Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2114599	03/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Austin Neuromuscular Center	4705 Spicewood Springs Road, Ste # 200, Austin, TX	

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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observations and interview will facility personnel, the laboratory failed to ensure expired reagents and solutions were not available for use in patient testing on March 27, 2018. The findings included: 1. At 09:40 hours on March 27, 2018 in the laboratory, the surveyor observed the following expired reagents and solutions in the cabinet above the sink: Poly Scientific R and D Corp Crystal Violet 1 percent in Phosphate Buffer Lot: 346532, Expiration: 7/08/2017 Poly Scientific R and D Corp Sodium Chloride Saturated in 80 percent Reagent Alcohol Lot: 346551, Expiration: 7/08/2017 Blue bottle labeled "85 percent Propylene Glycol v/v Deionized Water Prepared: 05/15/2017, expiration: 11/01/2017 McKesson USP Normal Saline - 250 mL (Sterile 0.9 percent Sodium Chloride) Re-order: 37-6270 Lot: 1504234 Expiration: 04/2017 2. In an interview at 09:40 hours on 3/27/2018 in the laboratory, the Laboratory Manager stated that the expired solutions had not been used in patient testing.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The

	laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, patient records, and interview with facility personnel, the laboratory failed to test staining materials for intended reactivity to ensure predictable staining characteristics each day of use between September 2016 and March 2018. The findings included: 1. Based on review of the laboratory's policy "QUALITY MANAGEMENT", the policy states: "Positive controls will be run each time patient specimens are processed." 2. Based on a review of the laboratory procedures, the laboratory performs the following morphology, special, fluorescent, and immunohistochemical stains: Modified Gomori Trichrome Hematoxylin and Eosin (H&E) Adenosine Triphosphate Congo Red - Amyloid Adenylate Deaminase Deficiency DAB Method for Cytochrome Oxidase Succinic Dehydrogenase Oil Red O (ORO) for lipids Periodic Acid -Schiff's (PAS) NADH - Diaphorase Phosphorylase PGP 9.5/Collagen 4 at 1:16K CD3 3. Based on review of patient records, the laboratory did not have quality control records for assessing stain acceptability or positive and negative reactivity, when appropriate, when the following 4 of 4 patient specimens were processed: Accession: 166 Collected: 01/31 /2018 Reported: 3/01/2018 Stains: H and E, Congo Red Accession: 173 Collected: 2 /15/2018 Reported: 3/08/2018 Stains: H and E, Congo Red, Gomori Trichrome, nicotinamide adenine dinucleotide tetrazolium reductase (NADH-TR), Sudan Black, ATPase PH 9.4/4.6/4.3, Cytochrome oxidase (COX) stain, Succinate Dehydrogenase (SDH), myophosphorylase stain, Alkaline Phosphatase stain, Periodic Acid-Schiff (PAS) stain, Non-specific Esterase. Accession: 175 Collected: 2/26/2018 Reported: 3 /15/2018 Stains: H and E, Congo Red Accession: 176 Collected: 2/27/2018 Reported: 3/15/2018 Stains: H and E, Congo Red The laboratory reports an estimated annual volume in histopathology of 150 tests per year. 4. At 09:54 hours on 3/27/2018 in the laboratory, the surveyor asked the laboratory manager for quality control documentation for the acceptability of stains on each day of patient testing and assessing control materials for both positive and negative reactivity, as appropriate. The laboratory manager stated the laboratory evaluated stains but did not document the evaluations for quality control. The laboratory manager stated the laboratory did not stain positive control slides each day of use for special, fluorescent, or immunohistochemical stains as indicated in the Quality Managment procedure.
D5475	CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, patient records, and interview with facility personnel, the laboratory failed to check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use between September 2016 and March 2018. The findings included: 1. Based on review of the laboratory's policy "QUALITY MANAGEMENT", the policy states: "Positive controls will be run each time patient specimens are processed." 2. Based on a review of the laboratory procedures, the laboratory performs the following fluorescent and

