Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0962384	06/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Baton Rouge Family Medical At Livingston	13960 Florida Blvd, Livingston, LA	

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

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A CERTIFICATION SURVEY was performed at Baton Rouge Family Medical at Livingston - CLIA # 19D0962384 on June 21, 2018. Baton Rouge Family Medical at Livingston was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1240 CONDITION: Preanalytic Systems. 42 CFR 493.1403 CONDITION: Laboratory Director performing moderate complexity testing.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel the laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory did not have a policy detailing how to address, document and handle complaints or problems reported to the laboratory. 2. Interview with personnel 2 and 4 on June 21, 2018 confirmed the laboratory did not have a complete policy and procedure manual.
D5207	COMMUNICATIONS CFR(s): 493.1234 The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.

	This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory failed to have a system in place to ensure that it identifies and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the did not have detailed policies and procedure to identify and document problems that occur due to a breakdown in communication between the laboratory and an authorized person who orders or receives test results. 2. Interview with personnel 2 and 4 on June 21, 2018 confirmed the laboratory did not have a complete policy and procedure manual.
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 review of laboratory policy and procedure manual, and interview with personnel, the laboratory failed to establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel involved in any phase of 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. 2. Interview with personnel 2 and 4 on June 21, 2018 confirmed the laboratory did not have a complete policy and procedure manual.
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 include the specimen collection time on the patient test requisition for eight (8) of eight (8) patients received. Refer to D5305.

	2. The laboratory failed to ensure patient samples for Syphilis Serology, General Immunology, Routine Chemistry, Endocrinology, Toxicology, Hematology /Coagulation, ABO, Rh and Antibody Screen testing are processed according to Greiner Bio-One Vacuette Blood Collection System package instructions. Refer to D5311. 3. The laboratory failed to maintain and/or establish detailed written instructions for samples sent to an outside source for laboratory services for to ensure the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 4. The laboratory failed to establish written quality assessment policies and procedures for monitoring, identifying and correcting problems identified with with the preanalytic system. Refer to D5391.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory failed to include the specimen collection time on the patient test requisition for eight (8) of eight (8) patients received. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory did not include a policy detailing what information is required on test requisitions, such as: 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. 2. Review of a random selection of patient test requisitions from July 31, 2017 through June 19, 2018 revealed the following eight (8) patients test requisition did not include the specimen collection time: On June 19, 2018 Patient 1 for Complete Blood Cell counts (CBC) testing. On May 3, 2018 Patient 2 for CBC and Urine Microscopic testing. On April 17, 2018 Patient 3 for CBC and Urine Microscopic testing. On March 21, 2018 Patient 4 for CBC and Urine Microscopic testing. On February 7, 2018 Patient 5 for CBC testing. On January 31, 2018 Patient 6 for CBC and Urine Microscopic testing. On September 22, 2017 Patient 7 for CBC testing. On July 31, 2017 Patient 8 for CBC testing. 3. Interview with personnel 2 and 4 on June 21, 2018

