Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0648908	12/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Leonard J Chabert Medical Center Lab	1978 Industrial Boulevard, Houma, 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 LEONARD J CHABERT MEDICAL CENTER LAB - CLIA # 19D0648908 on December 3, 2018 through December 7, 2018. LEONARD J CHABERT MEDICAL CENTER LAB was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.803 CONDITION: Successful Participation 42 CFR 493.1240 CONDITION: Preanalytic Systems 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 493.1423 CONDITION: Laboratories performing moderate complexity, Testing Personnel. 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing, Laboratory Director.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

	This CONDITION is not met as evidenced by: Based on review of Proficiency Testing records from College of American Pathologist (CAP), and interview with the Blood Bank Supervisor, the laboratory failed to successfully participate in Proficiency Testing as follows: 1. The laboratory failed to achieve a satisfactory score for two of three Proficiency Testing (PT) Events resulting in an initial unsuccessful participation in Compatibility Testing. Refer to D2181. 2. Interview with Personnel 5 on December 3, 2018 confirmed the laboratory failed to achieve a satisfactory score for two of three PT Events for Compatibility Testing.
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review, and interview with the Blood Bank Supervisor, the laboratory failed to achieve a satisfactory for two of three Proficiency Testing (PT) Events resulting in an initial unsuccessful participation in Compatibility Testing. Findings: 1. Review of College of American Pathology (CAP) Proficiency Testing records revealed the laboratory received the following scores for Compatibility Testing resulting in failure of two out of three events: a) 2018 Event 1: score of 80% b) 2018 Event 3: score of 60% 2. Interview with Personnel 5 (Blood Bank Supervisor) on December 3, 2018 confirmed the laboratory failed to achieve satisfactory scores for two of three PT Events for Compatibility Testing in 2018.
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 Clinical Consultants and Technical Consultants were complete. Findings: 1. Review off the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the following personnel serve as Clinical Consultants or Technical Consultants: a) Clinical Consultants: Personnel 21 Personnel 22 Personnel 23 b) Technical Consultants: Personnel 2 Personnel 3 Personnel 4 Personnel 5 Personnel 6 Personnel 17 2. Review of the laboratory's Personnel Competency policy revealed the laboratory did not include competency assessment criteria or frequency for personnel serving as Clinical and Technical Consultants. 3. Review of personnel records for the nine (9) identified personnel revealed the laboratory did not perform competency assessments for the duties of Clinical Consultant or Technical Consultant. 4. In interview on December 3, 2018 at approximately 4:00 pm, Personnel 1 stated he did not perform a competency assessment on the identified Clinical Consultants. Personnel 1 further stated he was

	unaware that a competency assessment was needed for Clinical Consultants. 5. In interview on December 4, 2018 at 9:56 am, Personnel 2 stated the laboratory did not perform competency assessments for the identified six (6) Technical Consultants.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to verify the accuracy of the performance of Procalcitonin Assay at least twice annually. Findings: 1. Review of the Task 1 and 3 Form submitted to surveyors on December 3, 2018 revealed the laboratory performed and reported Procalcitonin. 2. Review of the laboratory's policy and procedure manual revealed the laboratory had a policy for twice a year verification for those tests the laboratory is unable to obtain Proficiency Testing for. 3. Review of twice a year verification revealed the laboratory had performed a check in May 2018; however as of December 7, 2018 the laboratory failed to perform a second verification for procalcitonin in 2018. 4. Interview with Personnel 4 on December 7, 2018 confirmed the laboratory had not performed a second verification for procalcitonin for 2018. Personnel 4 revealed the main campus hospital failed to have enough samples for the laboratory to perform a second verification in 2018.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory system failed to monitor, assess, and correct problems identified with the preanalytic system. Findings: 1. The laboratory failed to ensure that patient samples for Ammonia testing are separated within fifteen (15) minutes after collection according to the manufacturer's requirements for twenty eight (28) of two hundred and four (204) patients reviewed. Refer to D5311 I. 2. The laboratory failed to ensure that patient samples for Lactic Acid testing are separated within fifteen (15) minutes after collection and analyzed promptly according to laboratory policy and procedure for eighteen (18) of three hundred nineteen (319) patients reviewed. Refer to D5311 II. 3. The laboratory failed to ensure that patient samples for Chemistry testing are platelet poor after centrifugation according to the manufacturer's requirements. Refer to D5311 III. 4. The laboratory failed to establish detailed written instructions for laboratory services provided for inpatient and outpatient testing and for maintaining the integrity of samples and ensuring accurate and reliable testing according to current manufacturers guidelines. Refer to D5317. 5. The laboratory's Quality Assurance

	(QA) system failed to monitor, assess, and correct problems identified with the Pre-analytic system. Refer to D5391.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on observation, record review and interview with personnel, the laboratory failed to ensure that patient samples for Ammonia testing are separated within fifteen (15) minutes after collection according to the manufacturer's requirements for twenty eight (28) of two hundred and four (204) patients reviewed. Findings: 1. Observation by the surveyor on December 3, 2018 revealed the laboratory was performing Ammonia testing on the Abbott Architect Plus Chemistry Analyzer. 2. Review of the Abbott Architect Ammonia package insert revealed under "Specimen Collection and Handling" that "Rapid separation of plasma from blood cells is critical for obtaining reliable results. The standard recommendation is no more than 15 minutes from sample collection to the start of centrifugation." 3. Review of patient records for Ammonia from June 3, 2018 through December 4, 2018 revealed the laboratory did not separate Ammonia samples within 15 minutes for the following twenty eight (28) patients: On June 19, 2018 Patient 1 was documented as collected at 20:57 pm and received by the laboratory at 21:14 pm - two (2) minutes over the manufacturer's instructions of separation within 15 minutes On June 20, 2018 Patient 2 was documented as collected at 09:40 am and received by the laboratory at 10:00 am - five (5) minutes over the manufacturer's instructions of separation within 15 minutes On June 27, 2018 Patient 3 was documented as collected at 03:17 am and received by the laboratory at 03:39 am - seven (7) minutes over the manufacturer's instructions of separation within 15 minutes On July 12, 2018 Patient 4 was documented as collected at 19:24 pm and received by the laboratory at 19:42 pm - three (3) minutes over the manufacturer's instructions to analyze promptly On August 8, 2018 Patient 5 was documented as collected at 00:12 am and received by the laboratory at 01:01 am - thirty four (34) minutes over the manufacturer's instructions to analyze promptly On August 19, 2018 Patient 6 was documented as collected at 04:54 am and received by the laboratory at 05:10 Am - one (1) minute over the manufacturer's instructions to analyze promptly On August 20, 2018 Patient 7 was documented as collected at 16:14 pm and received by the laboratory at 16:51 pm - twenty two (22) minutes over the manufacturer's instructions to analyze promptly On August 21, 2018 Patient 8 was documented as collected at 05:02 am and received by the laboratory at 05:22 am - five (5) minutes over the manufacturer's instructions to analyze promptly On August 21, 2018 Patient 9 was documented as collected at 17:17 pm and received by the laboratory at 17:54 pm - twenty two (22) minutes over the manufacturer's instructions to analyze promptly On August 26, 2018 Patient 10 was documented as collected at 04:11 am and received by the laboratory at 04:46 am - twenty (20) minutes over the manufacturer's instructions to analyze promptly On August 27, 2018 Patient 11 was documented as collected at 04:29 am and received by the laboratory at 05:09 Am - thirty (30) minutes over the manufacturer's instructions to analyze promptly On

August 27, 2018 Patient 12 was documented as collected at 17:22 pm and received by the laboratory at 17:51 pm - fourteen (14) minutes over the manufacturer's instructions to analyze promptly On September 2, 2018 Patient 13 was documented as collected at 20:34 pm and received by the laboratory at 22:55 pm - one hundred twenty six (126) minutes over the manufacturer's instructions to analyze promptly On September 6, 2018 Patient 14 was documented as collected at 00:26 am and received by the laboratory at 00:54 am - nine (9) minutes over the manufacturer's instructions to analyze promptly On September 13, 2018 Patient 15 was documented as collected at 19:48 pm and received by the laboratory at 20:04 pm - one (1) minute over the manufacturer's instructions to analyze promptly On September 16, 2018 Patient 16 was documented as collected at 20:50 pm and received by the laboratory at 21:09 pm - four (4) minutes over the manufacturer's instructions to analyze promptly On September 17, 2018 Patient 17 was documented as collected at 10:10 am and received by the laboratory at 10:26 am - one (1) minute over the manufacturer's instructions to analyze promptly On September 20, 2018 Patient 18 was documented as collected at 09:17 am and received by the laboratory at 09:35 am - three (3) minutes over the manufacturer's instructions to analyze promptly On September 21, 2018 Patient 19 was documented as collected at 04:40 am and received by the laboratory at 04:57 am - two (2) minutes over the manufacturer's instructions to analyze promptly On September 21, 2018 Patient 20 was documented as collected at 18:51 pm and received by the laboratory at 19:24 pm - eighteen (18) minutes over the manufacturer's instructions to analyze promptly On September 21, 2018 Patient 21 was documented as collected at 22:18 pm and received by the laboratory at 22:36 pm - three (3) minutes over the manufacturer's instructions to analyze promptly On October 16, 2018 Patient 22 was documented as collected at 11:31 am and received by the laboratory at 12:00 pm - fourteen (14) minutes over the manufacturer's instructions to analyze promptly On October 26, 2018 Patient 23 was documented as collected at 03: 49 am and received by the laboratory at 04:12 am - eight (8) minutes over the manufacturer's instructions to analyze promptly On October 28, 2018 Patient 24 was documented as collected at 10:50 am and received by the laboratory at 11:11 am - six (6) minutes over the manufacturer's instructions to analyze promptly On November 3, 2018 Patient 25 was documented as collected at 22:25 pm and received by the laboratory at 22:42 pm - two (2) minutes over the manufacturer's instructions to analyze promptly On November 29, 2018 Patient 26 was documented as collected at 11:40 am and received by the laboratory at 12:04 pm - nine (9) minutes over the manufacturer's instructions to analyze promptly On December 1, 2018 Patient 27 was documented as collected at 09:16 am and received by the laboratory at 09:36 am - five (5) minutes over the manufacturer's instructions to analyze promptly On December 4, 2018 Patient 28 was documented as collected at 13:29 pm and received by the laboratory at 13:45 pm - one (1) minute over the manufacturer's instructions to analyze promptly 4. Interview with Personnel 3 and 4 on December 5, 2018 confirmed the laboratory did not ensure Ammonia samples were separated within 15 minutes as required by the manufacturer. II. Based on observation, record review and interview with personnel, the laboratory failed to ensure that patient samples for Lactic Acid testing are separated within fifteen (15) minutes after collection and analyzed promptly according to laboratory policy and procedure for eighteen (18) of three hundred nineteen (319) patients reviewed. Findings: 1. Observation by the surveyor on December 3, 2018 revealed the laboratory was performing Lactic Acid testing on the Abbott Architect Plus Chemistry Analyzer. 2. Interview with Personnel 4 on December 5, 2018 revealed that Lactic Acids are to be spun with fifteen (15) minutes and analyzed immediately. 3. Review of patient records for Lactic Acid from November 1, 2018 through December 5, 2018 revealed the laboratory did not separate Lactic Acids samples within 15 minutes for the following eighteen (18) patients: On

November 1, 2018 Patient 31 was documented as collected at 15:10 pm and received by the laboratory at 15:32 pm - seven (7) minutes over. On November 3, 2018 Patient 32 was documented as collected at 12:50 pm and received by the laboratory at 13:07 pm - two (2) minutes over the manufacturer's instructions to analyze promptly On November 3, 2018 Patient 33 was documented as collected at 23:30 pm and received by the laboratory at 23:47 pm - two (2) minutes over the manufacturer's instructions to analyze promptly On November 5, 2018 Patient 34 was documented as collected at 09: 12 am and received by the laboratory at 09:28 pm - one (1) minute over the manufacturer's instructions to analyze promptly On November 6, 2018 Patient 35 was documented as collected at 13:25 pm and received by the laboratory at 13:44 pm - four (4) minutes over the manufacturer's instructions to analyze promptly On November 6, 2018 Patient 36 was documented as collected at 13:35 pm and received by the laboratory at 13:54 pm - four (4) minutes over the manufacturer's instructions to analyze promptly On November 8, 2018 Patient 37 was documented as collected at 20:12 pm and received by the laboratory at 20:34 pm - seven (7) minutes over the manufacturer's instructions to analyze promptly On November 9, 2018 Patient 38 was documented as collected at 11:07 am and received by the laboratory at 11:28 am - six (6) minutes over the manufacturer's instructions to analyze promptly On November 15, 2018 Patient 39 was documented as collected at 04:45 am and received by the laboratory at 05:09 pm - nine (9) minutes over the manufacturer's instructions to analyze promptly On November 20, 2018 Patient 40 was documented as collected at 08:40 am and received by the laboratory at 09:09 am - fourteen (14) minutes over the manufacturer's instructions to analyze promptly On November 20, 2018 Patient 41 was documented as collected at 14:29 pm and received by the laboratory at 14:52 pm - eight (8) minutes over the manufacturer's instructions to analyze promptly On November 20, 2018 Patient 42 was documented as collected at 16:45 pm and received by the laboratory at 17:03 pm - three (3) minutes over the manufacturer's instructions to analyze promptly On November 23, 2018 Patient 43 was documented as collected at 04:51 am and received by the laboratory at 05:13 am - seven (7) minutes over the manufacturer's instructions to analyze promptly On November 24, 2018 Patient 44 was documented as collected at 20:10 pm and received by the laboratory at 20:42 pm - seventeen (17) minutes over the manufacturer's instructions to analyze promptly On November 2, 2018 Patient 45 was documented as collected at 12:45 pm and received by the laboratory at 13:03 pm - three (3) minutes over the manufacturer's instructions to analyze promptly On December 1, 2018 Patient 46 was documented as collected at 15:36 pm and received by the laboratory at 15:52 pm - one (1) minute over the manufacturer's instructions to analyze promptly On December 4, 2018 Patient 47 was documented as collected at 13:29 pm and received by the laboratory at 13:45 pm - one (1) minute over the manufacturer's instructions to analyze promptly On December 4, 2018 Patient 48 was documented as collected at 14:30 pm and received by the laboratory at 14:46 pm - one (1) minute over the manufacturer's instructions to analyze promptly 4. Interview with Personnel 4 on December 5, 2018 confirmed the laboratory did not ensure Lactic Acid samples were separated within 15 minutes and analyzed promptly. III. Based on observation, record review and interview with personnel, the laboratory failed to ensure that patient samples for Chemistry testing are platelet poor after centrifugation according to the manufacturer's requirements. Findings: 1. Observation by the surveyor on December 3, 2018 revealed the laboratory maintained a Abbott Architect Plus Chemistry Analyzer which performed the following tests: Alanine Aminotransferase (ALT), Albumin (Alb), Alkaline phosphatase (ALP), Ammonia (Ammon), Amylase (Amy), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Cholesterol (Chol), High Density Lipoprostein Cholesterol (HDL), Carbon Dioxide (CO2), Creatine Kinase (CK), Creatinine (Creat), Glucose

