Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2219692	09/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mindx Sciences Inc	351 West 10th St, Rm 101, Indianapolis, IN	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: The laboratory failed to verify the accuracy twice annually for six of six tests the laboratory performed. Findings include: 1. Review of the CMS 116 revealed that the laboratory performed six tests: MindX Sciences Pain Test, MindX Sciences Mood Test, MindX Science Stress Test, MindX Sciences Suicidality Test, MindX Sciences Longevity Test, and MindX Sciences Memory Test. 2. Review of the laboratory's proficiency testing records revealed Test Name "Precision & accuracy Pain" was performed 10/13/2021 and "Precision & accuracy Mood" was performed on 06/03 /2022. 3. Review of procedure "Quality Assurance_V1" section "5.10 Proficiency Testing" revealed no frequency listed for proficiency testing. 4. The laboratory director confirmed on September 7, 2022 at approximately 4:45 P.M. that the laboratory did not verify the accuracy of all six test twice annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6)

	The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: The laboratory failed to include the biomarkers used in each panel in the test procedure for six out of six tests performed by the laboratory. Findings include: 1. Review of the CMS 116 revealed that the laboratory performed six tests: MindX Sciences Pain Test, MindX Sciences Mood Test, MindX Science Stress Test, MindX Sciences Suicidality Test, MindX Sciences Longevity Test, and MindX Sciences Memory Test. 2. Review of the laboratory's procedures revealed that the individual biomarkers for each panel were not listed. 3. The laboratory director confirmed that the individual biomarkers for each panel were not listed in the test procedure on September 7, 2022 at approximately 4:45 P.M.