

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2307499	(X3) Date Survey Completed 03/04/2025
Name of Provider or Supplier Linus Biotechnology	Street Address, City, State 675 Us Highway One, North Brunswick, NJ	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Procedure Manual (PM) and interview with the Technical Supervisor (TS), the Laboratory failed to follow their procedure for "Proficiency Testing" (PT) from 7/10/25 to 3/4/25. The findings include: 1) The procedure for "Proficiency Testing" , stated as follows: a. "8.3 A minimum of 5 patient samples per PT round, per testing personnel, will be randomly selected for re-analysis. Samples will be another hair strand available from a patient sample for which the StrandDx device has previously provided a diagnostic output." 2) The laboratory uses Calibration and Quality Control material to perform PT. 3) The TS confirmed on 3/4/25 at 12:00pm that the laboratory did not follow the above mentioned procedure.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with Technical</p>

Supervisor (TS) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 7/10/24 to 3/4/25. The finding includes: 1. The laboratory failed to have a procedure to verify new lots of controls and calibrator before they were put in use on the Agilent 8900 Triple Quad analyzer. 2. The TS confirmed on 3/4/25 at 11:40 am that the laboratory failed to have a procedure to verify new lots of controls and calibrators before they were put in use.