	(Glu), Iron (Fe), Lacate Dehydrogenase (LDH), Lactate, Lipase, Magnesium (Mg), Phosphorous (Phos), Potassium (K), Total Protein (TP), Sodium (NA), Triglyceride (Trig), Uric Acid (Uric), Gamma Glutamyl Transferase (GGT), Blood Urea Nitrogen (BUN), Parathyroid Hormone (PTH), Acetaminophen (Acet), Carbamazepine (CRRBM), Digoxin (Dig), Gentamicin (Gent), Lithium (Li), Phenobarbital (Phenob), Phenytoin (Dil), Prostate Specific Antigen (PSA), Salicylate (Sali), Free thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Transferrin (Trans), Valproic Acid (Valp), Vancomycin (Vanco), Carcinoembryonic Antigen (CEA), Prealbumin (Prealb), Microalbumin (Microalb), Alpha Fetoprotein (AFP), Cortisol, Ferritin, Folate, Vitaminn B12, Blood Alcohol (ETOH), CKMB, Troponin, Hemoglobin A1C (HgbA1C), Brain Natriuretic Peptide (BNP), C Reactive Protein (CRP), Beta Human Chorionic Gonadatropin (BHCG), Tricyclics, Amphetamine (Amph), Barbirurates (Barb), Benzodiazepine (Benzo), Cocaine (COC), Methadone (Meth), Opiates (OPI), Phencyclidine (PCP), and Tetrahydrocanabinol (THC). 2. Review of the following Abbot Architect package inserts states that samples are to be "platelet poor": CK, DBil, Gent, Glu, HDL, Fe, Lactate, LDH, Lipase, Li, Mg, Phos, TBil, TP, Trans, BUN, Valp, and Vanco. 3. Interview with Personnel 4 on December 5, 2018 revealed she was unaware that samples had to be platelet poor. Personnel 4 stated she was unaware of any studies that would have been done to ensure that samples are platelet poor. 4. Review of the Task 1 and 3 Form submitted to surveyors on December 3, 2018 revealed the laboraotry performed the following annual volumes without ensuring that samples are platelet poor: CK - 1200, DBil - 250, Gent - 75, Glu - 55000, HDL - 17000, Fe - 2200, Lactate - 3500, LDH - 575, Lipase - 3100, Li, Mg - 13200, Phos - 13200, TBil - 47000, TP - 47000, Trans, BUN - 55000, Valp - 550, and Vanco - 2000.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Findings: 1. Surveyors requested from Personnel 2 on December 3, 5, 6 and 7 a copy of the manual available to outside facilities that provides that provide written policies and procedures for each of the following: a) Patient preparation. b) Specimen collection. c) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. d) Specimen storage and preservation. e) Conditions for specimen transportation. f) Specimen processing. g) Specimen acceptability and rejection. h) Specimen referral. 2. Personnel 2 provided to the surveyors on December 7, 2017 the following policies for: APTT, PT, Mixing Studies for PTT and PT, Fibrinogen, D-Dimer, Complete Blood Count, Glucose, Lactic Acid, Ammonia, Comprehensive Metabolic Panel [which includes: Albumin (Alb), Alkaline Phosphatase (ALK), Aspartate Aminotransferase (AST), Total Bilirubin (TBil), Blood Urea Nitrogen (BUN), Calcium (CA), Chloride (CL), Creatinine (Creat), Glucose (Glu), Potassium (K), Sodium (NA), Carbon Dioxide (CO2), Total Protein (TP and Alanine Aminotransferase (ALT)]. The laboratory provides laboratory services to include: Bacteriology, Mycology, Parasitology, Virology, General Immunology,

	Routine Chemistry, Urinalysis, Endocrinology, Toxicology, Hematology, ABO, Rh, Antibody Screen Testing, Antibody Identification Compatibility Testing, Histopathology, Oral Pathology, and Cytology. Not all policies and procedures were provided to the surveyors. The policies provided failed to include: Specimen collection, specimen labeling, including patient name or unique patient identifier, specimen source, specimen storage and preservation, conditions for specimen transportation, and specimen acceptability and rejection. Further review of the policies received revealed that policies failed to meet manufacturer requirements Examples: Complete Metabolic Panel states to transport blood to laboratory within 4 hours. Abbott Architect requires that samples be centrifuged within two (2) hours of collection - 4 hours would not meet this requirement. PT, PTT, Fibrinogen, D-Dimer states to separate plasma and to freeze sample; however it does not state the temperature to be frozen and not to place in a frost free freezer. Glucose states to get to laboratory within two (2) hours. The manufacturer states that Glucose will metabolize 5% per hour. 3. Interview with personnel 2 on December 7, 2018 revealed the laboratory provides instructions online to all outside facilities that the laboratory does testing for. Personnel 2 confirmed the manual does not include all the information required to maintain the integrity of patient samples. Personnel 2 also revealed the laboratory maintained no documentation to support who had access to the instructions and that the outside facilities have read and agree to the instructions provided.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish written quality assessment policies and procedures for monitoring, identifying and correcting problems identified with the preanalytic system. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory failed to establish written quality assessment policies and procedure for monitoring, identifying and correcting problems identified with preanalytic systems. 2. Problems identified in the Preanalytic System found during the survey that failed to be addressed by the laboratory: a) The laboratory failed to ensure that patient samples for Ammonia testing are separated within fifteen (15) minutes after collection according to the manufacturer's requirements for twenty eight (28) of two hundred and four (204) patients reviewed. Refer to D5311 I. b) The laboratory failed to ensure that patient samples for Lactic Acid testing are separated within fifteen (15) minutes after collection and analyzed promptly according to laboratory policy and procedure for eighteen (18) of three hundred nineteen (319) patients reviewed. Refer to D5311 II. c) The laboratory failed to ensure that patient samples for Chemistry testing are platelet poor after centrifugation according to the manufacturer's requirements. Refer to D5311 III. d) The laboratory failed to establish detailed written instructions for laboratory services provided for inpatient and outpatient testing and for maintaining the integrity of samples and ensuring accurate and reliable testing according to current manufacturers guidelines. Refer to D5317. 2. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory policies and procedures failed to identify, monitor, assess and correct the problems found during the survey. 3. Interview with

	personnel 2, 3, 4 and 5 on December 7, 2018 confirmed the laboratory failed to identify and correct the issue cited above.
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 observatio, 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 perform Gram Stain Quality Control each day of patient testing with each testing person reporting a Gram Stain for eleven (11) of thirty seven (37) patients reviewed as required by laboratory policy. Refer to D5401 I. 2. The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5401 II. 3. The laboratory failed to follow their policy for documenting the date for Emergency Release of blood units. Refer to D5401 III. 4. The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5403. 5. The laboratory failed to ensure that patient samples for Ammonia testing are tested within two (2) hour after collection according to the manufacturer's requirements for two (2) of two hundred and four (204) patients reviewed. Refer to D5411 I. 6. The laboratory failed to use normal donors as required by manufacturer to verify reference intervals and establish their own normal Prothrombin (PT) mean with each new lot of thromboplastin. Refer to D5411 II. 7. The laboratory failed to label Histopathology reagents, and solutions with the strength or concentration of the material, storage requirements, preparation and/or expiration dates. Refer to D5415. 8. The laboratory failed to ensure that Blood Collection tubes, Calibrators and Calibrator Verification material are not used beyond their expiration dates. Refer to D5417. 9. The laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for two (2) of two (2) new Abbott Architect Plus Analyzers. Refer to D5421 I. 10. The laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for two (2) of two (2) new Sysmex XN 2000 Hematology Analyzers. Refer to D5421 II. 11. The laboratory failed to verify the Laboratory Information System (LIS) for accuracy. Refer to D5421 III. 12. The laboratory failed to establish and verify performance specifications for accuracy, precision, reportable and reference ranges, analytical sensitivity, and specificity for Sickle cell Screen, Platelet Function Assay and PT/PTT Mixing Studies performed by the laboratory. Refer to D5423. 13. The laboratory failed to ensure the Daily Maintenance on the Abbott Architect Plus Analyzers I and II were performed as required by the manufacturer, for six (6) of three hundred thirty four (334) days reviewed. Refer to D5429 I. 14. The laboratory failed to ensure the Weekly Maintenance on the Abbott Architect Plus Analyzers I and II were performed as required by the manufacturer, for one (1) of forty eight (48) weeks reviewed. Refer to D5429 II. 15. The laboratory failed to ensure the Maintenance of the Stain for Frozen Sections was performed each day of patient testing for two (2) of five (5) patient test days reviewed. Refer to D5429 III.

	16. The laboratory failed to perform two levels of control materials each day of patient testing for Cerebrospinal Total Protein (CFTP) performed on the Abbott Architect Plus Analyzer, for one (1) of thirty eight (38) patients reviewed. Refer to D5447. 17. The laboratory failed to perform a positive and negative control each day of patient testing for the Pacific Hemostasis SickleScreen Sickling Hemoglobin Screening Kit for sickle cell disease, for one (1) of ten (10) patients reviewed. Refer to D5449. 18. The laboratory failed to utilize control material of a similar matrix for Urine Ethanol (ETOH) for forty four (44) of forty four (44) patients reviewed. Refer to D5465. 19. The laboratory failed to document visual inspections for each batch /shipment of BD BACTEC Aerobic, Anaerobic and Peds Plus Culture Bottles for six (6) of six (6) lot numbers reviewed. Refer to D5477. 20. The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for D-Dimer testing performed on the Instrumentation Laboratory (IL) ACL Top 500 Coagulation Analyzer, for six (6) of sixty four (64) patients reviewed. Refer to D5545 I. 21. The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for Fibrinogen testing performed on the Instrumentation Laboratory (IL) ACL Top 500 Coagulation Analyzer, for three (3) of thirty two (32) patients reviewed. Refer to D5545 II. 22. The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for Platelet Function (Closure Time) testing performed on the Dade Behring PFA-100 Platelet Function Analyzer, for twelve (12) of twelve (12) patients reviewed. Refer to D5545 III. 23. The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for PTT Mixing Study testing performed on the Instrumentation Laboratory (IL) ACL Top 500 Coagulation Analyzer, for five (5) of five (5) patients reviewed.Refer to D5545 IV. 24. The laboratory failed to assure the quarterly blood bank alarm checks recorded on the circular temperature charts. Refer to D5555. 25. The laboratory failed to perform and document a control slide of known reactivity for the Hematoxylin and Eosin (H&E) Staining utilized for histopathology slides for twenty (20) of twenty (20) patient test days reviewed. Refer to D5601 I. 26. The laboratory failed to perform and document a positive and negative control slide for Immunohistochemical Staining utilized for histopathology slides for twenty one (21) of twenty one (21) immunohistochemical stains affecting seven (7) patients reviewed. Refer to D5601 II. 27. The laboratory failed to perform and document a control slide of known reactivity for each special stain performed for eight (8) of eight (8) special stains affecting three (3) patients reviewed. Refer to D5601 III. 28. The laboratory failed to perform and document a control slide of known reactivity for Frozen Sections for five (5) of five (5) patients reviewed. Refer to D5601 IV. 29. The the laboratory failed to have a system in place for twice a year comparison testing for the two (2) Abbott Architect Plus Analyzers. Refer to D5775. 30. The laboratory failed to retain instrument printouts for General Immunology, Routine Chemistry, Endocrinology, Toxicology, Hematology and Coagulation. Refer to D5789. 31. The laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. Refer to D5791.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
I. Based on observation, record review and interview with personnel, the laboratory failed to perform Gram Stain Quality Control each day of patient testing with each testing person reporting a Gram Stain for eleven (11) of thirty seven (37) patients reviewed as required by laboratory policy. Findings: 1. Observation by the surveyor on December 3, 2018 during the tour of the laboratory noted the laboratory performed Gram Stains. 2. Review of the Laboratory's Policy and Procedure Manual revealed that quality control for Gram Stains is to be performed each day of patient testing and with each testing personnel performing a patient Gram Stain on that day. Quality Control consists of checking for positive and negative reactivity using control organisms. 3. Review of Patient Gram Stain testing and Quality Control records from June 1, 2018 through August 30, 2018 revealed the following eleven (11) patients were tested and reported without having Gram Stain controls performed each day of patient testing and with each testing person reporting a Gram Stain on that day. On June 10, 2018 Patient 120 On June 21, 2018 Patient 121 On June 22, 2018 Patient 122 On June 26, 2018 Patient 123 On July 14, 2018 Patient 124 On July 16, 2018 Patient 125 On July 20, 2018 Patient 126 On July 23, 2018 Patient 127 On August 15, 2018 Patient 128 On August 25, 2018 Patient 129 On August 30, 2018 Patient 130 4. Interview with Personnel 3 and 5 on December 6, 20 18 confirmed the laboratory failed to document the performance of Gram Stain Quality Control each day with each testing person reporting a Gram Stain for the eleven (11) patients cited above. II. Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory failed to have policies and procedures for: Test Requisitions: what mandated information needs to be on the test requisition: a) 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. b) The patient's name or unique patient identifier. c) The sex and age or date of birth of the patient. d) The test(s) to be performed. e) The source of the specimen, when appropriate. f) The date and, if appropriate, time of specimen collection. g) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. Performance specifications to include: a) Detailed policies and procedures for testing personnel that instructed testing personnel what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. b) Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges and analytical sensitivity and specificity. c) Policies and procedures for when data from the studies for precision, accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. d) Policies on how to maintain the documentation to show that the laboratory participated in the studies. e) Policies for when the laboratory only needs to verify performance specification vs. when the laboratory actually has to establish performance specifications for test systems not FDA approved or introducing a laboratory developed test (LDT). Proficiency Testing (PT): a) Ordering and ensuring that you are enrolled for Proficiency Testing. b) What to do when you receive samples from the PT Provider. c) How to handle the samples; who will test, when to test, how do you assure no inter and intra laboratory communication takes place d) How to record results to send into the PT Provider to be

