

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0659589	(X3) Date Survey Completed 07/15/2019
Name of Provider or Supplier Utswmc Mineral Metabolism Laboratory	Street Address, City, State 5323 Harry Hines Blvd J4-102, Dallas, TX	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of CMS 209 form, personnel records and confirmed in interview, the laboratory failed to ensure consultant competency procedures were established and followed for 1 of 2 Technical Supervisors (TS-1), 2 of 2 General Supervisors (GS-1) and Technical Consultants (TC-1) for 2018 and Testing Person (TP) #4 Findings included: 1. Review of the CMS 209 form listed TS-1/GS-1/TC-1 and TP #1 as supervisors/consultants for moderate and high complexity testing. Review of personnel records did not include competency assessments for TP #4. 2. During an interview on 07/15/2019 at 11:00 hrs, TS-1 and GS-1 are one in the same confirmed the above findings.</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p>

This STANDARD is not met as evidenced by:
Based on a review of quality control records for the corrective action policy and confirmed in interview, the laboratory failed to evaluate all patient test results obtained since the last acceptable quality control run when controls failed to meet the laboratory's established criteria for acceptability. Findings were as follows: a .At the time of the survey the laboratory failed to provide a Quality Control policy to include patients prior to quality control failures back to the last successful quality control run were evaluated to ensure the accuracy of the patient results reported. b. An interview of the Technical Supervisor on 07/15/2019 at 13:00 hours in the laboratory confirmed the above findings.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, CMS 209 form, personnel records, and in interview with staff, the laboratory director failed to ensure policies were established and competency assessment was maintained for individuals who perform testing and provide technical oversight, as evidenced by: a. The laboratory failed to establish and follow written policies to assess consultant competency for 1 of 1 technical consultant (TC), technical supervisor (TS), and general supervisor (GS) in 2018 for the TS #1 from the CMS 209 . Refer to D5209, I. b. The laboratory failed to perform personnel competency on Testing Person#4 from the CMS form 209 for 2018 according to personnel competency assessment policy. Refer to D5209, II.