Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0481787	02/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Trace Elements, Inc	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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, 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.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, review of the laboratory's policies, and staff interview, it was revealed the laboratory failed to have documentation of performing competency assessments on its general supervisor. The findings were: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 1 general supervisor. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of competency assessments being performed on the general supervisor. 3. A review of the laboratory's policies revealed performing competency assessments on the general supervisor and the frequency of the

	assessments were not part of the laboratory's personnel policy. 4. An interview with the general supervisor on 02/01/2021 at 930 hours in the conference room revealed she had not had competency assessment performed. This confirmed the findings.
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 review of laboratory's test menu, review of laboratory policy, review of analyzer calibration records and confirmed in interview, the laboratory failed to follow its own policy for performing calibration verification every 6 months. The findings were: 1. Review of laboratory's test menu 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 Antimony Uranium Arsenic Beryllium Mercury Cadmium Lead Aluminum Germanium Barium Bismuth Rubidium Lithium Nickel Platinum Thallium Vanadium Strontium Tin Titanium Tungsten Zirconium 2. A review of the laboratory policy titled "Nexion 1000 ICP-MS Calibration Verification" revealed: "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 2019 and 2020 revealed the laboratory performed calibration verifications on the following days: a) Instrument 1 9 /23/2019 8/28/2020 (11 months later) b) Instrument 2 9/24/2019 8/31/2020 (11 months later) 4. According to laboratory records, 2,695,6800 tests were performed annually. 5. During an interview on 02/01/2021 at 1035 hours in the conference room, the General Supervisor confirmed the above findings.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment plan, review of the laboratory's quality assessment records from 2019 and 2020, and staff interview, it was revealed the laboratory director failed to ensure the laboratory's quality assessment plan was followed. The findings were: 1. A review of the laboratory's policy titled "Trace Elements Product Quality Assurance Program" revealed: "Other aspects of the laboratory will also be monitored to ensure the lab is [in] compliance with CLIA regulations and with standard operating procedures. The following will be monitored on a quarterly basis (i.e. every three months): 1. Proficiency Testing was performed as required and is acceptable, corrective action as appropriate. 2. All laboratory environmental monitoring was done and is documented. 3. Reagents are

	within expiry date and have date of receipt, date open and date of expiry documented. 4. Equipment maintenance records are complete. 5. Records are filed for retrieval. 6. Calibration/Verification testing was performed as required. 7. Personnel competency was reviewed. 8. Any laboratory safety issues were addressed and discussed with Laboratory Director." 2. A review of the laboratory's quality assessment records from 2019 and 2020 revealed the laboratory failed to have documentation of performing this quarterly monitoring for all of 2019 and 2020. The last record found of it being performed was in March 2018. 3. An interview with the general supervisor on 02/01 /2021 at 1055 hours in the conference room revealed the quarterly quality assessments had not been performed in 2019 and 2020. This confirmed the findings.