Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2135111	04/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Louisiana Internal Medicine & Pediatric Associates	7444 Picardy Avenue, Baton Rouge, 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	An Initial Certification survey was performed at Louisiana Internal Medicine & Pediatric Associates - CLIA # 19D2135111 on April 5, 2018. Louisiana Internal Medicine & Pediatric Associates 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
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 have a complete policy and procedure manual. Refer to D5403 2. The laboratory failed to use control material before reconstitution expiration date provided by the manufacturer for Total Bilirubin. Refer to D5415 3. The laboratory failed to have complete performance specification verification studies for three of three instruments reviewed. Refer to D5421 4. The laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for chemistry testing. Refer to D5469 5. The laboratory failed to follow established policies to monitor, assess, and correct quality issues in Analytic Systems. Refer to D5791
D5403	PROCEDURE MANUAL

	CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the manual did not include detailed instructions for the following: a) Quality Control - detailed instructions on how to verify QC ranges for Horiba Pentra 400 N&P and Minotrol, how to establish the laboratory's means and ranges for Bio-Rad QC, when and how to assess patients after failed QC. b) Specimen labeling - what information is required to be labeled on specimens collected. c) Labeling of reconsitution and expiration dates for quality control and reagents utilized. 2. Interview with Personnel 2 on April 5, 2018 confirmed the policy did not address the above practices.
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, record review, and interview with personnel, the laboratory failed to use control material before reconstitution expiration date provided by the manufacturer for Total Bilirubin. Findings: 1. Observation by surveyor during the laboratory tour on April 5, 2018 revealed the laboratory utilizes the ABX Pentra 400 instrument with ABX Pentra P & N quality control material chemistry testing, including Total Bilirubin (T.Bili). 2. Review of the ABX Pentra P & N package insert under the Storage and Stability section revealed "Stability of total bilirubin following reconstitution (when protected from light): 8 hours at 15-25 degrees Celsius, 24 hours at 2 - 8 degrees Celsius, 2 weeks at -25 to -15 degrees Celsius." 3. Further observation

	of the following ABX Pentra P & N reagents in-use revealed the laboratory did not label with the appropriate reconstitution epiration: ABX Pentra P Control: Lot number 1703701, expiration date 2019/04/10 ABX Pentra N Control: Lot number 1703801, expiration date 2019/10/04 4. In interview on April 5, 2018, Personnel 2 stated that the laboratory reconstitutes quality control every Monday to be utilized all week. Personnel 2 stated the quality control material is kept in the refrigerator at 2-8 degrees Celsius throughout the week. Personnel 2 confirmed that the laboratory was not following the manufacturers stability for total bilirubin following reconstitution.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance specification verification studies for three of three instruments reviewed. Findings: 1. Observation by surveyor during the laboratory tour on April 5, 2018 revealed the laboratory utilizes the following instrumentation: a) Beckman Coulter Access II for Immunology and Endocrinology testing b) Micros 60 for Hematology testing c) ABX Pentra 400 for Chemistry testing 2. Review of the laboratory's performance verification studies revealed the following information was not included: a) Beckman Coulter Access II - Accuracy, complete precision (day to day, run to run and operator variance), and reference ranges b) Micros 60 - Accuracy, complete precision (day to day, run to run and operator variance), reference ranges c) ABX Pentra 400 - Accuracy, complete precision (day to day, run to run and operator variance), reference ranges 3. Further review of the data available for performance specifications revealed there was no documentation of laboratory participation in the studies provided. 4. In interview on April 5, 2018 at 10: 45am, Personnel 2 stated she was not here for the installation and could not confirm if the laboratory participated in the testing or that all required information was included.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must

	document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for chemistry testing. Findings: 1. Observation by surveyors during laboratory tour on April 5, 2018, revealed the laboratory utilizes the Access II instrument with BioRad Immunoassay Plus Chemistry Controls for chemistry testing. 2. Review of the manufacturer's package insert for the BioRad Liquichek Urine Chemistry controls under the "Assignment of Values" section revealed "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." 3. Review of the laboratory's policy and procedure manual revealed no policy was written for how the laboratory should establish its own acceptable ranges. 4. Review of QC records revealed the laboratory utilized the following BioRad Immunoassay Plus Chemistry Controls control without establishing their own means or ranges: a) Level 1 Lot # 40961 b) Level 2 Lot # 40962 c) Level 3 Lot # 40963 5. Interview with Personnel 2 on April 5, 2018 confirmed the laboratory inputs the manufacturer ranges into the instrument to determine quality control acceptability. The laboratory has not established their own means and ranges.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to follow established policies to monitor, assess, and correct quality issues in Analytic Systems. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5403 2. The laboratory failed to use control material before reconstitution expiration date provided by the manufacturer for Total Bilirubin. Refer to D5415 3. The laboratory failed to have complete performance specification verification studies for three of three instruments reviewed. Refer to D5421 4. The laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for chemistry testing. Refer to D5469
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 laboratory personnel performed testing as required. Refer to D6014. 3. The Laboratory Director failed to ensure that the quality control was maintained to assure quality laboratory services were provided. Refer to D6020. 4. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D6022. 5. The laboratory director failed to ensure that all testing personnel were assessed for training and competency prior to patient testing. Refer to D6029 6. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with laboratory personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D5415
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the quality control was maintained to assure quality laboratory services were provided. Refer to D5469.
D6022	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 and quality assessment programs are established and maintained 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 in the Analytic System and to identify failures as they occur. Refer to D5791.
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, the laboratory director failed to ensure that all testing personnel were assessed for training and competency prior to patient testing. Refer to D6053
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 a complete policy and procedure manual was available for all aspect of the testing process. Refer to D5403.
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 failed to evaluate and document the performance of testing personnel at least semi-annually during the first year for three (3) of three (3) testing personnel. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory had a detailed policy for competency assessment prior to patient testing, semi annually and annually thereafter. 2. Review of personnel records revealed the laboratory did not have documentation of initial or semi-annual competency assessment for the following personnel: Personnel 3 - 6 3. In interview on April 5, 2018 Personnel 2 confirmed the initial competency assessments were not documented following the laboratory procedure. Personnel 2 also stated that not all employees had reached their semi annual evaluation.