Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1057542	08/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Neuro Pain Consultants	30675 Stephenson Highway Suite L 3, Madison Heights, 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
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 Technical Supervisor #2 (TS2), the laboratory failed to follow its policy to assess employee competency for 1 (Testing Personnel #2) of 3 testing personnel listed on the CMS-209 form. 1. A review of the laboratory's "Neuro Pain Consultants Personnel" policy revealed a section stating, "Verify that a formal employee performance appraisal is conducted at the end of the first six months of employment and each year of employment thereafter." 2. A review of Testing Personnel #2's personnel documentation revealed a lack of documentation of competency assessments since the personnel was hired at the Neuro Pain Consultants laboratory on 10/26/20. 3. An interview on 8/17/21 at 1:55 pm with TS2 confirmed Testing Personnel #2 did not have documentation of competency assessments for testing at Neuro Pain Consultants since their hire date of 10/26/20.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as

	applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Supervisor #2 (TS2), the laboratory failed to establish the storage stability of refrigerated urine specimens prior to testing patients since the test system was approved on 4/25/18. Findings include: 1. A review of the laboratory's "Neuro Pain Consultants LC-MS/MS Initial Sample Processing and Storage" policy revealed a section stating, "Sample may be stored at room temperature for 5 days for testing and up to ten days refrigerated. Or it will be rejected by lab for testing. Doctor will be notified." 2. A review of the laboratory's establishment of performance specifications "MXP5 Validation" revealed it did not establish the storage stability for refrigerated urine samples. 3. An interview on 8/17 /21 at 2:14 pm with TS2 confirmed the laboratory did not have documentation of establishing the storage stability of refrigerated urine samples.