	confirmed the laboratory did not document the specimen collection time for the patients cited above.
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: Based on observation, record review and interview with personnel, the laboratory failed to ensure patient samples for Syphilis Serology, General Immunology, Routine Chemistry, Endocrinology, Toxicology, Hematology/Coagulation, ABO, Rh and Antibody Screen testing are processed according to Greiner Bio-One Vacuette Blood Collection System package instructions. Findings: 1. Observation by surveyor on June 21, 2018 revealed the laboratory maintained a Drucker Horizon Model 614 B Centrifuge for the processing of patient samples to be sent to the reference laboratory. Further observation by the surveyor on June 21, 2018 revealed the laboratory utilized Greiner Bio-One Vacuette Blood Collection Tubes for the collection of patient samples to be sent to the reference laboratory. 2. Interviews with personnel 3 and 4 on June 21, 2018 revealed that patient samples are collected for Syphilis Serology, General Immunology, Routine Chemistry, Endocrinology, Toxicology, Hematology /Coagulation, ABO, Rh and Antibody Screen testing. Personnel 3 revealed that after collecting patients samples they are spun in the centrifuge for twenty five (25) minutes then the separated serum/plasma is placed into the refrigerator until the courier for the reference laboratory comes to pick up the samples. Personnel 2 and 3 revealed the courier normally comes once a day to pick up patient samples to be delivered to the reference laboratory. 3. Review of the Drucker Diagnostic Horizon Model 614 B Centrifuge Operators Manual Under "Specifications" revealed the top speed for the centrifuge is 1200 "g". 4. Review of the Greiner Bio-One Vacuette Blood Collection Tube System package insert revealed: Coagulation tubes: Platelet rich plasma (PRP): centrifuge speed 150 g for 5 minutes. Platelet poor plasma (PPP): centrifuge speed 1500 - 2000 g for 10 minutes. Platelet free plasma (PFP): centrifuge speed 2500 - 3000 g for 20 minutes. Serum tubes: centrifuge speed 1800 - 2200 g for 10 - 15 minutes. Serum Sep Clot Activator: centrifuge speed 1800 - 2200 g for 10 - 15 minutes Serum Beads Clot Activator: centrifuge speed 1800 - 2200 g for 10 - 15 minutes. Heparin tubes: centrifuge speed 1800 - 2200 g for 10 - 15 minutes. Heparin Separator: 1800 - 2200 g for 10 - 15 minutes. EDTA Separator: centrifuge speed 1800 - 220 g for 10 - 15 minutes. Lavender: centrifuge speed 2000 - 2200 g for 10 minutes. Sodium Fluoride/Potassium Oxalate (gray top): centrifuge at 2000 - 3000 g for 15 minutes. 5. Review of the test list for the reference laboratory revealed the following tests and type of blood collection tube that would be used by laboratory for the reference lab for patient testing: Coagulation all collected in Sodium Citrate (blue top) : Prothrombin Time (PT)/ International Normalized Ration (INR), Activated Partial Thromboplastin Time (APTT), Fibrinogen (Fib), D-Dimer (DDim), Antithrombin 3 (AT3), Protein C, Protein S, Heparin Low Molecular Weight (Anti Xa), Platelet Response by Aspirin, and P2Y12-PRU testing. Blood Bank: ABO, Rh Antibody Screen (AbScr), Rhogam, and Antibody Titer. Serology: a) Collect in Serum Sep Clot

Activator tube: Cryptococcus, HIV, Meningitis, Mono, Mycoplasma, RPR, RPR titer and Serum HCG. b) Collect in Serum Tube: Group B Strep Infant, RPR, RPR Titer, and Serum HCG. c) Collect in Heparin tube: Mono Chemistry: a) Collect in Serum Sep Clot Activator or Heparin: Acetaminophen (Acet) Alpha Fetoprotein (AFP), Albumin (Alb), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), Amylase (Amy), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Indirect Bilirubin (InBil), Total Bilirubin (TBil), Blood Urea Nitrogen (BUN), Complement component 3 (C3), Complement component 4 (C4), Calcium (CA), CA125, CA15-3, CA19-9, Carcinoembyonic Antigen (CEA), Carbon Dioxide (CO2), Creatinine (Creat), Magnesium (Mg), Sodium (NA), and Phenobarbital (Phenob). b) Collect in Serum tube, Serum Sep Clot Activator or Heparin: Cholesterol (Chol), Creatine Kinase (CK), CKMB, Chloride (CL), Carbamazepine (CRBM), C-Reactive Protein (CRP), Digoxin (Dig), Estradiol (E2), Ferritin (Fer), Folate (Fol), Follicle Stimulating Hormone (FSH), Free Triiodothyronine (FT3), Free Thyroxine (FT4), Gamma Glutamyltransferase (GGT), Glucose (Glu), Haptoglobin (Hapt), High Density Lipoprotein Cholesterol (HDL), Hepatitis A Virus (HepAV), Hepatitis B core IgM (HepBcM), Hepatitis B Surface Antigen (HepBsAg), Hepatitis C Virus (HepCV), Homocysteine (Homo), IGA, IGE, IGG, IGM, Iron (Fe), Potassium (K), Lactate dehydrogenase (LDH), Low Density Lipoprotein Cholesterol (LDL), Leutinizing Hormone (LH), Lipase, Phenytoin (Dil), Phosphorous (Phos), Prealbumin (Palb), Progesterone (Prog), Prolactin (Prol), Rheumatoid Factor (RF), Thyroxine (T4), Theophylline (Theo), Thyroid Cascade, Total Iron Binding Capacity (TIBC), Tobramycin (Tobra), total Protein (TP), Thyrotropin Releasing Factor (TRF), Triglyceride (Trig), Troponin (Trop), Thyroid Stimulating Hormone (TSH), Uric Acid (Uric), Valproic Acid (Valp), Vancomycin (Vanco), and Vitamin B12 (B12). c) Collect in Serum Sep Clot Activator, Heparin or Lavender tube: Autoantibody against thyroid peroxidase (aTPO), and Pro- Brain Natriuretic Peptide (ProBNP), d) Collect in Serum Sep Clot Activator or Lavender tube: Amikacin (Amik). e) Collect in Serum tube or Serum Sep Clot Activator tube: Caffeine (Caff), Cortisol (Cort), Prostate Specific Antigen (PSA), Quantitative Beta Human Chorionic Gonadatropin (Quant HCG), Salicylate (Sali), Triiodothyronine (T3), Testosterone (Test), and Vitamin D (VitD) f) Collect in Lavender tube: Brain Natriuretic Peptide (BNP), Hemoglobin A1C (HA1C) g) Collect in Serum Sep Clot Activator tube: Gentamycin (Gent), and Insulin. h) Collected in Sodium Fluoride/Potassium Oxalate (gray top): Lactic Acid. 6. Review of a random sample of patient records from June 18, 2018 through June 20, 2018 revealed the following patients failed to be centrifuged at the correct speed and times as required by the manufacturer for accurate and reliable test results: NOTE: Complete Metabolic Panel (CMP) includes: Albumin (Alb), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Carbon Dioxide (CO2), Creatinine (Creat), Glucose (Glu), Potassium (K), Sodium (NA), Total Protein (TP), and Blood Urea Nitrogen (BUN). Lipid Panel (Lipid) includes: Cholesterol, High Density Lipoprotein Cholesterol (HDL), Low Density Lipoprotein Cholesterol (LDL) and Triglyceride (Trig). Basic Metabolic Panel (BMP) includes a Gluc, BUN, Creat, Ca, NA, K, CL, and CO2. Cardiac Enzyme Panel (CE) includes a Creatine Phosphokinase (CPK), Creatine Kinase MB (CKMB), and Troponin (Trop) Hepatic Panel (Hep) includes a TP, Alb, ALK, AST, ALT, TBil, and DBil. Thyroid Cascade Profile includes: TSH with automatic reflex (as diagnostically warranted) to FT3, FT4, and/or aTPO. a) On June 18, 2018: Patient 9 had a BMP; Patient 10 had a CMP, Lipid, and a Thyroid Cascade Profile; Patient 11 had a CMP, Lipid and TSH; Patient 13 had a BMP; Patient 14 had a CMP, Lipid, Thyroid Cascade Profile, and VitD; Patient 15 had a CMP, Lipid and Thyroid Cascade Profile; Patient 16 had a CMP, Lipid and TSH; Patient 17 had a CMP, Lipid and TSH; Patient 18 had a CMP and Lipase;