	scored. e) What records to maintain. f) How to evaluate when you receive your scores from the PT Provider. g) What steps to take if corrective action is needed. h) What steps are required when the laboratory has their first and second two (2) out of three (3) failures. Twice a year verification for Procalcitonin accuracy: a) What system are you going to use to meet the twice a year verification for procalcitonin accuracy. b) How to handle the samples; who will test, when to test, how do you assure no inter and intra laboratory communication takes place c) How to record results and who will score. d) What acceptability criteria will be used to score the verification. e) What records to maintain. f) What steps to take if corrective action is needed. Complaint policies and procedures (for both inhouse and outside complaints). Communication policies and procedures (for both inhouse and outside communications). 2. Interviews with personnel 2, 3 4 and 5 on December 7, 2 018 confirmed the policy and procedure manual was incomplete 36645 III. Based on record review and interview with personnel, the laboratory failed to follow their policy for documenting the date for Emergency Release of blood units. Findings: 1. Review of the laboratory's policy and procedure manual revealed a policy for Emergency Release of blood units including a form. 2. Further review of the laboratory's Emergency Release form revealed date of release was included. 3. Review of a total of twenty five (25) patients from 2017 and 2018 revealed the forms the laboratory utilized for Emergency Release did not include the date of release. 4. In interview on December 4, 2018 at 2:38 pm, Personnel 5 stated she is unsure when the form utilized without the date went into use.
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 review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory failed to have detailed written policies and procedures for: a) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection that meet the manufacturer's requirements. b) Microscopic examination, including the detection of inadequately prepared slides. Examples are Quality Control

	for Histology slides for Hematoxylin and Eosin (H&E), Immunohistochemical Stains, Special Stains and Frozen Sections. c) Step-by-step performance of the procedure, including test calculations and interpretation of results. Examples are calculating the Normal Mean Prothrombin Time (NMPT) and How to calculate mean and Standard Deviation when having to establish Quality Control ranges d) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing for all areas of the laboratory. e) Control procedures. Examples are Platelet Function /Closure Time and Mixing Studies for Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) to include but not limited to: two (2) levels of quality control material every eight (8) hours of patient testing, what material are you going to use to fulfill two (2) levels, how to make you quality control material, what is the acceptability criteria for the quality control material. If Establishing QC ranges how to do the calculations for mean and Standard Deviation and then how you are going to implement those ranges and if changes are to be made to the ranges what your procedure will be for accomplishing that. h) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability for all areas of the laboratory. i) Limitations in the test methodology, including interfering substances. j) Pertinent literature references. Examples if using Geographical Reference Ranges, For determining Normal Patients for Normal Mean Prothrombin Time Study. k) Policy for determining Platelet Poor Plasma to fulfill the requirement of the Abbott Architect Plus analyte accuracy for Alkaline phosphatase (ALK), Alanine Aminotransferase (ALT), Calcium (CA), Creatine Kinase (CK), Direct Bilirubin (DBil), Total Bilirubin (TBil), Gentamicin (Gent), Glucose (Glu), High Density Lipoprotein Cholesterol (HDL), Iron (Fe), Lactate, Lipase, Lithium (Li), Magnesium (Mg), Phosphorous (Phos), Total Protein (TP), Transferrin, Blood Urea Nitrogen (BUN) Valproic Acid (Valp), and Vancomycin (Vanco). l) Detailed Policy for performing a Normal Mean Prothrombin Time (NMPT) study to include but not limited to: number of patients to be included in study, what determines who is a normal patient and how are you going to document that (use of questionnaire), Calculating the geometric mean. m) Policy in Histopathology that details staining and the maintenance of the staining material to include but not limited to: what is to be used, when does it need to be changed , and how is it to be labeled. n) Detailed policies and procedure for an Individualized Quality Control Plan (IQCP): detailing who is going to perform, what is going to be performed, when it is going to be performed, where it is going to be performed and how it will be performed. What data is needed to support the IQCP and how that data will be retained. Also what will be the acceptability criteria, and who needs to review and sign off on the IQCP and when to implement the outcome. 2. Interview with personnel 2, 3, 4, and 5 on December 7, 2018 confirmed the laboratory failed to have a complete policy and procedure manual.
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 that patient samples for Ammonia testing are tested within two (2) hour after collection according to the manufacturer's requirements for two (2) of two

	hundred and four (204) patients reviewed. Findings: 1. Observation by the surveyor on December 3, 2018 revealed the laboratory was performing Ammonia testing on the Abbott Architect Plus Chemistry Analyzer. 2. Review of the Abbott Architect Ammonia package insert revealed under "Specimen Collection and Handling" that specimen storage is stable at 2 - 8 degrees Celsius for 2 hours. If storage is longer than 2 hours then the sample must be stored at - 20 degrees Celsius up to 3 weeks. 3. Review of patient records for Ammonia from June 3, 2018 through December 4, 2018 revealed the laboratory failed to complete patient Ammonia levels within 2 hours without storing the patient sample at - 20 degrees Celsius for the following two (2) patients On November 12, 18 Patient 29 was documented as collected at 09:58 am and reported by the laboratory at 12:08 pm - ten (10) minutes over the manufacturer's instructions. On December 1, 2018 Patient 30 was documented as collected at 09:36 am and reported by the laboratory at 13:07 pm - ninety one (91) minutes over the manufacturer's instructions. 4. Interview with Personnel 3 and 4 on December 5, 2018 confirmed the laboratory did not ensure Ammonia samples were stored correctly and reported within two hours as required by the manufacturer. II. Based on observation, record review, and interview with personnel, the laboratory failed to use normal donors as required by manufacturer to verify reference intervals and establish their own normal Prothrombin (PT) mean with each new lot of thromboplastin. Findings: 1. Observation by surveyor during laboratory tour on December 3, 2018 revealed the laboratory utilizes the Instrumentation Laboratory (IL) ACL TOP 500 for testing the following analytes: Prothrombin Time (PT)/ International Normalized Ratio (INR), Activated Partial Thromboplastin Time (APTT), Fibrinogen, and D-Dimer. 2. Review of the laboratory's policy/procedure manual did not include guidelines for normal donors for mean PT. Additionally, the laboratory could not produce the manufacturer requirements of normal donors. 3. Review of PT Reagent package insert revealed normal values vary from one laboratory to the next, depending on reagents, instrumentation and technique. So, each laboratory must determine its own expected values based on technique and instrumentation in use. 4. Interviews with Personnel 3 and 6 on December 5, 2018 stated the laboratory tested twenty (20) normal patients for PT. Personnel 3 and 6 stated the normal samples used came from the main campus location. Personnel 3 and 6 stated the laboratory did not have written criteria for normal donors or document donors meeting any requirements. 5. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs 9500 PT/INR annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the laboratory failed to label Histopathology reagents, and solutions with the strength or concentration of the material, storage requirements, preparation and/or expiration dates. Findings 1. Observation by surveyor 1 on December 6, 2018 revealed the laboratory maintained an area where Histopathology samples are stained for the pathologist to be able to read patient sample slides for interpretation and diagnosis. The surveyor noted

	Hematoxylin, Eosin, Alcohol Solutions, Bluing Agent and Xylene Solutions that were only labeled with the name of the material in each container. Further observation by surveyor 1 noted the labels failed to contain the strength or concentration of the material, storage requirements, preparation and/or expiration dates. 2. Interview with the Histotech on duty on December 6, 2018 confirmed the labels did not include all the required information.
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 laboratory personnel, the laboratory failed to ensure that Blood Collection tubes, Calibrators and Calibrator Verification material are not used beyond their expiration dates. Findings: 1. Observation by Surveyor 2 during the tour of the laboratory on December 3, 2018 revealed the following expired items in place for patient testing: One (1) tube of BD Vacutainer Buff Na Citrate - lot number 8121976 with an expiration date 2018-11-30. One (1) box of Architect Folate Calibrators - lot number 770234100 with an expiration date 2018-11-08. Two (2) boxes of GC4C Calibration Verification Test Set - lot number 14AH23017 with an expiration date of 2018-08-29. One (1) box HbA1C Calibration Verification Test Set - lot number 6JAH17417 with an expiration date of 2018-10-13. Two (2) boxes LP Calibration Verification Test Set - lot number JOAH20917 with an expiration date of 2018-10-10. 2. Interview with Personnel 3 on December 3, 2018 confirmed by observation the expired items that were in place for patient testing. 3. In interview on December 3, 2018 at 11:08 am, Personnel 4 stated the identified Calibration Verification material was used for validation. Personnel 4 further stated she forgot to discard the material after the results were received.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: I. Based on observation, record review and interview with personnel, the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for two (2) of two (2) new Abbott Architect Plus Analyzers. Findings: 1. Observation by surveyors on December 3, 2018 revealed the laboratory maintained the following two (2) new Abbott Architect Plus Analyzers for patient testing: a) Abbott Architect Plus Chemistry Analyzer I (Serial number 3457120038), which performed the following tests: Alanine Aminotransferase (ALT),

Albumin (Alb), Alkaline phosphatase (ALP), Ammonia (Ammon), Amylase (Amy), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Carbon Dioxide (CO2), Creatine Kinase (CK), Creatinine (Creat), Glucose (Glu), Lactate, Lipase, Magnesium (Mg), Phosphorous (Phos), Potassium (K), Total Protein (TP), Sodium (NA), Triglyceride (Trig), Blood Urea Nitrogen (BUN), Acetaminophen (Acet), Salicylate (Sali), Vancomycin (Vanco), Prealbumin (Prealb), Microalbumin (Microalb), Blood Alcohol (ETOH), CKMB, Troponin, Brain Natriuretic Peptide (BNP), Beta Human Chorionic Gonadatropin (BHCG), Tricyclics, Amphetamine (Amph), Barbirurates (Barb), Benzodiazepine (Benzo), Cocaine (COC), Methadone (Meth), Opiates (OPI), Phencyclidine (PCP), and Tetrahydrocanabinol (THC). b) Abbott Architect Plus Chemistry Analyzer II (Serial number F3457120079), which performed the following tests: Alanine Aminotransferase (ALT), Albumin (Alb), Alkaline phosphatase (ALP), Amylase (Amy), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Carbon Dioxide (CO2), Creatine Kinase (CK), Creatinine (Creat), Glucose (Glu), Iron (Fe), Lacate Dehydrogenase (LDH), Lactate, Lipase, Magnesium (Mg), Phosphorous (Phos), Potassium (K), Total Protein (TP), Sodium (NA), Triglyceride (Trig), Uric Acid (Uric), Gamma Glutamyl Transferase (GGT), Blood Urea Nitrogen (BUN), Parathyroid Hormone (PTH), Carbamazepine (CRRBM), Digoxin (Dig), Gentamicin (Gent), Lithium (Li), Phenobarbital (Phenob), Phenytoin (Dil), Prostate Specific Antigen (PSA), Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Transferrin (Trans), Valproic Acid (Valp), Carcinoembryonic Antigen (CEA), Prealbumin (Prealb), Microalbumin (Microalb), Alpha Fetoprotein (AFP), Cortisol, Ferritin, Folate, Vitaminn B12, Blood Alcohol (ETOH), CKMB, Troponin, Hemoglobin A1C (HgbA1C), Brain Natriuretic Peptide (BNP), and C Reactive Protein (CRP). 2. Review of the Laboratory's Policy and Procedure Manual revealed Policy "CHAH.LabAdmisPRS.1004 Test Method Validation Implementation or Revision Process" which included written policies and procedure for: Accuracy- verifies that the method produces correct results. Verification of accuracy may be accomplished by: * Testing reference materials; * Comparing results of tests performed by the laboratory against the results of a reference method; * Comparing split sample results with results obtained from another method, which has already been shown to provide accurate results. Analytical Sensitivity - The laboratory must determine minimum detection limits for each analyte. This is often part of the linearity experiment and must be validated against manufacturer claim for the analyte (published in assay package insert). Analytical Specificity (Interference) - The laboratory must determine the extent to which the method measures the analyte it is reporting. The laboratory must document information regarding interfering substances from production information, literature, or its own testing. These may include specimen hemolysis, anticoagulant, lipemia, and turbidity; patients' clinical conditions, disease states and medications. Precision - Verifies the reproducibility of results. Precision studies must include day-to-day run, run-to-run, and with-in run variation, as well as operator variance, when applicable. Verification of precision may be accomplished by: * Repeat testing of known patient samples over time; * Testing QC material in duplicate and over time; or * Repeat testing of calibration materials over time. Reportable Range Validation - To include Analytical Measured Range and Clinically Reportable Range (Maximum Dilution/Concentration). Verification of reportable range may be accomplished by: * Assaying low and high calibration materials or control materials; * Evaluating known samples of abnormal high and abnormal low values. * Establishment of maximum dilution and/or concentration procedures that falls within the AMR to obtain a numeric reportable result for each

