Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2233879	09/29/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cypress Family Medicine	10562 South Glenstone Place, 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/Complaint survey was performed at Cypress Family Medicine, CLIA ID # 19D2233879, on September 29, 2021. Cypress Family Medicine was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic Systems 42 CFR 493.1290 CONDITION: Post Analytic Systems 42 CFR 493.1441 CONDITION: Laboratories Performing High Complexity Testing; Laboratory Director 42 CFR 493.1487 CONDITION: Laboratories Performing High Complexity Testing; Testing Personnel
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 review of the laboratory's policies and interview with personnel, the laboratory failed to have a system for handling complaints and problems reported to the laboratory. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have a written procedure for reporting complaints, including who is responsible for handling. 2. In interview on September 29, 2021 at 1:07 pm, the Laboratory Director confirmed the laboratory did not have a written procedure for reporting/handling complaints.
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 review of the laboratory's policies and interview with personnel, the laboratory failed to have a system in place to ensure that the documentation of communication problems are reported to the laboratory. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory did not have written policies and procedure 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. 2. In in interview on September 29, 2021 at 1:07 pm, the Laboratory Director confirmed the laboratory failed to have a communication policy in place.
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 the laboratory's policies and interview with personnel, the laboratory failed to establish written policies and procedures to assess competency assessment policies for testing personnel. Findings: 1. Review of the laboratory's polices revealed the laboratory did not have a written policy for assessing the competency of personnel performing laboratory testing that included frequency of performance and the following six (6) procedures as a minimal requirement: 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. In interview on September 29, 2021 at 1:07 pm, the Laboratory Director confirmed the laboratory does not have a competency assessment policy for Testing Personnel.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's records and interview with laboratory personnel, the laboratory failed to verifiy the accuracy of the performance of Live Blood Cell Analysis testing at least twice per year. Findings: 1.

	Observation by surveyor during the laboratory tour on September 29, 2021 at 1:07 pm revealed the laboratory utilizes the American Biologics Bradford Microscope along with a BVPM-8e Fiber optic Controller for Live Blood Cell Analysis testing. 2. Review of the laboratory's policy manual revealed the laboratory did not have written, detailed instructions for verifying the accuracy of the performance of Live Blood Cell Analysis testing at least twice annually. 3. In interview on September 29, 2021 at 1:07 pm, the Laboratory Director confirmed she did not verify the accuracy of Live Blood Cell Analysis testing of patients at least twice per year.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy manual and interview with personnel, the laboratory failed to establish detailed, written instructions for monitoring, assessing, and correcting problems identified in the General Laboratory Systems. Findings: 1. Review of the laboratory policy manual revealed the laboratory did not have detailed instructions to assess problems found in the General Laboratory Systems for the following: 1. The laboratory failed to have a system for handling complaints and problems reported to the laboratory. Refer to D5205. 2. The laboratory failed to have a system in place to ensure that the documentation of communication problems are reported to the laboratory. Refer to D5207. 3. The laboratory failed to establish written policies and procedures to assess competency assessment policies for testing personnel. Refer to D5209. 4. The laboratory failed to verifiy the accuracy of the performance of Live Blood Cell Analysis testing at least twice per year. Refer to 5215. 2. In interview on September 29, 2021 at 1:07 pm, the Laboratory Director confirmed the laboratory did not establish policy and procedures for monitoring, assessing and correcting problems in General Laboratory systems.
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 by surveyor, 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 establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish a complete policy and procedure manual. Refer to D5403. 3. The laboratory failed to establish performance specifications for Live Blood Cell Analysis testing. Refer to D5423. 4. The laboratory failed to establish

