Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1033284	04/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bienville Medical Center	1175 Pine Street, Suite 200, Arcadia, 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 COMPLAINT UP SURVEY was performed at Bienville Medical Center - CLIA # 19D1033284 on April 4, 2018 through April 5, 2018. Bienville Medical Center was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic Systems 42 CFR 493.1403 CONDITION: Laboratories performing Moderate Complexity Testing, LABORATORY DIRECTOR 42 CFR 493.1409 CONDITION: Laboratories performing Moderate Complexity Testing, TECHNICAL CONSULTANT 42 CFR 493.1421 CONDITION: Laboratories performing Moderate Complexity Testing, TESTING PERSONNEL
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: I. Based on observation, record review and interview with personnel, the laboratory failed to follow the manufacturer's intended use and instructions for the McKesson Quintet AC Blood Glucose Monitoring System as approved by the Food and Drug Administration (FDA) for waived testing. Findings: 1. Observation by the surveyor on April 4, 2018 revealed the laboratory was performing Blood Glucose testing utilizing the McKesson Quintet AC Blood Glucose Monitoring System. 2. Interview with the Director of Nursing (DON) revealed the McKesson AC Glucometers are maintained in the Emergency Room and throughout the hospital. The DON revealed there was a total of five (5) units of the McKesson AC Blood Glucose Monitoring Systems throughout the hospital. 3. Review of the McKesson Quintet AC Blood Glucose Monitoring System "User Guide" revealed: a) Under Intended Use: "it is to be used for self-testing in the home or professional, clinical use." b) Under Precautions: The McKesson Quintet AC Blood Glucose Monitoring System is intended for self-testing

or professional use. It is not used to diagnose diabetes mellitus. c) Under Limitations: The glucose test may be interfered under abnormal concentrations of: Uric Acid > 10.0 mg/dl, L-Dopa > 3 mg/dl, Dopamine > 2 mg/dl, Ascorbic acid (Vitamin C) > 5 mg/dl. Abnormal high concentrations of Acetaminophen, Ibuprofen, Methyldopa, Salicylic Acid, Tetracycline, Tolbutamide, Bilirubin conjugated, Cholesterol, Creatinine, Triglyceride, Maltose, Xylose, Galactose and Lactose may cause inaccurate results. 4. Review of a random selection of Patient Test Records from March 5, 2018 through April 5, 2018 revealed the following non-diabetic patients were tested and reported utilizing the McKesson Quintet AC Blood Glucose Monitoring System: Patient 37: Admitting Diagnosis - Cardiac Arrest. Admitted in the Emergency Room. March 5, 2018; Blood Glucose of 200 mg/dl. Patient 38: Admitting Diagnosis - Gastritis. Admitted in the Emergency Room. March 14, 2018; Blood Glucose of 107 mg/dl. Patient 39: Admitting Diagnosis - Gout Right foot exacerbation. Admitted in the Emergency Room. March 15, 2018; Blood Glucose of 133 mg/dl. Patient 40: Admitting Diagnosis - Allergic Reaction. Admitted in the Emergency Room. March 19, 2018; Blood Glucose of 155 mg/dl. Patient 41: Admitting Diagnosis - Hyperglycemia secondary to steroids., Admitted in SB Ward. March 20, 2018; Blood Glucose of 464 mg/dl. Patient 42: Admitting Diagnosis - Shoulder Pain, Hyperglycemia. Admitted in the Emergency Room. March 23, 2018; Blood Glucose 359 mg/dl. Patient 43: Admitting Diagnosis - Cardiopulmonary Failure, Renal Failure, Dialysis. Admitted in Emergency Room. March 24, 2018; Blood Glucose 127 mg/dl. Patient 44: Admitting Diagnosis - Mental Status Change. Admitted in the Emergency Room. March 25, 2018; Blood Glucose 111 mg/dl. Patient 45: Admitting Diagnosis - Urinary Retention. Admitted in the Emergency Room. March 29, 2018; Blood Glucose of 102 mg/dl. Patient 46: Admitting Diagnosis Acute Cerebrovascular Accident. Admitted in the Emergency Room. April 3, 2018; Blood Glucose of 125 mg/dl. 5. Interview with the DON on April 5, 2018 revealed she was unaware of the manufacturer requirements for the McKesson