Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2123286	08/25/2026
Name of Provider or Supplier	**Street Address, City, State**	
Precision Testing Labs Dba Lynk Diagnostics	1804 Carnegie Ave, Santa Ana, CA	

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 on-site validation survey was conducted on 08/25/2026, with the following standard-level deficiencies cited:
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on observation, review of laboratory policies, staff interview, and review of patient test reports, the laboratory failed to establish and follow written policies and procedures to monitor and document specimen storage and preservation conditions for 2 of 2 specimens received for testing. Findings: 1. On 08/25/2026 at approximately 11:00 AM, during a tour of the specimen receiving room the surveyor observed that the laboratory did not document the condition of specimens upon receipt to ensure proper storage (e.g., maintained at room temperature, refrigerated after separation, or separated and frozen). 2. Review of the laboratory's policies and procedures showed the laboratory had not established policies addressing the documentation of specimen storage and preservation conditions at receipt. 3. Review of 2 randomly selected final patient test reports, accession number 114382 (received 11/08/2025) and accession number 136576 (received 2/14/2026), showed no documentation of the specimen's condition at receipt (e.g., room temperature, refrigerated, or frozen), and this information could not be traced. 4. On 08/25/2026 at 12:00 PM, during an interview,

	the Technical Supervisor confirmed the laboratory had no process in place to document specimen receipt conditions. 5. The laboratory reported performing 5,000,000 toxicology tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the Beckman Coulter AU680 instrument maintenance log and staff interview, the laboratory failed to perform the required monthly maintenance for 1 of 8 months reviewed. Findings: 1. Review of Beckman Coulter AU680 instrument maintenance records from 1/2026 to 8/2026 revealed the laboratory did not performed and documented the required monthly maintenance for the month of May 2026. 2. Review of the Beckman Coulter AU680 laboratory maintenance log showed the following tasks were required monthly: remove and clean the washing nozzle with 50% IPA and DI H2O; remove and clean the DI H2O tank and all filters; clean the liquid level sensors, sample pot, and tubing; sonicate metal filters in DI H2O for 10 minutes; wash the sample pre-dilution bottle; and record the halogen lamp life hours, replacing the lamp if hours exceeded 2,000. 3. On 8/25/26 at 11:05 AM, during an interview, the Technical Supervisor confirmed the laboratory failed to document performance of the Beckman Coulter AU680 May 2026 monthly maintenance in the log. 4. The laboratory reported performing 5,000,000 toxicology tests annually.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, temperature monitoring log review and staff interview, the laboratory failed to identify that the toxicology laboratory room temperature exceeded its established acceptable range, and failed to document corrective action for 1 of 1 out-of-range condition. Findings include: 1. On 8/25/26 at 11:10 AM, during a tour of the toxicology laboratory room, the surveyor observed a room temperature monitoring log documenting an acceptable range of 18C to 25C. At the time of observation, the surveyor noted the thermo-hygrometer displayed a current reading of 28C, exceeding the upper limit of the laboratory's established range by 3C. Review of laboratory practice showed that room temperature was recorded manually once daily, in the morning, and that the laboratory had no alarm system capable of detecting an out-of-range condition between manual checks. 2. On 8/25/26 at 11:30 AM, during an

	interview, the Technical Supervisor confirmed the toxicology laboratory room temperature was outside the laboratory's established acceptable range and that the laboratory had not identified the out-of-range condition and had not documented corrective action in response to it. 3. The laboratory reported performing 5,000,000 toxicology tests annually.