Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1020001	03/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Our Lady Of Lourdes Heart Hospital	1105 Kaliste Saloom Road, Lafayette, 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 VALIDATION Survey was performed at Heart Hospital of Lafayette-CLIA # 19D1020001 on March 5, 2018 through March 9, 2018. Heart Hospital of Lafayette was found not in compliance with the following CONDITION LEVEL DEFICIENCIES which constitute an IMMEDIATE JEOPARDY to the patients serviced by the laboratory: 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 performing moderate complexity testing; Technical Consultant 42 CFR 493.1421 CONDITION: Laboratories performing moderate complexity testing; Testing personnel 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing; Laboratory Director 42 CFR 493.1447 CONDITION: Laboratories performing high complexity testing; Technical Supervisor 42 CFR 493.1459 CONDITION: Laboratories performing high complexity testing; General Supervisor
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 patient samples for Lactic Acid testing are received and separated within 15 minutes according to the manufacturer for twenty four (24) of one hundred thirty two (132) patients reviewed. Refer to D5411 I. 2. The laboratory failed

	to ensure patient samples for Total Iron Binding Capacity (IBCT) testing are separated within 2 hours according to the manufacturer for four (4) of fifty five (55)patients reviewed. Refer to D5411 II. 3. The laboratory failed to ensure that patient inoculated plates for Methicillin Resistant Staphylococcus Aureus (MRSA) Select testing are read within 28 hours according to the manufacturer for five (5) of eight (8) patients reviewed. Refer to D5411 III. 4. The laboratory failed to ensure that patient sample volumes collected in the BacT/ALERT FA and BacT/ALERT SN Culture Bottles meet the manufacturer's recommendation of ten (10) mL for six (6) of seven (7) patients reviewed. Refer to D5411 IV. 5. The laboratory failed to ensure blood collection tubes, transport swabs/media, reagents, solutions, and supplies have not exceeded their expiration date. Refer to D5417 I. 6. The laboratory failed to ensure the Ortho Confidence Blood Bank Controls have not exceeded their expiration dates. Refer to D5417 II. 7. The laboratory failed to ensure the Thermoscientific Shandon Crytome Electronic Cryostat was cleaned each day of use as required by laboratory policy. Refer to D5429. 8. The laboratory failed to include in house quality control (QC) data and pertinent literature to support the reduction of frequency of QC in their Individualized Quality Control
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: I. Based on observation, record review and interview with personnel, the laboratory failed to ensure patient samples for Lactic Acid testing are received and separated within 15 minutes according to the manufacturer for twenty four (24) of one hundred thirty two (132) patients reviewed. Findings: 1. Observation by the surveyors on March 5, 2018 revealed the laboratory was performing Lactic Acid testing on the Siemens Dimension EXL with LM Chemistry Analyzer. 2. Review of the Siemens Dimension Lactic Acid package insert revealed "Collection of a satisfactory specimen for lactate analysis requires special procedures to prevent changes in lactate while and after the specimen is drawn. Blood is best collected without stasis in a container of sodium fluoride/potassium oxalate, followed by immediate chilling of the specimen and separation of the cells within 15 minutes. Keep sample on ice and analyze promptly." 3. Review of a random selection of patient records for Lactic Acid from October 1, 2017 through March 8, 2018 revealed the laboratory did not receive the following patients within 15 minutes in order to separate as required by the manufacturer: On October 4, 2017 Patient 179 was collected at 13:05 pm and received at 13:37 pm -- 17 minutes over the manufacturer's instructions of 15 minutes On October 21, 2017 Patient 178 was collected at 07:30 am and received at 07:50 am -- 5 minutes over the manufacturer's instructions of 15 minutes On November 10, 2017 Patient 159 was collected at 04:06 am and received at 04:28 am -- 7 minutes over the manufacturer's instructions of 15 minutes On November 25, 2017 Patient 177 was collected at 20:08 pm and received at 20:25 pm -- 2 minutes over the manufacturer's instructions of 15 minutes On November 27, 2017 Patient 176
