Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2014831	05/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cypress Pointe Surgical Hospital	42570 S Airport Road, Hammond, 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 Cypress Pointe Surgical Hospital - CLIA # 19D2014831 on May 7, 2018 through May 10, 2018. Cypress Pointe Surgical Hospital was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic Systems. 42 CFR 493.1403 CONDITION: Laboratory Director performing moderate complexity testing. 42 CFR 493.1409 CONDITION: Technical Consultant performing moderate complexity testing. 42 CFR 493.1441 CONDITION: Laboratory Director performing high complexity testing. 42 CFR 493.1459 CONDITION: General Supervisor performing high complexity testing.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to address competency for the Technical Consultant, Technical Supervisor, and General Supervisor were complete. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 3 and Personnel 4 serve as Technical Consultants. 2. Further review of the laboratory's CMS-209 (Laboratory Personnel Report) revealed Personnel 20 served as Technical Consultant, Technical Supervisor, and General Supervisor. 3. Review of the laboratory's policy manual revealed the laboratory did have a policy for competency assessement for the Technical Consultant, Technical Supervisor, and General Supervisor; However, the policy did not include the frequency the assessments are performed. 4. Review of the personnel records for Personnel 3, 4, and 20 revealed competency assessments for the duties of Technical Consultant, Technical Supervisor,

	and General Supervisor were performed. 5. In interview on May 8, 2018 at 8:22 am, Personnel 4 confirmed the laboratory policy did not include the frequency competency assessments are performed.
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 record review and interview with personnel, the laboratory failed to include the specimen collection time and specimen receipt time for Arterial Blood Gas and ACT testing. Findings: 1. Review of the laboratory's "Ordering, Collecting, Receiving Specimens in the LIS Policy" revealed under "Collecting - All samples collected must have the date and time of collection on both the sample and documented in CPSI; Be specific with this information" and under "Receiving - All samples received in the laboratory must have the date and time of receipt documented in CPSI; Be specific with this information." 2. Review of the manufacturer's instructions revealed the laboratory must test samples for Arterial Blood Gas testing within ten (10) minutes of collection and samples for ACT testing within thiry (30) minutes of collection. 3. Review of patient records for Arterial Blood Gas testing revealed the laboratory did not document the accurate collection time and receipt time into the laboratory for the following eighteen (18) of twenty (20) patients reviewed: a. Patient 1 - collected on November 18, 2017 at 03:19 am; no receipt time documented; result time of November 18, 2017 at 07:03 am (sample resulted 3 hours 34 minutes over time of collection) b. Patient 1 - collected on November 18, 2017 at 05:08 am; no receipt time documented; result time of November 18, 2017 at 07:07 am (sample resulted 1 hour 49 minutes over time of collection) c. Patient 1 - collected on November 18, 2017 at 07:00 am; no receipt time documented; result time of November 20, 2017 at 06:02 am (sample resulted 46 hours 52 minutes over time of collection) d. Patient 3 - collected on December 13, 2017 at 11:07 am; no receipt time documented; result time of December 14, 2017 at 08:32 am (sample resulted 22 hours 15 minutes over time of collection) e. Patient 3 - collected on December 13, 2017 at 11:13 am; no receipt time documented; result time of December 14, 2017 at 08:33 am (sample resulted 22 hours 10 minutes over time of collection) f. Patient 3 - collected on December 13, 2017 at 11:17 am; no receipt time documented; result time of December 14, 2017 at 08:35 am (sample resulted 22 hours 8 minutes over time of collection) g. Patient 4 - collected on December 14, 2017 at 15:16 pm; no receipt time documented; result time of December 14, 2017 at 15:30 pm (sample resulted 5 minutes over time of collection) h. Patient 5 - collected on January 17, 2018 at 11:03 am; no receipt time documented;

result time of January 18, 2018 at 07:44 am (sample resulted 20 hours 31 minutes over time of collection) i. Patient 6 - collected on January 21, 2018 at 04:30 am; no receipt time documented; result time of January 21, 2018 at 06:13 am (sample resulted 1 hour 33 minutes over time of collection) j. Patient 6 - collected on January 21, 2018 at 05: 39 am; no receipt time documented; result time of January 21, 2018 at 06:12 am (sample resulted 22 minutes over time of collection) k. Patient 6 - collected on January 21, 2018 at 08:33 am; no receipt time documented; result time of January 22, 2018 at 05:52 am (sample resulted 21 hours 9 minutes over time of collection) l. Patient 6 - collected on January 22, 2018 at 05:00 am; no receipt time documented; result time of January 22, 2018 at 05:50 am (sample resulted 40 minutes over time of collection) m. Patient 8 - collected on February 5, 2018 at 06:38 am; no receipt time documented; result time of February 5, 2018 at 06:51 am (sample resulted 3 minutes over time of collection) n. Patient 9 - collected on February 8, 2018 at 09:09 am; no receipt time documented; result time of February 8, 2018 at 17:53 pm (sample resulted 8 hours 34 minutes over time of collection) o. Patient 9 - collected on February 8, 2018 at 09:21 am; no receipt time documented; result time of February 8, 2018 at 11:23 am (sample resulted 1 hour 52 minutes over time of collection) p. Patient 9 - collected on February 8, 2018 at 09:39 am; no receipt time documented; result