

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2017756	(X3) Date Survey Completed 09/27/2024
Name of Provider or Supplier North Shore Pain Management, Llc	Street Address, City, State 77 Herrick Street, Suite 201, Beverly, MA	
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 CLIA COLA validation survey was conducted for the North Shore Pain Management LLC laboratory on 9/27/2024 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: . Based on proficiency testing (PT) review and interview with Laboratory Consultant (LC) on 9/27/2024, the laboratory failed to have the testing analyst sign the attestation form as evidenced by the following: The surveyors reviewed the American Proficiency Institute (API) PT records for calendar years 2022, 2023, and 2024. The review revealed the attestation statement was not signed by the testing analyst for the API 2023 Chemistry Miscellaneous 2nd Event. The LC confirmed in an interview on 9/27/2024 at 10:02 AM that the testing analyst did not sign the attestation form for the API 2023 Chemistry Miscellaneous 2nd Event. The laboratory performs 8,640 toxicology tests annually. .</p>
D2111	<p>TOXICOLOGY CFR(s): 493.845(c)</p> <p>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</p>

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 proficiency testing (PT) review and interview with Laboratory Consultant (LC) on 9/27/2024, the laboratory failed to participate in an HHS approved PT program for the subspecialty of Toxicology as evidenced by the following: The surveyors reviewed the American Proficiency Institute (API) PT records for calendar years 2022, 2023, and 2024. The review revealed that the laboratory was enrolled in the API PT program and failed to participate in the API 2023 Chemistry Miscellaneous 1st Event resulting in unsatisfactory performance and a score of zero (0) percent for the testing event for the subspecialty of Toxicology. The LC confirmed in an interview on 9/27/2024 at 10:02 AM that the laboratory failed to participate in the API 2023 Chemistry Miscellaneous 1st Event for the subspecialty of Toxicology. The laboratory performs 8,640 toxicology tests annually.

D6041

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(3)

(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

This STANDARD is not met as evidenced by:

. Based on proficiency testing (PT) review and interview with Laboratory Consultant (LC) on 9/27/2024, the Technical Consultant (TC) failed to have the laboratory participate in an HHS approved PT program for the subspecialty of Toxicology as evidenced by the following: The surveyors reviewed the American Proficiency Institute (API) PT records for calendar years 2022, 2023, and 2024. The review revealed that the laboratory was enrolled in the API PT program and failed to participate in the API 2023 Chemistry Miscellaneous 1st Event resulting in unsatisfactory performance and a score of zero (0) percent for the testing event for the subspecialty of Toxicology. The LC confirmed in an interview on 9/27/2024 at 10:02 AM that the TC failed to have the laboratory participate in the API 2023 Chemistry Miscellaneous 1st Event for the subspecialty of Toxicology. The laboratory performs 8,640 toxicology tests annually.