analyte; * Evaluate a commercially available standard reference linearity material. Reference Range Validation - Verification of reference range may be accomplished by: * Evaluating an appropriate number of specimens to verify (in order of priority): Existing network-wide reference intervals Manufacturer's claims for normal values As applicable published reference ranges. Validation Data Summary Review: A summary of the data is prepared by the PhD Discipline and/or Laboratory Supervisor for CLIA Medical Director Review. However the Laboratory Policy for Method Validation failed to include: a) Detailed policies and procedures for testing personnel that instructed testing personnel exactly what to do for the studies to demonstrate: accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. b) Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges and analytical sensitivity and specificity. c) Policies and procedures for when data from the studies for precision, accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. d) Policies on how to maintain the documentation to show that the laboratory participated in the studies. e) Policies for when the laboratory only needs to verify performance specification vs. when the laboratory actually has to establish performance specifications for test systems not FDA approved or introducing a laboratory developed test (LDT). 3. Review of Installation Records for the two (2) new Abbott Architect Plus Analyzers revealed: a) EP Evaluator Reports for: Simple Precision, Linearity, and a Method Comparison. Further review of the EP Evaluator Report revealed the Technical Application Specialist for Abbott is listed as the Analyst. NOTE: No instrument printouts were available to support the EP Evaluator Reports. b) Reference Range Study performed by the laboratory The laboratory failed to demonstrate that they could obtain performance specifications comparable to those established by the manufacturer for accuracy, precision, and reportable range. 4. Review of the Task 1 and 3 Form submitted to the surveyors on December 3, 2018 revealed the laboratory performs the following annual volumes: ALT - 46000, Alb - 55000, ALP - 46000, Amy - 300, Ammon - 320, AST - 47000, DBil - 250, TBil - 47000, CA - 55000, CL - 55000 , Chol - 17000, HDL - 17000, CO2 - 55000, CK - 1200, Creat - 57800, Glu - 55000, Fe - 2200, LDH - 575, Lactate - 3500, Lipase - 3100, Mg - 13200, Phos - 13200, K - 55000, TP - 47000, NA - 55000, Trig - 17000, Uric - 2000, GGT - 175, BUN - 55000, PTH - 1350, CRBM - 40, Dig - 120, Gent - 75, Li - 175, Phenob - 12, Dil - 50, PSA - 3500, FT4 - 3400, TSH - 15000, Trans - 2017, Valp - 550, Vanco - 2000, BHCG - 520, CEA - 500, Prealb - 200, Microalb - 2700, Acet - 1700, AFP - 900, Cortisol - 150, Ferritin - 2100, Folate - 850, Vitamin B12 - 1700, ETOH - 2250, CKMB - 169, Sali - 220,Troponin - 8200, HgbA1C - 16000, BNP - 3400, CRP - 2700, Tricyclics - , Amph - , Barb - 7000, Benzo - 7000, COC - 7000, Meth - 7000, OPI - 7000, PCP - 7000, and THC - 7000. 5. In interview on December 7, 2018 at 10:12 am, Personnel 4 stated the laboratory performed the reference interval and LIS validation studies. Personnel 4 further stated the Technical Application Specialist performed the Simple Precision, Linearity, and Method Comparison studies. II. Based on observation, record review and interview with personnel, the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for two (2) of two (2) new Sysmex XN 2000 Hematology Analyzers. Findings: 1. Observation by surveyors on December 3, 2018 revealed the laboratory maintained the following two (2) new Sysmex XN 2000 Hematology Analyzers (Serial numbers: 27674 and 27676) for patient testing for Complete Blood Cell (CBC) testing which includes: White Blood Cell counts (WBC), Red Blood Cell counts (RBC), Hemoglobin (Hgb), Hematocrit (Hct), Platelet (Plt), Reticulocyte (Retic), and Automated Differential. 2. Review of the Laboratory's Policy and Procedure Manual revealed Policy "CHAH.

LabAdmisPRS.1004 Test Method Validation Implementation or Revision Process" which included written policies and procedure for: Accuracy- verifies that the method produces correct results. Verification of accuracy may be accomplished by: * Testing reference materials; * Comparing results of tests performed by the laboratory against the results of a reference method; * Comparing split sample results with results obtained from another method, which has already been shown to provide accurate results. Analytical Sensitivity - The laboratory must determine minimum detection limits for each analyte. This is often part of the linearity experiment and must be validated against manufacturer claim for the analyte (published in assay package insert). Analytical Specificity (Interference) - The laboratory must determine the extent to which the method measures the analyte it is reporting. The laboratory must document information regarding interfering substances from production information, literature, or its own testing. These may include specimen hemolysis, anticoagulant, lipemia, and turbidity; patients' clinical conditions, disease states and medications. Precision - Verifies the reproducibility of results. Precision studies must include day-to-day run, run-to-run, and with-in run variation, as well as operator variance, when applicable. Verification of precision may be accomplished by: * Repeat testing of known patient samples over time; * Testing QC material in duplicate and over time; or * Repeat testing of calibration materials over time. Reportable Range Validation - To include Analytical Measured Range and Clinically Reportable Range (Maximum Dilution/Concentration). Verification of reportable range may be accomplished by: * Assaying low and high calibration materials or control materials; * Evaluating known samples of abnormal high and abnormal low values. * Establishment of maximum dilution and/or concentration procedures that falls within the AMR to obtain a numeric reportable result for each analyte; * Evaluate a commercially available standard reference linearity material. Reference Range Validation - Verification of reference range may be accomplished by: * Evaluating an appropriate number of specimens to verify (in order of priority): Existing network-wide reference intervals Manufacturer's claims for normal values As applicable published reference ranges. Validation Data Summary Review: A summary of the data is prepared by the PhD Discipline and/or Laboratory Supervisor for CLIA Medical Director Review. However the Laboratory Policy for Method Validation failed to include: a) Detailed policies and procedures for testing personnel that instructed testing personnel exactly what to do for the studies to demonstrate: accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. b) Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges and analytical sensitivity and specificity. c) Policies and procedures for when data from the studies for precision, accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. d) Policies on how to maintain the documentation to show that the laboratory participated in the studies. e) Policies for when the laboratory only needs to verify performance specification vs. when the laboratory actually has to establish performance specifications for test systems not FDA approved or introducing a laboratory developed test (LDT). 3. Review of Installation Records for the two (2) new Sysmex XN 2000 Hematology Analyzers revealed: a) EP Evaluator Reports for: Simple Precision, Linearity, Carryover, and Method Comparison. Further review of the EP Evaluator Report revealed the Technical Application Specialist for Sysmex is listed as the Analyst. NOTE: No instrument printouts were available to support the EP Evaluator Reports. b) No study was performed for Reference Ranges being utilized by the laboratory. The laboratory failed to demonstrate that they could obtain performance specifications comparable to those established by the manufacturer for accuracy, precision, reportable and reference ranges. 4. Review of the Task 1 and 3 Form submitted to the surveyors on

	December 3, 2018 revealed the laboratory performs the following annual volumes: WBC - 51000, RBC - 51000, Hgb - 51000, Hct - 51000, Plt - 51000, Retic - 1200, and Automated Differential - 51000. 5. Interview with personnel 3 on December 5, 2018 revealed the Sysmex Technical Representative performed the install and the studies for Simple Precision, Linearity, Carryover and Method Comparison. Personnel 3 stated the Past Hematology Supervisor was present when the instruments were installed; however Personnel 3 confirmed the documentation revealed only the Sysmex Representative participated and that the Hematology Supervisor reviewed. Personnel 4 confirmed the laboratory did not have any documentation that the laboratory participated in the performance specification studies. III. Based on observation, record review and interview with personnel, the laboratory failed to verify the Laboratory Information System (LIS) for accuracy. Findings: 1. Observation by surveyor on December 3, 2018 through December 7, 2018, 2018 found the laboratory utilized a LIS for capturing and reporting patient test results. 2. Review of laboratory policy and procedure manual revealed the laboratory failed to have a written policy and procedures for LIS Verification. Their failed to be written detailed instructions on how testing personnel would verify the accuracy. 3. Review of Instrument Print Outs and Patient Final Reports generated by the LIS revealed the LIS failed to capture all the information from the instrument printouts (examples but not inclusive are error, and flag codes). 4. Interview with Personnel 3, 4 and 5 on December 7, 2018 confirmed the laboratory failed to verify the LIS to assure that all information is transmitted successfully and correctly from the instruments to the LIS. Personnel 3, 4, and 5 also confirmed the laboratory failed to ensure that all the data entered into the LIS matches the instrument printouts.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish and verify performance specifications for accuracy, precision, reportable and reference ranges, analytical sensitivity, and specificity for Sickle cell Screen, Platelet Function Assay and PT/PTT Mixing Studies performed by the laboratory. Findings: 1. Observation by surveyor during the laboratory tour on December 3, 2018 revealed the laboratory utilized the following: a) Pacific Hemostasis SickleScreen Hemoglobin Screening Kit for Sickle cell Screen testing. b) Instrumentation Laboratory (IL) ACL TOP 500 Coagulation Analyzer for PT/PTT Mixing Studies. c) Dade Behring PFA-100 Analyzer for Platelet Function Assay /Closure Time. 2. Review of the Food and Drug (FDA) website for test complexity revealed the following test systems failed to go through the FDA process for test categorization and thus would be considered a Laboratory Developed Test (LDT)/

	High Complexity. a) Pacific Hemostasis SickleScreen Hemoglobin Screening Kit for Sickle cell Screen testing. b) Instrumentation Laboratory (IL) ACL TOP 500 Coagulation Analyzer for PT/PTT Mixing Studies. c) Dade Behring PFA-100 Analyzer for Platelet Function Assay/Closure Time.. 3. Review of the laboratory's policy and procedure manual revealed the laboratory failed to include policies and procedures for performance specifications to include: a) Detailed policies and procedures for testing personnel that instructed testing personnel what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. b) Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges and analytical sensitivity and specificity. c) Policies and procedures for when data from the studies for precision, accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. d) Policies on how to maintain the documentation to show that the laboratory participated in the studies. e) Policies for when the laboratory only needs to verify performance specification vs. when the laboratory actually has to establish performance specifications for test systems not FDA approved or introducing a laboratory developed test (LDT). 4. Interview with Personnel 3 on December 5, 2018, revealed he was unaware the Pacific Hemostasis SickleScreen Hemoglobin Screening Kit, IL ACL TOP 500 Coagulation Analyzer for PT/PTT Mixing Studies and Dade Behring PFA-100 Analyzer for Platelet Function Assay /Closure Time had not gone through the FDA process for test categorization. Personnel 3 confirmed the laboratory had not established performance specifications for accuracy, precision, reportable and reference ranges, and analytical sensitivity and specificity. 5. Review of the Task 1 and 3 form submitted to surveyors on December 3, 2018 revealed the laboratory performed the following annual volumes: 10 Sicklecell Screening tests, 10 Mixing Studies and 30 Platelet Function tests.
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 observation, record review and interview with personnel, the laboratory failed to ensure the Daily Maintenance on the Abbott Architect Plus Analyzers I and II were performed as required by the manufacturer, for six (6) of three hundred thirty four (334) days reviewed. Findings: 1. Observation by surveyors on December 3, 2018 revealed the laboratory maintained two (2) Architect Analyzers labeled I and II for patient Immunology, Chemistry, Endocrinology and Toxicology testing: a) Abbott Architect Plus Chemistry Analyzer I, which performed the following tests: Alanine Aminotransferase (ALT), Albumin (Alb), Alkaline phosphatase (ALP), Ammonia (Ammon), Amylase (Amy), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Carbon Dioxide (CO2), Creatine Kinase (CK), Creatinine (Creat), Glucose (Glu), Lactate, Lipase, Magnesium (Mg), Phosphorous (Phos), Potassium (K), Total Protein (TP), Sodium (NA), Triglyceride (Trig), Blood Urea Nitrogen (BUN), Acetaminophen (Acet), Salicylate (Sali), Vancomycin (Vanco), Prealbumin (Prealb), Microalbumin (Microalb), Blood Alcohol (ETOH), CKMB, Troponin, Brain Natriuretic Peptide (BNP), Beta Human Chorionic

Gonadatropin (BHCG), Tricyclics, Amphetamine (Amph), Barbirurates (Barb), Benzodiazepine (Benzo), Cocaine (COC), Methadone (Meth), Opiates (OPI), Phencyclidine (PCP), and Tetrahydrocanabinol (THC). b) Abbott Architect Plus Chemistry Analyzer II, which performed the following tests: Alanine Aminotransferase (ALT), Albumin (Alb), Alkaline phosphatase (ALP), Amylase (Amy), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Carbon Dioxide (CO2), Creatine Kinase (CK), Creatinine (Creat), Glucose (Glu), Iron (Fe), Lacate Dehydrogenase (LDH), Lactate, Lipase, Magnesium (Mg), Phosphorous (Phos), Potassium (K), Total Protein (TP), Sodium (NA), Triglyceride (Trig), Uric Acid (Uric), Gamma Glutamyl Transferase (GGT), Blood Urea Nitrogen (BUN), Parathyroid Hormone (PTH), Carbamazepine (CRRBM), Digoxin (Dig), Gentamicin (Gent), Lithium (Li), Phenobarbital (Phenob), Phenytoin (Dil), Prostate Specific Antigen (PSA), Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Transferrin (Trans), Valproic Acid (Valp), Carcinoembryonic Antigen (CEA), Prealbumin (Prealb), Microalbumin (Microalb), Alpha Fetoprotein (AFP), Cortisol, Ferritin, Folate, Vitaminn B12, Blood Alcohol (ETOH), CKMB, Troponin, Hemoglobin A1C (HgbA1C), Brain Natriuretic Peptide (BNP), and C Reactive Protein (CRP). 2. Review of Maintenance Logs submitted for the Abbott Architect Plus Analyzers I and II revealed the laboratory is to perform the following Daily Maintenance: 6024 Check 1 ml Syringes 6028 Check DI Water Purity 6070 Daily Maintenance Further review of the Maintenance Logs for 2018 revealed: a) For Abbott Architect Plus Analyzer I; the laboratory failed to document daily maintenance on May 31, 2018, and July 12, 2018. b) For Abbott Architect Plus analyzer II; the laboratory failed to document daily maintenance on June 16, 2018, June 18, 2018, July 25, 2018, and July 30, 2018. 3. Interview with personnel 4 on December 7, 2018 confirmed the laboratory did not document the daily maintenance for both Abbott Architect Plus Analyzer I and II. II. Based on observation, record review and interview with personnel, the laboratory failed to ensure the Weekly Maintenance on the Abbott Architect Plus Analyzers I and II were performed as required by the manufacturer, for one (1) of forty eight (48) weeks reviewed. Findings: 1. Observation by surveyors on December 3, 2018 revealed the laboratory maintained two (2) Architect Analyzers labeled I and II for patient Immunology, Chemistry, Endocrinology and Toxicology testing: a) Abbott Architect Plus Chemistry Analyzer I, which performed the following tests: Alanine Aminotransferase (ALT), Albumin (Alb), Alkaline phosphatase (ALP), Ammonia (Ammon), Amylase (Amy), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Carbon Dioxide (CO2), Creatine Kinase (CK), Creatinine (Creat), Glucose (Glu), Lactate, Lipase, Magnesium (Mg), Phosphorous (Phos), Potassium (K), Total Protein (TP), Sodium (NA), Triglyceride (Trig), Blood Urea Nitrogen (BUN), Acetaminophen (Acet), Salicylate (Sali), Vancomycin (Vanco), Prealbumin (Prealb), Microalbumin (Microalb), Blood Alcohol (ETOH), CKMB, Troponin, Brain Natriuretic Peptide (BNP), Beta Human Chorionic Gonadatropin (BHCG), Tricyclics, Amphetamine (Amph), Barbirurates (Barb), Benzodiazepine (Benzo), Cocaine (COC), Methadone (Meth), Opiates (OPI), Phencyclidine (PCP), and Tetrahydrocanabinol (THC). b) Abbott Architect Plus Chemistry Analyzer II, which performed the following tests: Alanine Aminotransferase (ALT), Albumin (Alb), Alkaline phosphatase (ALP), Amylase (Amy), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Carbon Dioxide (CO2), Creatine Kinase (CK), Creatinine (Creat), Glucose (Glu), Iron (Fe), Lactate Dehydrogenase (LDH), Lactate, Lipase, Magnesium (Mg), Phosphorous (Phos),

