

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  25D2147200	<b>(X3) Date Survey Completed</b>  01/08/2019
<b>Name of Provider or Supplier</b>  Byrd Family Medical Clinic	<b>Street Address, City, State</b>  705 North State Street, Clarksdale, MS	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and confirmation with staff at 2:30 on the day of survey, 1/8/19, the laboratory did not have available on the day of survey, written approved procedures that included the following when applicable to the test procedure: Findings include: 1. Requirements for patient preparation, storage, preservation, transportation, processing and referral; and criteria for specimen acceptability and rejection as described in 493.1242 (this subpart.) 2. Written procedure for specimen collection to include steps for venipuncture and capillary collection. 3. A system for entering results in the patient record and reporting patient</p>

results including, when appropriate, the protocol for reporting imminent life threatening results (panic or alert) values. 4. Written urine collection procedures for both male and female. 5. Written procedures for the steps that are taken when the Sysmex XP 300 hematology analyzer becomes inoperable. 6. Written labeling policy that includes unique identifiers when labeling laboratory specimens. 7. Quality Control Procedures for the Sysmex XP 300 hematology analyzer to include: a) The levels of control and type of calibration material to be performed b) The frequency of control and calibration performance c) The criteria for determining the acceptability of control results 8. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability

**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:  
A. Based on review of a patient CBC (complete blood count) report resulted the day of survey (1/8/19) and printed from the Sysmex XP 300 hematology analyzer, the patient CBC printout did not have the patient name or the clinic location (name and address) where the testing was performed--the chart number and testing personnel initials are the only identification on the printout which is retained in the patient chart. The test report must indicate the patient's name and identification number as well as the name and address of the laboratory location where the test was performed. B. (1) Based on review of the patient report mentioned in section (A) above and the CBC report printed from the laboratory ATHENA system, it was revealed that the name of the clinic did not appear on this printout. Instead "Main Office" was printed on the report along with the address and CLIA number. The test report must indicate the name of the clinic where the testing occurred. (2) Based on the review of the patient CBC report printed from the ATHENA system, the units of measurement for the CBC parameters are not available on the report. According to interview with staff at 4:30 pm on the day of survey, this is the report that would be faxed or shared with collaborating providers. Units of measurement must be included on the report.

**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 a lack of a written quality control procedure appropriate for the testing performed, the laboratory director had not established parameters for acceptable levels of analytic performance for testing performed on the Sysmex XP 300 hematology analyzer. Refer to D5403

**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 surveyor review of laboratory policies and procedures on 1/8/2019, the laboratory director failed to ensure a comprehensive QA (quality assessment) program designed to monitor and evaluate the overall quality of the total testing process (general laboratory, preanalytic, analytic and postanalytic systems) was established and maintained to assure the quality of the laboratory services provided. Findings include: The laboratory director had not ensured the laboratory had a written QA program available the day of survey for review, that included the practices or issues related to the following when applicable to the test procedure: 1. Patient confidentiality. 2. Specimen integrity. 3. Complaint investigations. 4. Communications. 5. Personnel competency (education, training, evaluation). 6. Proficiency testing or QA activities. 7. Specimen submission, handling, and referral. 8. Establishment and verification of method performance specifications. 9. Control procedures. 10. Review and documentation of the effectiveness of corrective actions taken to resolve problems. 11. Monitoring and evaluating the accuracy and completeness of the laboratory test reports. 12. Performance and periodic review of quality control, proficiency testing, and patient results. 13. Specifications of which qualified personnel will conduct QA reviews and how often these reviews will be conducted, systems and retention of QA records. 14. Revision of policies and procedures necessary to prevent recurrence of problems. 15. Discussion of laboratory QA reviews with appropriate testing personnel. 16. Documentation of QA activities.

**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 review of the manufacturer's procedure manual for the Sysmex XP 300 hematology analyzer and the written laboratory procedure manual put into use for

patient testing in September 2018, the laboratory director failed to approve both the Sysmex XP 300 manufacturer's procedure manual for use by testing personnel for CBC testing and the laboratory's written procedure manual used by testing personnel for the entire laboratory as of the day of survey 1/8/2019.

**D6067**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(4)(ii)

Each individual performing moderate complexity testing must have training to ensure that the individual has-- (A) 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) the skills required for implementing all standard laboratory procedures; (C) the skills required for performing each test method and for proper instrument use; (D) the skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed; (E) a working knowledge of reagent stability and storage; (F) the skills required to implement the quality control policies and procedures of the laboratory; (G) an awareness of the factors that influence test results; and (H) the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on testing personnel records available the day of survey 1/8/2019, the testing personnel listed on the CMS (Centers For Medicare & Medicaid Services) 209 personnel form had not been documented as trained for the complete laboratory testing process to include preanalytic, analytic and postanalytic phases of the laboratory. Documentation of training available the day of survey revealed testing personnel were only trained on the Sysmex XP 300 hematology analyzer on 9/10/18. The testing personnel did not have the following laboratory training before being allowed to collect samples, perform and report patient testing: a. Skills required for proper specimen collection, including patient preparation. b. Skills required for implementing all standard laboratory procedures. c. A working knowledge of reagent stability and storage d. The skills required to implement the quality control policies and procedures of the laboratory. e. The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results. f. Knowledge of how to report patient results (charting, electronically, etc.)