

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0927621	(X3) Date Survey Completed 08/01/2019
Name of Provider or Supplier University Of Minnesota Neuromuscular	Street Address, City, State 515 Delaware St Se Room 13-129, Minneapolis, MN	
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: . Based on document review, and interview with laboratory personnel, the laboratory failed to establish a written procedure for patient tissue slide labeling requirements. Findings are as follows: 1. The laboratory performed Histopathology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 1:00 p.m on 08/01/19. 2. The procedures located in the Muscle and Nerve Biopsy Manual did not include criteria for patient tissue slide labeling. 3. The laboratory was unable to provide a slide labeling procedure upon request. 4. In an interview at 2:45 p.m. on 08 /01/19, the LD confirmed the above finding.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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</p>

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:

. Based on document review and interview with laboratory personnel, the laboratory failed to establish a written procedure for patient tissue slide retention. Findings are as follows: 1. The laboratory performed Histopathology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 1:00 p.m on 08/01/19. 2. The procedures located in the Muscle and Nerve Biopsy Manual did not include criteria for patient tissue slide retention. 3. The laboratory was unable to provide a slide retention procedure upon request. 4. In an interview at 2:45 p.m. on 08/01/19, the LD confirmed the above finding.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to document temperatures for incubators, freezers, refrigerators and the cryostat from 01/01/18 to date of survey, 08/01/19. Findings are as follows:: 1. The laboratory performed Histopathology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 1:00 p.m on 08/01/19. 2. The following equipment was observed as present and available for use during the tour of the laboratory. Each incubator, freezer, refrigerator, and the cryostat had either an integrated digital thermometer or an alcohol thermometer in use to monitor temperatures. Cryostat -Leica CM1900 Incubators -Blue M -Fisher Isotemp Oven Freezers -Sanyo Freezer RFPC1319 -Sanyo Biomed Freezer RFPC1325 -Nuair Glacier Freezer RFPC1317 -Sanyo Freezer RFPC1318 Refrigerator -Fisher Scientific Isotemp RFPC1324 3. Daily temperatures for the above equipment were not documented from 01/01/18 to date of survey, 08/01/19. The temperature check form in use for 2018 and 2019 did not include acceptable temperature ranges or actual temperature data for each piece of equipment. 4. The laboratory was unable to provide specific temperature documentation upon request. 5. In an interview at 1:05 p.m. on 08 /01/19, the LD confirmed the above finding.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to perform and document required maintenance on 2 of 2 pieces of Histopathology tissue processing equipment. Findings are as follows: 1. The laboratory performed Histopathology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 1:00 p.m. on 08/01/19. 2. A Leica CM1900 cryostat and a Leica Autostainer XL were observed as present and available for use in the laboratory. 3. The manufacturer's operators manuals were used as procedure in the laboratory. Cleaning of the equipment was required by the manufacturer. 4. Documentation of cryostat and autostainer cleaning was not found in laboratory records for the timeframe reviewed, 09/06/17 through date of survey, 08/01/19. The laboratory was unable to provide documentation of equipment cleaning upon request. 5. In an interview at 2:40 p.m. on 08/01/19, the LD confirmed the above findings.

D5435

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to establish a function check protocol and perform and document function checks for all ancillary laboratory equipment. Findings are as follows: 1. The laboratory performed Histopathology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 1:00 p.m on 08/01/19. 2. The following equipment was observed as present and available for use during the tour of the laboratory. Each incubator, freezer, refrigerator, and the cryostat had either an integrated digital thermometer or an alcohol thermometer in use to monitor temperatures. Timers -Serial number 102140106, calibration expired 12/15/12 -Serial number 72075701, calibration expired 02/15/09 -Daigger timer with no serial number of calibration information Cryostat -Leica CM1900 Incubators -Blue M -Fisher Isotemp Oven Freezers -Sanyo Freezer RFPC1319 -Sanyo Biomed Freezer RFPC1325 -Nuair Glacier Freezer RFPC1317 -Sanyo Freezer RFPC1318 Refrigerator -Fisher Scientific Isotemp RFPC1324 3. The Equipment Calibration procedure found in the Muscle and Nerve Biopsy Manual did not include function check performance criteria for timers or thermometers. 4. Documentation of timer and thermometer function checks was not found in laboratory records from September

2017 through date of survey, 08/01/19. 5. The laboratory was unable to provide timer and thermometer function check documentation upon request. 6. In an interview at 2:00 p.m. on 08/01/19, the LD confirmed the above finding.