1418.5 10^3/uL Manufacturer's reportable range: PLT: 0-1000 10^3/uL Laboratory reportable range: PLT: 0-1000 10^3/uL The laboratory's established reportable range did not coincide with the reportable range obtained in the verification studies. 3. Review of laboratory records revealed the laboratory had an annual volume of 481 CBC tests 4. During an interview on 12/15/2021 at 12:28 am, the Technical Consultant confirmed the above findings. Word Key: WBC- white blood cell HGB- hemoglobin RBC- red blood cell PLT- platelet CBC- complete blood count
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 review of manufacturer's instructions, laboratory documents, FDA (Food and Drug Administration) website, establishment/verification studies for the Dimension EXL chemistry analyzer, and confirmed in interview, the laboratory failed to establish, for each test system, the performance specifications for analytical sensitivity, analytical specificity (to include interfering substances) prior to patient testing. Findings included: 1. Review of the manufacture's package insert for lactate revealed: "Specimen Collection and Handling: Collection of a satisfactory specimen for lactate analysis requires special procedures to prevent changes in lactate while and after the specimen is drawn. The patient should be fasting and at complete rest. Blood is best collected without stasis in a container of sodium fluoride/potassium oxalate, followed by immediate chilling of the specimen and separation of the cells within 15 minutes ... Avoid hemolysis. Keep sample on ice and analyze promptly. If testing cannot be performed immediately refrigerate the separated plasma sample for up to 24 hours or freeze it for up to 1 month... Heparinized plasma is not recommended. Higher

	results will be obtained due to the absence of antiglycolytic agent in the collection tubes. Blood collection tubes containing sodium iodoacetate may be used for the LA method." 2. Review of laboratory records revealed documentation of electronic mail dated 12/30/2020 from the Technical Consultant to the Clinical Practice Nurse Manager that stated: "Per our conversation please see the package insert statements below about heparin tubes in our testing ... For the lactic acid the heparin isn't the preferred tube type but the values we have obtained have been in normal ranges thus far. I am sending the package insert excerpt: Specimen Stability Collection of a satisfactory specimen for lactate analysis requires special procedures to prevent changes in lactate while and after the specimen is drawn. The patient should be fasting and at complete rest. Blood is best collected without stasis in a container of sodium fluoride/potassium oxalate, followed by immediate chilling of the specimen and separation of the cells within 15 minutes ... Avoid hemolysis. Keep sample on ice and analyze promptly. If testing cannot be performed immediately refrigerate the separated plasma sample for up to 24 hours or freeze it for up to 1 month... Heparinized plasma is not recommended. Higher results will be obtained due to the absence of antiglycolytic agent in the collection tubes. Blood collection tubes containing sodium iodoacetate may be used for the LA method." The laboratory received patient samples collected in sodium heparin collection tubes for testing on the Dimension EXL chemistry analyzer resulting in a preanalytical modification of the FDA approved test system. Refer to D5311, I and D5311, II. According to the FDA website for categorization of tests, the Dimension EXL chemistry analyzer was categorized as moderate complexity for all chemistry analytes. 3. The laboratory's establishment/verification studies performed on 12/2020 for the Dimension EXL chemistry analyzer revealed performance specifications for specimen stability, analytical sensitivity, and analytical specificity (to include interfering substances) were not established prior to patient testing. 4. During an interview on 12/16/2021 at 2: 50 pm, the Technical Consultant stated that lactate specimens were collected in sodium heparin collection tubes, confirming the above findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policy, laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to have in house data in the IQCP risk assessment to support its reduction in QC frequency to every 14 days and failed to perform one level of liquid QC material each 8 hours of operation for the EPOC blood gas analyzer. Findings Included: 1. During a tour of the facility on 12/15/2021 at 12: 15 PM, the surveyor observed two EPOC analyzers (Serial numbers: 35195 and 35911). The laboratory used the EPOC analyzers to analyze arterial blood specimens for pH, PCO2, cHCO3, BE, SO2 and PO2. 2. Review of laboratory policy titled,

