Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0461104	08/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
St Martin Hospital	210 Champagne Blvd, Breaux Bridge, LA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Certification Survey was performed at St. Martin Hospital, CLIA ID # 19D461104, on August 19, 2019 through August 23, 2019. St. Martin Hospital was found not in compliance with the following CONDITION LEVEL DEFICIENCES: 42 CFR 493.803 CONDITION: Successful Participation 42 CFR 493.1250 CONDITION: Analytic systems 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing; Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories Performind Moderate Complexity Testing; Technical Consultant
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of proficiency test results from the CMS 155D and American

	Proficiency Institute (API) and interview with personnel, the laboratory failed to successfully participate in proficiency testing. Refer to D2163.
D2163	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(g) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to achieve an overall satisfactory proficiency test score for two (2) out of three (3) consecutive events for ABO/RHO in 2017. Findings: 1. Review of the laboratory's American Proficiency Institute (API) proficiency test results for the Immunohematology 3rd event revealed the laboratory received an 80% for D (Rho) type. 2. Review of the CMS CASPER Report 0155D for proficiency test scores revealed the laboratory received less than 100 percent for the following two (2) out of three (3) events for ABO/RHO: 2017 1st Event 80% ABO Group 2017 3rd Event 80% D (Rho) type 3. In interview on August 23,2019, Testing Personnel 1 confirmed the laboratory had an unsuccessful proficiency test score for the Rh 3rd event in 2017. Testing Personnel 1 stated the laboratory performed an assessment for the identified unsuccessful proficiency test results.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to verify the accuracy of all non-regulated analytes at least twice annually. Findings: 1. Review of the laboratory's "Proficiency Testing" policy revealed "The Laboratory participates in the American Proficiency Institute (API) proficiency testing program. The specimens are scheduled to be shipped three times each year (or two times a year, where applicable)." 2. Review of the laboratory's API PT records for 2018 and 2019 revealed the laboratory failed to participate for the 2019 1st event for the following analytes: 2019 Chemistry Miscellaneous 1st Event: "Notes Failure to Participate" PSA, Ammonia, Ferritin, Folate, Prealbumin, Transferring, Urine Chloride, Urine Creatinine, Urine Microalbumin, Urine Potassium, Urine Sodium, Urine Total Protein, Vitamin B-12, Amphetamines, Barbiturates, Benzodiazepine, Cannabinoids, Cocaine, Opiates, and Phencyclidine 3. Further review of the the API records for the identified Chemistry Event revealed API ships proficiency samples twice a year. 4. Review of the laboratory's "Performance Review and Corrective Action" revealed the laboratory documented the following: "API submitted after due date/time. Reminder submitted in daily/monthly task calendar implemented in order to prevent missing due dates for API submission." The document was dated "6-7-19" 5. The laboratory did not have documentation of verification of accuracy for the identified analytes during

	the time of the survey. 6. In interview on August 22, 2019, Testing Personnel 1 confirmed the laboratory did not have documentation of verification of accuracy for the identified analytes.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to perform an assessment for unsatisfactory proficiency proficiency test (PT) results. Findings: 1. Review of the laboratory's 2017, 2018, and 2019 American Proficiency Institute (API) PT results revealed the laboratory received the following "unacceptable" results : 2019 Chemistry Core 1st Event: Sample CH-04 for Phenobarbital, API grade: "unacceptable" 80% 2. Review of the laboratory's PT records revealed the laboratory did not perform an assessment for the identified "unacceptable" API PT result. 3. Review of the laboratory's "Proficiency Testing" policy revealed "If the results are unacceptable, the Lab Manager is responsible for ensuring that adequate troubleshooting and corrective actions has occurred with each issue and all actions are documented. This includes documenting clerical or keypunch errors, missing response codes, communication with CAP, reasons for failure, process improvement, and/or the appropriate corrective action plans are instituted. This report then goes back to the Lab Director for final review of corrective actions." 4. In interview on August 22, 2019 at 6:45 pm, Testing Personnel 1 stated the laboratory did not perform an assessment for the "unacceptable" Phenobarbital result. II. Based on record review and interview with personnel, the laboratory failed to document all corrective actions performed for unsatisfactory proficiency test (PT) results. Findings: 1. Review of the laboratory's 2019 American Proficiency Institute (API) PT results revealed the laboratory received the following "unacceptable" results: 2019 Chemistry Core 2nd Event: D-dimer Sample CM-08, API grade: "unacceptable" 80% 2019 Chemistry Core 2nd Event: CO2 Samples CH-06, CH-07, CH-08, CH-09, and CH-10, API results:"unacceptable" 2019 Chemistry Core 2nd Event: TIBC Samples CH-07 and CH-08, API results: "unacceptable" 2019 Chemistry Core 2nd Event: pCO2 Sample IB-10, API result: "unacceptable" 80% 2. Review of the laboratory's API "Proficiency Testing Performance Evaluation" form for the identified event revealed the laboratory documented the following corrective action: "Checked QC, QC ok." 3. Review of the laboratory's "Proficiency Testing" policy revealed "If the results are unacceptable, the Lab Manager is responsible for ensuring that adequate troubleshooting and corrective actions has occurred with each issue and all actions are documented. This includes documenting clerical or keypunch errors, missing response codes, communication with CAP, reasons for failure, process improvement, and/or the appropriate corrective action plans are instituted. This report then goes back to the Lab Director for final review of corrective actions." 4. In interview on August 22, 2019 at 6:45 pm, the General Supervisor stated she checked other monitors such as the instrument log to see if any problems, submission to ensure correct, and the quality control. The General Supervisor confirmed she did not document all corrective actions performed for the identified PT event.
D5305	TEST REQUEST CFR(s): 493.1241(c)

