

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0690592	(X3) Date Survey Completed 05/09/2018
Name of Provider or Supplier St Louis Medical Clinic Pc	Street Address, City, State 3009 N Ballas Rd, Suite 100b, Saint Louis, 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 the urinalysis procedure manual and interview with the technical consultant on May 9, 2018 at 12:30 PM confirmed, the procedure manual failed to include reference intervals (normal values) for microscopic examination of urine sediment.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p>

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of calibration verification records and interview with the technical consultant, the laboratory failed to perform calibration verification procedures at least once every six months during 2017 and to date 2018 to verify the laboratory's reportable range for two of seven analytes performed on the Tosoh chemistry analyzer. Findings: 1. Review of calibration verification records revealed the laboratory failed to include a mid-point value to verify the laboratory's reportable range for PSA and ferritin testing performed on the Tosoh chemistry analyzer. 2. Interview with the technical consultant on May 9, 2018 at 12:30 PM confirmed, the laboratory failed to ensure calibration verification procedures for PSA and ferritin included at least a minimal value, mid-point value and maximum value at least once every six months to verify the reportable range of the test system.

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 approved corrective action plan, proficiency testing (PT) results for 2018, and interview with the technical consultant, laboratory director failed to ensure the corrective action plan was followed for PT results found to be unacceptable. Findings: 1. The approved PT Review policy states, " Unacceptable results are repeated and a written reason given for the unacceptable performance. This includes documentation of any corrective action taken. Highlight the tests with less than 100 % and review to see if specimens were resulting in the same direction or

fluctuating. For example, if a score of 60% on an analyte was achieved, check for a trend of low results, high results and sporadic results." 2.. Review of PT results revealed the laboratory obtained an unacceptable score of forty percent for the creatinine analyte for the first testing event of 2018. Results showed specimen CH-03, CH-04, and CH-05 were unacceptable and trended lower than the expected results determined by the PT provider. 3. The laboratory did not have documentation / written reason given for the unacceptable performance or trend evaluation of unacceptable PT results obtained for the creatinine analyte for the first event of 2018. 4. Interview with the technical consultant on May 9, 2018 at 12:30 PM confirmed, the laboratory director failed to ensure the approved PT Review policy was followed for unacceptable results.