time of February 8, 2018 at 11:24 am (sample resulted 1 hour 35 minutes over time of collection) q. Patient 9 - collected on February 8, 2018 at 10:14 am; no receipt time documented; result time of February 8, 2018 at 11:26 am (sample resulted 1 hour 2 minutes over time of collection) r. Patient 9 - collected on February 8, 2018 at 11:00 am; no receipt time documented; result time of February 8, 2018 at 11:27 am (sample resulted 17 minutes over time of collection) 4. Review of patient records for ACT testing revealed the laboratory did not document the accurate collection time and receipt time into the laboratory for the following twenty five (25) of thirty (30) patients reviewed: a. Patient 11 - collected on December 14, 2017 at 09:31 am; no receipt time documented; result time of December 14, 2017 at 12:47 pm (sample resulted 2 hours 46 minutes over time of collection) b. Patient 11 - collected on December 14, 2017 at 10:45 am; no receipt time documented; result time of December 14, 2017 at 11:57 am (sample resulted 42 minutes over time of collection) c. Patient 12 - collected on December 14, 2017 at 11:12 am; no receipt time documented; result time of December 14, 2017 at 12:52 pm (sample resulted 1 hour 10 minutes over time of collection d. Patient 13 - collected on December 27, 2017 at 11:57 am; no receipt time documented; result time of December 28, 2017 at 09:18 am (sample resulted 20 hours 51 minutes over time of collection) e. Patient 13 - collected on December 27, 2017 at 13:25 pm; no receipt time documented; result time of December 27, 2017 at 14:28 pm (sample resulted 33 minutes over time of collection) f. Patient 14 - collected on December 13, 2017 at 09:17 am; no receipt time documented; result time of December 14, 2017 at 08:37 am (sample resulted 22 hours 50 minutes over time of collection) g. Patient 15 - collected on December 27, 2017 at 11:57 am; no receipt time documented; result time of December 28, 2017 at 09:19 am (sample resulted 20 hours 52 minutes over time of collection) h. Patient 16 - collected on December 28, 2017 at 11:30 am; no receipt time documented; result time of December 28, 2017 at 14:28 pm (sample resulted 2 hours 28 minutes over time of collection) i. Patient 18 - collected on January 26, 2018 at 09:05 am; no receipt time documented; result time of January 26, 2018 at 12:33 pm (sample resulted 2 hours 58 minutes over time of collection) j. Patient 19 - collected on January 18, 2018 at 13:10 pm; no receipt time documented; result time of January 18, 2018 at 15:46 pm (sample resulted 2 hours 6 minutes over time of collection) k. Patient 19 - collected on January 18, 2018 at 13:37 pm; no receipt time documented; result time of January 18, 2018 at 15:46 pm (sample resulted 1 hour 39 minutes over time of collection) l. Patient 20 - collected on February 8, 2018 at 11:08 am; no receipt time documented; result time of

	February 8, 2018 at 13:15 pm (sample resulted 1 hour 37 minutes over time of collection) m. Patient 20 - collected on February 8, 2018 at 11:44 am; no receipt time documented; result time of February 8, 2018 at 13:15 pm (sample resulted 1 hour 1 minute over time of collection) n. Patient 20 - collected on January 25, 2018 at 1215: pm; no receipt time documented; result time of January 25, 2018 at 16:05 pm (sample resulted 3 hours 20 minutes over time of collection) o. Patient 20 - collected on January 25, 2018 at 13:02 pm; no receipt time documented; result time of January 26, 2018 at 12:35 pm (sample resulted 23 hours 3 minutes over time of collection) p. Patient 21 - collected on February 7, 2018 at 13:56 am; no receipt time documented; result time of February 7, 2018 at 15:07 pm (sample resulted 41 minutes over time of collection) q. Patient 23 - collected on February 21, 2018 at 11:02 am; no receipt time documented; result time of February 21, 2018 at 11:41 am (sample resulted 9 minues over time of collection) r. Patient 24 - collected on February 20, 2018 at 10:21 am; no receipt time documented; result time of February 20, 2018 at 11:53 am (sample resulted 1 hour 2 minutes over time of collection) s. Patient 25 - collected on March 21, 2018 at 10:13 am; no receipt time documented; result time of March 21, 2018 at 11:13 am (sample resulted 30 minutes over time of collection) t. Patient 27 - collected on April 2, 2018 at 09:54 am; no receipt time documented; result time of April 2, 2018 at 12:20 pm (sample resulted 1 hour 56 minutes over time of collection) u. Patient 28 - collected on April 3, 2018 at 11:51 am; no receipt time documented; result time of April 3, 2018 at 16:24 pm (sample resulted 4 hours 3 minutes over time of collection) v. Patient 29 - collected on April 16, 2018 at 09:56 am; no receipt time documented; result time of April 16, 2018 at 12:45 pm (sample resulted 2 hours 19 minutes over time of collection) w. Patient 29 - collected on April 16, 2018 at 09:28 am; no receipt time documented; result time of April 16, 2018 at 12:45 pm (sample resulted 2 hours 47 minutes over time of collection) x. Patient 30 - collected on May 1, 2018 at 09:20 am; no receipt time documented; result time of May 1, 2018 at 10:03 am (sample resulted 13 minutes over time of collection) y. Patient 31 - collected on May 2, 2018 at 11:35 am; no receipt time documented; result time of May 2, 2018 at 13:30 pm (sample resulted 1 hour 25 minutes over time of collection) 5. In interview on May 8, 2018 at 1:07 pm, Personnel 4 stated the Arterial Blood Gas and ACT testing is performed by the nursing staff and the results are given to the lab to input the results into the LIS system. Personnel 4 further stated the iSTAT insturment tapes show the patient result times but the actual collection and receipt times are not always documented. Personnel 4 confirmed the laboratory did not document collection and receipt times for the above patients.