Quintet AC Blood Glucose Test System. The DON confirmed the McKesson Quintet AC Blood Glucose Test System is utilized throughout the hospital and utilized for Glucose testing on diabetic and non-diabetic patients. II. Based on observation, record review, and interview with personnel, the laboratory failed to report Urine Drug Screen (UDS) test results as preliminary results and failed to confirm all preliminary positive UDS test results as required by the manufacturer. Findings: 1. Observation by the surveyor on April 4, 2018 revealed the laboratory utilized the Alere iScreen Dx Multi-Drugs of Abuse Dip Test System for Urine Drug Screen (UDS) testing and reporting of d-amphetamine (AMP), Secobarbital (Barb), Benzoylegonine (COC), 3,4-Methylenedioxymethamphetamine (MDMA), d-Methamphetamine (MET), Methadone (MTD), Morphine (MOP), Oxazepam (BZO), Buprenorphine (BUP), Oxycodone (OXY), Nortriptyline (TCA), Phencyclidine (PCP), and 11-nor-9-Tetrahydrocannabinol-9-carboxylic acid (THC) in patient urine samples. 2. Review of the Alere iScreen Dx Multi-Drugs of Abuse Dip Test System package insert revealed "This is a preliminary screening test that detects drugs-of-abuse in urine at specified detection levels. To confirm preliminary positive results, a more specific method such as Gas Chromatography/Mass Spectrometry (GC/MS) must be used." 3. Review of a random selection of Patient UDS Final Reports from January 1, 2018 through April 3, 2018 revealed the following patients failed to be reported as preliminary test results for UDS testing and the preliminary positive results failed to be confirmed by GC/MS as required by the manufacturer: Patient 50 on January 2, 2018 ; all results negative Patient 48 on January 3, 2018; AMP - positive, the rest of the results negative. Patient 52 on January 20, 2018; COC and THC - positive, the rest of the results negative. Patient 54 on January 21, 2018; MET and AMP - positive, the rest of the results negative. Patient 56 on February 8, 2018; THC - positive, the rest of the results

negative. Patient 47 on February 12, 2018; all results negative. Patient 49 on February 24, 2018; all results negative. Patient 51 on March 23, 2018; MET and AMP - positive, the rest of results negative. Patient 58 on March 23, 2018; COC and TCA - positive, the rest of results negative. Patient 53 on March 29, 2018; THC - positive, the rest of results negative. Patient 55 on April 1, 2018; THC - positive, the rest of results negative. Patient 57 on April 3, 2018; all results negative. 4. Interviews with Personnel 11 and the Director of Nursing (DON) on April 5, 2018 confirmed that patient urine drug screen test results were not reported as preliminary results and confirmed the laboratory does not confirm preliminary positive results as required by the manufacturer. III. Based on observation, record review and interview with personnel, the laboratory failed to analyze whole blood samples for Chemistry testing performed on the Abaxis Picollo Clinical Chemistry Analyzer within sixty (60) minutes of collection as required by the manufacturer. Findings: 1. Observation by the surveyor on April 4, 2018 revealed the laboratory was performing Routine Chemistry testing utilizing the Abaxis Picollo Clinical Chemistry Analyzer. Routine Chemistry testing includes the following panels: a) Comprehensive Metabolic Panel (CMP); Albumin (Alb), Alkaline phosphatase (ALP), Alanine aminotransferase (ALT), Aspartate aminotransferase (AST), Blood Urea Nitrogen (BUN), Calcium (CA), Chloride (CL), Creatinine (Creat), Glucose (Glu), Sodium (NA), Potassium (K), Carbon Dioxide (CO2), Total Bilirubin (TBil), and Total Protein (TP). b) Basic Metabolic Panel (BMP); BUN, CA, CL, Creat, Glu, NA, K, and CO2. c) Liver /Hepatic Panel; Alb, ALP, ALT, AST, TBil, TP d) Lipid Panel: Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Low Density Lipoprotein Cholesterol (LDL), and Triglyceride (Trig). e) Amylase (Amy). f) Magnesium (Mg). 2. Review of the Abaxis Picollo Operators Manual revealed "Whole Blood must be analyzed within 60 minutes of collection." 