	Potassium (K), Total Protein (TP), Sodium (NA), Triglyceride (Trig), Uric Acid (Uric), Gamma Glutamyl Transferase (GGT), Blood Urea Nitrogen (BUN), Parathyroid Hormone (PTH), Carbamazepine (CRRBM), Digoxin (Dig), Gentamicin (Gent), Lithium (Li), Phenobarbital (Phenob), Phenytoin (Dil), Prostate Specific Antigen (PSA), Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Transferrin (Trans), Valproic Acid (Valp), Carcinoembryonic Antigen (CEA), Prealbumin (Prealb), Microalbumin (Microalb), Alpha Fetoprotein (AFP), Cortisol, Ferritin, Folate, Vitaminn B12, Blood Alcohol (ETOH), CKMB, Troponin, Hemoglobin A1C (HgbA1C), Brain Natriuretic Peptide (BNP), and C Reactive Protein (CRP). 2. Review of Maintenance Logs submitted for the Abbott Architect Plus Analyzers I and II revealed the laboratory is to perform the following Weekly Maintenance: 6407 Probe Cleaning - Manual 6445 Pipettor/WZ Probe Cleaning 6450 Wash Cup Cleaning 6019 Check ICT Compnents 6021 Clean Mixers 6023 Clean Sample/Reagent Probes 6056 Clean Cuvetter with Detergent 6308 Check HC Waste Pump Tubing 9100 Wiping Exterior Surfaces 9103 Wash Cup/Mixer Cup Bleach Further review of the Maintenance Logs for 2018 revealed: a) For Abbott Architect Plus Analyzer I; the laboratory failed to document weekly maintenance for the week beginning June 8, 2018. 3. Interview with personnel 4 on December 7, 2018 confirmed the laboratory did not document the weekly maintenance for Abbott Architect Plus Analyzer I. III. Based on observation, record review and interview with personnel, the laboratory failed to ensure the Maintenance of the Stain for Frozen Sections was performed each day of patient testing for two (2) of five (5) patient test days reviewed. Findings: 1. Observation by surveyors on December 6, 2018 revealed the laboratory maintained a staining station containing: Alcohols, Xylenes, Ammonia Water, Eosin, Hematoxylin, and Water Solutions for staining Frozen Sections for Histopathology for review for diagnostic purposes. 2. Review of Staining Maintenance Logs submitted for the five (5) patient test days revealed the laboratory failed to document daily stain maintenance on February 23, 2018 and November 21, 2018. 3. Interview with the Histotech on duty on December 6, 2018 confirmed the laboratory did not document the daily maintenance for the stain maintenance for the two dates cited above.
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 levels of control materials each day of patient testing for Cerebrospinal Total Protein (CFTP) performed on the Abbott Architect Plus Analyzer, for one (1) of thirty eight (38) patients reviewed. Findings: 1. Observation by the surveyor on December 3, 2018 during the tour of the laboratory noted the laboratory maintained a Abbott Architect Plus Analyzer for the testing and reporting of CFTP. 2. Review of the Laboratory's Policy and Procedure Manual revealed personnel are to perform two levels of quality control each day of patient testing for patient CFTP testing. 3. Review of a random selection of Patient CFTP testing and CFTP Quality Control records from May 1, 2018 through December 4, 2018 revealed

	Patient 131 was tested and reported for CFTP on July 3, 2018 at 19:53 PM. CFTP Quality Control revealed quality control was performed on June 27, 2018 at 11:13 AM then not again until July 7, 2018 at 16:03 PM. 4. Interview with Personnel 4 on December 4, 2018 confirmed the laboratory failed to perform CFTP Quality Control for Patient 131 on July 3, 2018.
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 the Pacific Hemostasis SickleScreen Sickling Hemoglobin Screening Kit for sickle cell disease, for one (1) of ten (10) patients reviewed. Findings: 1. Observation by the surveyor on December 3, 2018 during the tour of the laboratory noted the laboratory performed Sickle Cell Screening with the Pacific Hemostasis SickleScreen Sickling Hemoglobin Screening Kit. 2. Review of the Laboratory's Policy and Procedure Manual revealed personnel are to perform positive and negative quality control each day of patient testing for patient Sickle Cell Screening testing. 3. Review of Patient Sickle Cell Screen testing and Quality Control records from June 1, 2018 through November 30, 2018 revealed that Patient 93 was tested and reported for Sickle Cell Screen testing without having a positive and negative control performed. 4. Interview with Personnel 3 on December 5, 20 18 confirmed the laboratory failed to document the performance of a positive and negative control for Patient 93.
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 record review and interview with personnel, the laboratory failed to utilize control material of a similar matrix for Urine Ethanol (ETOH) for forty four (44) of forty four (44) patients reviewed. Findings: 1. Review of the Task 1 and 3 Form submitted to surveyors on December 3, 2018 revealed the laboratory performed Urine Ethanol (ETOH) on the Abbott Architect Plus Analyzers. Further review of the Task 1 and 3 Form revealed the laboratory utilized the BIO-RAD ETOH/Ammonia Serum based quality control material for patient Urine ETOH testing. 2. Observation by surveyors on December 3, 2018 revealed the laboratory maintained two (2) Abbott Architect Plus analyzers for patient testing to include urine ethanol. 3. Review of Patient Urine ETOH Test Records from August 2018 revealed the laboratory performed Patient Urine ETOH without using a urine matrix quality control material

	for the following forty four (44) patients. On August 1, 2018 Patient 89 On August 2, 2018 Patients 55 and 84 On August 6, 2018 Patients 72 and 77 On August 7, 2018 Patients 85 and 90 On August 8, 2018 Patients 53, 71 and 73 On August 9, 2018 Patients 69 and 79 On August 10, 2018 Patients 65, 67, 78, and 80 On August 13, 2018 Patients 49, 58, 81 and 87 On August 14, 2018 Patients 52, and 62 On August 15, 2018 Patients 63, 68, and 83 On August 16 2018 Patient 92 On August 17, 2018 Patients 75 and 88 On August 21, 2018 Patient 81 On August 24, 2018 Patient 86 On August 27, 2018 Patients 60, 64, 66, and 91 On August 29, 2018 Patients 50, 51, 54, 56, 59, 61, 70, and 76 On August 30, 2018 Patient 57 On August 31, 2018 Patient 74 4. Interview with Personnel 4 on December 7, 2018 confirmed the laboratory utilized the BIO-RAD Ethanol/Ammonia quality control material for Patient Urine Ethanol testing. Personnel 4 confirmed the BIO-RAD Controls are a serum matrix and not a urine matrix.
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 observation, record review and interview with personnel, the laboratory failed to document visual inspections for each batch/shipment of BD BACTEC Aerobic, Anaerobic and Peds Plus Culture Bottles for six (6) of six (6) lot numbers reviewed. Findings: 1. Observation by the surveyors during the tour of the laboratory on December 3, 2018 revealed the laboratory utilized BD BACTEC Aerobic, Anaerobic and Ped Plus Blood Culture Bottles for patient testing. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not include quality control procedures for Microbiology media testing, that included documenting the physical characteristics of the media, when compromised,d and report any deterioration in the media to the manufacturer. 3. Interview with Personnel 2 on December 7, 2018 revealed Blood Culture bottles are visually inspected; however the laboratory does not have a policy on what is to be checked and how to document the visual inspection of blood culture bottle. 4. Review of the Laboratory's Log for Blood Culture Bottles received revealed the laboratory did not document quality control procedures for the following six (6) lot numbers: a) Aerobic Blood Culture Bottles; Lot 8205862 with an expiration date of 2019/5/31 that was put into use on 10/24/2018 a) Aerobic Blood Culture Bottles; Lot 8219948 with an expiration date of 2019/5/31 that was put into use on 11/8/2018 a) Anaerobic Blood Culture Bottles; Lot 8236635 with an expiration date of 2019/6/30 that was put into use on 10/24/2018 a) Anaerobic Blood Culture Bottles; Lot 8236621 with an expiration date of 2019/6/30 that was put into use on 11/8/2018 a) Peds Plus Blood Culture Bottles; Lot 8219898 with an expiration date of 2019/5/31 that was put into use on 10/24/2018 a) Peds Plus Blood Culture Bottles; Lot 8236606 with an expiration date of 2019/6/30 that was put into use on 11/8/2018 5. Interview with Personnel 2 on December 7, 2018 confirmed the

	laboratory failed to have a policy for Blood Culture Quality Control and also confirmed the laboratory did not document the visual inspection of the Blood Culture Bottles when received.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: I. Based on observation, record review and interview with personnel, the laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for D-Dimer testing performed on the Instrumentation Laboratory (IL) ACL Top 500 Coagulation Analyzer, for six (6) of sixty four (64) patients reviewed. Findings: 1. Observation by surveyors on December 3, 2018 noted the laboratory utilized the IL ACL Top 500 Coagulation Analyzer for D-Dimer testing. 2. Review of the laboratory policy and procedure manual revealed the laboratory is to perform two levels of quality control material every eight (8) hours of patient D-Dimer testing. 3. Review of D-Dimer Quality Control and Patient Test Records for August 2018 revealed the laboratory failed to perform two levels of quality control each eight hours of patient testing for D-Dimer testing for the following six (6) patients: On August 4, 2018 Patient 95 was reported for D-Dimer at 13:32 PM - quality control was performed at 1: 03 AM then again at 13:34 PM. On August 5, 2018 Patient 94 was reported for D-Dimer at 13:15 PM - quality control was performed on 8/4/2018 at 21:54 PM then again on 8/5/2018 at 13:16 PM. On August 24, 2018 Patient 99 was reported for D-Dimer at 00:55 AM - quality control was performed on 8/23/2018 at 11:02 AM then again on 8/24/2018 at 00:58 AM. On August 25, 2018 Patient 97 was reported for D-Dimer at 16:33 PM - quality control was performed on 8/24/2018 at 18:07 PM then again on 8/25/2018 at 16:36 PM. On August 28, 2018 Patient 98 was reported for D-Dimer at 03:21 AM - quality control was performed on 8/27/2018 at 09:34 AM then again on 8/282018 at 03:22 AM. On August 30, 2018 Patient 96 was reported for D-Dimer at 12:29 PM - quality control was performed on 8/29/2018 at 19:16 PM then again on 8/30/2018 at 12:36 PM. 4. Interview with Personnel 3 on December 6, 2018 confirmed the laboratory tested and reported the six (6) patients cited above without having two levels of quality control performed each eight (8) hours and prior to patient D-Dimer testing. II. Based on observation, record review and interview with personnel, the laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for Fibrinogen testing performed on the Instrumentation Laboratory (IL) ACL Top 500 Coagulation Analyzer, for three (3) of thirty two (32) patients reviewed. Findings: 1. Observation by surveyors on December 3, 2018 noted the laboratory utilized the IL ACL Top 500 Coagulation Analyzer for Fibrinogen testing. 2. Review of the laboratory policy and procedure manual revealed the laboratory is to perform two levels of quality control material every eight (8) hours of patient Fibrinogen testing. 3. Review of Fibrinogen Quality Control and Patient Test Records for July 2018 through August 2018 revealed the laboratory failed to perform two levels of quality control each eight hours of patient testing for Fibrinogen testing for the following three (3) patients: On August 12, 2018 Patients 100 and 101 were reported for Fibrinogen at 06:55 APM - quality control was performed on 8/11/2018 at 20:09 PM then again on 8/12/2018 at 11:04 AM. On August 18, 2018 Patient 100

