

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  25D2154983	<b>(X3) Date Survey Completed</b>  02/14/2019
<b>Name of Provider or Supplier</b>  Brooks Medical Clinic	<b>Street Address, City, State</b>  2113 South Tate Street, Corinth, 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>D5203</b>	<p><b>SPECIMEN IDENTIFICATION AND INTEGRITY</b> CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on interview with testing personnel (TP) #2 as listed on the Centers For Medicaid &amp; Medicare Services (CMS) 209 form, on day of survey 2/14/19 at 2:00 pm, lack of documentation of a specimen labeling procedure, review of 2 CBC (complete blood count) final results, and observation of 4 patient purple top specimens collected on 2/14/19, the laboratory failed to establish and follow written policies and procedures to ensure positive identification of the patient specimen from the time of collection through testing and reporting for CBC results. Findings include: 1) Observation of patient specimens revealed only a first initial and last name of the patient on the specimen tube. 2) Interview with TP #2 at 2:00 pm on 2/14/19 indicated that TP routinely entered the patient account number, patient's first initial and last name, and the TP's initials into the hematology analyzer. 3) The resulting CBC printout was then scanned into the LIS. 4) This process does not ensure positive identification of a patient's specimen from the time of collection through reporting of results.</p>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> 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</p>

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 procedure manual and confirmation with technical consultant at 2:00 pm on the day of survey, 2/14/19, the laboratory did not have available written approved procedures that included the following when applicable to the test procedure: Findings include: There were no written approved procedures covering the following areas: 1. Requirements for patient preparation, labeling, storage, preservation, transportation, processing and referral; and criteria for specimen acceptability and rejection as described in 493.1242 (this subpart.) 2. Written procedures for specimen collection including venipuncture, fingerstick and capillary collection. 3. The laboratory's system for entering results in the patient record and reporting patient results including the protocol for reporting imminent life threatening results (panic or alert). 4. Written urine collection procedures for male and female patients. 5. Written procedures to follow when the Sysmex XP 300 hematology analyzer becomes inoperable. 6. Written labeling policy for specimens to ensure positive identification. 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 used 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.

**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 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 Syxmex 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 2/14/2019, 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 identification and integrity. 3. Complaint investigations. 4. Communications. 5. Personnel competency (education, training, evaluation). 6. Proficiency testing or verification of accuracy. 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.