3. Review of a random selection of Patient Test Records from January 1, 2018 through April 2, 2018 revealed the following patients were tested and reported utilizing the Abaxis Picollo Chemistry Analyzer and exceeded the 60 minute manufacturer requirement for accurate and reliable test results: On January 1, 2018 - Patient 21: was collected for a CMP at 5:40 AM, and not tested until 7:03 AM, exceeding the 60 minute requirement by 23 minutes. On January 1, 2018 - Patient 22: was collected for a CMP at 6:10 AM, and not tested until 7:14 AM, exceeding the 60 minute requirement by 4 minutes. On January 1, 2018 - Patient 25: was collected for a CMP at 5:40 AM, and not tested until 7:45 AM, exceeding the 60 minute requirement by 65 minutes. On January 1, 2018 - Patient 26: was collected for a CMP at 17:50 PM, and not tested until 19:16 PM, exceeding the 60 minute requirement by 26 minutes. On January 4, 2018 - Patient 28: was collected for a BMP at 10:15 AM, and not tested until 11:23 AM, exceeding the 60 minute requirement by 8 minutes. On January 20, 2018 - Patient 31: was collected for a CMP at 14:00 PM, and not tested until 16:33 PM, exceeding the 60 minute requirement by 93 minutes. On February 13, 2018 - Patient 23: was collected for a Mg at 5:30 AM, and not tested until 6:56 AM, exceeding the 60 minute requirement by 26 minutes. On February 24, 2018 - Patient 27: was collected for a CMP at 6:38 AM, and not tested until 7:39 AM, exceeding the 60 minute requirement by 1 minute. On February 24, 2018 - Patient 24: was collected for a Lipid Panel at 10:36 AM, and not tested until 11:45 AM, exceeding the 60 minute requirement by 9 minutes. On March 25, 2018 - Patient 29: was collected for a CMP and Amy at 5:20 AM, and not tested until 6:38 AM, exceeding the 60 minute requirement by 18 minutes. On March 25, 2018 - Patient 30: was collected for a CMP at 5:45 AM, and not tested until 6:51 AM, exceeding the 60 minute requirement by 6 minutes. On March 29, 2018 - Patient 32: was collected for a CMP and Mg at 14:09 PM, and the CMP was not tested until 15:28 PM, exceeding the 60 minute requirement by 19 minutes. Mg was not testing until 15:46 M, exceeding the 60 minute requirement by 35 minutes. On March 30, 2018 - Patient 33:

	was collected for a CMP at 21:33 PM, and not tested until 23:04 PM, exceeding the 60 minute requirement by 31 minutes. On March 30, 2018 - Patient 34: was collected for a CMP at 00:05 AM, and not tested until April 1, 2018 at 01:24 AM, exceeding the 60 minute requirement by 24 hours and 19 minutes. On April 2, 2018 - Patient 35: was collected for a CMP and a Lipid Panel at 6:30 AM, and the CMP was not tested until 12:59 PM, exceeding the 60 minute requirement by 5 hours and 29 minutes. Lipid Panel was not testing until 13:06 M, exceeding the 60 minute requirement by 5 hours and 36 minutes. 5. Interview with Personnel 11 and the Director of Nursing (DON) on April 5, 2018 revealed they were unaware of the 60 minute manufacturer requirement. The DON confirmed the laboratory failed to test the patients cited above within the 60 minute manufacturer required time.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to ensure that patient samples for Prothrombin Time (PT)/ International Normalized Ratio (INR) testing are analyzed within three (3) minutes of collection as required by the manufacturer for thirteen (13) of eighteen (18) patients reviewed. Refer to D5411 I. 2. The laboratory failed to ensure that patient samples for Arterial Blood Gas (ABG) testing are analyzed within ten (10) minutes of collection as required by the manufacturer for one (1) of one (1) patients reviewed. Refer to D5411 II. 3. The laboratory failed to ensure that patient samples for Brain natriuretic peptide (BNP) testing are analyzed within thirty (30) minutes of collection as required by the manufacturer for eight (8) of eighteen (18) patients reviewed. Refer to D5411 III. 4. 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.