was reported for Fibrinogen at 04:55 AM - quality control was performed on 8/17 /2018 at 20:09 PM then again on 8/18/2018 at 05:51 AM. 4. Interview with Personnel 3 on December 6, 2018 confirmed the laboratory tested and reported the six (6) patients cited above without having two levels of quality control performed each eight (8) hours and prior to patient D-Dimer testing. III. Based on observation, record review and interview with personnel, the laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for Platelet Function (Closure Time) testing performed on the Dade Behring PFA-100 Platelet Function Analyzer, for twelve (12) of twelve (12) patients reviewed. Findings: 1. Observation by surveyors on December 3, 2018 noted the laboratory utilized the Dade Behring PFA-100 Platelet Function Analyzer for Platelet Function/Closure Time testing. 2. Review of the laboratory policy and procedure manual revealed the laboratory performs one level of normal pooled plasma with each new shipment of cartridges received. Further review of the laboratory policy and procedure revealed that a Self Test (electronic check) is to be performed each eight (8) hours of patient testing. 3. Review of Platelet Function/Closure Time Quality Control and Patient Test Records for June 2018 through December 3, 2018 revealed the laboratory failed to perform two levels of quality control each eight hours of patient testing for Platelet Function/Closure Time testing for the following twelve (12) patients: On June 18, 2018 Patient 112 was reported for Platelet Function/Closure Time at 12:18 PM. The laboratory maintained no quality control results for the normal pooled plasma or for the Self Test. On August 7, 2018 Patient 114 was reported for Platelet Function/Closure Time at 12:04 PM. The laboratory maintained no quality control results for the normal pooled plasma or for the Self Test. On August 20, 2018 Patient 103 was reported for Platelet Function/Closure Time at 15:28 PM. The laboratory maintained no quality control results for the normal pooled plasma or for the Self Test. On August 24, 2018 Patient 110 was reported for Platelet Function/Closure Time at 11:49 AM. The laboratory maintained no quality control results for the normal pooled plasma or for the Self Test. On September 18, 2018 Patient 107 was reported for Platelet Function/Closure Time at 19:37 PM. The laboratory maintained no quality control results for the normal pooled plasma or for the Self Test. On September 27, 2018 Patient 111 was reported for Platelet Function/Closure Time at 14:40 PM. The laboratory maintained no quality control results for the normal pooled plasma or for the Self Test. On October 4, 2018 Patient 106 was reported for Platelet Function/Closure Time at 17:34 PM. The laboratory maintained no quality control results for the normal pooled plasma or for the Self Test. On October 5, 2018 Patient 108 was reported for Platelet Function /Closure Time at 16:03 PM. The laboratory maintained no quality control results for the normal pooled plasma or for the Self Test. On October 17, 2018 Patient 113 was reported for Platelet Function/Closure Time at 14:13 PM. The laboratory maintained no quality control results for the normal pooled plasma or for the Self Test. On October 24, 2018 Patient 105 was reported for Platelet Function/Closure Time at 06: 57 AM. The laboratory maintained no quality control results for the normal pooled plasma or for the Self Test. On November 16, 2018 Patient 104 was reported for Platelet Function/Closure Time at 10:33 AM. The laboratory maintained no quality control results for the normal pooled plasma or for the Self Test. 4. Interview with Personnel 3 on December 6, 2018 confirmed the laboratory tested and reported the twelve (12) patients cited above without having two levels of quality control performed each eight (8) hours and prior to patient Platelet Function/Closure Time testing. IV. Based on observation, record review and interview with personnel, the laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for PTT Mixing Study testing performed on the Instrumentation Laboratory (IL) ACL Top 500 Coagulation Analyzer, for five (5) of five (5) patients reviewed. Findings: 1. Observation by surveyors on December 3, 2018 noted the

	laboratory utilized the IL ACL Top 500 Coagulation Analyzer for PTT Mixed Study testing. 2. Review of the laboratory policy and procedure manual revealed the laboratory failed to develop a policy and procedure that included two levels of quality control material every eight (8) hours of patient PTT Mixed Study testing. 3. Review of Patient PTT Mixed Study Test Records for February 26, 2018 through November 15, 2018 revealed the laboratory failed to perform two levels of quality control each eight hours of patient testing for PTT Mixed Study testing for the following five (5) patients: On February 26, 2018 Patient 115 was reported for PTT Mixed Study testing at 14:26 PM - No quality control was performed. On February 28, 2018 Patient 116 was reported for PTT Mixed Study testing at 10:25 AM - No quality control was performed. On May 3, 2018 Patient 117 was reported for PTT Mixed Study testing at 10:23 AM - No quality control was performed. On July 7, 2018 Patient 118 was reported for PTT Mixed Study testing at 07:59 AM - No quality control was performed. On November 15, 2018 Patient 119 was reported for PTT Mixed Study testing at 09:08 AM - No quality control was performed. 4. Interview with Personnel 3 on December 6, 2018 confirmed the laboratory tested and reported the five (5) patients cited above without having two levels of quality control performed each eight (8) hours and prior to patient PTT Mixed Study testing.
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 record review and interview with personnel, the laboratory failed to document all quarterly alarm check information. Findings: 1. Review of the Blood Bank's Policy and Procedure Manual revealed quarterly alarm checks were to be performed on blood bank refrigerators. Laboratory policy does not detail the information to be documented for quarterly alarm checks. 2. Review of the Blood Bank's Circular Temperature Charts for 2017 and 2018 revealed the Blood Bank Refrigerator did not have documentation of quarterly alarm checks as follows: a) 2017: June 1, 2017, Septermber 5, 2017 and December 7, 2017 alarm checks do not reflect the needle on the circular chart to have met the temperatures documented as alarmed, the temperature at which the alarm sounded is not documented. b) 2018: June and December alarm check: no indication on the circular chart of an alarm check performed, no needle movement on the circular chart indicated a change in temperature, the temperature at which the alarm sounded is not documented. c) Dates of alarm check performance are not documented for each alarm check, only target dates. 3. Interviews with Personnel 5 on December 7, 2018 stated the hospital Biomed team performs the quarterly arlarm checks. Personnel 5 confirmed the alarm checks are not reflected on the circular chart. Personnel 5 also confirmed that the documentation provided by Biomed for alarm checks does not include the date the alarm check is performed or the temperature at which the alarm sounds.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
I. Based on record review and interview with personnel, the laboratory failed to perform and document a control slide of known reactivity for the Hematoxylin and Eosin (H&E) Staining utilized for histopathology slides for twenty (20) of twenty (20) patient test days reviewed. Findings: 1. Review of a random selection of Histopathology Quality Control and Patient Test Reports from January 4, 2018 through December 4, 2018, revealed the laboratory reported the following twenty (20) patients without documenting quality control results for the for H&E Stained Slides . Patient 135 was collected on January 4, 2018 and reported on January 9, 2018. Patient 136 was collected on January 10, 2018 and reported on January 15, 2018. Patient 137 was collected on January 17, 2018 and reported on January 19, 2018. Patient 138 was collected on February 23, 2018 and reported on March 7, 2018. Patient 139 was collected on March 15, 2018 and reported on March 21, 2018. Patient 141 was collected on March 19, 2018 and reported on March 21, 2018. Patient 140 was collected on July 16, 2018 and reported on July 18, 2018. Patient 142 was collected on April 23, 2018 and reported on April 25, 2018. Patient 143 was collected on May 11, 2018 and reported on May 23, 2018. Patient 144 was collected on May 31, 2018 and reported on June 7, 2018. Patient 145 was collected on June 1, 2018 and reported on June 6, 2018. Patient 146 was collected on June 4, 2018 and reported on June 12, 2018. Patient 147 was collected on June 7, 2018 and reported on June 13, 2018. Patient 148 was collected on August 9, 2018 and reported on August 14, 2018. Patient 149 was collected on September 16, 2018 and reported on September 20, 2018. Patient 150 was collected on October 15, 2018 and reported on October 18, 2018. Patient 151 was collected on October 22, 2018 and reported on October 25, 2018. Patient 152 was collected on October 31, 2018 and reported on November 6, 2018. Patient 153 was collected on November 2, 2018 and reported on November 19, 2018. Patient 154 was collected on November 27, 2018 and reported on December 4, 2018. 2. Interview with Personnel 24 on December 6, 2018 revealed quality control was being performed at the main campus (New Orleans) by the individuals processing the samples. Personnel 24 was able to obtain copies of the QC performed at the main campus; however the laboratory failed to document a control slide of known reactivity for H&E staining. II. Based on record review and interview with personnel, the laboratory failed to perform and document a positive and negative control slide for Immunohistochemical Staining utilized for histopathology slides for twenty one (21) of twenty one (21) immunohistochemical stains affecting seven (7) patients reviewed. Findings: 1. Review of a random selection of Histopathology Quality Control and Patient Test Reports from January 4, 2018 through December 4, 2018, revealed the laboratory reported the following seven (7) patients without documenting quality control for a positive and negative reaction for twenty one (21) immunohistochemical stains performed. Patient 138 was collected on February 23, 2018 and reported on March 7, 2018 with: p63, WSK, AE1/AE3, and CAM immunohistochemical stains. Patient Final Report states "control stains adequately" however the laboratory failed to document a positive and negative reaction and control stains adequately is not defined by the laboratory. Patient 143 was collected on May 11, 2018 and reported on May

23, 2018 with: WSK, AE1/AE3, and CAM immunohistochemical stains. Patient Final Report states "immunostains with appropriate controls" however the laboratory failed to document a positive and negative reaction. Patient 145 was collected on June 1, 2018 and reported on June 6, 2018 with: p16 immunohistochemical stains. Patient Final Report states "immunohistochemical stains with appropriate controls" however the laboratory failed to document a positive and negative reaction. Patient 146 was collected on June 4, 2018 and reported on June 12, 2018 with: AMARCR immunohistochemical stains. Patient Final Report states "immunohistochemical stains with appropriate controls" however the laboratory failed to document a positive and negative reaction. Patient 147 was collected on June 7, 2018 and reported on June 13, 2018 with: Helicobacter pylori immunohistochemical stains. Patient Final Report states "appropriately controlled stain for Helicobacter pylori is negative" however the laboratory failed to document a positive and negative reaction. Patient 149 was collected on September 16, 2018 and reported on September 20, 2018 with: p53, CK7, CK20, TTF-1, Calretinin, and GCDFP-15 immunohistochemical stains. Patient Final Report did not state anything for the immunohistochemical stain controls. Patient 153 was collected on November 2, 2018 and reported on November 19, 2018 with: CAM, WSK, AE1/AE3, p63, and CK 5/6 immunohistochemical stains. Patient Final Report did not state anything for the immunohistochemical stain controls. 2. Interview with Personnel 24 on December 6, 2018 revealed quality control was being performed at the main campus (New Orleans) by the individuals processing the samples. Personnel 1 and 24 stated the doctors at the laboratory usually state in the report what the quality control results where for the different immunohistochemical stains were. Personnel 24 confirmed she had no documentation for the positive and negative reactivity of the various immunohistochemical stains. III. Based on record review and interview with personnel, the laboratory failed to perform and document a control slide of known reactivity for each special stain performed for eight (8) of eight (8) special stains affecting three (3) patients reviewed. Findings: 1. Review of a random selection of Histopathology Quality Control and Patient Test Reports from August 9, 2018 through December 4, 2018, revealed the laboratory reported the following twenty (20) patients without documenting a control slide of known reactivity for each special stain performed. Patient 148 was collected on August 9, 2018 and reported on August 14, 2018 with: Reticulin, Iron, and Trichrome Special Stains. Patient Final Report states "all with appropriate control" however the laboratory failed to document a control slide of known reactivity for each special stain performed. Patient 149 was collected on September 16, 2018 and reported on September 20, 2018 with a Mucicarmine Special Stain. Patient Final Report states "with adequate controls" however the laboratory failed to document a control slide of known reactivity, and the laboratory failed to define with adequate controls. Patient 154 was collected on November 27, 2018 and reported on December 4, 2018 with: PAS, Trichrome, Iron and Retic Special Stains. Patient Final Report states "controls stain adequately" however the laboratory failed to document a control slide of known reactivity, and the laboratory failed to define controls stain adequately. 2. Interview with Personnel 24 on December 6, 2018 revealed quality control was being performed at the main campus (New Orleans) by the individuals processing the samples. Personnel 1 and 24 stated the doctors at the laboratory usually state in the report what the quality control results where for the different immunohistochemical stains were. Personnel 24 confirmed she had no documentation of a control slide of known reactivity for each special stain performed . IV. Based on record review and interview with personnel, the laboratory failed to perform and document a control slide of known reactivity for Frozen Sections for five (5) of five (5) patients reviewed. Findings: 1. Review of a random selection of Histopathology Quality Control and Patient Test Reports from January 4, 2018 through December 4, 2018, revealed the laboratory reported the following twenty (20)

	patients a control slide of known reactivity for Frozen Sections Patient 135 was collected for a Frozen Section on the Left and Right Ovaries on January 4, 2018 and reported on January 9, 2018. Patient 138 was collected for a Frozen Section on the Left Axillary Sentinel Lymph Node on February 23, 2018 and reported on March 7, 2018. Patient 143 was collected for a Frozen Section of the Left Sentinel Lymph Node on May 11, 2018 and reported on May 23, 2018. Patient 152 was collected for a Frozen Section of the Right Parathyroid Tissue and Right Lower Parathyroid on October 31, 2018 and reported on November 6, 2018. Patient 153 was collected for a Frozen Section of the Right Axillary Sentinel Lymph Node on November 2, 2018 and reported on November 19, 2018. 2. Interview with Personnel 1 on December 6, 2018 revealed he was unaware he had to document a control slide for Frozen Sections.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to have a system in place for twice a year comparison testing for the two (2) Abbott Architect Plus Analyzers. Findings: 1. Observation by surveyors on December 3, 2018 revealed the laboratory maintained the following two (2) new Abbott Architect Plus Analyzers for patient testing: a) Abbott Architect Plus Chemistry Analyzer I (Serial number 3457120038), which performed the following tests: Alanine Aminotransferase (ALT), Albumin (Alb), Alkaline phosphatase (ALP), Ammonia (Ammon), Amylase (Amy), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Carbon Dioxide (CO2), Creatine Kinase (CK), Creatinine (Creat), Glucose (Glu), Lactate, Lipase, Magnesium (Mg), Phosphorous (Phos), Potassium (K), Total Protein (TP), Sodium (NA), Triglyceride (Trig), Blood Urea Nitrogen (BUN), Acetaminophen (Acet), Salicylate (Sali), Vancomycin (Vanco), Prealbumin (Prealb), Microalbumin (Microalb), Blood Alcohol (ETOH), CKMB, Troponin, Brain Natriuretic Peptide (BNP), Beta Human Chorionic Gonadatropin (BHCG), Tricyclics, Amphetamine (Amph), Barbirurates (Barb), Benzodiazepine (Benzo), Cocaine (COC), Methadone (Meth), Opiates (OPI), Phencyclidine (PCP), and Tetrahydrocanabinol (THC). b) Abbott Architect Plus Chemistry Analyzer II (Serial number F3457120079), which performed the following tests: Alanine Aminotransferase (ALT), Albumin (Alb), Alkaline phosphatase (ALP), Amylase (Amy), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Carbon Dioxide (CO2), Creatine Kinase (CK), Creatinine (Creat), Glucose (Glu), Iron (Fe), Lacate Dehydrogenase (LDH), Lactate, Lipase, Magnesium (Mg), Phosphorous (Phos), Potassium (K), Total Protein (TP), Sodium (NA), Triglyceride (Trig), Uric Acid (Uric), Gamma Glutamyl Transferase (GGT), Blood Urea Nitrogen (BUN), Parathyroid Hormone (PTH), Carbamazepine (CRRBM), Digoxin (Dig), Gentamicin (Gent), Lithium (Li), Phenobarbital (Phenob), Phenytoin (Dil), Prostate Specific Antigen (PSA), Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Transferrin (Trans), Valproic Acid (Valp),