	"Epoc Individualized Quality Control Plan Protocol"(Reviewed by the Laboratory Director on (02/08/2021) revealed the following: "12.0 Test Care Execution 12.2 Southwest Transplant Alliance will run 2 control materials of different concentration each day of testing for 14 consecutive days and record data. This will be done on all tests on the EPOC system ... This plan will continually monitor QC samples on a 14-day basis once established." 3. Review of laboratory's Individualized Quality Control Plan (IQCP) for the EPOC revealed the following days of QC performed in the risk assesment: "Quality Control Level 1: Day 1: February 8/2021 Time: 23:37 Day 2: February 9/2021 Time: 19:56 Day 3: February 10/2021 Time: 18:00 Day 4: February 11/2021 Time: 16:22 Day 5: February 12/2021 Time: 22:42 Day 6: February 13/2021 Time: 17:27 Day 7: February 14/2021 Time: 17:22 Day 8: February 15/2021 Time: 18: 53 Day 9: February 16/2021 Time: 16:26 Day 10: February 17/2021 Time: 22:49 Day 11: February 19/2021 Time: 00:38 Day 12: February 19/2021 Time: 23:51 Day 13: February 20/2021 Time: No time given Day 14: February 21/2021 Time: 17:19 Quality Control Level 2: Day 1: February 8/2021 Time: 23:42 Day 2: February 9 /2021 Time: 20:01 Day 3: February 10/2021 Time: 17:32 Day 4: February 11/2021 Time: 16:27 Day 5: February 12/2021 Time: 22:22 Day 6: February 13/2021 Time: 17: 21 Day 7: February 14/2021 Time: 17:13 Day 8: February 15/2021 Time: 18:58 Day 9: February 16/2021 Time: 16:36 Day 10: February 17/2021 Time: 22:55 Day 11: February 19/2021 Time: 00:26 Day 12: February 19/2021 Time: 23:55 Day 13: February 20/2021 Time: 17:33 Day 14: February 21/2021 Time: 17:13" The laboratory failed to perform one level of external quality control each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing, as required for blood gas test systems, per CFR 493.1267. 4. Random review of quality control records revealed the following days quality control was performed on the EPOC analyzer: "a. October 30, 2021 16:15 Quality Control Levels 1 and 3 Pass b. November 6, 2021 15:01 Quality Control Levels 1 and 3 Pass c. November 29, 2021 00:01 Quality Control Levels 1 and 3 Pass c. December 11, 2021 16:00 Quality Control Levels 1 and 3 Pass" 5. A random sampling of patients, revealed the following patients tested when one level of quality control was not performed every 8 hours of patient testing: a. Patient UNOS Number: AIJ5383 Date Performed: 11/01/2021 b. Patient UNOS Number: AJKA098 Date Performed: 11/03 /2021 c. Patient UNOS Number: AJKE111 Date Performed: 11/06/2021 d. Patient UNOS Number: AIKF095 Date Performed: 11/08/2021 e. Patient UNOS Number: AILE085 Date Performed: 12/07/2021 f. Patient UNOS Number: AILK065 Date Performed: 12/12/2021 6. During an interview with the Technical Supervisor (TS-1) on 12/15/2021 at 11:00 AM in the conference room, the TS confirmed the laboratory failed to have in house data in the IQCP risk assessment to support its reduction in QC frequency to every 14 days and failed to perform one level of liquid QC material each 8 hours of operation for the EPOC blood gas analyzer. Word Key: PCO2= Partial pressure of carbon dioxide PO2= Partial pressure of oxygen cHCO3= Bicorbonate BE= Base Excess SO2= Oxygen Saturation
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

	This STANDARD is not met as evidenced by: Based on review of laboratory records, laboratory verification protocol, and confirmed in interview, the laboratory failed to verify at least twice annually the accuracy of 1 of 1 analytes in 2020/2021 on two Panther Instruments. Findings Included: 1. Review of laboratory records revealed the laboratory performed West Nile Virus NAT (Nucelic Acid Testing) on two separate Panther Instruments (Serial Number 1: Serial Number 2:). 2. Review of laboratory, "Move Verification Protocol" revealed the laboratory performed one accuracy verification between the Panther instruments on 9/27/2020 for West Nile Virus. 3. During an interview on 12/15/2021 at 10:30 a.m. in the conference room, the General Supervisor (GS-1) was asked for other verifications performed between the two analyzers for West Nile Virus. The supervisor stated no other verifications were performed. This confirmed the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory policy, chemistry quality control (QC) records, and confirmed in interview, the laboratory failed to document corrective actions for 16 of 32 runs that included failures in 2021 (10/2021-12/2021). Findings: 1. Review of the laboratory policies revealed the laboratory did not have a policy for documenting corrective actions for QC failures for chemistry analytes tested on the Dimension EXL analyzer. A sampling review of individual analyte policies revealed the following: "LACTIC ACID (LA) ... QUALITY CONTROL ... At least once each day of use, analyze two levels of Quality Control (QC) material with known albumin concentration. Follow your laboratory Internal QC procedures if the results obtained are outside acceptable limits." 2. Review of Dimension EXL QC records revealed the laboratory failed to document corrective actions for QC failures in 2021 on the following dates and times: QC level 1 control lot #56671; expiration date: 06/30/2023 QC level 3 control lot # 56673; expiration date: 06/30/2023 10/04/2021 Level 3 control 23:02 hours QC failed for CRE2 23:49 hours QC was repeated and passed 10 /06/2021 Level 1 control 00:20 hours QC failed for ALTI, CKI 01:16 hours QC was repeated and passed 10/09/2021 Level 3 control 23:28 hours QC failed for CKI 23:59 hours QC was repeated and passed 10/10/2021 Level 3 control 23:52 hours QC failed for ALB, ALTI, BUN, CA, CKI, CRE2, DBI, GGT, GLUC, LA, Lipl, MG 10/11 /2021 00:23 hours QC was repeated and passed for ALB, ALTI, BUN, CA, CRE2, DBI, GGT, GLUC, LA, Lipl, MG and failed for CKI 00:37 hours QC was repeated for CKI and passed 10/11/2021 Level 3 control 23:27 hours QC failed for ALTI 23:58 hours QC was repeated and passed 10/16/2021 Level 1 control 17:49 hours QC failed for Lipl 18:43 hours QC was repeated and passed 10/17/2021 Level 1 control 17:35 hours QC failed for ALB, ALTI, AMY, AST, BUN, CA, CKI, CRE2, DBI, GGT, GLUC, LA, Lipl, MG 18:33 hours QC was repeated and passed 10/19/2021 Level 3