	Patient 19 had a CMP and Lipid; Patient 20 had a CMP, Lipid and Thyroid Cascade Profile; Patient 23 had a BMP; and Patient 24 had a CMP. b) On June 19, 2018: Patient 29 had a CMP, Lipid, PSA, Uric and Thyroid Cascade Profile; Patient 30 had a CMP, PSA and Thyroid Cascade Profile; Patient 33 had a CMP, Lipid and TSH; Patient 35 had a BMP and VitD; Patient 36 had a BMP; Patient 37 had a CMP, TSH and VitD; Patient 38 had a CMP, Ferr, Transferrin, Fe, TIBC, Fol and B12; Patient 39 had a BMP; Patient 40 had a CMP, TSH and Lipid; Patient 41 had a CMP, TSH, Fol and B12; Patient 43 had a CMP, CRP, and Thyroid Cascading Profile; Patient 44 had a CMP and Lipid; Patient 46 had a CMP, TSH, Fe and TIBC; Patient 49 had a BMP, CRP and Human Immunodeficiency Virus (HIV); Patient 71 had a CMP, Lipid and TSH; Patient 72 had a CMP, Lipid, Fol, B12, Test, Prol, FSH, LH and Thyroid Cascading Profile; and Patient 73 had a CMP, Lipid and Thyroid Cascading Profile. c) On June 20, 2018: Patient 51 had a CMP, Lipid and TSH; Patient 52 had a CMP, Lipid, VitD and Thyroid Cascading Profile; Patient 53 had a CMP, Lipid and Thyroid Cascading Profile; Patient 54 had a BMP and Lipid; Patient 55 had a CMP, Lipid, PSA and Thyroid Cascading Profile; Patient 56 had a CMP, Lipid and TSH; Patient 57 had a BMP, Fol and B12; Patient 58 had a CMP, Lipid, PSA and VitD; Patient 59 had a CMP; Patient 60 had a CMP, Lipid and TSH; Patient 62 had a CMP, Lipid, TSH, FT4, FT3 and VitD; Patient 63 had a CMP, Lipid and TSH; Patient 64 had a CMP, Lipid, Uric, PSA and Thyroid Cascading Profile; Patient 65 had a CMP, Lipid and Thyroid Cascading Profile; Patient 66 had a BMP, TSH, FT3, and FT4; Patient 67 had a CMP and TSH; Patient 68 had a CMP and TSH; Patient 69 had a CMP, Lipid, B12, and Thyroid Cascading Profile; Patient 74 had a BMP, TSH, FT3, FT4, and VitD; 7. Interviews with Personnel 2, 3 and 4 revealed they were unaware of the Greiner Bio-One Vacuette Blood Collection System requirements. Personnel 3 stated the centrifuge and collection tubes came from the reference laboratory. Personnel 2 and 4 confirmed the laboratory did not centrifuge samples according the Greiner Bio-One requirements.
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 maintain and/or establish detailed written instructions for samples sent to an outside source for laboratory services for to ensure the integrity of samples and ensure accurate and reliable testing. Findings: 1. Review of the Laboratory's Policy and Procedure Manual failed to include a manual for facilities that utilize the laboratory for Bacteriology, Parasitology, Virology and Histopathology testing with detailed instructions for: (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. 2. Interview with personnel 2, 3 and 4 on June 21, 2018 revealed the facility collects and processes patient samples to be sent to a reference laboratory for patient testing. Personnel 2, 3, and 4 also revealed the centrifuge and collection tubes with instructions come from the reference laboratory; however personnel 2, 3 and 4 confirmed the manual did not contain all the required information for ensuring