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 Prothrombin Time (PT)/ International Normalized Ratio (INR) testing are analyzed within three (3) minutes of collection as required by the manufacturer for thirteen (13) of eighteen (18) patients reviewed.

Findings: 1. Observation by the surveyor on April 4, 2018 revealed the laboratory was performing PT/INR testing on the Abbott iSTAT Clinical Analyzers. 2. Review of the Abbott iSTAT PT/INR package insert and Laboratory Policy and Procedure Manual revealed that samples for PT/INR are to be tested within three (3) minutes of collection. 3. Interviews with Personnel 11 and the Director of Nursing (DON) on April 5, 2018 revealed they were unaware that PT/INR samples are to be collected and tested within three (3) minutes. 4. Review of a random selection of patient records for PT/INR from January 1, 2018 through April 2, 2018 revealed the laboratory failed to document testing of patient samples for PT/INR within three (3) minutes of collection for the following thirteen (13) patients: On January 3, 2018 Patient 3 was collected at 9:28 AM, the patient was reported on January 4, 2018 at 5:22 AM - exceeding the three (3) minutes by nineteen (19) hours and fifty one (51) minutes. On February 8, 2018 Patient 10 was collected at 16:53 PM, the patient was reported at 17: 06 PM - exceeding the three (3) minutes by ten (10) minutes. On February 12, 2018 Patient 1 was collected at 5:53 AM, the patient was reported at 6:21 AM - exceeding the three (3) minutes by twenty five (25) minutes. On February 14, 2018 Patient 1 was collected at 5:50 AM, the patient was reported at 6:42 AM - exceeding the three (3) minutes by forty nine (49) minutes. On February 22, 2018 Patient 3 was collected at 8: 25 AM, the patient was reported at 8:43 AM - exceeding the three (3) minutes by fifteen (15) minutes. On February 22, 2018 Patient 4 was collected at 10:18 AM, the patient was reported at 10:31 AM - exceeding the three (3) minutes by ten (10) minutes. On February 23, 2018 Patient 5 was collected at 8:27 AM, the patient was reported at 8:38 AM - exceeding the three (3) minutes by eight (8) minutes. On February 24, 2018 Patient 2 was collected at 18:15 PM, the patient was reported at 18: 22 PM - exceeding the three (3) minutes by four (4) minutes. On March 24, 2018 Patient 6 was collected at 17:35 PM, the patient was reported at 17:46 PM - exceeding the three (3) minutes by eight (8) minutes. On March 25, 2018 Patient 7 was collected at 11:30 AM, the patient was reported at 11:41 AM - exceeding the three (3) minutes by eight (8) minutes. On March 29, 2018 Patient 8 was collected at 23:09 PM, the patient was reported at 23:42 PM - exceeding the three (3) minutes by thirty (30) minutes. On April 1, 2018 Patient 9 was collected at 11:59 AM, the patient was reported at 12:44 PM - exceeding the three (3) minutes by forty two (42) minutes. On April 2, 2018 Patient 11 was collected at 12:05 PM, the patient was reported at 12:15 PM - exceeding the three (3) minutes by seven (7) minutes. 5. Interviews with Personnel 11 and the Director of Nursing (DON) on April 5, 2017 confirmed the laboratory failed to analyze patient PT/INR samples within three (3) minutes of collection for the thirteen (13) patients cited. II. Based on observation, record review and interview with personnel, the laboratory failed to ensure that patient samples for Arterial Blood Gas (ABG) testing are analyzed within ten (10) minutes of collection as required by the manufacturer for one (1) of one (1) patients reviewed. Findings: 1. Observation by the surveyor on April 4, 2018 revealed the laboratory was performing ABG testing on the Abbott iSTAT Clinical Analyzers. NOTE: ABG consists of the following tests: pH, PCO2, PO2, Base Excess, HCO3, TCO2 and Oxygen Saturation. 