	Carcinoembryonic Antigen (CEA), Prealbumin (Prealb), Microalbumin (Microalb), Alpha Fetoprotein (AFP), Cortisol, Ferritin, Folate, Vitaminn B12, Blood Alcohol (ETOH), CKMB, Troponin, Hemoglobin A1C (HgbA1C), Brain Natriuretic Peptide (BNP), and C Reactive Protein (CRP). 2. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to include a written policy for the laboratory to perform twice a year verification between the two Abbott Architect Plus Analyzers 3. Interview with Personnel 4 on December 6, 2018 revealed the laboratory had not performed a twice a year verification of the Two Abbott Architect Analyzers. 4. Review of the Task 1 and 3 Form submitted to the surveyors on December 3, 2018 revealed the laboratory performs the following annual volumes: ALT - 46000, Alb - 55000, ALP - 46000, Amy - 300, Ammon - 320, AST - 47000, DBil - 250, TBil - 47000, CA - 55000, CL - 55000 , Chol - 17000, HDL - 17000, CO2 - 55000, CK - 1200, Creat - 57800, Glu - 55000, Fe - 2200, LDH - 575, Lactate - 3500, Lipase - 3100, Mg - 13200, Phos - 13200, K - 55000, TP - 47000, NA - 55000, Trig - 17000, Uric - 2000, GGT - 175, BUN - 55000, PTH - 1350, CRBM - 40, Dig - 120, Gent - 75, Li - 175, Phenob - 12, Dil - 50, PSA - 3500, FT4 - 3400, TSH - 15000, Trans - 2017, Valp - 550, Vanco - 2000, BHCG - 520, CEA - 500, Prealb - 200, Microalb - 2700, Acet - 1700, AFP - 900, Cortisol - 150, Ferritin - 2100, Folate - 850, Vitamin B12 - 1700, ETOH - 2250, CKMB - 169, Sali - 220,Troponin - 8200, HgbA1C - 16000, BNP - 3400, CRP - 2700, Tricyclics - , Amph - , Barb - 7000, Benzo - 7000, COC - 7000, Meth - 7000, OPI - 7000, PCP - 7000, and THC - 7000.
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on record review and interview with personnel the laboratory failed to retain instrument printouts for General Immunology, Routine Chemistry, Endocrinology, Toxicology, Hematology and Coagulation. Findings: 1. Observation by surveyors on December 3, 2018 revealed the laboratory maintained the following two (2) new Abbott Architect Plus Analyzers for patient testing: a) Abbott Architect Plus Chemistry Analyzer I (Serial number 3457120038), which performed the following tests: Alanine Aminotransferase (ALT), Albumin (Alb), Alkaline phosphatase (ALP), Ammonia (Ammon), Amylase (Amy), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Carbon Dioxide (CO2), Creatine Kinase (CK), Creatinine (Creat), Glucose (Glu), Lactate, Lipase, Magnesium (Mg), Phosphorous (Phos), Potassium (K), Total Protein (TP), Sodium (NA), Triglyceride (Trig), Blood Urea Nitrogen (BUN), Acetaminophen (Acet), Salicylate (Sali), Vancomycin (Vanco), Prealbumin (Prealb), Microalbumin (Microalb), Blood Alcohol (ETOH), CKMB, Troponin, Brain Natriuretic Peptide (BNP), Beta Human Chorionic Gonadatropin (BHCG), Tricyclics, Amphetamine (Amph), Barbirurates (Barb), Benzodiazepine (Benzo), Cocaine (COC), Methadone (Meth), Opiates (OPI), Phencyclidine (PCP), and Tetrahydrocanabinol (THC). b) Abbott Architect Plus Chemistry Analyzer II (Serial number F3457120079), which performed the following tests: Alanine Aminotransferase (ALT), Albumin (Alb), Alkaline phosphatase (ALP), Amylase (Amy), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Carbon Dioxide (CO2), Creatine Kinase (CK),

	Creatinine (Creat), Glucose (Glu), Iron (Fe), Lacate Dehydrogenase (LDH), Lactate, Lipase, Magnesium (Mg), Phosphorous (Phos), Potassium (K), Total Protein (TP), Sodium (NA), Triglyceride (Trig), Uric Acid (Uric), Gamma Glutamyl Transferase (GGT), Blood Urea Nitrogen (BUN), Parathyroid Hormone (PTH), Carbamazepine (CRRBM), Digoxin (Dig), Gentamicin (Gent), Lithium (Li), Phenobarbital (Phenob), Phenytoin (Dil), Prostate Specific Antigen (PSA), Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Transferrin (Trans), Valproic Acid (Valp), Carcinoembryonic Antigen (CEA), Prealbumin (Prealb), Microalbumin (Microalb), Alpha Fetoprotein (AFP), Cortisol, Ferritin, Folate, Vitaminn B12, Blood Alcohol (ETOH), CKMB, Troponin, Hemoglobin A1C (HgbA1C), Brain Natriuretic Peptide (BNP), and C Reactive Protein (CRP). c) (2) Sysmex XN 2000 Hematology Analyzers (Serial numbers: 27674 and 27676) for patient testing for Complete Blood Cell (CBC) testing which includes: White Blood Cell counts (WBC), Red Blood Cell counts (RBC), Hemoglobin (Hgb), Hematocrit (Hct), Platelet (Plt), Reticulocyte (Retic), and Automated Differential. d) Instrumentation Laboratory (IL) ACL TOP 500 Coagulation Analyzer for patient testing for: Prothrombin Time (PT), International Normalized Ratio (INR), Activated Prothromboplastin Time (APTT), Fibrinogen and D-Dimer. e) Dade Behring PFA-100 Analyzer for Platelet Function /Closure Time testing. 2. Interviews with Personnel 2, 3 4, and 5 throughout the survey process from December 3, 32018 through December 7, 2018 all stated and confirmed the laboratory does not retain instrument printouts for any of the instruments.
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 establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the 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 perform Gram Stain Quality Control each day of patient testing with each testing person reporting a Gram Stain for eleven (11) of thirty seven (37) patients reviewed as required by laboratory policy. Refer to D5401 I. b) The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5401 II. c) The laboratory failed to follow their policy for documenting the date for Emergency Release of blood units. Refer to D5401 III. d) The laboratory failed to have a complete policy and procedure manual. Refer to D5403. e) The laboratory failed to ensure that patient samples for Ammonia testing are reported within two (2) hour after collection according to the manufacturer's requirements for two (2) of two hundred and four (204) patients reviewed. Refer to D5411 I. f) The laboratory failed to use normal donors as required by manufacturer to verify reference intervals and establish their own normal Prothrombin (PT) mean with each new lot of thromboplastin. Refer to D5411 II. g) The laboratory failed to label Histopathology reagents, and solutions with the strength or concentration of the material, storage requirements, preparation and/or expiration dates. Refer to D5415. h) The laboratory

failed to ensure that Blood Collection tubes, Calibrators and Calibrator Verification material are not used beyond their expiration dates. Refer to D5417. i) The laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for two (2) of two (2) new Abbott Architect Plus Analyzers. Refer to D5421 I. j) The laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for two (2) of two (2) new Sysmex XN 2000 Hematology Analyzers. Refer to D5421 II. k) The laboratory failed to verify the Laboratory Information System (LIS) for accuracy. Refer to D5421 III. l) The laboratory failed to establish and verify performance specifications for accuracy, precision, reportable and reference ranges, analytical sensitivity, and specificity for Sickle cell Screen, Platelet Function Assay and PT/PTT Mixing Studies performed by the laboratory. Refer to D5423. m) The laboratory failed to ensure the Daily Maintenance on the Abbott Architect Plus Analyzers I and II were performed as required by the manufacturer, for six (6) of three hundred thirty four (334) days reviewed. Refer to D5429 I. n) The laboratory failed to ensure the Daily Maintenance on the Abbott Architect Plus Analyzers I and II were performed as required by the manufacturer, for one (1) of forty eight (48) weeks reviewed. Refer to D5429 II. o) The laboratory failed to ensure the Maintenance of the Stain for Frozen Sections was performed each day of patient testing for two (2) of five (5) patient test days reviewed. Refer to D5429 III. p) The laboratory failed to perform two levels of control materials each day of patient testing for Cerebrospinal Total Protein (CFTP) performed on the Abbott Architect Plus Analyzer, for one (1) of thirty eight (38) patients reviewed. Refer to D5447. q) The laboratory failed to perform a positive and negative control each day of patient testing for the Pacific Hemostasis SickleScreen Sickling Hemoglobin Screening Kit for sickle cell disease, for one (1) of ten (10) patients reviewed. Refer to D5449. r) The laboratory failed to utilize control material of a similar matrix for Urine Ethanol (ETOH) for forty four (44) of forty four (44) patients reviewed. Refer to D5465. s) The laboratory failed to document visual inspections for each batch/shipment of BD BACTEC Aerobic, Anaerobic and Peds Plus Culture Bottles for six (6) of six (6) lot numbers reviewed. Refer to D5477. t) The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for D-Dimer testing performed on the Instrumentation Laboratory (IL) ACL Top 500 Coagulation Analyzer, for six (6) of sixty four (64) patients reviewed. Refer to D5545 I. u) The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for Fibrinogen testing performed on the Instrumentation Laboratory (IL) ACL Top 500 Coagulation Analyzer, for three (3) of thirty two (32) patients reviewed. Refer to D5545 II. v) The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for Platelet Function (Closure Time) testing performed on the Dade Behring PFA-100 Platelet Function Analyzer, for twelve (12) of twelve (12) patients reviewed. Refer to D5545 III. w) The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for PTT Mixing Study testing performed on the Instrumentation Laboratory (IL) ACL Top 500 Coagulation Analyzer, for five (5) of five (5) patients reviewed.Refer to D5545 IV. x) The laboratory failed to assure the quarterly blood bank alarm checks recorded on the circular temperature charts. Refer to D5555. y) The laboratory failed to perform and document a control slide of known reactivity for the Hematoxylin and Eosin (H&E) Staining utilized for histopathology slides for twenty (20) of twenty (20) patient test days reviewed. Refer to D5601 I. z) The laboratory failed to perform and document a positive and negative control slide for Immunohistochemical Staining utilized for histopathology slides for twenty one (21) of twenty one (21) immunohistochemical stains affecting seven (7) patients reviewed. Refer to D5601 II. aa) The laboratory failed to perform and document a control slide of known reactivity for each special

	stain performed for eight (8) of eight (8) special stains affecting three (3) patients reviewed. Refer to D5601 III. ab) The laboratory failed to perform and document a control slide of known reactivity for Frozen Sections for five (5) of five (5) patients reviewed. Refer to D5601 IV. ac) The the laboratory failed to have a system in place for twice a year comparison testing for the two (2) Abbott Architect Plus Analyzers. Refer to D5775. ad) The laboratory failed to retain instrument printouts for General Immunology, Routine Chemistry, Endocrinology, Toxicology, Hematology and Coagulation. Refer to D5789. 2. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory policies and procedures failed to identify, monitor, assess and correct the problems found during the survey. 3. Interview with personnel 2, 3, 4 and 5 on December 7, 2018 confirmed the laboratory failed to identify and correct the issue cited above.
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: I. Based on observation and record review, the laboratory failed to include the disclaimer contained in the Abbott Architect package inserts on the report for Urine Drug Screen testing. Findings: 1. Observation by the surveyors on December 3, 2018 revealed the laboratory utilized the Abbott Architect Plus Analyzer for Urine Drug Screen (UDS) testing and reporting of Amphetamine (Amph), Barbiturates (Barb), Benzodiazepines (Benzo), Cocaine (COC), Methadone (Meth), Opiates (OPI), Phencyclidine (PCP), and Cannabinoids (THC) in patient urine samples. 2. Review of the Abbott Architect package inserts for Amph, Barb, Benzo, COC, Meth, OPI, PCP, and THC revealed under the "Intended Use: 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 judgement should be applied to any drug of abuse test result, particularly when preliminary results are used." 3. Review of a random selection of patient final reports for Urine Drug Screen testing that utilized the Abbott Architect Plus Analyzer from April 17, 2017 through December 6, 2018 revealed the laboratory failed to include the full disclaimer from the manufacturer for the following three (3) patients: On April 17, 2018 Patient 132. On November 19, 2018 Patient 133. On December 6, 2018 Patient 134. 4. Review of the Task 1 and 3 Form submitted to surveyors on December 3, 2017 revealed the laboratory performs the following annual volumes for UDS testing: Amph - 7000, Barb - 7000, Benzo - 7000, COC - 7000, Meth - 7000, OPI - 7000, PCP - 7000, and THC - 7000. 5. Interview with Personnel 4 and 5 on December 7, 2018 confirmed that patient urine drug screen reports failed to include the full disclaimer from the manufacturer. II. Based on observation and record review, the laboratory failed to include on the report for PT Mixing Studies, PTT Mixing Studies and Sickle Cell Screening tests a statement that states "The performance

