Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D1037150	12/02/2024
Name of Provider or Supplier	**Street Address, City, State**	
Diagnostic Immunology Lab At Uchsc	12700 E 19th Ave, Aurora, CO	

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
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality assessment plan (QA plan), the laboratory's policies and procedures manual, and an interview with general supervisor 1 (GS 1), the laboratory failed to establish a policy or procedure to document all complaints and problems reported to the laboratory, and to investigate complaints when appropriate, since the laboratory's last survey was conducted on 3/24/2021. The laboratory performs approximately 600 tests annually. Findings include: 1. A review of the laboratory's QA plan revealed the laboratory failed to establish a policy or procedure to document all complaints and problems reported to the laboratory, and to investigate complaints when appropriate. 2. A review of the laboratory's policies and procedures manual revealed the laboratory failed to establish a policy or procedure to document all complaints and problems reported to the laboratory, and to investigate complaints when appropriate. 3. An interview with GS 1, on 12/2/2024, at approximately 12:15 PM, confirmed that the laboratory failed to establish a policy or procedure to document all complaints and problems reported to the laboratory, and to investigate complaints when appropriate.
D5207	COMMUNICATIONS CFR(s): 493.1234 The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality assessment plan (QA plan), the laboratory's policies and procedures manual, and an interview with general supervisor 1 (GS 1), the laboratory failed to establish a policy or procedure to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results since the laboratory's last survey was conducted on 3/24/2021. The laboratory performs approximately 600 tests annually. Findings include: 1. A review of the laboratory's QA plan revealed that the laboratory failed to establish a policy or procedure to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. 2. A review of the laboratory's policies and procedures manual revealed that the laboratory failed to establish a policy or procedure to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. 3. Based on an interview with GS 1, on 12/2/2024, at approximately 12:15 PM confirmed that the laboratory failed to establish a policy or procedure to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures manual, and an interview with general supervisor 1 (GS 1), the laboratory failed to include imminently life-threatening test results, panic or alert values, and a description of the course of action to take if a test system becomes inoperable in their procedures for their Lymphocyte Proliferation Assay (LPA), and Human Interferon-Gamma ELISpot assay (ELISpot) since the laboratory's last survey was conducted on 3/24/2021. The laboratory performs approximately 100 LPA and 100 ELISpot tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual

	revealed that the laboratory failed to include imminently life-threatening test results, panic or alert values, and a description of the course of action to take if a test system becomes inoperable in their procedures for their LPA, and ELISpot assays. 2. An interview with GS 1, on 12/2/2024, at approximately 12:45 PM confirmed that the laboratory failed to include imminently life-threatening test results, or panic or alert values, and a description of the course of action to take if a test system becomes inoperable in their procedures for their LPA, and ELISpot assays.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures manual, and an interview with general supervisor 1 (GS 1), the laboratory failed to ensure that the laboratory director (LD) had approved, signed and dated all the laboratory's policies and procedures prior to their use in the laboratory since the laboratory's last survey was conducted on 3/24/2021. The laboratory performs approximately 600 tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual revealed the laboratory's policies and procedures for quality assurance (QA), and equipment maintenance was not signed or dated by the LD. 2. An interview with GS 1, on 12/2/2024, at approximately 12:45 PM confirmed that the laboratory's policies and procedures for QA, and equipment maintenance was not signed or dated by the LD.