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 procedure manual contained complete policies and procedures. Refer to D5403. 2. The laboratory failed to perform a one hundred twenty

	(120) patient study for Prothrombin Time (PT) normal mean and to utilize acceptable patient donors per manufacturer requirements. Refer to D5411. 3. The laboratory failed to ensure supplies have not exceeded their expiration date. Refer to D5417. 4. The laboratory failed to have complete performance specification verification studies for the Sysmex Ca 620 instrument. Refer to D5421. 5. The laboratory failed to ensure quarterly maintenance for the Sysmex Ca 620 instrument was performed and documented. Refer to D5429 I. 6. The laboratory failed to ensure quarterly maintenance for the Blood Bank alarm checks was performed and documented as required by laboratory policy. Refer to D5429 II. 7. The laboratory failed to perform calibration as required by the manufacturer for the Horiba Pentra XL80 analyzer. Refer to D5437. 8. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC). Refer to D5445. 9. The laboratory failed to perform two (2) levels of Quality Control prior to patient testing. Refer to D5447. 10. The laboratory failed to perform a positive and negative control each day of patient testing for Serum Pregnancy for one (1) of fourteen (14) patients reviewed. Refer to D5449. 11. The laboratory failed to test control material in the same manner as patient testing for nine (9) of two hundred eleven (211) days reviewed. Refer to D5465. 12. The laboratory failed to perform and document visual inspections for each batch/shipment of MRSA Select culture medium. Refer to D5477. 13. The laboratory failed to take corrective action when Quality Control (QC) samples were unaccecptable for Coagulation testing. Refer to D5783. 14. The laboratory failed to follow established policies to monitor, assess, and correct quality issues in Analytic Systems. Refer to D5791.
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 procedure manual contained complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have written policies that included the following: a) Step-by-step performance of the procedure: to include the collection, receive and result times for Blood Gas and ACT testing. b) Quality Control (QC) Range Establishment: instructions for

	establishment of the laboratory's means and ranges for the Sysmex Ca-620 QC. c) Step-by-step performance of the procedure, including test calculations and interpretation of results, for manual check of International Normalized Ration (INR) calculation d) Corrective actions: to include addressing of flags on Hematology QC e) Proficiency Testing: instructions for the rotation of personnel performing testing. 2. In interview on April 9, 2018, Personnel 4 confirmed the current manual did not include the above policies.
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 perform a one hundred twenty (120) patient study for Prothrombin Time (PT) normal mean and to utilize acceptable patient donors per manufacturer requirements. Findings: 1. Observation by surveyor during laboratory tour on May 7, 2018 revealed the laboratory utilized the Sysmex Ca-620 analyzer for PT and International Normalized Ratio (INR) testing. 2. Review of the laboratory's "Normal Patient Mean PT Determination for INR Calculation Policy" revealed "When a new lot number of prothrombin reagent is introduced into the laboratory, a new normal patient mean will be determined for the correct INR calculation." 3. Further review of the laboratory's policy manual revealed under "Sample Collection and Processing" the following policy: *Minimum of 20 hematologically "normal" volunteer donors and draw one 3.2% sodium citrate tube from each *Donors must be from a healthy population (no known pathological condition) *Donors must not be taking any medications, including aspirin *A reasonable distribution of males and females should be selected *All samples should be processed within 4 hours of collection 4. Review of the coagulation instrument records revealed the laboratory changed platforms from the Beckman Coulter ACL 1000 coagulation analyzer to the Sysmex Ca 620 coagulation analyzer in February 2017. 5. Further review of the coagulation records revealed the laboratory did have a donor questionnaire form along with twenty (20) data points for the normal mean study; However, the laboratory did not have documentation of completed donor questionnaire forms used for the following lot number of Innovin in use: * Lot 539387 Exp 5/18/2019 6. In interview on May 7, 2018 at 3:40 pm, Personnel 5 stated she was unaware of a questionnaire for normal patient donors. Personnel 4 stated she found a blank questionnaire but was unable to find any completed donor forms. 7. In further interview on May 7, 2018 at 3:40 pm, Personnel 4 confirmed the laboratory did not perform a full one hundred twenty (120) patient mean study and did not use acceptable donors for the Mean PT studies performed. 8. Review of the laboratory's Task 1 and 3 form revealed the laboratory performs 1,659 PT/INR tests annually.
