

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0481787	(X3) Date Survey Completed 02/28/2019
Name of Provider or Supplier Trace Elements, Inc	Street Address, City, State 4501 Sunbelt Drive, Addison, 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
D0000	<p>Noted deficiency and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, Nexion 1000 ICP-MS (Serial number 815N8030502X) analyzer calibration records and confirmed in interview, the laboratory failed to follow its own policy for performing calibration verification every 6 months in 2018 to ensure the accuracy of all elements (analytes) tested on the Nexion 1000 analyzer. Findings included: 1. Review of laboratory records revealed the following elements (analytes) were measured on hair samples using the Nexion 1000 ICP-MS analyzer: Calcium Magnesium Sodium Potassium Copper Zinc Phosphorus Iron Manganese Chromium Selenium Boron Cobalt Molybdenum Sulfur</p>

Antimony Uranium Arsenic Beryllium Mercury Cadmium Lead Aluminum
Germanium Barium Bismuth Rubidium Lithium Nickel Platinum Thallium Vanadium
Strontium Tin Titanium Tungsten Zirconium

2. The laboratory policy titled "Calibration/Verification Procedures" stated, "The laboratory must perform calibration or recalibration of each automated procedure at least every six months, or more frequently if specified by the manufacturer, using a complete range of calibrators."

3. Review of Nexion 1000 analyzer calibration records from 2018 revealed the laboratory performed calibration verifications on 05/23/2018. As of the survey date (02/28/2019), the laboratory had not performed any calibration verifications on the Nexion 1000 since 05/23/2018. This is an elapsed period of 9 months.

4. According to laboratory records, 2,405,000 tests were performed annually.

5. During an interview on 02/28/2019 at 1015 hours, Technical Supervisor #2 confirmed the above findings.