Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0148202	10/31/2025
Name of Provider or Supplier	**Street Address, City, State**	
Mark Benkel Md	6410 Veterans Avenue, Brooklyn, NY	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of reagent kit manufacturer package inserts, lack of Quality Control (QC) records, as well as interview with the Laboratory Director (LD), the laboratory failed to follow the manufacturers' instructions for performing the test. FINDINGS: 1. There was no documentation of QC testing for CorDx Flu A/B & COVID-19 Multiplex Rapid Test kits from January 2024 through the survey date. a. This is contrary to kit manufacturer's instructions which specify external controls should be tested with each new lot, shipment received, and with each new untrained operator. b. Approximately 506 patient samples were tested. 2. There was no documentation of QC testing for Pro Advantage Urine Reagent Strips from January 2024 through the survey date. a. This is contrary to manufacturer's instructions which indicate testing commercially available positive and negative QC with each new lot, each new shipment of strips, and when you open a new bottle of reagent strips. b. Approximately 54 patient samples were tested. 3. The LD confirmed the findings on October 31, 2025, at 11:00 A.M.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:

	This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plan (IQCP), lack of QC and Certificate of Analysis (CoA) records, as well as interview with the LD, the laboratory failed to retain QC records as well as records documenting all analytic system activities. FINDINGS: 1. There was no documentation of Aidian Uricult CoA. 2. There was no documentation of throat culture taxo disc QC performance. 3. These are contrary to instructions included in the current, approved IQCP. 4. The LD confirmed the findings on October 31, 2025, at 11:00 A.M.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. This STANDARD is not met as evidenced by: Based on a review of IQCP, lack of QC records, as well as interview with the LD, the laboratory failed to check each batch of media for sterility before use. FINDINGS: 1. There was no documentation of Uricult paddle media physical characteristics and sterility testing QC from January 2024 through the survey date. a. This is contrary to instructions indicated in the current, approved IQCP which specify performance and documentation of media system physical characteristics and sterility for each box prior to use for patient testing. b. Approximately 72 patient samples were tested. 2. There was no documentation of Hardy Diagnostics Blood Agar Plates physical characteristics and sterility testing QC from January 2024 through the survey date. a. This is contrary to instructions indicated in the current, approved IQCP which specify performance and documentation of physical characteristics and media with each packet prior to patient testing. b. Approximately 942 patient samples were tested. 3. The LD confirmed the findings on October 31, 2025, at 11:00 A.M.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of the IQCP, lack of QC and CoA records, as well as interview with the LD, the LD failed to ensure that the QC and Quality Assessment (QA) programs were maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D5477 and D3031.