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: Based on observation and interview with personnel, the laboratory failed to ensure supplies have not exceeded their expiration date. Findings: 1. Observation by surveyor during laboratory tour on May 7, 2018 revealed the following expired items: * Phlebotomy area - in cabinet a) MiniCollect 1mL Lithium Heparin tubes - Lot 161116, Exp 05/04/18, Quantity 1 box (100 tubes) b) BD Vacutainer Trace Element K2 EDTA 10.8 mg - Lot 7067544, Exp 03/31/18, Quantity 1 tube c) BD Vacutainer Trace Element K2 EDTA 10.8 mg - Lot 7100550, Exp 04/30/2018, Quantity 1 tube * Phlebotomy area - in tray d) Vacuette Z Serum Clot Activator tubes 9mL - Lot B16083QM, Exp 02/15/2018, Quantity 31 tubes * Phlebotomy area - on top of cabinets e) BD Vacutainer SST tubes - Lot 7024613, Exp 01/31/2018, Quantity 300 tubes f) BD Vacutainer SST tubes - Lot 7061909, Exp 02/28/2018, Quantity 100 tubes *Phlebotomy area - in drawer by Phlebotomy chair g) MiniCollect 1ml Lithium Heparin - Lot 161116, Exp 05/04/2018, Quantity 20 tubes 2. In interview on May 7, 2018 at 01:41 pm, Personnel 24 stated she was unaware that some of the supplies were expired and that she was told not to use the SST tubes. Personnel 4 confirmed the above 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: Based on observation, record review and interview with personnel, the laboratory failed to have complete performance specification verification studies for the Sysmex Ca 620 instrument. Findings: 1. Observation by surveyor during laboratory tour on May 7, 2018 revealed the laboratory utilizes the Sysmex Ca 620 instrument for patient testing of Prothrombin Time (PT), International Normalized Ratio (INR), and Activated Partial Thromboplastin Time (APTT). 2. Review of the laboratory's records revealed the laboratory did have the following studies performed; However, the laboratory did not include the complete in-house data to support the studies: a) Method Comparison for accuracy b) Simple Precision c) Reference Range d) Reportable Range 3. Further review of the laboratory's records revealed that Complete Precision (day-to-day, run-to-run, and operator variance) was not included in the studies. 4. In interview on May 7, 2018, Personnel 5 stated the studies were performed by the previous supervisor and was not sure if any other data for the studies could be found. Personnel 4 confirmed the laboratory did not have the data to support the performance studies. 5. Review of the Task 1 & 3 list revealed the laboratory performs the following number of tests annually: a) PT/INR - 1,659 b) APTT - 1,404
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: I. Based on record review and interview with personnel, the laboratory failed to ensure quarterly maintenance for the Sysmex Ca 620 instrument was performed and documented. Findings: 1. Review of the Sysmex Ca 620 maintenance records revealed the laboratory was to perform and document quarterly maintenance for the following tasks: a) Perform LED Calibration b) Clean Filters 2. Further review of the Sysmex Ca 620 maintenance records revealed the laboratory did not document quarterly maintenance for the following date: * November 2017 3. In interview on May 8, 2018, Personnel 4 confirmed the dates above did not have quarterly maintenance documented for the Sysmex Ca 620 instrument. II. Based on record review and interview with personnel, the laboratory failed to ensure quarterly maintenance for the Blood Bank alarm checks was performed and documented as required by laboratory policy. Findings: 1. Review of the "Blood Bank Refrigerator Low/High Alarm Activation" policy revealed "To ensure that the alarm on the blood bank refrigerator is operating at high and low temperatures. This will be performed quarterly." 2. Further review of the "Blood Bank Refrigerator Low/High Alarm Activation" policy revealed the laboratory is to log the low and high alarm activation and check/log the reaction of the remote monitor during these test procedures. 3. Review of the Blood Bank circular alarm checks revealed the laboratory did not perform or document quarterly maintenance for the following date: * September 2017 4. Further review of the Blood Bank circular alarm checks revealed the laboratory did not document the alarm check temperatures in log as required by the laboratory policy. 5. In interview on May 9, 2018 at 10:55 am, Personnel 5 stated that Personnel 20 uses a Blood Bank Equipment check schedule for Quality Assurance and was not sure why the temperatures were not recorded in the log as required. 6. In further interview on May 9, 2018, Personnel 5 confirmed the laboratory did not perform and document maintenance as required.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for 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 as required by the manufacturer for the Horiba Pentra XL80 analyzer. Findings: 1. Observation by the surveyor during the laboratory tour on

