

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2245218	(X3) Date Survey Completed 11/17/2025
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
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing records, and interview with the Technical Supervisor (TS) on November 17, 2025, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Routine Chemistry for each analyte in 2025. The findings included: 1.The laboratory enrolled in the American Proficiency Institute (API) proficiency testing program for routine chemistry testing using Beckman Coulter AU400 analyzer. According to the API evaluation, the laboratory attained the following unsatisfactory scores: Q1- 2025: CO2= 0% Q2- 2025: Creatinine= 60% Q3- 2025: Alkaline Phosphatase= 0% Q3- 2025: Glucose = 0% Q3- 2025: Iron = 20% Q3- 2025: Magnesium =0% Q3- 2025: Triglycerides =0% 2. On November 17, 2025, at approximately 11:00 am, the Technical Supervisor affirmed that the laboratory received the above unsatisfactory proficiency scores. 3. The laboratory's testing declaration form, signed by the owner on November 17, 2025, stated that the laboratory performed approximately 500 routine chemistry tests annually. Thus, the accuracy and reliability of patient test reports cannot be determined.</p>
D2089	<p>ROUTINE CHEMISTRY CFR(s): 493.841(c)</p> <p>(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended</p>

during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) proficiency testing records, and interview with the Technical Supervisor (TS) on November 17, 2025, it was determined that the laboratory failed to participate in the second testing event of 2024 for the specialty of routine chemistry. The findings included: 1. The laboratory enrolled in the American Proficiency Institute (API) proficiency testing program for routine chemistry testing using Beckman Coulter AU400 analyzer. According to the API evaluation, the laboratory attained scores of 0 % in routine chemistry in the second testing event of 2024. 2. On November 17, 2025, at approximately 11:00 am, the Technical Supervisor affirmed that the laboratory did not participate in a testing event and received the above unsatisfactory proficiency scores.

D2098

ENDOCRINOLOGY
CFR(s): 493.843(a)

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) proficiency testing records, and interview with the Technical Supervisor (TS) on November 17, 2025, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for specialty of Endocrinology for each analyte in 2025. The findings included: 1. The laboratory enrolled in the American Proficiency Institute (API) proficiency testing program for endocrinology testing using Beckman Access 2 analyzer. According to the API evaluation, the laboratory attained the following unsatisfactory scores: Q3- 2025: Luteinizing Hormone (LH) = 0% Q3- 2025: Prolactin =40% 2. On November 17, 2025, at approximately 11:00 am, the Technical Supervisor affirmed that the laboratory received the above unsatisfactory proficiency scores. 3. The laboratory's testing declaration form, signed by the owner on November 17, 2025, stated that the laboratory performed approximately 250 endocrinology tests annually. Thus, the accuracy and reliability of patient test reports cannot be determined.

D2100

ENDOCRINOLOGY
CFR(s): 493.843(c)

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of

patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on review of the American Proficiency Institute (API) proficiency testing records, and interview with the Technical Supervisor (TS) on November 17, 2025, it was determined that the laboratory failed to participate in the second testing event of 2024 for the specialty of endocrinology. The findings included: 1. The laboratory enrolled in the American Proficiency Institute (API) proficiency testing program for endocrinology testing using Beckman Access 2 analyzer. According to the API evaluation, the laboratory attained scores of 0 % in endocrinology in the second testing event of 2024. 2. On November 17, 2025, at approximately 11:00 am, the Technical Supervisor affirmed that the laboratory did not participate in a testing event and received the above unsatisfactory proficiency scores.

D2121

HEMATOLOGY
CFR(s): 493.851(a)

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:
Based on review of the American Proficiency Institute (API) proficiency testing records, and interview with the Technical Supervisor (TS) on November 17, 2025, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Hematology for each analyte in 2024 and 2025. The findings included: 1. The laboratory enrolled in the American Proficiency Institute (API) proficiency testing program for hematology testing using Horiba ABX Pentra 80 XL80. According to the API evaluation, the laboratory attained the following unsatisfactory scores: Q1- 2024: MCH = 20% Q2- 2025: White Cell count (WBC)= 60% Q2- 2025: Monocytes: 40% 2. On November 17, 2025, at approximately 11:00 am, the Technical Supervisor affirmed that the laboratory received the above unsatisfactory proficiency scores. 3. The laboratory's testing declaration form, signed by the owner on November 17, 2025, stated that the laboratory performed approximately 500 hematology tests annually. Thus, the accuracy and reliability of patient test reports cannot be determined.

D6090

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(ii)

(e)(4)(ii) The results are returned within the timeframes established by the proficiency testing program;

This STANDARD is not met as evidenced by:
Based on review of the American Proficiency Institute (API) proficiency testing records, and interview with the Technical Supervisor (TS) on November 17, 2025, it was determined that the laboratory director failed to ensure proficiency testing results for routine chemistry and endocrinology during the second test event of 2024 were

returned within the timeframe set by the proficiency testing program. See D2089, D2100,