Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D2245218	**(X3) Date Survey Completed** 07/15/2025
Name of Provider or Supplier Neom Diagnostic Laboratories	**Street Address, City, State** 2424 Torrance Blvd, Ste A, Torrance, 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**
D0000	A proficiency testing desk review survey as performed on 07/15/2025, the laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES D2016 - 42 C.F.R. 493.803 Condition: Successful American Proficiency Institute participation; and D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) - 0155D and American Proficiency Institute (API) records (2024-2, 2025-1, and 2025-2), the laboratory failed to successfully participate in a proficiency testing

	program approved by HHS for each specialty, subspecialty and analyte or test in which the laboratory is certified under CLIA, the laboratory failed to successfully participate in the analytes Cholesterol, HDL and Free Thyroxine resulting in unsuccessful performances. See D2096 and D2107.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) (f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and API - American Proficiency Institute (API) report, the laboratory failed to achieve satisfactory performances for three events (2024-2, 2025-1, and 2025-2) for the analyte Cholesterol, HDL. Findings include: Cholesterol, HDL 0% - 2024 second test event; Cholesterol, HDL 20% - 2025 first test event; Cholesterol, HDL 40% - 2025 second test event; A review of the 2024 & 2025 scores from American Proficiency Institute (API) confirmed the above findings.
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) (f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and API - American Proficiency Institute (API) report, the laboratory failed to achieve satisfactory performances for three events (2024-2, 2025-1, and 2025-2) for the analyte Free Thyroxine. Findings include: Free Thyroxine 0% - 2024 second test event; Free Thyroxine 60% - 2025 first test event; Free Thyroxine 60% - 2025 second test event; A review of the 2024 & 2025 scores from American Proficiency Institute (API) confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of the CASPER 0155D report and

	American Proficiency Institute records for 2024-2, 2025-1, and 2025-2 events, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of the CASPER 0155D report and American Proficiency Institute records for 2024-2, 2025-1, and 2025-2 events, the laboratory director failed to ensure successful participation in an HHS proficiency testing program. Refer to D2096 and D2107.