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: I. Based on observation and interview with personnel, the laboratory failed to ensure blood collection tubes, transport swabs/media, reagents, solutions, and supplies have not exceeded their expiration date. Findings: 1. Observation by surveyors during the laboratory tour on March 5, 2018 revealed the following expired items: a) 50% Acetic Acid - one (1) 25ml bottle Lot # 4606E50 Exp 09/09/2017 b) Greiner Bio-One Vacuette 6ml K3E K3EDTA Blood Collection Tubes Lot # B160839G Exp 02/07 /2018 Forty-three (43) tubes c) Copan Transystem Sterile Transport Swab - L0 Stuart Lot # 010H43 L1 H8GQ00 Exp 01/2018 Eight (8) swabs d) Bayer Clinitest Tablet Lot # XB5020C Exp 02/2018 Thirty (30) tablets e) Copan Classic Swabs *Lot 819551 Exp 03/2016 Twenty-three (23) swabs *Lot 818044 Exp 06/2015 Eighteen (18) swabs *Lot 816639 Exp 11/2014 Five (5) swabs f) Zoster Vaccine Live Lot M030139 Exp 8 /18/2017 Six (6) 965ml vials g) Remel Microtest M5 Transport Media (Tube) Lot 917302 Exp 02/20/2018 Six (6) tubes h) Siemens Quiklyte Dilution Check Lot 7CD719 Exp 03/01/2018 Two (2) bottles 2. Interview with Personnel 2 and 3 on March 5, 2018 confirmed the above items were expired and in place for patient testing. II. Based on observation, record review and interview with personnel, the laboratory failed to ensure the Ortho Confidence Blood Bank Controls have not exceeded their expiration dates. Findings: 1. Observation by surveyors during laboratory tour revealed the laboratory utilized the Ortho Confidence Controls to incl
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 observation, record review and interview with personnel, the laboratory failed to ensure the Thermoscientific Shandon Crytome Electronic Cryostat was cleaned each day of use as required by laboratory policy. Findings: 1. Observation by the surveyors during tour on March 8, 2018 revealed the laboratory utilized the Thermoscientific Shandon Crytome Electronic Cryostat for Histology testing. 2. Review of the laboratory's "Frozen Section Room/Cryostat Maintenance/Supply Checklist" log indicated the Cryostat was to be cleaned as needed. 3. In Interview on March 8, 2018 at 830am, Personnel 45 stated maintenance on the cryostat is done each day that frozen sections are performed on patients. 4. Review of the laboratory's maintenance log and patient records revealed the following four (4) of five (5) days with no documentation of maintenance performed: On February 26, 2016 - Patient 147 On April 20, 2016 - Patient 151 On July 1, 2016 - Patient 148 On February 23, 2018 - Patient 149 5. Interview with Personnel 45 on March 8, 2018 confirmed the laboratory did not perform maintenance on the above days of patient testing.
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 record review and interview with personnel, the laboratory failed to include in house quality control (QC) data and pertinent literature to support the reduction of frequency of QC in their Individualized Quality Control Plan (IQCP). Findings: 1. Review of the laboratory's policy and procedures revealed the laboratory utilized IQCP to reduce the frequency of quality control for the following: a) D-dimer b) O2 Sat c) ACT d) Platelet Function Activity (PFA) 2. Further review of the laboratory's IQCP documents revealed the laboratory did perform a Risk Assessment; However the laboratory did not include the in-house QC data and pertinent literature to support the reduction of performing QC to that of the manufacturer. 3. In interview on March 6, 2018, Personnel 2 and 3 confirmed the laboratory did not include the in house data and literature supporting the quality control reduction in the Individualized Quality Control Plans. 4. Review of the laboratory's Task 1 & 3 forms revealed the laboratory performs the following test volumes annually: a) D-dimer - two hundred forty four (244) b) O2 Sat - five hundred thirty four (534) c) ACT - one thousand (1000) d) PFA - six hundred thirty (630)
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 external positive and negative controls for Rapid Strep A and Bactistaph for each day of patient testing. Findings: 1. Observation by surveyors during laboratory tour on March 5, 2018 revealed the laboratory utilizes the following test kits for patient testing: a) Quidel Quick Vue Strep A test kit for Rapid Strep A b) Remel Bactistaph test kit for Staphylococcus Aureus 2. Review of the laboratory's Quality Control records for Rapid Strep A revealed the following patients without external positive and negative controls documented for three (3) of thirty six (36) days reviewed: a) Patient 24 - January 5, 2017 b) Patient 31 - March 5, 2017 c) Patient 34 & 35 - April 4, 2017 3. Review of the laboratory's Quality Control records for Bactistaph revealed the following patients without external positive and negative controls documented for seven (7) of eight (8) days reviewed: a) Patient 10 - July 26, 2017 b) Patient 11 - July 5, 2017 c) Patient 12 - May 19, 2017 d) Patient 13 - March 2, 2017 e) Patient 14 - January 4, 2017 f) Patient 15 - November 19, 2016 g) Patient 16 -