	The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to include the specimen collection time for blood gas testing. Findings: 1. Observation by surveyor during laboratory tour on August 19, 2019 revealed the laboratory utilizes the i-Stat 1 for blood gas (pH, pO2, pCo2) testing. 2. Review of the laboratory's "I-STAT G3+" policy under the "For specimen collection in blood collection tube" section revealed "Label with patient label, date/time of collection and initials." 3. Review of the manufacturer's instrument manual under "Time to Test" section revealed "For the most accurate results, test samples immediately after draw. Samples for pH, PCO2, TCO2, and ionized calcium should be tested within 10 minutes." 4. In interview on August 20, 2019 at 9:28 am, Respiratory Testing Personnel 1 stated she thought blood gas samples should be analyzed within thirty (30) minutes. 5. In further interview on August 20, 2019 at 5:15 pm, Respiratory Testing Personnel 1 stated the i-Stat instrument does not leave the Emergency Room (ER) station. Respiratory Testing Personnel 1 further stated the respiratory staff walks the blood gas samples to the ER station, which may be collected from patients in different areas of the hospital. 6. Review of random selection of blood gas patient instrument printouts and final reports from July 2019 revealed the laboratory documented the time the sample was received/tested as the collection time. 7. In interview on August 20, 2019 at 5:15 pm, Respiratory Testing Personnel 1 stated the collection time documented is the time from the instrument, the time the sample ran, not necessarily the actual collection time. Respiratory Testing Personnel 1 stated the respiratory staff does not update the collection time in the system. 8. Further review of random selection of patient records for blood gas testing from July 2019 revealed the laboratory did not document the actual collection time for the following ten (10) patients: July 5, 2019: Patient 19-186-0563 July 9, 2019: Patient 19-190-5076 July 15, 2019: Patient 19-196-2563 July 22, 2019: Patient 19-203-2224 July 25, 2019: Patient 19-206-1278 July 29, 2019: Patient 19-210-0782, Patient 19-210-4755, Patient 19-210-5737, and Patient 19-210-4054 July 30, 2019: Patient 19-211-3693 July 31, 2019: Patient 19-212-4359 and Patient 19-212-3063 9. Review of the laboratory's test menu revealed the laboratory performs 537 blood gas tests annually.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish current and complete detailed written instructions for providers to maintain the integrity of samples. Findings: 1. Review of the laboratory's written instructions given to providers titled "St. Martin Hospital Department of Pathology" revealed the laboratory did not include the following: a) Specimen storage requirements b) Specimen acceptability and rejection c) Ammonia and Lactic Acid specimen handling requirements that reflect the manufacturer's instructions 2.. Further review of the laboratory's instructions given to providers under the "Laboratory Directory" section revealed the personnel listed to contact was not updated to current personnel. 3. In interview on August 23, 2019, Testing Personnel 1 confirmed the "St. Martin Hospital Department of Pathology" document is given to providers
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5403. 2. The laboratory failed to ensure policies and procedures were updated to current practices. Refer to D5407. 3. The laboratory failed to ensure patient samples for Ammonia were analyzed within thirty (30) minutes per manufacturer requirements. Refer to D5411. 4. The laboratory failed to ensure reagents were not used beyond their expiration dates. Refer to D5417. 5. The laboratory failed to have complete performance verification studies for Complete Blood Count (CBC) analyzers. Refer to D5421 I. 6. The laboratory failed to have complete performance verification studies for blood gas testing on the i-Stat analyzer. Refer to D5421 II. 7. The laboratory failed to have complete performance verification studies for Prothrombin Time/International Normalized Ratio (PT/INR) testing on the i-Stat analyzer. Refer to D5421 III. 8. The laboratory failed to have complete performance verification studies for Coagulation testing on the Sysmex CA-660 series analyzer. Refer to D5421 IV. 9. The laboratory failed to establish a reference (normal) range for Prothrombin Time and International Normalized Ration (PT/INR) testing prior to patient testing. Refer to D5421 V. 10. The laboratory failed to ensure thermal probe check was performed and documented as required by the manufacturer. Refer to D5429. 11. The laboratory failed to perform calibration verification procedures on the i-Stat utilized for blood gas testing at least every six (6) months. Refer to D5439. 12. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for blood gas testing. Refer to D5445 I. 13. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for Prothrombin Time/International Normalized Ratio (PT/INR) testing on the i-Stat

	analyzer. Refer to D5445 II. 14. The laboratory failed to perform two (2) levels of controls prior to patient testing for Phenytoin. Refer to D5447. 15. The laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for Complete Blood Count (CBC) testing. Refer to D5469. 16. The laboratory failed to monitor circular refrigerator temperature charts for blood storage. Refer to D5555 I. 17. The laboratory failed to ensure continuous temperature monitoring of the blood bank refrigerator. Refer to D5555 II. 18. The laboratory failed to perform method comparison testing for Chemistry and Coagulation testing at least twice a year. Refer to D5775. 19. The laboratory failed to follow their established quality control (QC) corrective action policy for Chemistry testing. Refer to D5779 I. 20. The laboratory failed to follow their established quality control (QC) corrective action policy for Coagulation testing. Refer to D5779 II. 21. The laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Refer to D5793.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory did not detail step-by-step instructions for performance of high /low quarterly blood bank refrigerator alarm checks. 2. In interview on August 23, 2019 at 11:45 am, Testing Personnel 1 stated the laboratory did not have a written procedure for quarterly alarm checks for the blood bank refrigerator.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure policies and procedures were updated to current practices. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have current policies/procedures for the following: a) "I-STAT G3+" specimen test time for blood gas was not updated to reflect instrument manufacturer's requirements b) "Laboratory Quality Control Policy: Original Date: 01-09-2013" instruments listed were not updated to reflect new instrumentation for Hematology, Coagulation, and blood gas testing in use since 2018. 2. In interview on August 20 ,2019, Respiratory Testing Personnel 1 confirmed the laboratory's blood gas policy did not reflect the manufacturer's testing requirements. 3. In interview on August 21, 2019, Testing Personnel 1 confirmed the laboratory's policy and procedure manual was not updated to include current instrumentation.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure patient samples for Ammonia were analyzed within thirty (30) minutes per manufacturer requirements. Findings: 1. Observation by surveyor during laboratory tour on August 19, 2019 revealed the laboratory utilizes the Siemens Dimension EXL 200 for Ammonia testing. 2. Review of the Siemens Dimension package insert revealed "The tube should be completely filled, stored tightly capped on ice and centrifuged without delay. Samples should be analyzed within 30 minutes of centrifugation. Separated samples are stable 2 hours at 2-8 degrees Celsius." 3. Review of the laboratory's "Ammonia Testing" policy revealed the "Once the specimen is collected, it is placed on ice. Once received by the laboratory, the specimen is centrifuged, the plasma is separated, and placed in a labeled tube. The tube is then run as a STAT specimen. Samples must be run within 30 minutes of centrifugation or stored at 2-8 degrees Celsius for up to 2 hours." 4. Review of patient records for Ammonia from May 2019 revealed the laboratory failed to analyze the following three (3) of ten (10) patients reviewed within thirty (30) minutes: May 1, 2019: Patient 19-121-1374, collected 4:47 am, received 7:53 am May 7, 2019: Patient 19-127-2512, collected 9:25 am, received 10:20 am May 15, 2019 Patient 19-134-0776, collected 4:35 am, received 5:41 am 5. In interview on August 23, 2019 at 3:25 pm, Testing Personnel 1 stated the the identified patients are from home health agencies. Testing Personnel 1 stated samples from home health are received unspun. Testing Personnel 1 confirmed the laboratory did not have documentation of the identified Ammonia samples being analyzed within thirty (30) minutes or stored at 2-8 degrees Celsius.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have

	deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: *** Repeat deficiency from survey performed June 5, 2017 through June 9, 2017. *** *** REPEAT DEFICIENCY from survey date September 30, 2015 through October 1, 2015*** Based on observation and interview with personnel, the laboratory failed to ensure reagents were not used beyond their expiration dates. Findings: 1. Observation by surveyor on August 19, 2019 during laboratory tour revealed the following expired items: Stat Strip Xpress Control Level 1, Lot 04182296301, Expiration date: 08-09-2019, Quantity: one (1) bottle Stat Strip Xpress Control Level 3, Lot 0418283303, Expiration date: 08-09-2019, Quantity: one (1) bottle 2. In interview on August 19, 2019 at 1:30 pm, Testing Personnel 1 and Nursing Testing Personnel 12 confirmed the identified items were expired.
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 observation, record review, and interview with personnel, the laboratory failed to have complete performance verification studies for Complete Blood Count (CBC) analyzers. Findings: 1. Observation by surveyor during laboratory tour on August 19, 2019 revealed the laboratory utilizes the following instruments for CBC testing: Sysmex XN-450 Sysmex XN-550 2. Review of the laboratory's validation records revealed the laboratory did not include the following information: Sysmex XN-450: Precision: operator variance and reference range studies, including raw data and acceptability criteria. Sysmex XN-550: Precision: operator variance and reference range studies, including raw data and acceptability criteria 3. Further review revealed the validation studies were approved by the laboratory director on the following dates: Sysmex XN-450: July 28, 2018 Sysmex XN-550: July 29, 2018 4. In interview on August 22, 2019 at 8:48 am, the Laboratory Director stated the laboratory is utilizing the same reference ranges as the hospital located in Lafayette. 5. Review of the laboratory's "INSTRUMENT AND METHOD IMPLEMENTATION PERFORMANCE VERIFICATION REPORT FORM" revealed no documentation of ranges in "Reference Range Interval" section. 6. Further review of the laboratory's "INSTRUMENT AND METHOD IMPLEMENTATION PERFORMANCE VERIFICATION REPORT FORM" revealed a post-it note that stated the following: " Please add reference ranges to each form." 7. In interview on August 22, 2019, Testing Personnel 1 confirmed the laboratory did not have documentation of the identified items. 8. Review of the laboratory's test menu revealed the laboratory performs 69,078 CBC tests annually. II. Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance verification studies for blood gas testing on the i-Stat analyzer. Findings: 1. Observation by surveyor during laboratory tour on August 19, 2019 revealed the

laboratory performs blood gas and Prothrombin Time/International Normalized Ratio (PT/INR) testing on the i-Stat. 2. In interview on August 19, 2019, Testing Personnel 1 stated blood gas testing was added to the i-Stat in 2018. 3. Review of the laboratory's i-Stat validation records for blood gas revealed the following document:" Pending items that need to be done to complete i-STAT ABG implementation. 1. Determine the reference ranges for pH, pCO2, and PO2. 3. Since the comparison studies of the i-STAT were satisfactory we can simply Adopt(Transference approach) LGMC normal ranges. However we need to verify the ranges by performing ABG on 5 normal patients. 3 Complete implementation forms by adding the reference ranges into implementation for." 4. Further review of the laboratory's "Pending items for i-STAT ABG implementation" revealed the following statement signed by the Laboratory Director " Keep documentation of the range interval verification." 5. Review of the laboratory's validation records revealed the laboratory did not include the following: reference range verification or values in use and precision (operator variance), including raw data and acceptability criteria. 6. In interview on August 21, 2019, Testing Personnel 1 stated the laboratory did not perform the reference range verification for blood gas testing as indicated in their validation records. Testing Personnel 1 confirmed the laboratory did not have documentation of operator variance for precision studies. 7. Review of the laboratory's test menu revealed the laboratory performs 537 blood gas tests annually. III. Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance verification studies for Prothrombin Time/International Normalized Ratio (PT/INR) testing on the i-Stat analyzer. Findings: 1. Observation by surveyor during laboratory tour on August 19, 2019 revealed the laboratory performs PT/INR testing on the i-Stat. 2. In interview on August 19, 2019, Testing Personnel 1 stated PT/INR testing was added to the i-Stat in 2018. 3. Review of the laboratory's validation studies revealed the following information was not included: reportable range. 4. In interview on August 21, 2019 at 10:00 am, Testing Personnel 1 stated the laboratory utilized the manufacturer's reportable range. 5. Review of the manufacturer's reportable range provided by Testing Personnel 1 on August 21, 2019 revealed the following: "Analyte: Prothrombin Time/PT, Unit: INR, and Reportable Range: 0.9-8.0. Performance characteristics have not been established for INRs above 6.0" Further review of the laboratory's validation records revealed the laboratory did not include documentation of the manufacturer's reportable range or verification studies. 6. In interview on August 22, 2019 at 8:48 am, the Laboratory Director stated the laboratory utilizes a cut-off value, not reportable range. The Laboratory Director further stated the cut-off value is utilized for stroke protocol. 7. Review of the laboratory's test menu revealed the laboratory performs 505 PT/INR tests annually on the i-Stat. IV. Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance verification studies for Coagulation testing on the Sysmex CA-660 series analyzer. Findings: 1. Observation by surveyor during laboratory tour on August 19, 2019 revealed the laboratory performs Prothrombin Time/International Normalized Ratio (PT/INR) , Partial Thromboplastin Time (PTT), and D-dimer testing on the Sysmex CA-600 series. 2. In interview on August 21, 2019, Testing personnel 1 stated the laboratory began utilizing the Sysmex CA-600 series for coagulation testing March 21, 2018. 3. Review of the laboratory's validation records revealed the laboratory did not include the following: PT, PTT, and D-dimer: Precision (day-to-day and operator variance) PT: Reference range, including documentation of normal donors utilized and raw data 4. Further review of the laboratory's validation records revealed the laboratory verification studies (accuracy, precision, reportable and reference ranges) were performed by the instrument's technical service representative, not the laboratory, on March 6, 2018. 5. In interview on August 21, 2019, Testing Personnel 1 confirmed the laboratory did not have