	characteristics of this test were determined by Leonard J Chabert Medical Center Lab. It has not been cleared or approved by the U.S. Food and Drug Administration." Findings: 1. Observation by surveyors during the tour of the laboratory on December 3, 2018 revealed the laboratory maintained: a) Instrumentation Laboratory (IL) ACL TOP 500 Coagulation analyzer utilized for testing and reporting: Prothrombin Time (PT), International Normalized Ratio (INR), Activated Partial Thromboplastin Time (APTT), Fibrinogen, D-Dimer and Mixing Studies for PT and PTT. b) Pacific Hemostasis SickleScreen Sickling Hemoglobin Screening Kit utilized for testing and reporting Sickle Cell Screening results. 2. Review of the Food and Drug Administration (FDA) website for CLIA Test categorization revealed Mixing Studies for PT and PTT and Pacific Hemostasis SickleScreen Sickling Hemoglobin Screening Kit had not been categorized by the FDA; thus being classified as high complexity and as a laboratory developed test. 3. Review of a random selection of patient records for PT mixing Studies, PTT Mixing Studies and Sickle Cell Screen testing from February 26, 2018 through November 30, 2018 revealed the laboratory failed to include a disclaimer on the patient final report that states "The performance characteristics of this test were determined by Leonard J Chabert Medical Center Lab. It has not been cleared or approved by the U.S. Food and Drug Administration" for the following patients: For Sickle Cell: On June 1, 2018 Patient 93 On June 5, 2018 Patient 158 On June 8, 2018 Patient 156 On June 22, 2018 Patient 157 On July 15, 2018 Patient 160 On July 26, 2018 Patient 163 On July 31, 2018 Patient 155 On August 27, 2018 Patient 159 On October 8, 2018 Patient 162 On November 30, 2018 Patient 161 For Mixing Studies: On February 26, 2018 Patient 115. On February 28, 2018 Patient 116. On May 3, 2018 Patient 117. On July 7, 2018 Patient 118. On November 15, 2018 Patient 119 . Review of the Task 1 and 3 Form submitted to surveyors on December 3, 2018 revealed the laboratory performed the following annual test volumes for: Sickle Cell - 10, Mixing Studies - 10 . 4. Interview with personnel 3 on December 6, 2018 revealed he was unaware the patient final reports had to include a disclaimer that stated the performance characteristics of these tests were determined by Leonard J Chabert Medical Center Lab. It has not been cleared or approved by the U.S. Food and Drug Administration. Personnel 3 confirmed that patient final reports failed to include the disclaimer.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D6013. 2. The Laboratory Director failed to ensure the laboratory personnel were performing test methods as required for accurate and reliable results. Refer to D6014. 3. The Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D6016. 4. The Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Refer to D6020. 5. 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. 6. The Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D6023. 7. The Laboratory Director failed to ensure final reports for urine drug screen tests included pertinent information required for interpretation. Refer to D6026. 8. The Laboratory Director failed to ensure testing personnel performing moderate complexity testing met educational requirements. Refer to D6029. 9. 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 D6030. 10. 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 personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Findings: 1. The laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for two (2) of two (2) new Abbott Architect Plus Analyzers. Refer to D5421 I. 2. The laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for two (2) of two (2) new Sysmex XN 2000 Hematology Analyzers. Refer to D5421 II. 3. The laboratory failed to verify the Laboratory Information System (LIS) for accuracy. Refer to D5421 III.
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 that patient samples for Ammonia testing are separated within fifteen (15) minutes after collection according to the manufacturer's requirements for twenty eight (28) of two hundred and four (204) patients reviewed. Refer to D5311 I. 2. The laboratory

	failed to ensure that patient samples for Lactic Acid testing are separated within fifteen (15) minutes after collection and analyzed promptly according to laboratory policy and procedure for eighteen (18) of three hundred nineteen (319) patients reviewed. Refer to D5311 II. 3. The laboratory failed to ensure that patient samples for Chemistry testing are platelet poor after centrifugation according to the manufacturer's requirements. Refer to D5311 III. 4. The laboratory failed to establish detailed written instructions for laboratory services provided for inpatient and outpatient testing and for maintaining the integrity of samples and ensuring accurate and reliable testing according to current manufacturers guidelines. Refer to D5317. 5. The laboratory failed to ensure that patient samples for Ammonia testing are reported within two (2) hour after collection according to the manufacturer's requirements for two (2) of two hundred and four (204) patients reviewed. Refer to D5411 I. 6. The laboratory failed to use normal donors as required by manufacturer to verify reference intervals and establish their own normal Prothrombin (PT) mean with each new lot of thromboplastin. Refer to D5411 II. 7. The laboratory failed to ensure that Blood Collection tubes, Calibrators and Calibrator Verification material are not used beyond their expiration dates. Refer to D5417. 8. The the laboratory failed to have a system in place for twice a year comparison testing for the two (2) Abbott Architect Plus Analyzers. Refer to D5775.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D5217.
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 a quality control program was established and maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to perform Gram Stain Quality Control each day of patient testing with each testing person reporting a Gram Stain for eleven (11) of thirty seven (37) patients reviewed as required by laboratory policy. Refer to D5401 I. 2. The

	laboratory failed to perform two levels of control materials each day of patient testing for Cerebrospinal Total Protein (CFTP) performed on the Abbott Architect Plus Analyzer, for one (1) of thirty eight (38) patients reviewed. Refer to D5447. 3. The laboratory failed to utilize control material of a similar matrix for Urine Ethanol (ETOH) for forty four (44) of forty four (44) patients reviewed. Refer to D5465. 4. The laboratory failed to document visual inspections for each batch/shipment of BD BACTEC Aerobic, Anaerobic and Peds Plus Culture Bottles for six (6) of six (6) lot numbers reviewed. Refer to D5477. 5. The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for D-Dimer testing performed on the Instrumentation Laboratory (IL) ACL Top 500 Coagulation Analyzer, for six (6) of sixty four (64) patients reviewed. Refer to D5545 I. 6. The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for Fibrinogen testing performed on the Instrumentation Laboratory (IL) ACL Top 500 Coagulation Analyzer, for three (3) of thirty two (32) patients reviewed. Refer to D5545 II.
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 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 D5391 and 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. Refer to D5429 I and D5429 II.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on 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 I.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure testing personnel performing moderate complexity testing met educational requirements. Refer to D6065.
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 observation, 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. Findings: 1. The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5401 II. 2. The laboratory failed to have a complete policy and procedure manual. Refer to D5403. 3. Testing personnel were unable to provide surveyors with policies and procedures upon request in the specialties they were actively testing. Upon request for policies, testing personnel referred surveyors to Technical Consultants to obtain policies from laptops not available to all 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 observation, record review, and interview with personnel, the Technical Consultants 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 Consultants failed to ensure performance specification verification studies were complete. Refer to D6040.
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 to the laboratory. Findings: 1. The laboratory failed to ensure that patient samples for Ammonia testing are separated within fifteen (15) minutes after collection according to the manufacturer's requirements for twenty eight (28) of two hundred and four (204) patients reviewed. Refer to D5311 I. 2. The laboratory failed to ensure that patient samples for Lactic Acid testing are separated within fifteen (15) minutes after collection and analyzed promptly according to laboratory policy and procedure for

	eighteen (18) of three hundred nineteen (319) patients reviewed. Refer to D5311 II. 3. The laboratory failed to ensure that patient samples for Chemistry testing are platelet poor after centrifugation according to the manufacturer's requirements. Refer to D5311 III. 4. The laboratory failed to establish detailed written instructions for laboratory services provided for inpatient and outpatient testing and for maintaining the integrity of samples and ensuring accurate and reliable testing according to current manufacturers guidelines. Refer to D5317. 5. The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5401 II. 6. The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5403. 7. The laboratory failed to ensure that patient samples for Ammonia testing are reported within two (2) hour after collection according to the manufacturer's requirements for two (2) of two hundred and four (204) patients reviewed. Refer to D5411 I. 8.The laboratory failed to use normal donors as required by manufacturer to verify reference intervals and establish their own normal Prothrombin (PT) mean with each new lot of thromboplastin. Refer to D5411 II. 9. The laboratory failed to ensure that Blood Collection tubes, Calibrators and Calibrator Verification material are not used beyond their expiration dates. Refer to D5417. 10. The laboratory failed to ensure the Daily Maintenance on the Abbott Architect Plus Analyzers I and II were performed as required by the manufacturer, for six (6) of three hundred thirty four (334) days reviewed. Refer to D5429 I. 11.The laboratory failed to ensure the Weekly Maintenance on the Abbott Architect Plus Analyzers I and II were performed as required by the manufacturer, for one (1) of forty eight (48) weeks reviewed. Refer to D5429 II. 12. The the laboratory failed to have a system in place for twice a year comparison testing for the two (2) Abbott Architect Plus Analyzers. Refer to D5775.
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 Consultants failed to ensure performance specification verification studies were complete. Findings: 1. The laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for two (2) of two (2) new Abbott Architect Plus Analyzers. Refer to D5421 I. 2. The laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for two (2) of two (2) new Sysmex XN 2000 Hematology Analyzers. Refer to D5421 II. 3. The laboratory failed to verify the Laboratory Information System (LIS) for accuracy. Refer to D5421 III.
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 Consultants failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to perform Gram Stain Quality Control each day of patient testing with each testing person reporting a Gram Stain for eleven (11) of thirty seven (37) patients reviewed as required by laboratory policy. Refer to D5401 I. 2. The laboratory failed to perform two levels of control materials each day of patient testing for Cerebrospinal Total Protein (CFTP) performed on the Abbott Architect Plus Analyzer, for one (1) of thirty eight (38) patients reviewed. Refer to D5447. 3. The laboratory failed to utilize control material of a similar matrix for Urine Ethanol (ETOH) for forty four (44) of forty four (44) patients reviewed. Refer to D5465. 4. The laboratory failed to document visual inspections for each batch/shipment of BD BACTEC Aerobic, Anaerobic and Peds Plus Culture Bottles for six (6) of six (6) lot numbers reviewed. Refer to D5477. 5. The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for D-Dimer testing performed on the Instrumentation Laboratory (IL) ACL Top 500 Coagulation Analyzer, for six (6) of sixty four (64) patients reviewed. Refer to D5545 I. 6. The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for Fibrinogen testing performed on the Instrumentation Laboratory (IL) ACL Top 500 Coagulation Analyzer, for three (3) of thirty two (32) patients reviewed. Refer to D5545 II.
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 that testing personnel met the educational qualifications for performing moderate complexity testing for one (1) of twenty five (25) testing personnel. 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 one (1) of twenty five (25) testing personnel. Findings: 1. Review of personnel records on December 5, 2018 revealed for Personnel 10 the laboratory maintained a copy of Personnel 10's certificate from St. Monica Secondary School in Isolo, Lagos. However Personnel 10 failed to have his foreign certificate evaluated to determine substantial equivalency as required. 2. Interview with Personnel 2 on December 5, 2018 revealed she was unaware that foreign certificates need to be evaluated for equivalency. Personnel 2 confirmed that Personnel 10 did not have his certificate evaluated.
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. Findings: 1. The Laboratory Director failed to establish pertinent performance characteristics for Hematology testing. Refer to D6086. 2. The Laboratory Director failed to ensure laboratory personnel were performing the test methods as required for accurate and reliable results. Refer to D6087. 3. The Laboratory Director failed to ensure that proficiency testing samples are satisfactory as required. Refer to D6089. 4. The Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Refer to D6093. 5. 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 D6094. 6. The Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D6095. 7. The Laboratory Director failed to ensure final reports for Hematology tests included pertinent information required for interpretation. Refer to D6098. 8. 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 D6103. 9. 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 D6106.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by:

	Based on observation, record review, and interview with personnel, the Laboratory Director failed to establish pertinent performance characteristics for Hematology testing. Refer to D5423.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel were performing the test methods as required for accurate and reliable results. Findings: 1. The laboratory failed to follow their policy for documenting the date for Emergency Release of blood units. Refer to D5401 III. 2. The laboratory failed to label Histopathology reagents, and solutions with the strength or concentration of the material, storage requirements, preparation and/or expiration dates. Refer to D5415. 3. The laboratory failed to assure the quarterly blood bank alarm checks recorded on the circular temperature charts. Refer to D5555.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that proficiency testing samples are satisfactory as required. Refer to D2181.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to perform a positive and negative control each day of patient testing for the Pacific Hemostasis SickleScreen Sickling Hemoglobin Screening Kit for sickle cell disease, for one (1) of ten (10) patients reviewed. Refer to D5449. 2. The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for Platelet Function (Closure Time) testing performed on the Dade Behring PFA-100 Platelet Function Analyzer, for twelve (12) of twelve (12) patients reviewed. Refer to D5545 III. 3. The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for PTT Mixing Study testing performed on the Instrumentation Laboratory (IL) ACL Top 500 Coagulation

	Analyzer, for five (5) of five (5) patients reviewed. Refer to D5545 IV. 4. The laboratory failed to perform and document a control slide of known reactivity for the Hematoxylin and Eosin (H&E) Staining utilized for histopathology slides for twenty (20) of twenty (20) patient test days reviewed. Refer to D5601 I. 5. The laboratory failed to perform and document a positive and negative control slide for Immunohistochemical Staining utilized for histopathology slides for twenty one (21) of twenty one (21) immunohistochemical stains affecting seven (7) patients reviewed. Refer to D5601 II. 6. The laboratory failed to perform and document a control slide of known reactivity for each special stain performed for eight (8) of eight (8) special stains affecting three (3) patients reviewed. Refer to D5601 III. 7. The laboratory failed to perform and document a control slide of known reactivity for Frozen Sections for five (5) of five (5) patients reviewed. Refer to D5601 IV.
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 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 D5391 and 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 record review and interview with laboratory personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D5429 III.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must 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 Hematology tests included pertinent information required for interpretation. Refer to D5805 II.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)

	The laboratory director must 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. Findings: 1. The laboratory failed to ensure written policies and procedures to address competency for Clinical Consultants and Technical Consultants were complete. Refer to D5209. 2. The Technical Supervisor failed to document the evaluation of competency for testing personnel performing Histopathology. Refer to D6120.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Refer to D5401 II. 2. The laboratory failed to have a complete policy and procedure manual. Refer to D5403. 3. Testing personnel were unable to provide surveyors with policies and procedures upon request in the specialties they were actively testing. Upon request for policies, testing personnel referred surveyors to General Supervisors to obtain policies from laptops not available to all personnel.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Technical Supervisor failed to document the evaluation of competency for testing personnel performing Histopathology. Findings: 1. Review of the laboratory's CMS-209 form

	(Laboratory Personnel Report) revealed the following four (4) personnel serve as testing personnel for Histopathology: Personnel 1, also serves as Laboratory Director, Clinical Consultant, Technical Supervisor, and General Supervisor Personnel 21 Personnel 22 Personnel 23 2. Review of the laboratory's policies and procedures revealed a policy for personnel competency including the six (6) part minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 3. Review of personnel records for the identified personnel revealed no documentation of competency assessment performance. 4. In interview on December 3, 2018 at approximately 4:00 pm, Personnel 1 stated he did not perform a competency assessment on the identified personnel. Personnel 1 further stated he was unaware that was required since the identified personnel are doctors.