	patient samples are collected and processed in a manner to ensure the integrity and accuracy of the patient tests and results.
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 with the preanalytic system. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory had a Quality Assurance Policy however, the monitors failed to identify any of the deficiencies identified with the preanalytic system as follows: a) The laboratory failed to include the specimen collection time on the patient test requisition for eight (8) of eight (8) patients received. Refer to D5305. b) The laboratory failed to ensure patient samples for Syphilis Serology, General Immunology, Routine Chemistry, Endocrinology, Toxicology, Hematology/Coagulation, ABO, Rh and Antibody Screen testing are processed according to Greiner Bio-One Vacuette Blood Collection System package instructions. Refer to D5311. c) The laboratory failed to maintain and/or establish detailed written instructions for samples sent to an outside source for laboratory services for to ensure the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 2. Interview with personnel 2 and 4 on June 21, 2018 confirmed the above findings.
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 laboratory personnel performed testing as required for accurate and reliable results. Refer to D6014. 2. 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 D 6021. 3. 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.
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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Findings: 1. The laboratory failed to include the specimen collection time on the patient test requisition for eight (8) of eight (8) patients received. Refer to D5305. 2. The laboratory failed to ensure patient samples for Syphilis Serology, General Immunology, Routine Chemistry, Endocrinology, Toxicology, Hematology /Coagulation, ABO, Rh and Antibody Screen testing are processed according to Greiner Bio-One Vacuette Blood Collection System package instructions. Refer to D5311. 3. The laboratory failed to maintain and/or establish detailed written instructions for samples sent to an outside source for laboratory services for to ensure the integrity of samples and ensure accurate and reliable testing. Refer to D5317.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory had a Quality Assurance Policy however, the monitors failed to identify any of the deficiencies identified with the preanalytic system as follows: a) The laboratory failed to include the specimen collection time on the patient test requisition for eight (8) of eight (8) patients received. Refer to D5305. b) The laboratory failed to ensure patient samples for Syphilis Serology, General Immunology, Routine Chemistry, Endocrinology, Toxicology, Hematology/Coagulation, ABO, Rh and Antibody Screen testing are processed according to Greiner Bio-One Vacuette Blood Collection System package instructions. Refer to D5311. c) The laboratory failed to maintain and/or establish detailed written instructions for samples sent to an outside source for laboratory services for to ensure the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 2. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to establish a Quality Assurance Plan that covered the preanalytic systems. The laboratory failed to identify and correct the problems cited above. Refer to D5391. 3. Interview with personnel 2 and 4 on June 21, 2018 confirmed the laboratory failed to identify the deficiencies cited above.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. The laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Refer to D5205. 2. The laboratory failed to have a system in place to ensure that it identifies and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. Refer to D5207. 3. The laboratory failed to establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. Refer to D5209. 4. The laboratory failed to maintain and/or establish detailed written instructions for samples sent to an outside source for laboratory services for to ensure the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 5. Interview with personnel 2 and 4 on June 21, 2018 confirmed the laboratory failed to have a complete policy and procedure manual.