	October 22, 2016 4. In interview on March 8, 2018 at 09:40 am, Personnel 3 stated the laboratory performs the Staph Latex QC with each new lot/shipment. 5. In further interview on March 8, 2018, Personnel 3 confirmed the laboratory did not perform controls for the above patients. 6. Review of the Task 1 & 3 form submitted by the laboratory to surveyors on March 5, 2018 revealed the following number of tests performed annually: %Rapid Strep A - forty (40) %Bactistaph - twenty seven (27)
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: I. Based on record review and interview with personnel, the laboratory failed to estalish their own means and ranges for two (2) of two (2) types of Quality Control materials. Findings: 1. Review of the Task 1 and 3 Form submitted to surveyors on March 5, 2018 revealed the quality control material being used for each analyte being tested as follows: a) Abbott Cell-Dyn 26 Plus Control: White Blood Cell count (WBC), Red Blood Cell count (RBC), Hemoglobin (Hgb), Hematocrit (Hct), Platelet count (Plt), and Auto Differential. b) Bio-Rad Liquichek D-dimer Control: D-dimer 2. Review of Quality Control package inserts revealed the following: a) Abbott Cell-Dyn 26 Plus Control: under "Performance Characteristics; The assigned values are presented as a mean and a recovery range. The mean assay values are derived from repetitive testing on several instruments operated and maintained according to the manufacturer's instructions; the do not necessarily apply to a single instrument. The recovery ranges are intended to reflect inter-laboratory and inter-instrument variability; thus, they are wider than the +/-2 SD QC range for one instrument." b) Bio-Rad Liquichek D-dimer Control: under "Assignment of Values; The mean values provided in the Assignment of Values Data Charts were derived from replicate analyses and are specific for each lot of product. Individual laboratory means should fall within the corresponding acceptable range; however, laboratory means may vary from the listed values during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications. It is recommended that each laboratory establish its own means and acceptable ranges and use those provided
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, sterility checks, and ability to support growth for each batch/shipment of MRSA Select culture medium, BacT/ALERT FA blood culture bottles, and BacT/ALERT SN blood culture bottles. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include quality control procedures for Microbiology media testing, that includes the following: a) Visual inspection b) Ability to support growth, select or inhibit specific organisms or produce biochemical response c) Sterility checks 2. Review of the laboratory's Quality Control records for Microbiology revealed the laboratory did not document lot numbers and receive dates of each batch/shipment of BacT/ALERT FA and BacT/ALERT SN blood culture bottles. 3. Further review of the laboratory's Quality Control records for Microbiology revealed the laboratory did not document quality control procedures for the following two (2) of ten (10) lot numbers of MRSA Select culture medium: a) Lot 64157496 b) Lot 7C3064 4. Review of a random selection of patient records for Blood Culture testing revealed the following seven (7) patients collected with no documentation of quality control procedures from March 6, 2017 through March 6, 2018: % Patients 17 - 23 5. Review of patient records for MRSA Select testing revealed the following patients performed on culture medium without documentation of quality control procedures: a) Lot 64157496 Patient 343 - February 25, 2018 Patient 344 - February 26, 2018 Patient 345 - March 2, 2018 b) Lot 7C3064 Patients 346 - 350 - March 29, 2017 6. Interview on March 8, 2018, Personnel 3 stated
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the laboratory failed to document the Quality Control (QC) for ABO, Rh, Antibody Screen (AbScr), and Compatibility (Xmatch) testing prior to patient testing for nine (9) of thirty five (35) days reviewed. Findings: 1. Observation during the laboratory tour on March 5, 2018 revealed the laboratory utilized the Ortho Clinical Diagnostic Gel System for Blood Bank testing. 2. Review of the laboratory's Blood Bank