	documentation the laboratory participated in the verification studies. 6. In further interview on August 23, 2019 at 3:36 pm, Testing Personnel 1 stated the laboratory did not have documentation of normal donors utilized for the PT reference range study. 7. Review of the laboratory's test menu revealed the laboratory performs the following: 2,005 PT/INR, 2,008 PTT, and 413 D-dimer tests annually. V. Based on observation, record review, and interview with personnel, the laboratory failed to establish a reference (normal) range for Prothrombin Time and International Normalized Ration (PT/INR) testing prior to patient testing. Findings: 1. Observation by surveyor during laboratory tour on August 19, 2019 revealed the laboratory utilizes the Sysmex CA-600 series analyzer for PT/INR testing. 2. In interview on August 19, 2019, Testing Personnel 1 stated the laboratory upgraded their previous Sysmex CA-560 analyzer to the Sysmex CA-600 series in March 2018 for coagulation testing. 3. Review of the laboratory's policy and procedure for PT revealed the laboratory had a procedure for establishing /verifying reference intervals for PT/INR testing that included the following: "Prior to implementing a new lot of reagents the following must be performed: Determine the geometric mean of 20 normal plasmas collected from 20 normal individuals selected using the 'Mean of Normal Patient Population' questionnaires. Select a minimum of 4 donors a day over several days who meet the criteria in the questionnaire. Donors should span the adult age ranges with even distribution of males and females. Run Prothrombin Time on each patient making sure to include multiple testing personnel in the runs. Calculated the Geometric mean of the normal donors." 4. Review of the laboratory's validation studies revealed the laboratory had documentation of twenty (20) questionnaires for donors; however, the following two (2) donors were unacceptable: Donor 2018-15: Answered "No" to being in "good health (i.e. No pathological conditions, no pre surgical or hospitalized patient)" Donor 2018-19: Answered "Yes" to being on medication, including aspirin, birth control, estrogen or hormone therapy 5. Review of the reference interval studies revealed the donor numbers on the identified questionnaires did not match those used in the reference interval study. For the donors utilized in the study, the laboratory did not include the corresponding donor questionnaires and raw data. Surveyor was unable to determine if donore included in the study met the manufacturer requirements for "normal" donors. 6. In interview on August 23, 2019 at 3:36 pm, Testing Personnel 1 stated the patients from the method comparison were used for the reference verification study. Testing Personnel 1 confirmed the laboratory did not include the donor questionnaires and raw data. 7. Review of the laboratory's test menu revealed the laboratory performs 2,005 PT/INR tests annually on the Sysmex CA-600 series analyzer.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure thermal probe check was performed and documented as required by the manufacturer. Findings: 1. Review of the i-Stat 1 Analyzer manual revealed "i-Stat recommends that the thermal probe check be verified every six months." 2. Review of the laboratory's "IQCP Final And Quality Assessment for Point of Care i-Stat" under "Quality Review" section revealed "Abbott Point of Care recommends that a thermal probe

	check be verified every 6 months." 3. Review of the laboratory's 2018 and 2019 maintenance logs for the i-Stat revealed the laboratory did not have documentation of the thermal probe check. 4. In interview on August 20, 2019 at 9:40 am, Respiratory Testing Personnel 1 stated the thermal probe check is not performed on the i-Stat.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to perform calibration verification procedures on the i-Stat utilized for blood gas testing at least every six (6) months. Findings: 1. Observation by surveyor during laboratory tour on August 19, 2019 revealed the laboratory utilizes a i-Stat 1 analyzer for blood gas testing. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not include a written calibration verification policy /procedure. 3. In interview on August 20, 2019 at 9:52 am, Respiratory Testing Personnel 1 stated the laboratory does not perform calibration verification at least every six (6) months. 4. Review of the laboratory's validation records for blood gas revealed the laboratory last performed a five point calibration verification on July 11, 2018. 5. Review of the laboratory's test menu revealed the laboratory performs 537 blood gas tests annually.
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: I. Based on observation, record review, and interview with personnel, the laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for blood gas testing. Findings: 1. Observation by surveyor during the laboratory tour on August 19, 2019 revealed the laboratory utilized one (1) i-Stat 1 analyzer for blood gas testing. 2. In interview on August 20, 2019 at 10:01 am, Respiratory Testing Personnel 1 stated the laboratory went live with patient testing on September 4, 2018. Respiratory Testing Personnel 1 stated the laboratory tests liquid controls monthly and new lot/shipment of cartridges. 3. Review of the laboratory's IQCP documents revealed the laboratory did not include in-house data to support the reduction in frequency of external QC. 4. In further interview on August 20, 2019, Respiratory Testing Personnel 1 confirmed the laboratory did not have data to support reduction in frequency of liquid (external) QC. 5. Review of the laboratory's test menu revealed the laboratory performs 537 blood gas tests annually. II. Based on observation, record review, and interview with personnel, the laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for Prothrombin Time/International Normalized Ratio (PT/INR) testing on the i-Stat analyzer. Findings: 1. Observation by surveyor during the laboratory tour on August 19, 2019 revealed the laboratory utilized one (1) i-Stat 1 analyzer for PT/INR testing. 2. In interview on August 22, 2019 at 11:30 am, Testing Personnel 1 stated the external controls are tested monthly and new lot/shipment of cartridges. 3. Review of the laboratory's IQCP documents revealed the laboratory did not include in-house data to support the reduction in frequency of external QC. 4. In further interview on August 22, 2019, Testing Personnel 1 confirmed the laboratory did not have data to support the reduction of frequency of external QC. 5. Review of the laboratory's test menu revealed the laboratory performs 505 PT/INR tests annually on the i-Stat analyzer.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to perform two (2) levels of controls prior to patient testing for Phenytoin. Findings: 1. Observation by surveyor during laboratory tour on August 19, 2019 revealed the laboratory utilizes the Siemens Dimension EXL with LM for Phenytoin testing. 2. Review of the laboratory's "Laboratory Quality Control Policy" under the "General Info for Quality Control" section revealed "Chemistry (EXL): Two (2) levels are run every 24 hours on the night shift and after calibration or major instrument repairs.' 3. Review of the quality control records for Phenytoin from February 2019 through August 2019 revealed the laboratory did not perform two (2) levels of QC for the following date: March 16, 2019: Mutltiqual Level 1 and Level 3 not performed 4.

	In interview on August 21, 2019, Testing Personnel 1 confirmed the laboratory did not perform two (2) levels of QC on the identified date. 5. Review of patient test records for the identified date revealed the following patient was reported without performance of two (2) levels of QC: Patient 19-075-0932
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: *** Repeat deficiency from survey performed June 5, 2017 through June 9, 2017. *** Based on observation, record review, and interview with personnel, the laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for Complete Blood Count (CBC) testing. Findings: 1. Observation by surveyor during the laboratory tour on August 19, 2019 revealed the laboratory utilizes the Sysmex XN-450 and Sysmex XN-550 for CBC testing with XN-L CHECK controls. 2. In interview on August 19, 2019 at 2:19 pm, Testing Personnel 1 stated the laboratory utilizes the manufacturer's QC ranges for CBC controls. 3. Review of the manufacturer's package insert under the "Performance characteristics and limitations" section revealed "The expected ranges listed on the assay sheet represent estimates of inter-laboratory variation for each parameter. These expected ranges should not be used as QC file limits." 4. Review of the laboratory's test menu revealed the laboratory performs 69,078 CBC tests annually.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: I. Based on record review and interview with personnel, the laboratory failed to monitor circular refrigerator temperature charts for blood storage. Findings: 1. Review of the laboratory's temperature charts revealed 1-6 degrees Celsius as the acceptable temperature range for blood storage. 2. Review of the laboratory's circular