2. Review of the Abbott iSTAT ABG package insert and Laboratory Policy and Procedure Manual revealed that samples for ABG are to be tested within ten (10) minutes of collection. 3. Interviews with Personnel 11 and the Director of Nursing (DON) on April 5, 2018 revealed they were unaware that ABG samples are to be collected and tested within ten (10) minutes. 4. Review of a random selection of patient records for PT/INR from January 1, 2018 through April 2, 2018 revealed the laboratory failed to document testing of patient samples for ABG within ten (10) minutes of collection; Patient 12 on collected on March 27, 2018 at 10:20 AM, the patient was reported at 10:44 AM - exceeding the ten (10) minutes by fourteen (14) minutes. 5. Interviews with the Director of Nursing (DON) on April 5, 2017

	confirmed the laboratory failed to analyze patient ABG samples within ten (10) minutes of collection for Patient 12. III. Based on observation, record review and interview with personnel, the laboratory failed to ensure that patient samples for Brain natriuretic peptide (BNP) testing are analyzed within thirty (30) minutes of collection as required by the manufacturer for eight (8) of eighteen (18) patients reviewed. Findings: 1. Observation by the surveyor on April 4, 2018 revealed the laboratory was performing BNP testing on the Abbott iSTAT Clinical Analyzers. 2. Review of the Abbott iSTAT BNP package insert and Laboratory Policy and Procedure Manual revealed that samples for BNP are to be tested within thirty (30) minutes of collection. 3. Interviews with Personnel 11 and the Director of Nursing (DON) on April 5, 2018 revealed they were unaware that BNP samples are to be collected and tested within thirty (30) minutes. 4. Review of a random selection of patient records for PT/INR from January 1, 2018 through April 2, 2018 revealed the laboratory failed to document testing of patient samples for PT/INR within three (3) minutes of collection for the following eight (8) patients: On January 1, 2018 Patient 14 was collected at 23: 45 PM, the patient was reported on January 2, 2018 at 0:31 AM - exceeding the thirty (30) minutes by sixteen (19) minutes. On February 8, 2018 Patient 20 was collected at 16:58 PM, the patient was reported at 18:18 PM - exceeding the thirty (30) minutes by fifty (50) minutes. On February 12, 2018 Patient 13 was collected at 23:55 PM, the patient was reported on February 13, 2018 at 00:33 AM - exceeding the thirty (30) minutes by eight (8) minutes. On February 23, 2018 Patient 15 was collected at 8:25 AM, the patient was reported at 9:00 AM - exceeding the thirty (30) minutes by five (5) minutes. On March 29, 2018 Patient 17 was collected at 22:45 PM, the patient was reported at 23:41 PM - exceeding the thirty (30) minutes by twenty six (26) minutes. On March 30, 2018 Patient 18 was collected at 21:33 PM, the patient was reported at 22:24 PM - exceeding the thirty (30) minutes by twenty one (21) minutes. On April 1, 2018 Patient 16 was collected at 07:00 AM, the patient was reported at 08:06 PM - exceeding the thirty (30) minutes by thirty six (36) minutes. On April 1, 2018 Patient 19 was collected at 11:59 AM, the patient was reported at 12:46 PM - exceeding the thirty (30) minutes by seventeen (17) minutes. 5. Interview with the Director of Nursing (DON) on April 5, 2017 confirmed the laboratory failed to analyze patient BNP samples within thirty (30) minutes of collection for the eight (8) patients cited.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues in Analytic Systems. Findings: 1. A review of patient test records and quality control records indicated problems as follows: a) The laboratory failed to ensure that patient samples for Prothrombin Time (PT)/ International Normalized Ratio (INR) testing are analyzed within three (3) minutes of collection as required by the manufacturer for thirteen (13) of eighteen (18) patients reviewed. Refer to D5411 I. b) The laboratory failed to ensure that patient samples for Arterial Blood Gas (ABG) testing are analyzed within ten (10) minutes of collection as required by the manufacturer for one (1) of one (1) patients reviewed. Refer to D5411 II. c) The laboratory failed to ensure

