Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2056200	08/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
Elite Diagnostics, Llc	10996 Four Seasons Pl, Suite 100 A, Crown Point, IN	

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	A validation survey was completed on 8/15/2024. It was determined that the following condition-level deficiencies existed: 42 CFR 492.1489: High Complexity Testing Personnel Qualifications
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review, observation, and interview, the laboratory failed to ensure one (SP-02) of three testing personnel performing preanalytic sample preparation on one of one liquid chromatography by mass spectrometry (LCMS) high complexity analyzer under the subspecialty of toxicology met the qualification requirements for high complexity testing personnel from 3-12-2024 to 8-13-2024 (refer to D6170).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60

semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on document review, observation and interview, the laboratory failed to ensure one (SP-02) of three testing personnel performing preanaltyic high complexity testing on the LCMS high complexity analyzer met the requirements for high complexity testing personnel from 3-12-2024 to 8-13-2024. Findings included: 1. Review of the "Laboratory Personnel Report (CLIA)" form (CMS-209), signed by the laboratory director on 7-30-2024 listed SP-02 as a testing personnel for the subspecialty of Toxicology. 2. During the laboratory tour on 8-13-2024 at 09:54 AM, SP-02 (testing

	personnel) was observed preparing samples for the high complexity LCMS analyzer Thermo Scientific "TQE" serial number (SN#) "TQH-E1-0180". SP-02 was pipetting liquid into a well plate to be analyzed on the LCMS. 3. Personnel file review for SP-02 indicated the following: a. The job description "Laboratory Assistant", signed by the "General Supervisor" and SP-02 on 3-16-2022, delegated the following duties to SP-02: calibration, sample preparation, and internal standard preparation per testing as required by method. The delegated duties did not include which instrument the duties would be performed. b. Education for SP-02 was a high school diploma but based on the gradutation date, did not meet the requirements under 42 Code of Federal Regulations (CFR) 493.1489(b)(3) or (b)(5). c. A signed annual competency for the high complexity LCMS Thermo Scientific Endura signed by SP-02 on 3-12-2024, shows SP-02 was evaluated on test performance, instrument maintenance, and function checks. 4. During an interview and observation on 8-13-2024 at 12:25 PM, SP-02 (testing Personnel) performed and explained the steps they follow in the policy titled "Confirmatory drug testing with LC-MS", page 16 of 43 (steps 1-6): "Sample Preparation for Calibrator, Quality Control and Patient Samples in Urine..." 5. In a phone interview on 8-15-2024 at 09:34 AM, SP-01 (Technical Supervisor) confirmed SP-02 (testing personnel) performs all the preanalytical steps to prepare the LCMS sample plate as described in the policy titled "Confirmatory drug testing with LC-MS", page 16 of 43 (steps 1-6). SP-01 stated, "SP-02 does not report any patient results on the LCMS". 6. Total annual test volume for the LCMS is 849,808.