	control 20:58 hours QC failed for Na, K, Cl 21:31 hours QC was repeated and passed 11/01/2021 Level 3 control 23:45 hours QC failed for CRE2 11/02/2021 00:37 hours QC was repeated and passed 11/03/2021 Level 1 control 08:30 hours QC failed for CRE2, LA 09:03 hours QC was repeated and passed for CRE2 and failed for LA 10: 05 hours QC was repeated for LA and passed 11/04/2021 Level 3 control 07:27 hours QC failed for CKI, CRE2 07:59 hours QC was repeated and passed for CKI and failed for CRE2 08:34 hours QC was repeated for CRE2 and passed 12/03/2021 Level 3 control 01:30 hours QC failed for ALPI 02:18 hours QC was repeated and passed 12 /07/2021 Level 3 control 00:07 hours QC failed for ALTI, CKI, CRE2 01:00 hours QC was repeated and passed 12/08/2021 Level 3 control 00:05 hours QC failed for CKI 00:35 hours QC was repeated and passed 12/12/2021 Level 3 control 17:28 hours QC failed for ALPI, Cl 19:59 hours QC was repeated and passed for ALPI, QC failed for Cl 20:18 hours QC was repeated for Cl and failed 12/14/2021 Level 3 control 16: 06 hours QC failed for CKI, CRE2, Cl 16:26 hours QC was repeated and passed for CKI, QC failed for CRE2, Cl 16:39 hours QC was repeated and passed CRE2, QC failed for Cl 17:11 hours QC was repeated for Cl and passed The laboratory failed to document corrective action for the above QC failures. 3. During an interview on 12/15 /2021 at 11:28 am, the Technical Consultant was asked for a corrective action documentation for QC failures. She stated that the only time corrective action was documented for QC failures was when testing personnel could not get QC to pass and patient specimens could not be tested. This confirmed the above findings. Word Key: CRE2- creatinine ALTI- alanine aminotransferase CKI- creatinine kinase Lipl- lipase ALB- albumin BUN- blood urea nitrogen CA- calcium DBI- direct bilirubin GGT- gamma glutamyl transferase GLUC- glucose LA- lactic acid MG- magnesium AMY- amylase LA- lactic acid PHOS- phosphate Na- sodium K- potassium Cl- chloride ALPI- alkaline phosphatase
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 manufacturer's instructions, laboratory policies, laboratory's specimen collection table, laboratory records, patient test records, and staff interview, the Laboratory Director failed to provide overall management as evidenced by: 1. The Laboratory Director failed to ensure all requirements were met for preanalytic systems. Refer to D6007. 2. The Laboratory Director failed to ensure test methodologies selected for lactate specimen testing had the capability of providing quality results for patient care. Refer to D6012. 3. The Laboratory Director failed to ensure testing personnel were performing test methods for accurate and reliable results. Refer to D6014.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policies, laboratory's specimen collection table, laboratory records, patient test records, and staff interview, the Laboratory Director failed to ensure pre-analytic systems provided quality results as evidenced by: 1. The laboratory failed to include patient preparation, specimen collection, specimen storage and preservation, specimen acceptability and rejection criteria in their specimen collection table provided to clients. Refer to D5311, I. 2. The laboratory failed to ensure patient lactate specimens were collected in sodium fluoride /potassium oxalate collection tubes followed by immediate chilling as required by manufacturer's instructions for 15 of 15 patients in 2021 (November-December random sampling) and failed to ensure specimens were received and processed within 15 minutes as required by manufacturer's instructions for 7 of 15 patients in 2021 (November-December random sampling). Refer to D5311, II.
D6012	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(i) 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) The test methodologies selected have the capability of providing the quality of results required for patient care; This STANDARD is not met as evidenced by: Based on laboratory policy, manufacturer's instructions, laboratory records, patient test records, and staff interview, the Laboratory Director failed to ensure test methodologies selected for lactate specimen testing had the capability of providing quality results for patient care. Refer to D5311, I and D5311, II.
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 laboratory policy, manufacturer's instructions, laboratory records, patient test records, and staff interview, the Laboratory Director failed to ensure testing personnel were performing test methods for accurate and reliable results. Refer to D5311, II.