	temperature charts for 2018 and 2019 revealed the following dates that temperatures were recorded outside of acceptable limits: August 4, 2019: recorded temperature 0 degrees Celsius August 5, 2019: recorded temperature -1 degrees Celsius at 2:00 am; at approximately noon through midnight recorded temperature -2 degrees Celsius August 6, 2019: recorded temperature -2 degrees Celsius August 7, 2019: recorded temperature -2 degrees Celsius through approximately noon; recorded temperature at approximately 11:00 am through 11:00 pm -1 degrees Celsius August 8, 2019: recorded temperature 0 degrees Celsius from midnight through approximately noon August 9, 2019 through August 16, 2019: recorded temperature 0 degrees Celsius 3. In interview on August 23, 2019, Testing Personnel 1 stated the laboratory was unaware of the identified blood bank refrigerator unacceptable temperatures. Testing Personnel 1 stated the blood bank alarm did not go off. II. Based on record review and interview with personnel, the laboratory failed to ensure continuous temperature monitoring of the blood bank refrigerator. Findings: 1. Review of the 2018 and 2019 circular temperature charts for the blood bank refrigerator revealed the laboratory did not have documentation of the temperature for the following dates: February 14, 2019 at approximately 7:00 pm through February 15, 2019 at 8:30 am March 21, 2019 at approximately 6:30 pm through March 22, 2019 at 8:00 am 2. In interview on August 23, 2019, Testing Personnel 1 confirmed the laboratory did not have documentation of the blood bank refrigerator temperatures for the identified dates. Testing Personnel 1 stated the refrigerators are monitored 24 hours, the alarm would sound if outside of acceptable temperature range.
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 observation, record review, and interview with personnel, the laboratory failed to perform method comparison testing for Chemistry and Coagulation testing at least twice a year. Findings: 1. Observation by surveyor during laboratory tour on August 19, 2019 revealed the laboratory utilizes the i-Stat 1 and Siemens Dimension EXL 200 analyzers for Troponin testing. 2. Further observation by surveyor during laboratory tour on August 19, 2019 revealed the laboratory utilizes the Sysmex CA-600 series and i-Stat 1 analyzers for Prothrombin Time/International Normalized Ratio (PT/INR) testing. 3. Review of laboratory records revealed the laboratory did not have documentation of comparison of troponin samples for the i-Stat 1 and Siemens Dimension EXL 200 analyzers for 2018 at least twice annually. 4. Further review of laboratory records revealed the laboratory did not have documentation of comparison of PT/INR samples for the i-Stat 1 and Sysmex CA-600 series analyzers 2018 at least twice annually. 5. In interview on August 23, 2019 at 3:23 pm, Testing Personnel 1 stated method comparisons were not performed for Troponin. Testing Personnel 1 confirmed the laboratory did not have documentation of a method comparison for PT/INR since method comparison in August 2018.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a)

Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

This STANDARD is not met as evidenced by:
*** Repeat deficiency from survey performed June 5, 2017 through June 9, 2017. ***
I. Based on observation, record review, and interview with personnel, the laboratory failed to follow their established quality control (QC) corrective action policy for Chemistry testing. Findings: 1. Observation by surveyor during laboratory tour on August 19, 2019 revealed the laboratory utilizes the Siemens Dimension EXL with LM and Siemens Dimension EXL 200 for Chemistry testing. 2. Review of the laboratory's test menu revealed the laboratory performs testing for the following analytes on the Dimension analyzers: Alanine aminotransferase (ALT), Albumin, Alkaline phosphatase (ALk Phos), Amylase, Ammonia, Aspartate aminotransferase (AST), Barbiturates, Benzodiazepine, Direct Bilirubin (Direct Bili), Total Bilirubin (Total Bili), Calcium, Cannabinoids, Carbamazepine (Carbamaz), Chloride, Cholesterol, Carbon dioxide (CO2), Cocaine, C-reactive protein (CRP), Creatinine kinase (CK), Creatinine kinase MB fraction (CKMB), Creatinine, Digoxin, Ethanol, Ferritin, Glucose, Glycosolated Hemoglobin (Hemoglobin A1c), Beta Human chorionic gonadotropin (HCG), HDL cholesterol, Iron, Total Iron binding capacity (TIBC), Lactic Acid, Lipase, Lithium, Magnesium, Methamphetamine/amphetamine, Opiates, Phencyclidine, Phenobarbital, Phenytoin, Phsophorus, Potassium, Prealbumin, Prostatic specific antigen (PSA), Total Protein, Salicylates, Sodium, Thyroid uptake (TU), Free T3, Theophylline, Thyroid stimulating hormone (TSH), Thyroxine (T4), Transferrin, Blood urea nitrogen (BUN), Uric acid, Valproic acid, NT-ProBNP, Troponin I, Vancomycin, Free Thyroxine (FT4), Urine Sodium, Urine Potassium, Urine Chloride, Urine Protein, and Urine Microalbumin. 3. Review of the laboratory's "Laboratory Quality Control Policy" revealed an "Action for Out of Range Controls" section which stated the following: a) "Do not analyze patient samples. Using 'QC Rule Definitions' section of this policy determines if QC run is rejected. Retain documentation of each and every QC value obtained and document all corrective action taken in Corrective Action Log." 4. Further review of the laboratory's "QC Rule Definitions" revealed the following: a) "1-2s-Indicates one control result has exceeded the established mean +/- 2SD. This is a 'warning rule ,' which does not indicate an "out of control" condition, but is intended to initiate further investigation. Corrective action: No corrective action is required." b) "1-3s-Indicates one control result has exceeded the established mean +/- 3SD range. This is 'rejection rule,' which is sensitive to random error. Corrective Action: Rerun the quality control level that is in question." c) " 2-2s_Indicates that two consecutive control results have exceeded the same mean +/- 2SD limit. This is a 'rejection rule' which is sensitive to systematic errors. Corrective action: to resolve systematic errors , corrective action should be conducted" d)" R-4s-Inidicates that one result has exceeded the mean +/- 2SD limit and the adjacent result has exceeded the mean +/-2SD limit. This is a 'rejection rule,' which is sensitive to random error. Corrective action: See Rule 1-3s" e) "4-1s-Inidcates four consecutive control results have exceeded the same mean +/- 1 SD limit. This is a 'rejection rule' only if the rule is broken in combination with a 1-2s rule fail. Corrective action: If QC result is within range, document this and accept the result." f) "10-x-Indicates ten consecutive control results have fallen on the same side of the mean. This is a 'rejection rule' only if the rule is broken in combination with a 1-2s rule fail. Corrective action: If QC result is within range, document this and accept the result." 5. Review of quality control records from February 2019 through August

