Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0314034	02/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Shelby County Health Care Corporation	3109 Walnut Grove Road, Memphis, TN	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 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. This STANDARD is not met as evidenced by: Based on review of the laboratory policy titled "Quality Assessment Plan", the laboratory's quality assessment records, and interview with the technical consultant, the laboratory failed to follow the policy for patient test management in 2017, 2018, and 2019. The findings include: 1. Review of the laboratory policy titled "Quality Assessment Plan" revealed that the following under the section titled "Patient Test Management": We will evaluate our criteria for: a. Patient preparation, specimen collection, labeling, preservation, and transportation; b. The laboratory test requisition requirements; c. The criteria used for specimen rejection; d. The test report for completeness, usefulness and accuracy of the report information necessary for the interpretation or utilization of report; and e. The timely reporting of test results based on testing priorities such as STAT or routine. 2. Review of the laboratory's quality assessment records revealed no patient test management records were present. 3. Interview with the technical consultant on February 21, 2019 at 9:30 am confirmed the laboratory did not follow the quality assessment policy for patient test management in 2017, 2018, and 2019.
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 patient number four and five electronic medical record (EMR), the laboratory procedure manual, and interview with the technical consultant, the laboratory failed to have a procedure for entering patient complete blood count (CBC) results into the electronic medical record in 2019. The findings include: 1. Review of patient numbers four and five EMR revealed the manual entry of CBC results into the patient EMR. 2. Review of the laboratory procedure manual revealed no procedure for manually entering patient CBC results into the EMR. 3. Interview with the techncial consultant on February 21, 2019 at 11:10 am confirmed the laboratory procedure manual does not include the process for manually entering patient CBC results in the patient EMR record. _____
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 of the laboratory, review of the complete blood count (CBC) control package insert, and interview with testing personnel number one, the laboratory failed to label CBC controls with open date and corrected expiration date in 2019. The findings include: 1) Observation of the laboratory on February 21, 2019 at 8:25 am revealed CBC controls in use that were not labeled with open date or corrected expiration date. 2) Review of the CBC control package insert revealed that the controls are good for 35 days after opening for a maximum of 20 samplings. 3) Interview with testing personnel number one on February 21, 2019 at 8:35 am confirmed the CBC controls were not labeled with open date and corrected expiration date in 2019. _____
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)

	Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the complete blood count (CBC) instrument operators manual, the laboratory's quality control (QC) records, and interview with the technical consultant, the laboratory failed to follow manufacturer instructions for calibration in 2017, 2018, and 2019. The findings include: 1. Review of the Beckman Coulter AcT Diff 2 operators manual for CBC revealed the following statements: To confirm calibration of the AcT diff 2 analyzer: 1. Verify that 95% of control results are within their ranges as listed in the TABLE OF EXPECTED RESULTS. 2. Verify that there are no unexplained shifts or trends in the data. 2. Review of the laboratory's quality control (QC) records for 2017, 2018, and 2019 revealed that the cumulative quality control data is not printed for review to verify 95% of controls are within acceptable ranges and that there are no unexplained shifts or trends in the data. The instrument was last calibrated on June 13, 2018. 3. Interview with the technical consultant on February 21, 2019 at 10:00 am confirmed the laboratory did not follow manufacturer instructions for calibration in 2017, 2018, and 2019.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy for proficiency testing, the laboratory proficiency testing records, and interview with the technical consultant, the laboratory director failed to ensure the laboratory corrective action plan for unacceptable proficiency testing results was followed in 2018. The findings include: 1) Review of the laboratory proficiency testing policy revealed that any unacceptable score is evaluated to determine cause of the failure. 2) Review of the laboratory's proficiency testing records revealed the following: 2018 Event two: red blood cell, sample number HD-8-Scored as Fail 2018 Event three: granulocyte %, sample number HD-12-Scored as Fail. Both reports were signed by the technical consultant and the laboratory director with no corrective action performed. 3) Interview with the technical

	consultant on February 21, 2019 at 10:00 am confirmed the laboratory director failed to ensure the corrective action plan for unacceptable proficiency testing results was followed in 2018.