Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2006336	02/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
Cyrex Laboratories, Llc	2602 S 24th St, Phoenix, AZ	

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
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 review of the laboratory's test procedures for Flow Cytometry and interview with the Laboratory Director (LD), the Flow Cytometry test procedures reviewed during the survey conducted on 2/23/2024 failed to include specific information on negative reagent quality control procedures. Findings include: 1. The laboratory performs Flow Cytometry utilizing the Beckman Coulter Navios EX analyzer in the subspecialty of General Immunology. 2. The Flow Cytometry procedures titled 'LymphocyteMap Flow Cytometry Panel 1' and 'Daily Staining QC Procedures for LymphocyteMap (Panel 1) Flow Cytometry Test' reviewed during the survey

	conducted on 2/23/2024 failed to include specific information on negative staining quality control procedures. 3. The LD interviewed on 2/23/2024 at 12:25 PM confirmed the Flow Cytometry procedures mentioned above failed to include specific information on negative quality control procedures. 4. The laboratory performes approximately 16,800 Flow Cytometry tests annually.
D5475	CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Quality Control (QC) documentation, laboratory policies and procedures and interview with the Laboratory Director (LD), the laboratory failed to perform and document Flow Cytometry negative reagent controls for each test cell preparation each time of use from 7/20/2021 through the date of the survey on 2/23 /2024. Findings include: 1. The laboratory performs Flow Cytometry testing on patient specimens under the subspecialty of General Immunology, with an approximate annual test volume of 16,800. 2. The 'Flow Cytometry Assay Coversheet' presented for review for patient block ID# B1 23 (117941-117947) from 11/16/2023 failed to include negative reagent control results. 3. The laboratory failed to perform and document a negative reagent control each time of use for each Flow Cytometry test performed by the laboratory from 7/20/2021 through 2/23/2024. 4. The number of patient specimens tested for Flow Cytometry during the timeframe indicated above could not be determined at the time of the survey. 5. The LD interviewed on 2/23 /2024 at 12:25 PM confirmed that the laboratory failed to document Flow Cytometry negative reagent controls for each test cell preparation each time of use.