2019 for annual test volumes less than 150 tests revealed unacceptable quality control results without documentation of corrective actions for the following analytes and dates: a) Salicylate: February 19, 2019: accepted QC level 3 36.600 L "Rules Failed: 1-2s and 4-1s" June 28, 2019: accepted QC level 1 8.500 "Rules Failed: R-4s"; QC level 3 37.000 "Rules Failed: R-4s" July 7, 2019: accepted QC level 1 8.900 H "Rules Failed: 1-2s and 4-1s" b) Lithium: May 23, 2019: accepted QC level 3 2.090 "Rules Failed: 1-2s and 2-2s" c) Ammonia: February 12, 2019: accepted QC level 1 81.4 "Rules Failed: R-4s" April 23, 2019: accepted QC level 3 506.0 "Rules Failed: R-4s" June 7, 2019: accepted QC level 1 108.7 H "Rules Failed: 1-2s and 4-1s" 6. Review of quality control records from September 2018 and July 2019 revealed the unacceptable quality control results without documentation of corrective actions for the following analytes and dates: a) Lipase: July 4, 2019: accepted QC level 3 593.0 "Rules Failed: R-4s" b) Potassium: July 15, 2019: accepted QC level 3 7.30 "Rules Failed: R-4s" c) Glucose: September 27, 2018: accepted QC level 3 344.00 L "Rules Failed: 1-2s and 2-2s" September 28, 2018: accepted QC level 3 344.00 L "Rules Failed: 1-2s, 2-2s, and 4-1s" d) Thyroid Stimulating Hormone (TSH): September 9, 2018: accepted QC level 1 0.7650 "Rules Failed: R-4s" e) Free T3: September 26, 2018: accepted QC level 1 1.8 "Rules Failed: R-4s" f) Urine Sodium: July 28, 2019: accepted QC level 1 77.0 "Rules Failed: R-4s", QC level 2 169.0 "Rules Failed: R-4s" 7. Review of patient records revealed the following patients were reported with unacceptable QC: a) Salicylate: February 19, 2019: Patient 19-050-5315 June 28, 2019: Patient 19-179-4351 July 7, 2019: Patient 19-188-0791 b) Lithium: May 23, 2019: Patient 19-143-1817 c) Ammonia: February 12, 2019: Patient 19-043-1507 April 23, 2019: Patient 19-113-0979 June 7, 2019: Patient 19-158-1196 d) Lipase: July 4, 2019: Patient 19-185-1461, Patient 19-185-1782, and Patient 19-185-2241 e) Potassium: July 15, 2019: Patient 19-196-0674, Patient 19-196-0683, Patient 19-196-0705,Patient 19-196-0752, and Patient 19-196-0944. A total of 959 patients were reported. f) Glucose: September 27, 2018: Patient 18-270-0127, Patient 18-270-0492, Patient 18-270-0494, Patient 18-270-0503, and Patient 18-270-0512. September 28, 2018: Patient 18-271-0535, Patient 18-271-0537, Patient 18-271-0540, Patient 18-271-0542, and Patient 18-271-0550 A total of 2,301 patients were reported. g)TSH: September 9, 2018: Patient 18-25-0456, Patient 18-252-0667, Patient 18-252-1572, and Patient 18-252-2015 h) Free T3: September 26, 2018: Patient 18-269-1056, Patient 18-269-1246, Patient 18-269-1391, Patient 18-269-1489, and Patient 18-269-1575 i) Urine Sodium: July 28, 2019: Patient 19-209-1020 8. In interview on August 21, 2019, Testing Personnel 1 stated the laboratory follows the "QC Rule Definitions" for QC acceptability. Testing Personnel 1 confirmed the laboratory did not perform corrective actions for the identified reported unacceptable quality control results. II. Based on observation, record review, and interview with personnel, the laboratory failed to follow their established quality control (QC) corrective action policy for Coagulation testing. Findings: 1. Observation by surveyor during laboratory tour on August 19, 2019 revealed the laboratory utilizes the Sysmex CA-600 series analyzer for Coagulation, to include D-dimer, Prothrombin Time/International Normalized Ration (PT/INR), and Partial Thromboplastin Time (PTT), testing. 2. Review of the laboratory's "Laboratory Quality Control Policy" revealed an "Action for Out of Range Controls" section which stated the following: a) "Do not analyze patient samples. Using 'QC Rule Definitions' section of this policy determines if QC run is rejected. Retain documentation of each and every QC value obtained and document all corrective action taken in Corrective Action Log." 3. Further review of the laboratory's "QC Rule Definitions" revealed the following: a) "1-2s-Indicates one control result has exceeded the established mean +/- 2SD. This is a 'warning rule ,' which does not indicate an "out of control" condition, but is intended to initiate further investigation. Corrective action: No corrective action is required." b) "1-3s-Indicates one control

	result has exceeded the established mean +/- 3SD range. This is 'rejection rule,' which is sensitive to random error. Corrective Actin: Rerun the quality control level that is in question." c) " 2-2s_Indicates that two consecutive control results have exceeded the same mean +/- 2SD limit. This is a 'rejection rule' which is sensitive to systematic errors. Corrective action: to resolve systematic errors , corrective action should be conducted" d)" R-4s-Inidicates that one result has exceeded the mean +/- 2SD limit and the adjacent result has exceeded the mean +/-2SD limit. This is a 'rejection rule,' which is sensitive to random error. Corrective action: See Rule 1-3s" e) "4-1s-Inidcates four consecutive control results have exceeded the same mean +/- 1 SD limit. This is a 'rejection rule' only if the rule is broken in combination with a 1-2s rule fail. Corrective action: If QC result is within range, document this and accept the result." f) "10-x-Indicates ten consecutive control results have fallen on the same side of the mean. This is a 'rejection rule' only if the rule is broken in combination with a 1-2s rule fail. Corrective action: If QC result is within range, document this and accept the result." 4. Review of quality control records for May 2018 and January 2019 revealed the following unacceptable quality control results reported without corrective action: D-dimer: January 25, 2019: reported QC level 1 0.40 "Rules Failed: R-4s" 5. Review of patient records revealed the following patient was reported with unacceptable QC: D-dimer: January 25, 2019: Patient 19-025-4309 6. In interview on August 21, 2019, Testing Personnel 1 stated the laboratory follows the "QC Rule Definitions" for QC acceptability. Testing Personnel 1 confirmed the laboratory did not perform corrective actions for the identified reported unacceptable quality control results.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. Review of the laboratory's "Quality Assessment Plan" revealed "Periodic ongoing review using Quality indicators will be performed addressing each phase of the work flow with documentation of ocollected data on qulaity indicator work sheets. The collected data will be evaluated monthly by the laboratory director. When problems or potential probalems are identified, corrective action plans will be implemented and follow up studies will be conducted to determine whetehr the problem has been solved." 2. Observation during laboratory tour and review of the laboratory's policy and procedure manual, quality control records, and patient test records revealed the laboratory's monitors did not identify the following issues: a) The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5403. b) The laboratory failed to ensure policies and procedures were updated to current practices. Refer to D5407. c) The laboratory failed to ensure patient samples for Ammonia were analyzed within thirty (30) minutes per manufacturer requirements. Refer to D5411. d) The laboratory failed to ensure reagents were not used beyond their expiration dates. Refer to D5417. e) The laboratory failed to have complete performance verification studies for Complete