	May 7, 2018 revealed the laboratory utilized the Horiba Pentra XL80 Hematology analyzer for the testing of Complete Blood Counts (CBC). 2. Review of the Horiba Pentra XL80 manual revealed that calibration procedures are to be performed every six months or any time a major component or maintenance is performed. 3. Review of the maintenance records revealed the laboratory performed a calibration on March 2, 2017; However, the laboratory did not perform another calibration until March 2018. 4. In interview on May 10, 2018 at 9:45 am, Personnel 5 stated the Horiba Field Service Representative usually performs a calibration along with the preventative maintenance check but was delayed. Personnel 5 further stated the field service representative told Personnel 20 that the laboratory staff could perform the calibration. 5. In further interview on May 10, 2018 at 9:45 am, Personnel 4 and 5 confirmed the Pentra XL80 six month calibration was not performed as needed.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on 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). Findings: 1. Observation by surveyors during the laboratory tour on May 7, 2018 revealed the laboratory utilized the following: a) Abbott i STAT for blood gas and ACT testing b) Biosite Triage Meter Pro for CKMB and Troponin testing 2. Review of the laboratory's IQCP documents revealed the laboratory did have a Risk Assessment, Quality Control Plan, and a Quality Assessment Plan; However, the laboratory did not include the in-house data to support the reduction in frequency of QC to monthly. 3. In interview on May 8, 2018 at 01:50 pm, Personnel 4 stated the laboratory did have a ten (10) day study, not thirty (30) for Blood Gas and Troponin testing. 4. In further interview on April 9, 2018 at 1: 50 pm, Personnel 4 confirmed the laboratory did not have the in-house data to support the reduction in frequency of QC. 5. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs the following tests annually: a) Blood Gas (includes pH, pCO2, & pO2) - forty three (43) b) ACT - thirty one (31) c) CKMB - twenty seven (27) d) Troponin - forty eight (48)
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 Quality Control prior to patient testing. Findings: 1. Observation by surveyors during laboratory tour on May 7, 2018 revealed the laboratory utilizes the Roche Cobas Integra 400 Plus analyzer for the following testing: *Cholesterol (CHOL), Triglycerides (TRIG), High Density Lipoprotein (HDL), Vancomycin (VANC), and Creatine Phosphokinase (CPK) 2. Review of the laboratory's Quality Control (QC) policy revealed "Routine assays are controlled every day of patient testing, using at least two levels of control. Infrequently used assays are controlled at the time the first test of the day is performed. Aday begins at 05:00 am and goes until 17:00 pm." 3. Review of QC and patient test records for CHOL, TRIG, and HDL from November 1, 2017 through May 7, 2018 revealed the laboratory did not perform two (2) levels of QC for the following: a) November 16, 2017: Patient 44 collected at 11:58 am then resulted 13:01 pm for Cholesterol, Triglycerides, and High Density Lipoprotein testing -- (QC for CHOL performed November 15, 2017 at 06:29 am then not again until November 17, 2017 at 06:19 am; QC for TRIG performed November 15, 2017 at 06:34 am then not again until November 17, 2017 at 06:24 am; QC for HDL performed November 15, 2017 at 06: 31 am then not again until November 17, 2017 at 06:21 am) 4. Review of QC and patient test records for VANC from November 1, 2017 through May 7, 2018 revealed the laboratory did not perform two (2) levels of QC prior to patient testing for nine (9) of twenty one (21) patients reviewed: a) Patient 35 -- resulted on November 15, 2017 at 06:42 am (QC resulted November 15,2017 at 07:27 after patient testing) b) Patient 45 -- resulted on March 3, 2018 at 07:40 am (QC resulted March 3, 2018 at 07:44 am after patient testing) c) Patient 46 -- resulted on February 17, 2018 at 07:19 am (QC resulted February 17, 2018 at 07:51 am after patient testing) d) Patient 46 -- resulted on February 18, 2018 at 06:32 am (QC resulted February 18, 2018 at 07:08 am after patient testing) e) Patient 46 -- resulted on February 19, 2018 at 06:49 am (QC resulted February 19, 2018 at 06:49 am after patient testing) f) Patient 47 -- resulted on January 12, 2018 at 08:11 am (QC resulted January 12, 2018 at 08:36 am after patient testing) g) Patient 48 -- resulted on December 28, 2017 at 01:20 am (QC resulted December 28, 2018 at 02:03 am after patient testing) h) Patient 49 -- resulted on March 10, 2018 at 07:16 am (QC resulted March 10, 2018 at 07:34 am after patient testing) i) Patient 50 -- resulted on January 4, 2018 at 20:34 pm (QC resulted January 4, 2018 at 21:45 pm after patient testing) 5. Review of QC and patient test records for CPK from November 1, 2017 through May 7, 2018 revealed the laboratory did not perform two (2) levels of QC prior to patient testing for one (1) of twenty one (21) patients reviewed: a) Patient 62 -- resulted on November 27, 2017 at 08:26 am (QC resulted November 27, 2017 at 08:36 am after patient testing) 5. In interview on May 9, 2018 at 12:05 pm, Personnel 5 confirmed the laboratory did not perform two (2) levels of QC proir to patient testing for the above patients. 6. Review of the Task 1 & 3 form revealed the laboratory performs the following number of tests annually: a) CHOL -- 180 b) TRIG -- 180 c) HDL -- 180 d) VANC -- 57 e) CPK -- 39
