Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2024541	06/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Center For Sight Pl	1370 East Venice Ave Suite 205, Venice, FL	

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 announced CLIA recertification survey was conducted at Center for Sight/Amara on 6/17/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, it was determined the laboratory failed to document the maintenance of one of two microscopes used for patient testing for two of two years (2023-2025) 1. On 6/17/25 at 10:30 a.m., two microscopes were observed in the laboratory, a Leica DM1000 and a Labomed. 2. The Laboratory Procedure Manual was reviewed and approved by the Laboratory Director on 09/19 /11. An Annual Review Sheet dated 5/2/23, included a procedure titled Microscope which listed one of the tasks to be done was to document daily and monthly care. The Review Sheet indicated no changes. 3. Review of microscope maintenance indicated only one microscope maintenance was being documented daily and monthly. 4. Histology Tech A on 6/17/25 at 11:40 a.m., stated only the maintenance for the Labomed microscope was documented daily and monthly. The Lab Director confirmed on 6/17/25 at 11:58 a.m., daily and monthly maintenance for the Leica DM1000 microscope was not documented for 2023-2025.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)

	(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory failed to document the Hematoxylin and Eosin (H&E) Histopathology staining materials for intended reactivity for three of three months reviewed (11/2023, 08/2024, and 04/2025). Findings included: 1. The Laboratory Procedure Manual was reviewed and approved by the Laboratory Director on 09/19/11. The Annual Review Sheet dated 5/2/23 with no changes documented, included a Quality Assurance for Routine Stains procedure which stated the Lab Director would determine whether the stain was acceptable for the day and was to be logged on the stain QC (Quality Control) chart. The Lab Director was the only Testing Person for H & E testing performed by the laboratory listed on the CMS-209, which was signed by the Lab Director on 06/12/2025. 2. The Quality Control Staining log for 04/2025, 8/2024, and 11/2023 did not document quality of the H&E staining for any of the testing days at this laboratory by the Lab Director. 3. The Lab Director confirmed on 06/17/2025 at 11:58 a.m., there was no documentation of the H&E Histopathology staining materials for intended reactivity for three, 11/2023, 08/2024, and 04/2025 months reviewed by him.