

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2130277	<b>(X3) Date Survey Completed</b>  09/27/2023
<b>Name of Provider or Supplier</b>  Neurodiagnostics, Inc, DbA Synaps Dx	<b>Street Address, City, State</b>  12441 Parklawn Drive Suite 2a, Rockville, MD	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5445</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure and interview with the technical supervisor (TS), the laboratory failed to perform two levels of quality control (QC) each day of patient testing as described in paragraph (d)(3) of this section and failed to establish an Individualized Quality Control Plan (IQCP) to reduce the frequency of QC testing performed for the morphometric imaging (MI), enzyme-linked immunosorbent assay (ELISA), and western blot assays. Findings: 1. The laboratory performed three assays (MI, ELISA, and western blot) on cell cultures derived from skin biopsies from patients with suspected Alzheimer's disease (AD). 2. The requirement in section (d)(3) of this section is to perform two levels of QC each day of patient testing unless an IQCP has been established. 3. The laboratory's MI procedure stated that "QC lines (one AD, one non-AD) must both be run approximately once per week and at least once every two weeks." The TS confirmed that the AD and non-AD cell lines are also run weekly for the ELISA and western blot assays. 4. During the survey on 09/27 /2023 at 12:50 PM, the TS confirmed that the laboratory did not establish an IQCP to reduce the frequency of QC testing performed for the MI, ELISA and western blot assays.</p>

**D6101**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(11)

The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart.

This STANDARD is not met as evidenced by:

Based on review of personnel credentials and interview with the technical supervisor (TS) and laboratory director (LD), the LD failed to ensure that testing personnel (TP) with degrees from foreign institutions had an evaluation of their credentials to determine United States equivalency. Findings: 1. The Laboratory Personnel Report (CMS-209) listed 11 TP. 2. The degrees for TP #3 were earned in India and there was no foreign credential equivalency evaluation present at the time of the survey. 3. During the survey exit on 09/27/2023 at 3:30 PM, the TS and LD confirmed that a foreign credential equivalency evaluation for TP #3 was not present at the time of the survey.