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to perform a positive and negative control each day of patient testing for Serum Pregnancy for one (1) of fourteen (14) patients reviewed. Findings: 1. Observation by surveyor during laboratory tour on May 7, 2018 revealed the laboratory utilized the Diagnostic Germaine Laboratories Aim Step Combo Pregnancy for Serum Pregnancy testing. 2. Review of the laboratory's policy and procedure manual revealed the laboratory is to perform a positive and negative control each day of patient testing for Serum Pregnancy testing. 3. Review of patient records for Serum Pregnancy testing from November 2017 through May 7, 2018 revealed the following one (1) of fouteen (14) patients were tested and reported without performing a positive and negative control: * On February 8, 2018 - Patient 32 4. In interview on May 8, 2018, Personnel 4 confirmed the laboratory did not document a positive and negative control for the patient cited above.
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(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--Test control materials in the same manner as patient specimens. (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 test control material in the same manner as patient testing for nine (9) of two hundred eleven (211) days reviewed. Findings: 1. Observation by surveyors during laboratory tour on May 7, 2018 revealed the laboratory utilized the Horiba Medical ABX Pentra XL 80 instrument for Complete Blood Count (CBC) testing. 2. Review of the Horiba Medical ABX Pentra XL 80 manual located on the instrument under "General Alarms" revealed the following conditions and actions to address: a) If WBC results are flagged with an "!" (BAS#, BAS%, LYM#, LYM%, MON#, MON%, EOS#, EOS%, NEU#, NEU%, ALY#, ALY%, LIC#, LIC% flagged with an "!") -- Rerun the sample or check it using a reference method. b) "*" on any parameter -- results are unreliable and must be reran if any flags are generated c) If a "*" appears on PLT count -- the PLT count must be rejected and confirmed by a manual count 3. Review of the laboratory's quality control records revealed Quality Control (QC) material did not fall within acceptable ranges on the following nine (9) days: a) June 21, 2017 -- BAS#, BAS%, LYM#, LYM%, MON#, MON%, EOS#, EOS%, NEU#, NEU% flagged with "!" b) July 4, 2017 -- PLT, MPV flagged with "*" c) July 5, 2017 -- WBC, NEU#, LYM#, MON#, EOS#, BAS# flagged with "*" d) August 3, 2017 -- BAS#, BAS%, LYM#, LYM%, MON#, MON%, EOS#, EOS%, NEU#, NEU% flagged with "!" e) November 13, 2017 -- BAS#, BAS%, LYM#, LYM%, MON#, MON%, EOS#, EOS%, NEU#, NEU% flagged with "!" f) January 14, 2018 -- BAS#, BAS%, LYM#, LYM%, MON#, MON%, EOS#, EOS%, NEU#, NEU% flagged with "!" g) January 15, 2018 -- BAS#, BAS%, LYM#, LYM%, MON#, MON%, EOS#, EOS%, NEU#, NEU% flagged with "!" h) February 9, 2018 -- BAS#, BAS%, LYM#, LYM%, MON#, MON%, EOS#, EOS%, NEU#, NEU% flagged with "!" i) April 21, 2018 -- BAS#, BAS%, LYM#, LYM%, MON#, MON%, EOS#, EOS%, NEU#, NEU% flagged with "!" 3. Review of patient records from June 2017 through April

	2018 revealed the laboratory resulted patients on the following nine (9) of two hundred eleven (211) days reviewed: a) June 21, 2017 -- Patients 113 - 138 b) July 4, 2017 -- Patients 91 - 92 c) July 5, 2017 -- Patients 92 - 112 d) August 3, 2017 -- Patients 141 - 146 e) November 13, 2017 -- Patients 147 - 152 f) January 14, 2018 -- Patients 66 - 67 g) January 15, 2018 -- Patients 68 - 81 h) February 9, 2018 -- Patients 82 - 88 i) April 21, 2018 -- Patients 63 - 65 4. In interview on May 10, 2018 at 9:15 am, Personnel 5 stated she spoke with a Horiba representative concerning the "!" and "*" flags and the representative stated that QC material should be treated the same as patient samples and should be rerun. 5. In further interview on May 10, 2018, Personnel 4 and 5 confirmed the laboratory did not test QC material in the same manner as patient samples.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to perform and document visual inspections for each batch/shipment of MRSA Select culture medium. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include quality control procedures for Microbiology media testing to include visual inspections. 