	quality control requirements and the frequency of performance for Live Blood Cell analysis testing. Refer to D5445. 5. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy manual and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy manual revealed the laboratory did not have written and detailed policies and procedures that included the following: a) Corrective action: to address failures that may occur in the preanalytic, analytic, and post analytic systems b) Record Retention requirements c) Twice a year verification for accuracy of Live Blood Cell Analysis testing to include frequency, acceptability criteria, and corrective action plan d) Performance specification: detailed procedures for performing accuracy and complete precision (day-to-day, run-to-run, and within-run, as well as, operator variance), analytical sensitivity and specificity, reportable and reference range studies, and actions to take when data from the studies do not meet acceptability criteria e) Complaint Investigations f) Communication g) Temperature and humidity monitoring: including corrective action for temperatures outside of acceptable range h) Corrected reports for errors in patient testing and reporting 2. In interview on September 29, 2021 at 1:07 pm, the Laboratory Director confirmed the laboratory did not have the identified policies included.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedures as well as interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's procedures revealed the laboratory did not have detailed, written policy and procedures that included the following: a) Detailed policies and procedures for patient preparation, specimen collection, specimen type, labeling, storage, preservation, transportation, processing, and referral b) Criteria for specimen acceptability and rejection c) Step-by-step performance of the Live Blood Cell Analysis procedure d) Quality Control to include, but not limited to: What quality control is required, frequency of performance; who is to monitor and corrective actions for unacceptable results e) Reportable range for test results for the test system as established f) Corrective action to take when control results fail to meet the laboratory's criteria for acceptability g) Limitations in the test methodology; including interfering substances h) Reference intervals (normal values) i) Imminently life-threatening test results, or panic or alert values j) Pertinent literature references k) Laboratory's system for entering results in the patient record and reporting patient test results l) Course of action if test system becomes inoperable 2. In interviw on September 29, 2021 at 1:07 pm, the Laboratory Director confirmed the laboratory did not have a policy manual for the identified procedures.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observation during the laboratory tour, review of patient test records, and interview with the Laboratory Director, the laboratory failed to establish performance specifications for Live Blood Cell Analysis testing. Findings: 1. Direct observation during the laboratory tour on September 29, 2021 at 1:07 pm revealed the laboratory utilizes an American Biologics Bradford microscope for Live Blood Cell analysis testing. 2. Review of patient test records revealed Live Blood Cell analysis testing was being performed on patients; however, there was no documentation of performance studies to show accuracy, complete precision, analytical sensitivity and specificity, reportable and reference ranges. 3. In interview on September 29, 2021 at 1:07 pm, the Laboratory Director stated she was unaware Live Blood Cell analysis was considered a high complexity test. The Laboratory Director confirmed that no performance studies were performed prior to patient testing for Live Blood Cell analysis.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)

	Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation during the laboratory tour, review of patient test records and interview with personnel, the laboratory failed to establish quality control requirements and the frequency of performance for Live Blood Cell analysis testing. Findings: 1. Observation during the laboratory tour on September 29, 2021 at 1:07 pm revealed the laboratory utilizes an American Biologics Bradford microscope for Live Blood Cell analysis patient testing. 2. Further observation during the laboratory tour on September 29, 2021 at 1:07 pm revealed the laboratory did not utilize any photomicrographs or charts of all possible live cell components that could meet quality control requirements. 3. Review of patient test records revealed the laboratory performed Live Blood Cell analysis testing on two (2) patients during May 2021 but did not have documentation of quality control being performed prior to patient testing. 4. In interview on September 29, 2021 at 1:40 pm, the Laboratory Director stated she can diagnosis and treat patients based on microscopic results from the live blood analysis testing. The Laboratory Director further stated that this is an older procedure and she is not sure if commercial quality control material or photomicrographs/charts are available.
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 by surveyors, record review, and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish a complete policy and procedure manual. Refer to D5403. 3. The laboratory failed to establish performance specifications for Live Blood Cell Analysis testing. Refer to D5423. 4. The laboratory failed to establish quality control requirements and the frequency of performance for Live Blood Cell analysis testing. Refer to D5445.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory procedures and interview with personnel, the laboratory failed to ensure the overall quality of the postanalytic systems. Findings: 1. The laboratory failed to include all required information on the final test report. Refer to D5805. 2. The laboratory failed to ensure appropriate reference ranges were available on the final report. Refer to D5807. 3. The laboratory failed to establish procedures to monitor, assess, and correct problems identified with the postanalytic system. Refer to D5891.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the patient test report provided and interview with personnel, the laboratory failed to include all required information on the final test report. Findings: 1. Review of "Bradford Scope" patient test report provided to surveyors revealed the laboratory did not include the following information on the final report: a) Laboratory's name and address of where patient testing performed b) Specimen source, if applicable c) Units of measurement or interpretation or both 2. In interview on September 29, 2021 at 1:07 pm, the Laboratory Director confirmed the patient final test reports did not include the identified information.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of patient final test reports, laboratory policy, and interview with personnel, the laboratory failed to ensure appropriate reference ranges were available on the final report. Findings: 1. Review of the patient final test reports revealed the laboratory did not mention normal or reference ranges for Live Blood Cell analysis testing. 2. Review of the laboratory's policies revealed the laboratory did not have a written, detailed policy stating how normal or reference ranges were established and

	/or reported on patient final reports. 3. In interview on September 29, 2021 at 1:07 pm, the Laboratory Director confirmed the laboratory did not include the normal or reference ranges on final reports.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems identified with the postanalytic system. Findings: 1. The laboratory failed to include all required information on the final test report. Refer to D5805. 2. The laboratory failed to ensure appropriate reference ranges were available on the final report. Refer to D5807.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction. Findings: 1. The Laboratory Director failed to establish performance specifications for Live Blood Cell Analysis testing. Refer to D6086. 2. The Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D6089. 3. The Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D6093. 4. The Laboratory Director failed to ensure a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D6094. 5. The Laboratory Director failed to ensure final reports included required pertinent information. Refer to D6098. 6. The Laboratory Director failed to ensure all personnel had the appropriate education and experience for performing high complexity testing. Refer to D6102. 7. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were complete. Refer to D6103. 8. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6106.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

