

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D1054082	(X3) Date Survey Completed 01/08/2019
Name of Provider or Supplier Southeast Cancer Center Laboratory	Street Address, City, State 789 S Mount Auburn Rd, Cape Girardeau, MO	
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
D5403	<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 blood bank procedures and interview with technical supervisor #2, #3 the laboratory failed to have step by step blood bank ABO Group and RH(D) procedure pertinent to the laboratory. Findings: 1. Review of "ABO Group and RH(D) Type (Gel testing)" procedure showed "Cold reacting autoantibodies", "Cold reacting alloantibodies" and "passively acquired Anti-A and/or Anti-B". Interview with technical supervisor #2 and #3 confirmed laboratory does not identify antibodies. 2.</p>

Interview with technical supervisor #2 and #3 on January 8, 2019 at 12:30 PM confirmed laboratory failed to have a step by step blood bank ABO Group and RH(D) procedure pertinent to the laboratory.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on review of the blood bank alarm check procedure, 13 of 13 alarm checks, manufacturer's manual for the blood bank refrigerator and interview with the general supervisor, the laboratory failed to follow the manufacturer's instructions for checking the low and high alarm on the blood bank refrigerator. Findings: 1. Review of the "Alarm Checks of Blood Bank Refrigerator" procedure revealed to manually select the "Start High Alarm Auto Test" and the "Start Low Alarm Auto Test" on the outside of the refrigerator to start the alarm tests. 2. Review of the blood bank refrigerator low /high alarm check logs showed the laboratory performed 13 alarm checks from 11/19 /2015-12/21/2018. 3. Review of the Helmer refrigerator manual for "Testing Alarms" revealed "test the alarms by placing the temperature probe in chilled or warm water and noting the temperature at which the alarm activates." 4. Interview with the general supervisor on January 8, 2019 at 11:30 AM confirmed "we push the button on the outside of the refrigerator to increase and decrease the temperature to make the alarm sound. We do not put the probe in cool or warm water." Interview with the general supervisor confirmed the laboratory failed to follow the manufacturer's instructions for performing alarm checks on the Helmer blood bank refrigerator.

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 three of three patient test reports and interview with the technical supervisors #2, #3, the test reports failed to include the address of the location at which the test was performed and the correct CLIA certificate number. Findings: 1. Review of three test reports revealed the laboratory failed to include the address of the testing laboratory. Review of the test reports showed the laboratory included the CLIA certificate number from a different laboratory. 2. Interview with the technical

supervisors #2, #3 on January 8, 2019 at 12:30 PM confirmed the laboratory failed to include the address and the correct CLIA number of the testing laboratory on the patient test report.