2. Review of the laboratory's Quality Control records for Microbiology revealed the laboratory did document lot numbers and receive dates of each batch/shipment of MRSA Select culture medium; However, the laboratory did not include the visual inspections as required by the manufacturer for the following: a) Lot 64119600 with Exp 09/22/17 - two (2) boxes b) Lot 64121042 with Exp 10/07/17 - five (5) boxes c) Lot 64128091 with Exp 10/27/17 - seven (7) boxes d) Lot 64130923 with Exp 11/10/17 - seven (7) boxes e) Lot 64137225 with Exp 12/12/17 - seven (7) boxes f) Lot 64146836 with Exp 01/19/18 - seven (7) boxes g) Lot 64154997 with Exp 02/23/18 - seven (7) boxes h) Lot 64160189 with Exp 03/25/18 - seven (7) boxes i) Lot 64166266 with Exp 04/13/18 - seven (7) boxes j) Lot 61476301 with Exp 05/25/18 - seven (7) boxes k) Lot 64182474 with Exp 06/23/18 - seven (7) boxes 3. Interview on May 9, 2018 at 2:15 pm, Personnel 7 stated she was unaware of procedures needed for Microbiology media testing. Personnel 7 confirmed the laboratory did not document the visual inspections for culture medium. 7. Review of the Task 1 & 3 submitted to surveyors revealed the laboratory performs one thousand two hundred fifty six (1256) MRSA tests annually.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test

	results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to take corrective action when Quality Control (QC) samples were unaccecptable for Coagulation testing. Findings: 1. Observation by surveyor during the laboratory tour on May 7, 2018 revealed the laboratory utilizes the Sysmex Ca 620 analyzer for Prothrombin Time (PT), International Normalized Ratio (INR), and Activated Partial Thromboplastin Time (APTT) testing. 2. Review of the laboratory's Control policy revealed "When QC results do not meet criteria, do not report patient results." 3. Review of the laboratory's April 2018 QC records revealed the laboratory did not take corrective action when QC was not within acceptable range for the following three (3) days: a) April 10, 2018 at 14:24: Citrol Level 3 for PT reported as 50.9 secs (acceptable range 42.6 - 50.6 secs) -- exclude results under comment b) April 30, 2018 at 15:30: Citrol Level 3 for PT reported as 50.9 secs (acceptable range 42.6 - 50.6 secs) -- exclude results under comment c) April 26, 2018 at 14:40: Citrol Level 3 for APTT reported as 60.0 secs (acceptable range 57.9 - 62.7) -- exclude results under comment 4. Review of patient test reports revealed the following six (6) patients were reported for PT and PTT without corrective action: April 10, 2018 at 14: 51: Patient 156 for PT April 26, 2018 at 15:39: Patient 159 for PTT April 26, 2018 at 16:00: Patient 160 for PTT April 26, 2018 at 18:55: Patient 161 for PTT April 30, 2018 at 15:59: Patient 162 for PT April 30, 2018 at 15:59: Patient 163 for PT 5. In interview on May 8, 2018 at 3:15 pm, Personnel 7 stated she was unsure why QC was not repeated or why the exclude results was not addressed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (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 failed to follow established policies to monitor, assess, and correct quality issues in Analytic Systems. Findings: 1. The laboratory failed to ensure the procedure manual contained complete policies and procedures. Refer to D5403. 2. The laboratory failed to perform a one hundred twenty (120) patient study for Prothrombin Time (PT) normal mean and to utilize acceptable patient donors per manufacturer requirements. Refer to D5411. 3. The laboratory failed to ensure supplies have not exceeded their expiration date. Refer to D5417. 4. The laboratory failed to have complete performance specification verification studies for the Sysmex Ca 620 instrument. Refer to D5421. 5. The laboratory failed to ensure quarterly maintenance for the Sysmex Ca 620 instrument was performed and documented. Refer to D5429 I. 6. The laboratory failed to ensure quarterly maintenance for the Blood Bank alarm checks was performed and documented as required by laboratory policy. Refer to D5429 II. 7. The laboratory failed to perform calibration as required by the manufacturer for the

	Horiba Pentra XL80 analyzer. Refer to D5437. 8. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC). Refer to D5445. 9. The laboratory failed to perform two (2) levels of Quality Control prior to patient testing. Refer to D5447. 10. The laboratory failed to perform a positive and negative control each day of patient testing for Serum Pregnancy for one (1) of fourteen (14) patients reviewed. Refer to D5449. 11. The laboratory failed to test control material in the same manner as patient testing for nine (9) of two hundred eleven (211) days reviewed. Refer to D5465. 12. The laboratory failed to perform and document visual inspections for each batch/shipment of MRSA Select culture medium. Refer to D5477. 13. The laboratory failed to take corrective action when Quality Control (QC) samples were unaccecptable for Coagulation testing. Refer to D5783.