	This STANDARD is not met as evidenced by: Based on observation by surveyors, review of patient records, and interview with personnel, the Laboratory Director failed to establish performance specifications for Live Blood Cell Analysis testing. Findings: 1. The laboratory failed to establish performance specifications for Live Blood Cell Analysis testing. Refer to D5423.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on review of laboratory's records and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Findings: 1. The laboratory failed to verifiy the accuracy of the performance of Live Blood Cell Analysis testing at least twice per year. Refer to D5215.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory's records and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to establish quality control requirements and the frequency of performance for Live Blood Cell analysis testing. Refer to D5445.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory's records and interview with personnel, the Laboratory Director failed to ensure a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Findings: 1. The laboratory failed to establish detailed, written instructions for monitoring, assessing, and correcting problems identified in the General Laboratory Systems. Refer to D5291. 2. The laboratory failed to establish procedures to monitor, assess, and correct problems identified with the analytic system. Refer to D5791. 3. The laboratory failed to establish procedures to monitor, assess, and correct problems identified with the postanalytic system. Refer to D5891.

D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of laboratory's records and interview with personnel, the Laboratory Director failed to ensure final reports included required pertinent information. Findings: 1. The laboratory failed to include all required information on the final test report. Refer to D5805. 2. The laboratory failed to ensure appropriate reference ranges were available on the final report. Refer to D5807.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 the laboratory's records and interview with personnel, the Laboratory Director failed to ensure all personnel had the appropriate education and experience for performing high complexity testing. Findings: 1. The laboratory failed to ensure one (1) of two (2) testing personnel met the state of Louisiana licensure requirement to perform high complexity testing. Refer to D6170. 2. The laboratory failed to provide documentation that one (1) of two (2) testing personnel met the educational qualifications for performing high complexity testing. Refer to D6171.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on the laboratory's policies and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were complete. Findings: 1. The laboratory failed to establish written policies and procedures to assess competency assessment policies for testing personnel. Refer to D5209.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)

	The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with 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 for handling complaints and problems reported to the laboratory. Refer to D5205. 2. The laboratory failed to have a system in place to ensure that the documentation of communication problems are reported to the laboratory. Refer to D5207. 3. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 4. The laboratory failed to establish a complete policy and procedure manual. Refer to D5403.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's CMS-209 form and interview with personnel, the laboratory failed to ensure Testing Personnel met state licensure and education requirements for high complexity testing. Findings: 1. The laboratory failed to ensure one (1) of two (2) testing personnel met the state of Louisiana licensure requirement to perform high complexity testing. Refer to D6170. 2. The laboratory failed to provide documentation that one (1) of two (2) testing personnel met the educational qualifications for performing high complexity testing. Refer to D6171.
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high 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 CMS-209 form, personnel records, patient testing records, and interview with personnel, the laboratory failed to ensure one (1) of two (2) testing personnel met the state of Louisiana licensure requirement to perform high complexity testing. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Record) form submitted to surveyors on September 29, 2021 at 1:50 pm revealed there were no Testing Personnel listed other than the Laboratory Director. 2. Review of two (2) patient testing records from May 2021 revealed documentation of one (1) testing personnel's initials different than personnel included on the CMS-209 form. 3. Review of the laboratory's personnel records revealed the laboratory did not have documention of a Louisiana state license for personnel performing testing. 4. In interview on September 29, 2021 at 1:27 pm, the Laboratory Director stated the nurse makes the slide for the Live Blood Cell analysis and then the Laboratory Director

	reads the results microscopically. 5. In further interview on September 29, 2021 at 1: 27 pm, the Laboratory Director confirmed the documented testing personnel did not have a Louisiana state license to perform high complexity testing.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)

	(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form, personnel records, patient testing records and interview with personnel, the laboratory failed to provide documentation that one (1) of two (2) testing personnel met the educational qualifications for performing high complexity testing. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed the laboratory had only one (1) testing personnel listed on the report. 2. Review of two (2) patient testing records from May 2021 revealed the intials of a testing personnel not listed on the laboratory's CMS-209 form. 3. Review of the laboratory's personnel records revealed the laboratory did not have documentation of education that met the minimum qualifications for high complexity testing. 4. In interview on September 29, 2021 at 1:50 pm, the Laboratory Director stated that she is the only personnel performing testing. The Laboratory Director confirmed she did not have documentation of education for other testing personnel to meet the minimum qualifications for high complexity testing.