	Procedure manual under "Quality Control" revealed "To recognize reagent deterioration and to confirm the specificity and reactivity, it is recommended that each lot be tested on each day of use with known antigen positive and antigen negative red cells". 3. In interview on March 6, 2018 at 2:27 pm, Personnel 9 stated that QC is performed after midnight (12:00 am) every night and is good for twenty four (24) hours. 4. Review of the Blood Bank QC and patient records from November 27, 2016 through March 5, 2018 revealed the laboratory did not perform and document daily QC prior to patient testing for the following dates: a. December 1, 2016 and December 2, 2016 - no ABO/Rh QC documented (QC documented on November 30, 2016 at 00:25 am and then not again until December 3, 2016 at 00:15 am) *Patient 329 - testing performed/resulted December 1, 2016 at 9:49 am *Patient 330 - testing performed/resulted December 1, 2016 at 8:14 am *Patient 331 - testing performed /resulted December 1, 2016 at 8:03 am *Patient 332 - testing performed/resulted December 1, 2016 at 14:32 pm *Patient 333 - testing performed/resulted December 1, 2016 at 11:53 am *Patient 334 - testing performed/resulted December 2, 2016 at 09: 01 am *Patient 335 - testing performed
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: Based on observation, record review and interview with personnel, the laboratory failed to assure the quarterly blood bank alarm checks recorded on the circular temperature charts. Findings: 1. Observation by surveyor during laboratory tour on March 5, 2018 revealed the laboratory utilized a ThermoForma Blood Bank refrigerator and a Helmer Scientific Platelet rotator/incubator. 2. Review of the Blood Bank's Policy and Procedure Manual revealed quarterly alarm checks were to be performed on blood bank refrigerator and platelet rotator/incubator. 3. Review of the Blood Bank's Circular Temperature Charts for 2016 and 2017 revealed the following: a. ThermoForma Blood Bank refrigerator * December 15, 2017: circular chart did not reflect a clear and defined mark to show alarm check was performed b. Helmer Scientific Platelet rotator/incubator 2017: March 27, 2017, June 12, 2017, September 21, 2017, and December 15, 2017 circular chart did not reflect a clear and defined mark to show alarm check was performed 4. In interview on March 7, 2018 at 11:09 am, Personnel 3 stated the hospital Biomed team performs the quarterly alarm checks. Personnel 3 confirmed the documentation provided by Biomed does include the date alarm checks were performed and the upper and lower temperatures but that the circular charts does reflect the temperatures documented .
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in

	facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to notify the patient's physician and the pathologist immediately upon identification of incompatible blood issued as emergency release as required by the laboratory's procedure. Findings: 1. Surveyor review of Emergency Transfusion Release Form for Patient 351 on March 8, 2018 at 1:56 pm revealed the following: a) A request for one (1) unit of O negative blood for Emergency Transfusion was received October 20, 2017 at 21:53 pm for Patient 351. b) Patient 351 was issued one (1) unit of O negative Leukoreduced Red Blood Cells (RBC) on October 20, 2017 at 22:02 pm. Unit W042016031565 (1st container) c) A request of additional two (2) units of O negative blood for Emergency Transfusion was received October 21, 2017 at 01:18 am for Patient 351. d) Patient 351 was issued two (2) units of O negative Leukoreduced Red Blood Cells (RBC) October 21, 2017 at 01:41 am. Units W042016031565 (2nd Container) and W042016031581 e) A final request of additional one (1) unit of O negative blood for Emergency Transfusion was received October 21, 2017 at 09:20 am for Patient 351. f) Patient 351 was issued one (1) unit of O negative Red Blood Cells (RBC) October 21, 2017 at 09:20 am. Unit W042016029859 2. Review of the Emergency Release of Blood Products form under "Procedure" revealed "After a specimen has arrived in the Blood Bank, a Technologist will complete compatibility testing as quickly as possible. If the Patient has an antibody or if the Patient has to be given products of a different Rh other than their blood type the Pathologist must be notified. If incompatibility is detected at any stage of testing, the blood bank technologist will immediately notify the patient's physici
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to perform corrective actions when the cuvette temperature failed to be within acceptable range as required by the manufacturer for the Siemens Dimension EXL with LM Chemistry analyzer. Findings: 1. Observation by surveyors during laboratory tour on March 5, 2018 revealed the laboratory utilized the Siemens Dimension EXL

