Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2174365	05/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Asteria Laboratory	8640 W 3rd St Ste 203, Los Angeles, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's anti-chromatin antibody test records, final reports and procedure manual, and interview with the laboratory testing person on May 8, 2025, at 1:40 p.m., the laboratory testing person did not follow the laboratory's procedure to perform the test. The findings include: 1. The laboratory tested patients' samples that were collected and stored in the refrigerator for more than 2 days. However, the laboratory's test procedure instructed to test the sample that were collected and stored in the refrigerator for no longer than 2 days. The following samples were collected and stored in the refrigerator before testing for 6 days: 49745, 49750-52; for 5 days: 49754, 49762-65; for 4 days: 49766-67, 49770, 49773; and for 3 days: 49777, respectively. The laboratory reported all the samples as negative. Therefore, the accuracy of the patients' test results rendered by the laboratory cannot be assured since it used compromised samples and may have harmed patient. 2. The laboratory testing person on May 8, 2025, at 1:40 p.m., affirmed that the laboratory did not follow its procedure and used compromised samples to test. 3. The laboratory's testing declaration form, signed by the laboratory director on 5/8/2025, stated that the laboratory performed approximately 5,000 tests, annually.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for

	accurate and reliable results; This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's anti-chromatin antibody test records, final reports and test procedure manual, and interview with the laboratory testing person on May 8, 2025, at 1:40 p.m., the laboratory testing person did not follow the laboratory's procedure to perform the test and was determined that the laboratory director failed to ensure that the laboratory personnel are performing the test methods as required for accurate and reliable results. The laboratory director's failure to ensure quality laboratory services has a consequence of potential erroneous test result reporting and patient harm. The findings include: See D5401 and D6175.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1) (b) Each individual performing high complexity testing must-- (b)(1) Follow the laboratorys procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results; This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's anti-chromatin antibody test records, final reports and test procedure manual, and interview with the laboratory testing person on May 8, 2025, at 1:40 p.m., it was determined that the laboratory testing person #1 did not follow the laboratory's procedure to perform the test. The findings include: See D5401.