

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2183496	(X3) Date Survey Completed 04/30/2024
Name of Provider or Supplier Trudiagnostic	Street Address, City, State 881 Corporate Drive, Lexington, KY	
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	An abbreviated survey investigating Complaint KY00042353 was conducted on 04/30/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on facility document review, policy review, and confirmed in staff interview, the laboratory failed to ensure that 1 of 1 individuals reviewed had the board certification to serve as a high complexity Laboratory Director (LD). Refer to D6078.</p>
D6078	<p>LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443</p> <p>The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to</p>

practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, review of Centers for Medicare and Medicaid (CMS) forms, review of laboratory documents, and confirmed in staff interview, the laboratory failed to ensure that 1 of 1 individuals reviewed met the regulatory requirements to serve as the Laboratory Director (LD) for high complexity testing. Findings included: Review of a laboratory policy titled, "Laboratory Director Responsibilities and Duties Including Delegation," developed on 01/06/2022 by the LD, revealed "The Laboratory Director is responsible for the overall operation and administration of the laboratory, including provision of timely, reliable and clinically relevant test results and compliance with applicable regulations and accreditation requirements." Review of the CMS "Clinical Laboratory Improvement Amendments (CLIA) Application for Certification" form, dated 04/30/2024, revealed the LD was listed as the laboratory's LD. Review of the CMS "Laboratory Personnel Report (CLIA)" form, dated 04/30/2024, revealed the LD was listed as the laboratory's LD. Review of the "Laboratory Director Responsibilities and Duties Including Delegation Forms," signed and dated by the LD on 11/15/2022, revealed all listed duties were delegated to the Technical Supervisor/General Supervisor (TS/GS). Those duties included technical and scientific oversight, method validation/verification studies, proficiency testing, quality control and quality management, monthly quality control /quality management review, remedial/corrective action, training, competency assessment, and procedure review. Review of an American Board of Forensic Toxicology (ABFT) certificate provided by the facility revealed the LD was granted certification on 01/01/2022. Review of a letter dated 02/14/2024 from a legal firm representing the ABFT revealed the that the LD did not have board certification from ABFT. The letter further revealed that the ABFT had no record of the LD having ever been a fellow and the certificate number listed on the LD's certificate was linked to a different fellow of the ABFT. During an interview on 04/30/2024 at 9:40 AM, the President of the ABFT stated the LD was not board certified During an interview on 04/30/2024 at 10:50 AM, the TS/GS provided a transcript showing the LD's doctorate degree was awarded on 12/15/2016 and a certificate from the ABFT was granted on 01 /01/2022. Review of the ABFT certificate that was presented revealed it was the

certificate that was reported. During an interview on 04/30/2024 at 4:00 PM, the TS /GS stated the certificate from the ABFT was the only board certification on file for the LD.