	with LM analyzer for chemisty testing. 2. Review of the Siemens Dimension EXL with LM analyzer maintenance logs revealed the acceptable cuvette temperature range as 36.8 to 37.2 degrees Celsius. 3. Further review of the maintenance logs revealed the laboratory did not take corrective action when the cuvette temperature was out of range for the following five (5) of twelve (12) months reviewed: a. April 20, 2017 through April 29, 2017 -- temperature recorded as 37.3 degrees celsius for one hundred sixty seven (167) patients resulted b. August 22, 2017 -- temperature recorded as 37.3 degrees celsius for forty three (43) patients resulted c. September 27, 2017 through September 30, 2017 -- temperature recorded as 37.3 degrees celsius for one hundred ninety eight (198) patients resulted d. October 2, 2017 -- temperature recorded as 37.3 degrees celsius for fifty nine (59) patients resulted e. October 23, 2017 through October 27, 2017 -- temperature recorded as 37.3 degrees celsius for two hundred seventy six (276) patients resuted f. November 2, 2017 -- temperature recorded as 37.3 degrees celsius for sixty six (66) patients resulted g. November 4, 2017 -- temperature recorded as 37.3 degrees celsius for thirty nine (39) patients resulted h. November 8, 2017 through November 10, 2017 -- temperature recorded as 37.3
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's Quality Assurance monitors failed to identify and correct quality issues in Analytic Systems. Findings: 1. A review of patient test records and quality control records indicated problems found in the analytic systems as follows: a) The laboratory failed to ensure patient samples for Lactic Acid testing are received and separated within 15 minutes according to the manufacturer for twenty four (24) of one hundred thirty two (132) patients reviewed. Refer to D5411 I. b) The laboratory failed to ensure patient samples for Total Iron Binding Capacity (IBCT) testing are received and separated within 2 hours according to the manufacturer for four (4) of fifty five (55)patients reviewed. Refer to D5411 II. c) The laboratory failed to ensure that patient inoculated plates for Methicillin Resistant Staphylococcus Aureus (MRSA) Select testing are read within 28 hours according to the manufacturer for five (5) of eight (8) patients reviewed. Refer to D5411 III. d) The laboratory failed to ensure that patient sample volumes collected in the BacT/ALERT FA and BacT/ALERT SN Culture Bottles meet the manufacturer's recommendation of ten (10) mL for six (6) of seven (7) patients reviewed. Refer to D5411 IV. e) The laboratory failed to ensure blood collection tubes, transport swabs/media, reagents, solutions, and supplies have not exceeded their expiration date. Refer to D5417 I. f) The laboratory failed to ensure the Ortho Confidence Blood Bank Controls have not exceeded their expiration dates. Refer to D5417 II. g) The laboratory failed to ensure the Thermoscientific Shandon Crytome Electronic Cryostat was cleaned each day of use as required by laboratory policy. Refer to D5429.
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 observation, record review, and interview with personnel, the laboratory failed to report Urine Drug Screen (UDS) results as required by the manufacturer. Findings: 1. Observation by surveyors during laboratory tour on March 5, 2018 revealed the laboratory utilized the Bio-Rad TOX/See Drug Screen Test for UDS tesing which includes: Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Opiate 300, Opiate 2000, Oxycodone, Phencyclidine, and Tricyclic Antidepressants. 2. Review of the Bio-Rad TOX/See Drug Screen Test package insert under the Intended Use section revealed "This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used." 3. Review of patient test reports for UDS testing revealed the laboratory included the statement "Positive results are presumptive and are only for Medical Purposes." 4. Further review of patient test reports for UDS revealed the laboratory did not report the following six (6) patients as required by the manufacturer: Patients 141-146 6. Further review of the laboratory's Task 1 and 3 form revealed the laboratory performs one hundred (100) Urine Drug Screens (UDS) annually.
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 the laboratory personnel were performing test methods as required for accurate and reliable results. Refer to D6014. 2. The Laboratory Director failed to ensure the quality control program was maintained to assure quality laboratory services were provided. Refer to D6020. 3. 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. 4. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D6024. 5. The Laboratory Director failed to ensure final reports for urine drug screen tests

	included pertinent information required for interpretation. Refer to D6026. 6. The Laboratory Director failed to provide written job descriptions for twenty (20) of twenty nine (29) Testing Personnel. Refer to D6032.
