Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0550324	02/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Westside Internal Medicine Laboratory	2121 Wilshire Blvd, 3rd Fl Lab, Santa Monica, CA	

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
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. This STANDARD is not met as evidenced by: Based on review the final patient test result reports requested, lack of instrument printouts, quality control documentation, and preventive maintenance records , and interview with the laboratory's testing personnel (TP); it was determined that the laboratory failed to retrieve patients' test records for at least 2 years. The findings included: 1. At the time of the survey on February 10, 2022, at approximately 2:15 p. m. the TP failed to retrieve for two (2) out of five (5) patients, documentation records requested of quality control, instruments printouts, and preventive maintenance records. 2. The TP affirmed that patients' records requested described in 1 were not retrievable at the time of the survey. 3. Based on the laboratory's testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 393,590 tests annually for which the laboratory was unable to retrieve test records and analytic documentation for two (2) out of five (5) patients records requested from the past two years.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on the lack of laboratory current written policies and procedures and interview with the laboratory testing personnel (TP), it was determined that the laboratory failed to have available and follow written procedures for all the test performed in the laboratory. The findings included: 1. On the day of the survey on February 10, 2022. at approximately 3:30 p.m. the laboratory failed to provide written policies and procedures for General Immunology, Urinalysis, Routine Chemistry, and Hematology tests currently performed in the laboratory. 2. The laboratory TP confirmed on February 10, 2022, that the laboratory did not have written policies and procedures available for the test performed in the laboratory. 3. Based on the laboratory annual test volume declaration signed by the laboratory director on 02/07/2022 the laboratory analyzed and reported approximately 393,590 tests for which no written tests procedures were available to the TP to follow.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on direct observation and interview with the laboratory testing personnel; it was determined that the laboratory director failed to ensure that an approved written procedure manual is available at all times to all personnel responsible for any aspect of the testing process. See D5041.