	immunohistochemical stains: PGP 9.5/Collagen 4 at 1:16K CD3 3. Based on review of patient records, the laboratory did not have quality control records for assessing stain acceptability or positive and negative reactivity, when appropriate, when the following 3 of 3 patient specimens were processed: Accession: 166 Collected: 01/31 /2018 Reported: 3/01/2018 Stains: PGP 9.5/Collagen 4 at 1:16K, CD3 Accession: 175 Collected: 2/26/2018 Reported: 3/15/2018 Stains: PGP 9.5/Collagen 4 at 1:16K, CD3 Accession: 176 Collected: 2/27/2018 Reported: 3/15/2018 Stains: PGP 9.5/Collagen 4 at 1:16K, CD3 The laboratory reports an estimated annual volume in histopathology of 150 tests per year. 4. At 09:54 hours on 3/27/2018 in the laboratory, the surveyor asked the laboratory manager for quality control documentation to check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use between September 2016 and March 2018. The laboratory manager stated the laboratory evaluated stains but did not document the evaluations for quality control. The laboratory manager stated the laboratory did not stain positive quality control each time patients were processed as listed in the laboratory's Quality Management procedure.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, patient records, and interview with facility personnel, the laboratory failed to test staining materials for intended reactivity to ensure predictable staining characteristics each day of use between September 2016 and March 2018. The findings included: 1. Based on review of the laboratory's policy "QUALITY MANAGEMENT", the policy states: "Positive controls will be run each time patient specimens are processed." 2. Based on a review of the laboratory procedures, the laboratory performs the following morphology, special, fluorescent, and immunohistochemical stains: Modified Gomori Trichrome Hematoxylin and Eosin (H&E) Adenosine Triphosphate Congo Red - Amyloid Adenylate Deaminase Deficiency DAB Method for Cytochrome Oxidase Succinic Dehydrogenase Oil Red O (ORO) for lipids Periodic Acid -Schiff's (PAS) NADH - Diaphorase Phosphorylase PGP 9.5/Collagen 4 at 1:16K CD3 3. Based on review of patient records, the laboratory did not have quality control records for assessing stain acceptability or positive and negative reactivity, when appropriate, when the following 4 of 4 patient specimens were processed: Accession: 166 Collected: 01/31 /2018 Reported: 3/01/2018 Stains: H and E, Congo Red Accession: 173 Collected: 2 /15/2018 Reported: 3/08/2018 Stains: H and E, Congo Red, Gomori Trichrome, nicotinamide adenine dinucleotide tetrazolium reductase (NADH-TR), Sudan Black, ATPase PH 9.4/4.6/4.3, Cytochrome oxidase (COX) stain, Succinate Dehydrogenase (SDH), myophosphorylase stain, Alkaline Phosphatase stain, Periodic Acid-Schiff (PAS) stain, Non-specific Esterase. Accession: 175 Collected: 2/26/2018 Reported: 3 /15/2018 Stains: H and E, Congo Red Accession: 176 Collected: 2/27/2018 Reported: 3/15/2018 Stains: H and E, Congo Red The laboratory reports an estimated annual volume in histopathology of 150 tests per year. 4. At 09:54 hours on 3/27/2018 in the

	laboratory, the surveyor asked the laboratory manager for quality control documentation for the acceptability of stains on each day of patient testing and assessing control materials for both positive and negative reactivity, as appropriate. The laboratory manager stated the laboratory evaluated stains but did not document the evaluations. The laboratory manager stated the laboratory did not stain positive controls each day of use for special, fluorescent, or immunohistochemical stains as listed in the laboratory's Quality Managment procedure.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 a review of laboratory policies and procedures, quality control records, patient records, and interview with facility personnel, the laboratory director failed to ensure that a quality control program had been established and maintained to assure the quality of laboratory services and identify failures in quality as they occur between September 2016 and March 2018. The findings indlucded: 1. The laboratory director failed to ensure staining materials were assessed for intended reactivity to ensure predictable staining characteristics each day of use between September 2016 and March 2018. Refer to D5473. 2. The laboratory director failed to ensure fluorescent and immunohistochemical stains were checked for positive and negative reactivity each time of use between September 2016 and March 2018. Refer to D5475. 3. The laboratory director failed to ensure staining materials were tested for intended reactivity to ensure predictable staining characteristics each day of use between September 2016 and March 2018. Refer to D5601.
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 laboratory policies and procedures, quality control records, quality assessment records, and interview with facility personnel, the laboratory director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services and identify failures in quality between September 2016 and March 2018. The findings included: 1. Review of the laboratory procedure "QUALITY MANAGMENT" states the following: "Steps have been established to monitor the quality: 1. Procedure protocols have been established for processing and handling of specimens. 2. Log Maintained by histotechnologist monitoring the equipment used and the room temperature. 3. Positive controls will be run each time patient specimens are processed. 4. Log maintained by the physician indicating acceptance/non-acceptance of the processed specimen. 5. Log maintained by the office receptionist to monitor the biopsy reports for accuracy before results are released. 6. Log maintained by the office receptionist to monitor temperature of the

	laboratory refrigerator and sub-zero freezer. 7. Proficiency reports will be procured from outside sources 8. Laboratory supplies will be monitored for expiration dates 9. A patient or employee complaint or concern from can be submitted." 2.Based on review of laboratory quality assessment records, signed by the laboratory director on 2 /15/2017: "Indicator: Continuing quality improvement meeting Purpose: To Do a general assessment of Policy and Procedure of the Histology Laboratory Frequency: The meeting is held quarterly Procedure: Laboratory performance, quality control, and assessment are discussed and evaluated. Any concerns or issues of the staff are discussed and evaluated, corrective action will be taken and noted in the meeting minutes." 3. Based on review of quality assessment records, the laboratory did not have documentation of quarterly quality assessment activities. 4. The laboratory's quality assessment activities failed to identify that the laboratory was not meeting item 3 from the QUALITY MANAGEMENT procedure: ". Positive controls will be run each time patient specimens are processed." Refer to D5473, D5475, and D5601. 5. The laboratory's quality assessment activities failed to identify that the laboratory was not meeting item 8 from the QUALITY MANAGEMENT procedure: "8. Laboratory supplies will be monitored for expiration dates. " Refer to D5417.