

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2315131	(X3) Date Survey Completed 08/19/2026
Name of Provider or Supplier Nextgen Diagnostics Inc	Street Address, City, State 8135 San Fernando Rd Ste B, Sun Valley, 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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the surveyors' review of laboratory's policies and procedures, equipment preventive maintenance (PM) documentation, and interviews with the Laboratory Director (LD), Technical Supervisor (TS), and Testing Personnel (TP) on August 19, 2026, the laboratory failed to document the PM on Biofire Film Array and Quant Studio TM5 instruments, and provide established preventive maintenance (PM) policy for the pipettes as defined by the manufacturer prior to patient testing. The findings include: 1. The laboratory failed to document the PM between 11/20/2025 through 3 /19/2026 for Biofire Film Array and Quant Studio TM5 instruments. The TP stated that decontamination documentation of the instruments were misplaced. 2. The laboratory presented two pipettes, the first pipettes, FourG's Scientific Pipette (100-1000 microliters), calibrated in-house on 1/15/2025, and the second pipette, Eppendoff (1000 microliters), equally calibrated in-house on 1/15/2026. From the surveyors' observation, the instrument PM was performed annually, but no PM policy was available for review at the time of the survey. 3. The LD, TS, and TP confirmed during the interview on August 19, 2026, at approximately 2:15 p.m., that the laboratory failed to provide PM documentation for the Biofire Film Array and Quant Studio TM5 due to misplaced documentation record. The laboratory equally confirmed that it lacked the PM policy for the two pipettes. 4. According to the testing volume declaration submitted at the time of survey, the laboratory performed and reported approximately 20,000 patients' Microbiology tests annually and during the period when it lacked the PM policy for the two pipettes and when the PM documentation record for the instruments were misplaced.

D6007

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(1)

(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on the surveyors' review of the laboratory's policies and procedures, equipment preventive maintenance (PM) documentation, and interviews with the Laboratory Director, Technical Supervisor, and Testing Personnel, the Laboratory Director failed to ensure that the laboratory documented the preventive maintenance performed on Biofire Film Array and Quant Studio TM5 instruments, and provide established PM policy for the pipettes as defined by the manufacturer prior to patient testing, and ensure that testing systems developed and used for each of the tests performed in the laboratory provided quality services for all aspects of testing including the preanalytic, analytic, and postanalytic phases of testing. See D5429.