Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2073394	**(X3) Date Survey Completed** 07/22/2026
Name of Provider or Supplier Aspira Labs,Inc	**Street Address, City, State** 12117 Bee Caves Rd ,Building 3 Suite 100, Austin, TX	

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	The Aspira Labs laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of an announced validation survey on 07/21/2026 and recertification is recommended. Standard level deficiencies were cited.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory stability and transport studies, laboratory's policies and procedures, test reports, pre-survey paperwork, and interview, the laboratory failed to validate the 8-day ambient transportation stability of Human Epididymal Protein 4 (HE4). Findings follow. A. Review of the Cobas Elecsys HE4 package insert, 2025-03 V 5.0, under Specimen Collection and Preparation stated, "Stable for 48 hours at 2-8 degrees Celsius (C), 5 hours at 15-25C, 12 weeks at -20C (+/- 5C). The samples may be frozen twice." B. Review of the OvaSuite Sample Stability Report, approved 09/22/2025, under 3. Conclusions stated, "Results from the sample stability study confirm that the algorithmic results for Ova1,

	Overa and OvaWatch as well as GCP/MCP (Germ Cell Panel/Mucinous Panel) were stable for the full 8 days for both ambient and simulated transport conditions. While there was some minor analyte variation, we concluded that it would be reasonable to report results for the OvaSuite algorithm scores and the GCP/MCP results for samples received within 8 days from date of collection following transport from providers office under standard shipping conditions." 4.2 Detailed Results stated, "At ambient temperature, HE4 demonstrated a >15% difference at Day 4 which grew to 34% difference at Day 8. Under simulated transport conditions, HE4 demonstrated a >15% difference at Day 3, growing to 46% difference at Day 8 but this did not significantly affect the algorithm calculation." Even though the decline in test results were not considered to be significant enough to affect the algorithm calculation, it did affect the HE4 result showing a " >15% difference at Day 3 growing to a 46% difference at Day 8". HE4 was reported as a reflex test to the algorithm calculation. C. Review of the laboratory's policy and procedure titled Human Epidiymal Protein 4 on the Cobas 6000 Immunoanalyzer, approved 04/24/2026, under 7.0 Stability stated, "Based on internal stability studies, samples may be stored and tested for up to 8 days under validated conditions without compromising assay performance. This extended stability may exceed the time frame specified in the package insert and is supported by documented stability data on file in RCD-000742." D. Review of a sampling of patient test reports for HE4 showed the following samples were greater than 4 days old when received by parcel service as listed by Accession number, Date collected, Date resulted, and Elapsed days: Accession Number / Date collected / Date resulted / Elapsed days 1. AO174966 / 11/20/2025 / 11/28/2025 / 8 days 2. AO175129 / 11/26 /2025 / 12/03/2026 / 7 days 3. AO175476 / 12/03/2025 / 12/09/2025 / 6 days 4. AO176526 / 12/22/2026 / 01/08/2026 / 8 days 5. AO176695 / 12/31/2025 / 01/06 /2026 / 6 days 6. AO176718 / 12/31/2025 / 01/06/2026 / 6 days E. Review of pre-survey paperwork of estimated annual test volumes showed an annual test volume of 8,751 in 2025 for HE4. F. Interview with the Laboratory Director by phone from the conference room on July 21, 2026 at 1440 hours confirmed the stability's acceptable criteria should be reevaluated for HE4. Interview with the Clinical Consultant /Assistant Laboratory Director on July 22, 2026 at 1200 hours in the conference room confirmed the study showed HE4 had a stability of four days.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory stability and transport studies, laboratory's policies and procedures, test reports, pre-survey paperwork, and interview, the Laboratory Director failed to validate the 8-day ambient transportation stability of Human Epididymal Protein 4 (HE4) (see D5423).