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 manufacturer's instructions, laboratory policies, laboratory's specimen collection table, laboratory records, patient test records, and staff interview, the Technical Consultant failed to provide technical oversight of the laboratory as evidenced by: 1. The Technical Consultant failed to ensure manufacturer's instructions were followed. Refer to D6036. 2. The Technical Consultant failed to ensure test methodologies selected for lactate specimen testing had the capability of providing quality of results for patient care. Refer to D6039.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on laboratory policy, manufacturer's instructions, laboratory records, patient test records, and staff interview, the Technical Consultant failed to ensure manufacturer's instructions were followed as evidenced by: 1. The laboratory failed to ensure patient lactate specimens were collected in sodium fluoride/potassium oxalate collection tubes followed by immediate chilling as required by manufacturer's instructions for 15 of 15 patients in 2021 (November-December random sampling) and failed to ensure specimens were received and processed within 15 minutes as required by manufacturer's instructions for 7 of 15 patients in 2021 (November-December random sampling). Refer to D5311, II.
D6039	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(1) The technical consultant is responsible for-- (b)(1) Selection of test methodology appropriate for the clinical use of the test results; This STANDARD is not met as evidenced by: Based on laboratory policy, manufacturer's instructions, laboratory records, patient test records, and staff interview, the Technical Consultant failed to ensure test methodologies selected for lactate specimen testing had the capability of providing quality results for patient care. Refer to D5311, I and D5311, II.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance

	with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policies, laboratory's specimen collection table, laboratory records, patient test records, FDA (Food and Drug Administration) website, establishment/verification studies for the Dimension EXL chemistry analyzer, and staff interview, the Laboratory Director failed to provide overall management as evidenced by: 1. The Laboratory Director failed to ensure test methodologies selected for lactate specimen testing had the capability of providing quality results for patient care. Refer to D6085. 2. The Laboratory Director failed to ensure establishment studies were complete prior to performing patient testing. Refer to D6086. 3. The Laboratory Director failed to ensure testing personnel were performing test methods for accurate and reliable results. Refer to D6087.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care. This STANDARD is not met as evidenced by: Based on laboratory policy, manufacturer's instructions, laboratory records, patient test records, and staff interview, the Laboratory Director failed to ensure test methodologies selected for lactate specimen testing had the capability of providing quality results for patient care. Refer to D5311, I and D5311, II.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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 manufacturer's instructions, laboratory documents, FDA (Food and Drug Administration) website, establishment/verification studies for the Dimension EXL chemistry analyzer, and confirmed in interview, the Laboratory Director failed to ensure establishment studies were complete prior to performing patient testing. Refer to D5423.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on laboratory policy, manufacturer's instructions, laboratory records, patient test records, and staff interview, the Laboratory Director failed to ensure testing

	personnel were performing test methods for accurate and reliable results. Refer to D5311, II.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policies, laboratory's specimen collection table, laboratory records, patient test records, FDA (Food and Drug Administration) website, establishment/verification studies for the Dimension EXL chemistry analyzer, and staff interview, the Technical Supervisor failed to provide overall technical supervision as evidenced by: 1. The Technical Supervisor failed to ensure test methodologies selected for lactate specimen testing had the capability of providing quality results for patient care. Refer to D6114. 2. The Technical Supervisor failed to ensure establishment studies were complete prior to performing patient testing. Refer to D6115.
D6114	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(1) The technical supervisor is responsible for selection of the test methodology that is appropriate for the clinical use of the test results. This STANDARD is not met as evidenced by: Based on laboratory policy, manufacturer's instructions, laboratory records, patient test records, and staff interview, the Technical Supervisor failed to ensure test methodologies selected for lactate specimen testing had the capability of providing quality results for patient care. Refer to D5311, I and D5311, II.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and 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 manufacturer's instructions, laboratory documents, FDA (Food and Drug Administration) website, establishment/verification studies for the Dimension EXL chemistry analyzer, and confirmed in interview, the Technical Supervisor failed to ensure establishment studies were complete prior to performing patient testing. Refer to D5423.