

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2130277	<b>(X3) Date Survey Completed</b>  09/13/2019
<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>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on interview with the technical supervisor and observation of RM 353 around 10:30 AM, the laboratory did not perform corrective action procedures when the microscope was inoperable and AD Index testing could not be performed for punch biopsy testing. Findings: 1. The laboratory performs skin punch biopsy for determining the presence of Alzheimer's disease. 2. The laboratory was unable to perform the AD Index procedures when the microscope in RM 353 was broken and testing could not be performed. 3. The technical supervisor stated the RM 353 had been unused for almost a year and the microscope is waiting to be repaired. 4. The laboratory did not document corrective action procedures when the microscope was broken and why, to let personnel know not to use RM 353, and that AD Index testing will be on hold until the microscope is repaired. 5. The technical supervisor confirmed that corrective action procedures were not performed.</p>
<b>D5791</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p>

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based review of laboratory records and interview with the technical supervisor (TS), the laboratory did not perform analytic system quality assessment procedures of laboratory operations to ensure accurate and reliable patient testing. Findings: Refer to D5781 1. The laboratory performs skin punch biopsy for determining the presence of Alzheimer's disease. 2. The laboratory did not monitor, assess, and correct problems throughout the analytic system process. 3. The laboratory did not monitor equipment, instruments, reagents, specimen and reagent storage condition; 4. Test systems, maintenance and function checks, corrective actions, and test records. 5. Laboratory forms completed by testing personnel were not reviewed for errors and corrective actions procedures were not performed. 6. The TS confirmed that quality assessment procedures were not performed throughout the analytic process of patient testing.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of the written procedure manual, interview with laboratory director (LD), and the technical supervisor, the LD failed to ensure that quality assessment (QA) procedures were maintained for the overall quality of laboratory testing. Findings: Refer to D5791 1. The laboratory written quality procedure states that the quality system consists of five tiers that will be monitored. 2. The tiers consists of the quality manual, quality system policies, standard operating procedures, forms and checklists, training material and will be evaluated and documented twice a year by the LD or designee. 3. The LD stated that he did not perform the QA procedures and it was an oversight.