	that patient samples for Brain natriuretic peptide (BNP) testing are analyzed within thirty (30) minutes of collection as required by the manufacturer for eight (8) of eighteen (18) patients reviewed. Refer to D5411 III. 2. The laboratory had a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory. However, the laboratory failed to include monitors that would correct the issues cited above. 3. Interview with personal 11 and the Director of Nursing (DON) on April 5, 2018 confirmed the laboratory was unaware of the issues cited above, and failed to monitor all phases of testing to assure that testing is being performed accurately and reliably.
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 employee a sufficient number of staff with the appropriate education and experience or training to provide apapropriate consultation. Refer to D6028. 4. The Laboratory Director failed to 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. Refer to D6029.
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 ensure that patient samples for Prothrombin Time (PT)/ International Normalized Ratio (INR) testing are analyzed within three (3) minutes of collection as required by the manufacturer for thirteen (13) of eighteen (18) patients reviewed. Refer to D5411 I. 2. The laboratory failed to ensure that patient samples for Arterial Blood Gas (ABG) testing are analyzed within ten (10) minutes of collection as required by the manufacturer for one (1) of one (1)

	patients reviewed. Refer to D5411 II. 3. The laboratory failed to ensure that patient samples for Brain natriuretic peptide (BNP) testing are analyzed within thirty (30) minutes of collection as required by the manufacturer for eight (8) of eighteen (18) patients reviewed. Refer to D5411 III.
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. A review of patient test records and quality control records indicated problems as follows: a) The laboratory failed to ensure that patient samples for Prothrombin Time (PT)/ International Normalized Ratio (INR) testing are analyzed within three (3) minutes of collection as required by the manufacturer for thirteen (13) of eighteen (18) patients reviewed. Refer to D5411 I. b) The laboratory failed to ensure that patient samples for Arterial Blood Gas (ABG) testing are analyzed within ten (10) minutes of collection as required by the manufacturer for one (1) of one (1) patients reviewed. Refer to D5411 II. c) The laboratory failed to ensure that patient samples for Brain natriuretic peptide (BNP) testing are analyzed within thirty (30) minutes of collection as required by the manufacturer for eight (8) of eighteen (18) patients reviewed. Refer to D5411 III. 2. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory establish a Quality Assurance Plan that covered all phases of testing; however the laboratory failed to identify and correct the problems cited above. Refer to D5791. 3. Interview with personnel 11 and the Director of Nursing (DON) on April 5, 2018 confirmed the laboratory failed to identify the deficiencies cited above.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by:

	Based on review of laboratory personnel records and interview with laboratory personnel, the Laboratory Director failed to ensure the laboratory employed a Technical Consultant. Refer to D6034.
