Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2059943	01/20/2026
Name of Provider or Supplier	**Street Address, City, State**	
Nxgen Mdx Llc	801 Broadway Ave, Nw Suite 203, Grand Rapids, MI	

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
D0000	A validation survey was performed on January 20, 2026 by the State of Michigan Licensing and Regulatory Affairs Department. The laboratory was found to be out of compliance with CLIA regulations (42 CFR Part 493, Laboratory Requirements) for standard-level deficiencies.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interview with the technical supervisor, the laboratory failed to establish and follow its competency assessment policy for one (technical supervisor/testing personnel #1) of eight total testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's "Competency Testing of Laboratory Personnel" policy revealed a section stating, "Failure to pass competency testing will result in the notification of the laboratory director or designee and disciplinary/corrective action." The policy failed to address the intervals in which the competency assessments were to be performed. 2. An interview on 1/20/26 at 2:40 pm with the technical supervisor revealed they were performing data analysis prior to reporting patient test results, which is part of the testing process. 3. The surveyor requested documentation of the technical supervisor/testing personnel #1's competency assessments from January 2024 to January 2026 on 1/20/26 at 2:49 pm and they were not made available. 4. An interview on 1/20/26 at 2:49 pm with the technical supervisor confirmed competency assessments for the technical supervisor /testing personnel #1 were not available.

D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) (e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: . Based on record review and interviews with the technical supervisor, the laboratory failed to include dates of discontinuance on procedures no longer in use for five (Oropharyngeal Swab Collection, Agarose Gel DNA Electrophoresis, Illumina MiSeq Loading, COVID-19 SARS CoV-2 Testing NxGen MDx Protocol, and RTM Open Array) of 42 procedures reviewed. Findings include: 1. A review of the laboratory's procedures revealed the following active procedures with no discontinuation dates: a. Oropharyngeal Swab Collection b. Agarose Gel DNA Electrophoresis c. Illumina MiSeq Loading d. COVID-19 SARS CoV-2 Testing NxGen MDx Protocol e. RTM Open Array 2. An interview on 1/20/26 at 10:44 am with the technical supervisor revealed the laboratory had discontinued its COVID-19 testing and its respiratory panels in 2022 and confirmed the COVID-19 policies listed above had not included discontinuation dates. 3. An interview on 1/20/26 at 1:28 pm with the technical supervisor confirmed the Agarose Gel DNA Electrophoresis procedure was not in use and had not included a discontinuation date. 4. An interview on 1/20/26 at 1:52 pm with the technical supervisor confirmed the Illumina MiSeq Loading procedure was not in use and did not included a discontinuation date.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: . Based on observation and interview with the technical supervisor, the laboratory failed to establish a system to evaluate and define the relationship between the laboratory's three QuantStudio 12K Flex molecular instruments performing vaginosis and urinary tract infection panels for two (January 2024 to January 2026) of two years reviewed. Findings include: 1. The surveyor observed three QuantStudio 12K Flex molecular instruments during a tour of the laboratory on 1/20/26 at 9:12 am. 2. The surveyor observed vaginosis and urinary tract infection panel processing and loading on 1/20/26 at 11:10 am, 11:51 am, and 2:09 pm. 3. An interview on 1/20/26 at 2:09 pm with the technical supervisor revealed the three QuantStudio 12K Flex molecular instruments all perform urinary tract infection and vaginosis panel testing. 4. The surveyor requested documentation of the three QuantStudie 12K Flex molecular instruments comparison evaluations on 1/20/26 at 2:23 pm and it was not made available. 5. An interview on 1/20/26 at 2:45 pm with the technical supervisor indicated the laboratory performs an annual calibration with the three QuantStudio 12K Flex instruments and had not evaluated and defined the relationship between test results using the different instruments.
D5785	CORRECTIVE ACTIONS

	CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: . Based on record review and interview with the technical supervisor, the laboratory failed to perform corrective actions when its criteria for storage of reagents and specimens were not met for its Pre-PCR refrigerator for three days (11/24/25, 12/8/25, and 12/14/25) of three months reviewed. Findings include: 1. A review of the laboratory's 2025 fourth quarter "LAB-FORM-0019 Daily Temperature Tracking" for its "Pre-PCR Fridge" revealed the acceptable range to be "2-8 degrees C". The following dates: a. 11/24/25, reading of 11.3 degrees C. b. 12/8/25, reading of 9.0 degrees C. c. 12/14/25, reading of 9.4 degrees C. 2. The surveyor requested documentation of the corrective action performed when the temperatures listed above failed to meet criteria on 1/20/26 at 1:30 pm and it was not made available. 3. An interview on 1/20/26 at 1:35 pm with the technical supervisor confirmed the laboratory did not perform and document corrective action for the dates listed above.