

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0694438	(X3) Date Survey Completed 08/07/2018
Name of Provider or Supplier Santiago Reyes, Md	Street Address, City, State 3366 Nw Expressway, Suite 330, Oklahoma City, OK	
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
D0000	The laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and general supervisor #2 /testing person during an exit conference performed at the conclusion of the survey.
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with general supervisor #2/testing person, the laboratory failed to verify the accuracy of proficiency testing results when the proficiency testing program had not evaluated submitted results. Findings include: (1) Surveyor #1 reviewed proficiency testing records for 2017 and 2018 and could not locate documentation to prove the laboratory identified and evaluated results not graded by the proficiency testing program for the Qualitative Sweat Chloride testing (Educational Challenge): (a) SW-B 2017 Event - For samples SW-04, SW-05, and SW-06, the proficiency testing program had not graded the results due to them being an "Educational Challenge". There was no evidence in the records the laboratory performed a self-evaluation by reviewing the "Participant Summary" report to ensure their responses agreed with the intended responses; (b) SW-A 2018 Event - For samples SW-01, SW-02, and SW-03, the proficiency testing program had not graded the results due to them being an "Educational Challenge". There was no evidence in the records the laboratory performed a self-evaluation by reviewing the "Participant Summary" report to ensure their responses agreed with the intended responses. (2) The findings were reviewed with general supervisor #2/testing person, who stated the laboratory did not perform a self-evaluation of the non-graded responses.</p>

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on a review of the policy and procedure manual and interview with the general supervisor #2/testing person, the laboratory failed to follow written procedures for quality control. Findings include: (1) At the beginning of the survey, the general supervisor #2/testing person stated to the surveyors Sweat Chloride testing was performed on the Gonotec Chloridmeter analyzer; (2) Later during the survey, surveyor #2 reviewed the written procedure titled, "MANAGING QUALITY CONTROL" which stated, (a) "The following steps will be taken when control values do not meet standards. a. Mix the control well and repeat with a vial of freshly pipetted acid reagent. If the value still does not come into an acceptable range then; b. Open a new vial of control. If the value still does not come into an acceptable range; c. Repeat 100 mmol/L standard to ensure correct value can be obtained. If the value is not acceptable; d. Clean electrodes and begin the Testing Sweat procedure again." (3) Surveyor #2 reviewed quality control records from January 2018 through July 2018. For 1 of 12 quality control records there was no indication the laboratory staff followed their written procedure as follows: (a) Quality Control tested on 03/13/18 - control level 1 result was 20 mmol/L (acceptable range 21 - 25 mmol/L). (3) Surveyor #2 reviewed the findings with the general supervisor #2/testing person who stated that the procedure had not been followed as indicated above.