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 review of laboratory personnel records and interview with laboratory personnel, the Laboratory Director failed to ensure that all personnel have the appropriate education and experience to accurately report patient test results. Findings: 1. The laboratory failed to ensure that the laboratory maintained documentation of a current Louisiana state laboratory license for eight (8) of seventeen (17) testing personnel performing moderate complexity testing. Refer to D 6064. 2. The laboratory failed to provide documentation that testing personnel met the educational qualifications for performing moderate complexity testing for two (2) of ten (10) testing personnel. Refer to D 6065
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 review of personnel records and interview with personnel, the Technical Consultant failed to meet the qualifications and provide technical oversight for a Technical Consultant of moderate complexity testing. Findings: 1. The laboratory failed to employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. Refer to D6034. 2. The Technical Consultant failed to provide technical and scientific oversight for the laboratory. Refer to D6036. 3. The Technical Consultant failed to ensure that testing personnel are determined to be competent prior to patient testing for two (2) of four (4) new personnel hired for laboratory testing. Refer to D6046. 4. The Technical Consultant (Personnel 1) failed to evaluate and document the performance of individuals at least semiannually during the first year, for one (1) of four (4) new personnel reviewed. Refer to D6053. 5. The Technical Consultant failed to evaluate and document the performance of individuals annually, for one (1) of eleven (11) personnel reviewed. Refer to D6054.

D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the laboratory failed to employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. Findings: 1. Review of FORM CMS 209 submitted to the surveyor on April 5, 2018 revealed the laboratory failed to list a Technical Consultant. 2. Interviews with Hospital Administration (Chief Financial Office, Chief Operations Office and Director of Nurses) on April 5, 2018 revealed the individual responsible for technical oversight was no longer employed at the facility and that her last date of employment was March 19, 2018. Further discussion with Hospital Administration revealed they were in the process of trying to locate and hire an individual to fulfill the role of the Technical Consultant. Hospital Administration confirmed the laboratory has been without a Technical Consultant since March 20, 2018.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to ensure that patient samples for Prothrombin Time (PT)/ International Normalized Ratio (INR) testing are analyzed within three (3) minutes of collection as required by the manufacturer for thirteen (13) of eighteen (18) patients reviewed. Refer to D5411 I. 2. The laboratory failed to ensure that patient samples for Arterial Blood Gas (ABG) testing are analyzed within ten (10) minutes of collection as required by the manufacturer for one (1) of one (1) patients reviewed. Refer to D5411 II. 3. The laboratory failed to ensure that patient samples for Brain natriuretic peptide (BNP) testing are analyzed within thirty (30) minutes of collection as required by the manufacturer for eight (8) of eighteen (18) patients reviewed. Refer to D5411 III.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(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 personnel, the Technical Consultant failed to ensure that testing personnel are determined to be competent prior to patient testing for two (2) of four (4) new personnel hired for laboratory testing. Findings: 1. Review of personnel records revealed the laboratory failed to maintain documentation of competencies for employees prior to patient testing , for Personnel 5 and 6. Further review of Personnel Records revealed that Personnel 5 was hired on March 30, 2018, and Personnel 6 was hired on February 5, 2018. The laboratory failed to maintain documentation of training and determination of competency before being allowed to test and turn out patient test results. 2. Review of Laboratory Policy and Procedure Manual revealed the laboratory had established policies and procedures for determining competency that included the following six (6) procedures 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. 2. Interview with the Director of Nursing (DON) revealed the Technical Consultant had left employment at the hospital on March 19, 2018. The DON did confirm the laboratory failed to maintain documentation of competency for Personnel 5 and 6 prior to patient testing.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant (Personnel 1) failed to evaluate and document the performance of individuals at least semiannually during the first year, for one (1) of four (4) new personnel reviewed. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory had written personnel policies and procedures for personnel competency that state the laboratory is to document competency/evaluation of new personnel for orientation (when hired), twice the first year (6 months and annual) then annually thereafter. 2. Review of Personnel Records revealed the laboratory failed to include documentation of competency/evaluation of new personnel at least semi annually for personnel 4. Personnel 4 was hire on July 14, 2017. 3. Interview with the Director of Nursing (DON) on April 5, 2018 confirmed the laboratory failed to maintain documentation for semiannual competency/evaluation for Personnel 4.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the

	performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to evaluate and document the performance of individuals annually, for one (1) of eleven (11) personnel reviewed. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory had written personnel policies and procedures for personnel competency that state the laboratory is to document competency/evaluation of new personnel for orientation (when hired), twice the first year (6 months and annual) then annually thereafter. 2. Review of Personnel Records for new personnel revealed the laboratory failed to include documentation of competency/evaluation of new personnel at least annually for Personnel 11. 3. Interview with the Director of Nursing (DON) on April 5, 2018 confirmed the laboratory failed to maintain documentation for an annual competency/evaluation for Personnel 11.
