

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D2145407	(X3) Date Survey Completed 07/27/2022
Name of Provider or Supplier Inflammatory Markers Diagnostic Laboratory	Street Address, City, State 9412 E Central Ave, Wichita, KS	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of available documentation and confirmed during interview with the Technical Supervisor #2 (TS#2), the laboratory failed to have procedures approved, signed, and dated by the current laboratory director before use. Findings: 1. Upon review of the laboratory procedures, the current Laboratory Director (LD) did not approve, sign, and date the laboratory procedure/policy for: 16 of 16 procedures in the laboratory at time of survey. 2. The following procedures were not signed by the current LD: a. G001-02/493.1242 IML Quality Policy b. G002-02/493.1231 Patient Confidentiality Policy c. G003-02/493.1232 Sample Identification d. G004-02/493.1233 Complaint Investigation e. G005-02/493.1234 Customer Complaint, Communications & Error Handling f. G006-02/493.1235 Personnel Competency g. G007-01/493/1242 Specimen Handling, Test Ordering & Reporting h. G008-01/493.1242 Reference Laboratory Services i. G009-01B/493.1236 Evaluation of Proficiency Testing j. T002-02,03/493.1251 11-Dehydro Thromboxane B2 k. T-004/493.1251 CRE2 Urinary Creatine Test Procedure l. M002-02/393.1254 Instrument Maintenance and function Checks m. G010-01/493.2328 Corrective Actions Policy n. G011-02/ Safety Procedures o. T004/493.1251 SARS-CoV-2 Total Antibody Test (CV2T) p. T005/493.1251 BioFire Respiratory Panel 2.1 (RP2.1) Testing a.k.a. Bio-Fire SARS-CoV-2 Testing 3. Interview with the TS#2 on July 27, 2022 at 9:10 a.m. confirmed, the laboratory failed to have procedures approved, signed, and dated by the current laboratory director before use.</p>