

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2183496	(X3) Date Survey Completed 02/02/2023
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	A recertification survey was conducted on 02/02/2023 and the facility was found not to be in substantial compliance with the laboratory requirements at 42 CFR Part 493, with deficiencies cited.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Supervisor (TS), the laboratory failed to twice annually verify the accuracy of epigenetic-methylation deoxyribonucleic acid (DNA) testing for two (2) of two (2) years reviewed (2021 and 2022). The findings include: Review of laboratory records revealed accuracy verification was performed once for 2021, on 01/07/2021, and once for 2022, on 07/25 /2022. Accuracy verification was not performed a second time as required for 2021 or 2022. Interview with the TS, on 02/02/2023 at 1:18 PM, revealed that accuracy verification was performed by giving five (5) samples to personnel for testing and comparing results to known values. The TS stated that the verification should be performed twice per year, but it was not consistent.</p>