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 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 laboratory personnel performed testing as required. Refer to D6014. 3. The Laboratory Director failed to ensure that the quality control was maintained to assure quality laboratory services were provided. Refer to D6020. 4. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D6021. 5. The Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D6023. 6. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D6024. 7. The Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D5209. 8. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. 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 laboratory personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory failed to include the specimen collection time and specimen receipt time for Arterial Blood Gas and ACT testing. Refer to D5305. 2. The laboratory failed to perform a one hundred twenty (120) patient study for Prothrombin Time (PT) normal mean and to utilize acceptable patient donors per manufacturer requirements. Refer to D5411. 3. The laboratory failed to ensure supplies have not exceeded their expiration date. Refer to D5417.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the quality control 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). Refer to D5445. 2. The laboratory failed to perform two (2) levels of Quality Control prior to patient testing. Refer to D5447. 3. The laboratory failed to perform a positive and negative control each day of patient testing for Serum Pregnancy for one (1) of fourteen (14) patients reviewed. Refer to D5449. 4. The laboratory failed to test control material in the same manner as patient testing for nine (9) of two hundred eleven (211) days reviewed. Refer to D5465. 5. The laboratory failed to perform and document visual inspections for each batch/shipment of MRSA Select culture medium. Refer to D5477.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D5791.
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 record review and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Findings: 1. The laboratory failed to ensure quarterly maintenance for the Sysmex Ca 620 instrument was performed and documented. Refer to D5429 I. 2. The laboratory failed to perform calibration as required by the manufacturer for the Horiba Pentra XL80 analyzer. Refer to D5437.
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 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 D5783.
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 established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D5209.
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 responsible for any aspect of the testing process. Refer to D5403.
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 Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D6036. 2. The Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D6040. 3. The Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D6042. 4. The Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D6044.

D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to include the specimen collection time and specimen receipt time for Arterial Blood Gas and ACT testing. Refer to D5305. 2. The laboratory failed to ensure the procedure manual contained complete policies and procedures. Refer to D5403. 3. The laboratory failed to perform a one hundred twenty (120) patient study for Prothrombin Time (PT) normal mean and to utilize acceptable patient donors per manufacturer requirements. Refer to D5411. 4. The laboratory failed to ensure supplies have not exceeded their expiration date. Refer to D5417. 5. The laboratory failed to ensure quarterly maintenance for the Sysmex Ca 620 instrument was performed and documented. Refer to D5429 I. 6. The laboratory failed to perform calibration as required by the manufacturer for the Horiba Pentra XL80 analyzer. Refer to D5437.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC). Refer to D5445. 2. The laboratory failed to perform two (2) levels of Quality Control prior to patient testing. Refer to D5447. 3. The laboratory failed to perform a positive and negative control each day of patient testing for Serum

	Pregnancy for one (1) of fourteen (14) patients reviewed. Refer to D5449. 4. The laboratory failed to test control material in the same manner as patient testing for nine (9) of two hundred eleven (211) days reviewed. Refer to D5465. 5. The laboratory failed to perform and document visual inspections for each batch/shipment of MRSA Select culture medium. Refer to D5477.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5783.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction to the laboratory. Refer to D6095.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must 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 record review and interview with personnel, the Laboratory Director failed to ensure documentation of maintenance procedures as required. Refer to D5429 II.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the

	General Supervisor failed to provide day to day supervision or oversight to ensure accurate and reliable patient test results. Refer to D6144.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel the General Supervisor failed to provide day-to-day supervision to testing personnel to ensure accurate and reliable test performance of laboratory testing. Findings: 1. Observation by surveyors during laboratory tour on May 7, 2018 revealed the laboratory did not have a General Supervisor on site to oversee the day-to-day supervision of testing personnel. 2. Review of the laboratory's CMS 209 (Laboratory Personnel Report) revealed Personnel 20 served as the Technical Consultant and General Supervisor. 3. In interview on May 8, 2018 at 8:12 am, Personnel 5 and 7 stated that Personnel 20 was no longer employed as of April 26, 2018 and that Pathology Group of Louisiana (PGL) was helping until another General Supervisor could be employed. 4. In further interview on May 8, 2018 at 9:10 am, Personnel 4 stated she and Personnel 3 were employees of PGL and were taking over the duties of Technical Consultant and General Supervisor. 5. In interview on May 8, 2018, Personnel 4 confirmed that there was not a General Supervisor on site for supervision of testing personnel.