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 the laboratory failed to provide documentation of current state licenses and education for individuals performing moderate complex testing. Findings: 1. The laboratory failed to ensure that the laboratory maintained documentation of a current Louisiana state laboratory license for eight (8) of seventeen (17) testing personnel performing moderate complexity testing. Refer to D 6064. 2. The laboratory failed to provide documentation that testing personnel met the educational qualifications for performing moderate complexity testing for two (2) of ten (10) testing personnel. Refer to D 6065 3. The laboratory failed to maintain documentation of skill, education and training for Personnel 11 for performing Manual Differentials. D6069. 4. Personnel 11 on April 20, 2017 confirmed the above findings.
D6064	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a) Each individual performing moderte complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, and interview, the laboratory failed to ensure that the laboratory maintained documentation of a current Louisiana state laboratory license for eight (8) of seventeen (17) testing personnel performing moderate complexity testing. Findings: 1. Review of personnel folders for laboratory personnel on April 4, 2018 revealed the laboratory failed to obtain a copy of a current Louisiana state licence for laboratory personnel for personnel; 6, 12, 13, 14, 15, 16,

	17, and 18. 2. Interviews with the Human Resource Representative and the Director of Nursing (DON) on April 5, 2018 confirmed the laboratory did not maintain documentation of a current license for laboratory personnel for the individuals cited above.
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 eight (8) of seventeen (17) testing personnel. Findings: 1. Review of personnel records on April 4, 2018 revealed the laboratory failed to maintain documentation of at least a High School Diploma or equivalent for moderate complexity laboratory testing for Personnel 4, 5, 6, 9, 10, 11, 12, and 15. 2. Interviews with the Human Resource Representative and the Director of Nursing (DON) on April 5, 2018 confirmed the laboratory did not maintain documentation of education for laboratory personnel for the individuals cited above.
D6069	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(a) Each individual performs only those moderate complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, testing personnel failed to have the skill, education and training for performing Manual Differentials. Findings: 1. Observation by the surveyor on April 4, 2018 noted the laboratory maintained a Sysmex XP-300 Hematology Analyzer for the performance of a Complete Blood Cell count (CBC) with an Automated Differential. 2. Review of the Laboratory's Policy and Procedure Manual revealed criteria for performing Manual Differentials. Policy stated that manual differentials are to be performed by Medical Technologist. Further review of the Laboratory Policy and Procedure Manual revealed if issues occurred and a Medical Technologist was not available that the lab was to refer the slide to the reference laboratory for the manual differential. 3. Review of a random selection of patient test records that included Manual Differentials revealed that Personnel 11 had signed out a Manual Differential on January 22, 2018 for

	Patient 36. 4. Review of Personnel Records for Personnel 11 revealed that she was a Licensed Laboratory Assistant with a High School Diploma. 5. Interview with Personnel 11 revealed she was aware that she was not allowed to perform a manual differential. Personnel 11 stated that she probably just input the information; however she was unable to show documentation of who actually performed the manual differential.