	Blood Count (CBC) analyzers. Refer to D5421 I. f) The laboratory failed to have complete performance verification studies for blood gas testing on the i-Stat analyzer. Refer to D5421 II. g) The laboratory failed to have complete performance verification studies for Prothrombin Time/International Normalized Ratio (PT/INR) testing on the i-Stat analyzer. Refer to D5421 III. h) The laboratory failed to have complete performance verification studies for Coagulation testing on the Sysmex CA-660 series analyzer. Refer to D5421 IV. i) The laboratory failed to establish a reference (normal) range for Prothrombin Time and International Normalized Ration (PT/INR) testing prior to patient testing. Refer to D5421 V. j) The laboratory failed to ensure thermal probe check was performed and documented as required by the manufacturer. Refer to D5429. k) The laboratory failed to perform calibration verification procedures on the i-Stat utilized for blood gas testing at least every six (6) months. Refer to D5439. l) The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for blood gas testing. Refer to D5445 I. m) The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for Prothrombin Time/International Normalized Ratio (PT/INR) testing on the i-Stat analyzer. Refer to D5445 II. n) The laboratory failed to perform two (2) levels of controls prior to patient testing for Phenytoin. Refer to D5447. o) The laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for Complete Blood Count (CBC) testing. Refer to D5469. p) The laboratory failed to monitor circular refrigerator temperature charts for blood storage. Refer to D5555 I. q) The laboratory failed to ensure continuous temperature monitoring of the blood bank refrigerator. Refer to D5555 II. r) The laboratory failed to perform method comparison testing for Chemistry and Coagulation testing at least twice a year. Refer to D5775. s) The laboratory failed to follow their established quality control (QC) corrective action policy for Chemistry testing. Refer to D5779 I. t) The laboratory failed to follow their established quality control (QC) corrective action policy for Coagulation testing. Refer to D5779 II.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to include the location where testing was performed for blood gas and coagulation testing. Findings: 1. Review of random selection of final patient test reports for testing performed on the i-Stat (blood gas and coagulation) revealed two testing locations listed. 2. Further review of random selection of final patient test reports for coagulation testing, Prothrombin Time/International Normalized Ratio (PT/INR) and Partial Thromboplastin Time (PTT), performed on the Sysmex CA-600 series revealed the "Performing location" listed was incorrect. 3. In interview on August 19, 2019, Respiratory Testing Personnel 1 and Testing Personnel 1 confirmed patient final

	test reports for blood gas listed two testing locations. 4. In interview on August 23, 2019 at 10:24 am, Testing Personnel 1 stated per the IT department for the i-Stat one server is shared for the hospital wide system and the way the location is reported can not be changed. 5. Review of the laboratory's test menu revealed the laboratory performs 537 blood gas and 505 PT/INR tests on the i-Stat analyzer annually. The laboratory performs 2,005 PT/INR and 2,008 PTT tests annually on the Sysmex CA-600 series analyzer.
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 observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D6013. 2. The Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. Refer to D6014. 3. The Laboratory Director failed to ensure proficiency samples are satisfactory as required. Refer to D6016. 4. The Laboratory Director failed to ensure the laboratory followed the corrective action plan for unacceptable proficiency testing results. Refer to D6019. 5. The Laboratory Director failed to ensure the quality control program was maintained to assure quality laboratory services were provided. Refer to D6020. 6. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D6022. 7. The Laboratory Director failed to ensure that the laboratory performed required maintenance and calibration to ensure acceptable levels of analytical performance. Refer to D6023. 8. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D6024. 9. The Laboratory Director failed to ensure final reports for blood gas and coagulation tests included pertinent information. Refer to D6026. 10. The Laboratory Director failed to ensure the Laboratory Manager serving as Technical Consultant met educational requirements. Refer to D6029. 11. The Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency. Refer to D6030. 12. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

	This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Findings: 1. The laboratory failed to have complete performance verification studies for Complete Blood Count (CBC) analyzers. Refer to D5421 I. 2. The laboratory failed to have complete performance verification studies for blood gas testing on the i-Stat analyzer. Refer to D5421 II. 3. The laboratory failed to have complete performance verification studies for Prothrombin Time/International Normalized Ratio (PT/INR) testing on the i-Stat analyzer. Refer to D5421 III. 4. The laboratory failed to have complete performance verification studies for Coagulation testing on the Sysmex CA-660 series analyzer. Refer to D5421 IV. 5. The laboratory failed to establish a reference (normal) range for Prothrombin Time and International Normalized Ration (PT/INR) testing prior to patient testing. Refer to D5421 V.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. Findings: 1. The laboratory failed to include the specimen collection time for blood gas testing. Refer to D5305. 2. The laboratory failed to establish current and complete detailed written instructions for providers to maintain the integrity of samples. Refer to D5317. 3. The laboratory failed to ensure patient samples for Ammonia were analyzed within thirty (30) minutes per manufacturer requirements. Refer to D5411. 4. The laboratory failed to ensure reagents were not used beyond their expiration dates. Refer to D5417. 5. The laboratory failed to perform method comparison testing for Chemistry and Coagulation testing at least twice a year. Refer to D5775.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are satisfactory as required. Refer to D5217.

D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory followed the corrective action plan for unacceptable proficiency testing results. Refer to D5221.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the quality control program was maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for blood gas testing. Refer to D5445 I. 2. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for Prothrombin Time/International Normalized Ratio (PT/INR) testing on the i-Stat analyzer. Refer to D5445 II. 3. The laboratory failed to perform two (2) levels of controls prior to patient testing for Phenytoin. Refer to D5447. 4. The laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for Complete Blood Count (CBC) testing. Refer to D5469.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by:

	Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D5793.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance and calibration to ensure acceptable levels of analytical performance. Findings: 1. The laboratory failed to ensure thermal probe check was performed and documented as required by the manufacturer. Refer to D5429. 2. The laboratory failed to perform calibration verification procedures on the i-Stat utilized for blood gas testing at least every six (6) months. Refer to D5439.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5779 I and D5779 II.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure final reports for blood gas and coagulation tests included pertinent information. Refer to D5805.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the Laboratory Manager serving as Technical Consultant met educational requirements. Refer to D6035.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency. Findings: 1. The Technical Consultant failed to evaluate and document the performance of individuals at least semi-annually during the first year for nine (9) of twenty five (25) testing personnel reviewed. Refer to D6053. 2. The Technical Consultant failed to evaluate and document competency assessments annually for nine (9) of twenty five (25) testing personnel reviewed. Refer to D6054.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5407.
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 record review and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The laboratory failed to ensure one (1) of two (2) Technical Consultants met the educational qualifications for a Technical Consultant of moderate complexity testing. Refer to D6035. 2. The Technical Consultant failed to evaluate and document the performance of individuals at least semi-annually during the first year for nine (9) of twenty five (25) testing personnel reviewed. Refer to D6053. 3. Evaluation and documentation of annual competency assessments were not performed at St. Martin Hospital by a qualified and designated Technical Consultants for nine (9) of twenty five (25) testing personnel reviewed. Refer to D6054.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or

biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the laboratory failed to ensure one (1) of two (2) Technical Consultants met the educational qualifications for a Technical Consultant of moderate complexity testing. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) revealed the laboratory listed the Laboratory Director as the Technical Consultant. 2. Review of personnel and laboratory records revealed the Laboratory Manager (General Supervisor) performed Technical Consultant responsibilities. 3. In interview on August 19, 2019, the General Supervisor stated she took over as the Laboratory Manager in March 2019. The laboratory's previous Laboratory Manager left in September 2018 and served as Technical Consultant and General Supervisor. The General Supervisor stated she serves in a supervisory role; does not perform laboratory testing. 4. Review of personnel records for the current General Supervisor revealed the Laboratory Director performed a competency assessment for her duties dated April 10, 2019. 5. Further review of the "(Laboratory Manager) Competency Assessment" revealed the following responsibilities: "The Laboratory Manager serve as technical supervisor in general chemistry and hematology as well as general supervisor and intermittent testing person." a)"Verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including precision and accuracy of each test and test system b) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis, and reporting of test results c) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specification d) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly e) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed f) Evaluating the competency of all testing personnel in Laboratory and respiratory and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently" 6. Further review of the personnel records for the General Supervisor revealed she did not meet the minimum educational requirement of Bachelor's degree in a chemical, physical, or biological science or medical technology. 7. In interview on August 21, 2019 at 9:37 am, the General Supervisor stated she has a Bachelor of Arts degree (College of Liberal Arts: Sociology). 8. Review of the laboratory's test menu revealed the chemistry and hematology testing performed are moderate complexity. 9. Review of the laboratory's quality control and proficiency test records revealed the following Technical Consultant duties performed

	by the General Supervisor: a) General Supervisor signed attestation statement as the Lab Director designee for the 2019 Chemistry Core Verification 1st Event, 2019 Immunology/Immunology 2nd Event, 2019 Hematology/Coagulation 2nd Event b) General Supervisor adjusted Chemistry quality control when needed c) General Supervisor signed competency assessments for the following respiratory staff dated October 2018: Respiratory Testing Personnel 5, Respiratory Testing Personnel 6, and Respiratory Testing Personnel 8
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: *** Repeat deficiency from survey performed June 5, 2017 through June 9, 2017. *** Based on record review and interview with personnel, the Technical Consultant failed to evaluate and document the performance of individuals at least semi-annually during the first year for nine (9) of twenty five (25) testing personnel reviewed. Findings: 1. Review of personnel records revealed the laboratory utilizes a competency assessment form for laboratory personnel which includes the six (6) competency assessment criteria required by CLIA. 2. Review of the laboratory's "Employee Competency" policy revealed "Documenting the performance of individuals responsible for moderate complexity testing is initiated upon hire of new employee, at 6 months, and annually thereafter." 3. Review of personnel records for testing personnel revealed the laboratory did not have documentation of performance of a semi-annual competency assessment for the following personnel: Main Lab Testing Personnel 5: Hired July 23, 2018 Respiratory Testing Personnel 3: Hired October 2018 Respiratory Testing Personnel 7: Hired January 22, 2018 Respiratory Testing Personnel 11: Hired August 2017 Nursing Testing Personnel 1: Hired January 20, 2019 Nursing Testing Personnel 7: Hired January 9, 2019 Nursing Testing Personnel 21: Hired May 14, 2018 Nursing Testing Personnel 22: Hired February 19, 2018 4. In interview on August 20, 2019, Respiratory Testing Personnel 1 and the Director of Nursing confirmed the laboratory did not have documentation of a semi-annual competency assessment performed for the identified respiratory and nursing personnel. 5. In further interview on August 22, 2019 at 11:14 am, Testing Personnel 1 confirmed the laboratory did not have documentation of a semi-annual competency assessment for the identified main lab personnel.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: *** Repeat deficiency from survey performed June 5, 2017 through June 9, 2017. *** Based on record review and interview with personnel, evaluation and documentation of annual competency assessments were not performed at St. Martin Hospital by a

	qualified and designated Technical Consultant for nine (9) of twenty five (25) testing personnel reviewed. Findings: 1. In interview on August 19, 2019 at 2:38 pm, the Critical Care Nurse Manager stated she performs the competency assessments for the nursing staff performing laboratory testing. The Critical Care Nurse Manager further stated prior to her taking the position the Director of Nursing performed the competency assessments. 2. In interview on August 19, 2019 the current laboratory manager (General Supervisor) confirmed respiratory and nursing staff competency assessments are performed by the Critical Care Nurse Manager and Director of Nursing. 3. In interview on August 20, 2019 at 2:49 pm, the Director of Nursing stated he performed the respiratory department's staff competency assessment after the previous laboratory manager left. 4. Review of personnel records for laboratory, respiratory, and random selection of nursing staff that perform moderate complexity laboratory testing revealed the laboratory had documentation of annual competency assessments; however, they were not performed by the Technical Consultant and/or at St. Martin for the following personnel: Main Lab Testing Personnel 6: 2017 and 2018 assessments not performed by Technical Consultant, not performed at St. Martin location Respiratory Testing Personnel 2: 2017, 2018, and 2019 assessments not performed by Technical Consultant Respiratory Testing Personnel 4: 2017 and 2018 assessments not performed by Technical Consultant, not performed at St. Martin location. 2019 assessment not performed by Technical Consultant Respiratory Testing Personnel 5: 2017 and 2018 assessments not performed by Technical Consultant Respiratory Testing Personnel 6: 2017 and 2018 assessments not performed by Technical Consultant Respiratory Testing Personnel 9: 2019 assessment not performed by Technical Consultant Respiratory Testing Personnel 10: 2017 and 2018 assessments not performed by Technical Consultant, not performed at St. Martin location Respiratory Testing Personnel 11: 2018 assessments not performed by Technical Consultant , not performed at St. Martin location Respiratory Testing Personnel 12: 2017 and 2018 assessments not performed by Technical Consultant , not performed at St. Martin location 5. In interview on August 19, 2019 the current laboratory manager (General Supervisor) confirmed respiratory and nursing staff competency assessments are performed by the Critical Care Nurse Manager and Director of Nursing.
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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Review D5555 I and D5555II.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by:

	Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are satisfactory as required. Refer to D2163.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.