

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0882688	(X3) Date Survey Completed 04/19/2018
Name of Provider or Supplier Scientific Research Consortium, Inc	Street Address, City, State 2840 Patton Road, Saint Paul, MN	
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
D5313	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)</p> <p>The laboratory must document the date and time it receives a specimen.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to document the time specimens for lipid testing were received into the laboratory. Findings are as follows: 1. The laboratory performed lipid testing under the Specialty of Chemistry as confirmed by the Laboratory Director (LD) during a tour of the laboratory on 04/19/18 at 10:05 a.m. 2. Requirements for documentation of specimen receipt time into the laboratory were found in the Sample Receipt, Storage and Disposal procedure located in the SOP manual.. 3. The time of specimen receipt into the laboratory was not documented in the lipid electronic receipt record reviewed on date of survey. 4. In an interview on 04/19/18 at 1:10 p.m., the General Supervisor confirmed the time of lipid specimen receipt was not documented.</p>
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</p>

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 observation, document review and interview with laboratory personnel, the laboratory failed to include lipid reference intervals (normal values) in the procedure manual (10). Findings are as follows: 1. The laboratory performed lipid testing under the Specialty of Chemistry as confirmed by the Laboratory Director (LD) during a tour of the laboratory on 04/19/18 at 10:05 a.m. 2. Shimadzu GC-2010 Gas Chromatographs were used to perform the lipid testing. Two units were observed during the tour of the laboratory. 3. Normal values for the lipid tests were not present in the Fatty Acid Methyl Ester Analysis by Direct Derivatization procedure located in the SOP manual. 4. In an interview on 04/19/18 at 1:10 p.m., the General Supervisor confirmed lipid reference ranges were not included in the procedure.

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 document review and interview with laboratory personnel, the laboratory failed to ensure the name and address of the laboratory location were indicated on the test report (c)(2). Findings are as follows: 1. The laboratory performed lipid testing under the Specialty of Chemistry as confirmed by the Laboratory Director (LD) during a tour of the laboratory on 04/19/18 at 10:05 a.m. 2. The lipid patient test report reviewed on date of survey, 04/19/18, did not indicate the name of the laboratory and address of the laboratory location. 3. In an interview on 04/19/18 at 1:10 p.m., the General Supervisor confirmed the above finding.