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 for accurate and reliable results. Findings: 1. The laboratory failed to ensure patient samples for Lactic Acid testing are received and separated within 15 minutes according to the manufacturer for twenty four (24) of one hundred thirty two (132) patients reviewed. Refer to D5411 I. 2. The laboratory failed to ensure patient samples for Total Iron Binding Capacity (IBCT) testing are separated within 2 hours according to the manufacturer for four (4) of fifty five (55)patients reviewed. Refer to D5411 II. 3. The laboratory failed to ensure that patient inoculated plates for Methicillin Resistant Staphylococcus Aureus (MRSA) Select testing are read within 28 hours according to the manufacturer for five (5) of eight (8) patients reviewed. Refer to D5411 III. 4. The laboratory failed to ensure that patient sample volumes collected in the BacT/ALERT FA and BacT/ALERT SN Culture Bottles meet the manufacturer's recommendation of ten (10) mL for six (6) of seven (7) patients reviewed. Refer to D5411 IV. 5. The laboratory failed to ensure blood collection tubes, transport swabs /media, reagents, solutions, and supplies have not exceeded their expiration date. Refer to D5417 I.
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 the quality control program was maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to include in house quality control (QC) data and pertinent literature to support the reduction of frequency of QC in their Individualized Quality Control Plan (IQCP). Refer to D5445. 2. The laboratory failed to perform external positive and negative controls for Rapid Strep A and Bactistaph for each day of patient testing. Refer to D5449. 3. The

	laboratory failed to estalish their own means and ranges for two (2) of two (2) types of Quality Control materials. Refer to D5469 I. 4. The laboratory failed to establish a control donor group for the Siemens Dade Platelet Function Activity-100 (PFA-100) insturment utilized for Platelet Function Activity (PFA) Collagen/EPI testing. Refer to D5469 II. 5. The laboratory failed to perform and document visual inspections, sterility checks, and ability to support growth for each batch/shipment of MRSA Select culture medium, BacT/ALERT FA blood culture bottles, and BacT/ALERT SN blood culture bottles. 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.
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 D5781.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure final reports for urine drug screen tests included pertinent information required for interpretation. Refer to D5805.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to provide written job descriptions for twenty (20) of twenty nine (29) Testing Personnel. Findings: 1. Review of the laboratory's policy and procedure manual and personnel records revealed the laboratory did not have written job descriptions for the following personnel: Personnel 14 - 19 Personnel 29 - 33 Personnel 35 Personnel 37 - 44 2. In interview on March 7, 2018, Personnel 3 confirmed the laboratory did not have written job descriptions for the above personnel.
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 Consultants failed to provide technical and scientific oversight for the laboratory. Refer to D6036. 2. The Technical Consultant failed to ensure that a quality control (QC) program was established and maintained to assure the quality of laboratory services provided. Refer to D6042. 3. 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 Consultants failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to ensure patient samples for Lactic Acid testing are received and separated within 15 minutes according to the manufacturer for twenty four (24) of one hundred thirty two (132) patients reviewed. Refer to D5411 I. 2. The laboratory failed to ensure patient samples for Total Iron Binding Capacity (IBCT) testing are separated within 2 hours according to the manufacturer for four (4) of fifty five (55)patients reviewed. Refer to D5411 II. 3. The laboratory failed to ensure that patient inoculated plates for Methicillin Resistant Staphylococcus Aureus (MRSA) Select testing are read within 28 hours according to the manufacturer for five (5) of eight (8) patients reviewed. Refer to D5411 III. 4. The laboratory failed to ensure that patient sample volumes collected in the BacT/ALERT FA and BacT/ALERT SN Culture Bottles meet the manufacturer's recommendation of ten (10) mL for six (6) of seven (7) patients reviewed. Refer to D5411 IV. 5. The laboratory failed to ensure blood collection tubes, transport swabs/media, reagents, solutions, and supplies have not exceeded their expiration date. Refer to D5417 I. 6. The laboratory failed to report Urine Drug Screen (UDS) results as required by the manufacturer. Refer to D5805.
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 laboratory personnel, the Technical Consultant failed to ensure that a quality control (QC) program was established and maintained to assure the quality of laboratory services provided. Findings: 1. The laboratory failed to include in house quality control (QC) data and pertinent literature to support the reduction of frequency of QC in their Individualized Quality Control Plan (IQCP). Refer to D5445. 2. The laboratory failed to perform external positive and negative controls for Rapid Strep A and Bactistaph for each day of patient testing. Refer to D5449. 3. The laboratory failed to estalish their own means and ranges for two (2) of two (2) types of Quality Control materials. Refer to D5469 I. 4. The laboratory failed to establish a control donor group for the Siemens Dade Platelet Function Activity-100 (PFA-100) insturment utilized for Platelet Function Activity (PFA) Collagen/EPI testing. Refer to D5469 II. 5. The laboratory failed to perform and document visual inspections, sterility checks, and ability to support growth for each batch/shipment of MRSA Select culture medium, BacT/ALERT FA blood culture bottles, and BacT/ALERT SN blood culture bottles. 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 D5781.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to provide documentation of individuals who meet the qualification requirements to perform the functions specified in a lab of moderate complexity. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to provide documentation that testing personnel met the educational qualifications for performing moderate complexity testing for six (6) of twenty nine (29) testing personnel. Findings: 1. Review of personnel records on March 7, 2018 revealed the laboratory failed to maintain documentation of at least a High School Diploma or equivalent for the following personnel: Personnel 21 - 22 Personnel 26 - 28 Personnel 30 2. In interview on March 7, 2017, Personnel 3 confirmed the laboratory did not have documentation of education for the above personnel.
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. Findings: 1. The Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D6087. 2. The laboratory director failed to ensure that quality control programs were established to assure the quality of laboratory testing. Refer to D6093. 3. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D6094. 4. The Laboratory Director failed to ensure the establishment and documentation of maintenance procedures as required. Refer to D6095.
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 observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to ensure the Ortho Confidence Blood Bank Controls have not exceeded their expiration dates. Refer to D5417 II. 2. The laboratory failed to notify the patient's physician and the pathologist immediately upon identification of incompatible blood issued as emergency release as required by the laboratory's procedure. Refer to D5559.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory director failed to ensure that quality control programs were established to assure the quality of laboratory testing. Refer to D5551.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the

	Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5791.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure the establishment and documentation of maintenance procedures as required. Findings: 1. The laboratory failed to ensure the Thermoscientific Shandon Crytome Electronic Cryostat was cleaned each day of use as required by laboratory policy. Refer to D5429. 2. The laboratory failed to assure the quarterly blood bank alarm checks recorded on the circular temperature charts. Refer to D5555.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to provide technical oversight for high complexity testing. Findings: 1. The Technical Supervisor failed to ensure laboratory personnel performed test methods as required. Refer to D6112. 2. The Technical Supervisor(s) failed to ensure that quality control programs are established to assure the quality of laboratory testing. Refer to D6117.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the Technical Supervisor failed to ensure laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to ensure the Ortho Confidence Blood Bank Controls have not exceeded their expiration dates. Refer to D5417 II. 2. The laboratory failed to ensure the Thermoscientific Shandon Crytome Electronic Cryostat was cleaned each day of use as required by laboratory policy. Refer to D5429. 3. The laboratory failed to assure the quarterly blood bank alarm checks recorded on the circular temperature charts. Refer to D5555. 4. The laboratory failed to notify the patient's physician and the pathologist immediately upon identification of

	incompatible blood issued as emergency release as required by the laboratory's procedure. Refer to D5559.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for 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 record review and interview with personnel, the Technical Supervisor(s) failed to ensure that quality control programs are established to assure the quality of laboratory testing. Refer to D5551.
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. The laboratory failed to ensure the Ortho Confidence Blood Bank Controls have not exceeded their expiration dates. Refer to D5417 II. 2. The laboratory failed to ensure the Thermoscientific Shandon Crytome Electronic Cryostat was cleaned each day of use as required by laboratory policy. Refer to D5429. 3. The laboratory failed to document the Quality Control (QC) for ABO, Rh, Antibody Screen (AbScr), and Compatibility (Xmatch) testing prior to patient testing for nine (9) of thirty five (35) days reviewed. Refer to D5551. 4. The laboratory failed to assure the quarterly blood bank alarm checks recorded on the circular temperature charts. Refer to D5555. 5. The laboratory failed to notify the patient's physician and the pathologist immediately upon identification of incompatible blood issued as emergency release as required by the laboratory's procedure. Refer to D5559.