

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2074675	(X3) Date Survey Completed 07/06/2021
Name of Provider or Supplier Neuromuscular Spine And Joint Center	Street Address, City, State 6720 Grelot Road, Suite A, Mobile, AL	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2019-2021 CAP (College of American Pathologists) proficiency testing (PT) records, and an interview with the Collections Supervisor, the surveyor determined the laboratory failed to ensure proficiency testing samples for Urine Drug Testing (UDS6 surveys) were rotated between all personnel who performed patient testing. This was noted on five of five UDS6 surveys reviewed. The findings include: 1. A review of CAP PT attestation statements revealed Testing Personnel #1 had performed all the UDS testing on five of five of the 2019-2021 UDS6 PT surveys. Testing Personnel #2 had not participated in any UDS6 PT testing since she was trained on 2/11/2019. 2. During an interview and review of the PT records on 7/6/2021 at 2:35 PM, the Collections Supervisor confirmed the above noted findings. .</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two</p>

years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:
Based on a review of the 2021 CAP (College of American Pathologists) proficiency testing (PT) records, and an interview with the Collections Supervisor, the surveyor determined the laboratory failed to print and retain records for two of two PT surveys performed in February and March 2021. The findings include: 1. A review of CAP PT records revealed the following: A.) A review of the instrument printouts for the Urine Adulterants / Urine Creatinine (DAI-A) survey revealed the testing was performed on 2/24/2021, however the scores, attestation statement and documentation of results review were not available for the surveyor's review. B.) A review of the instrument printouts for the Urine Drug Testing (UDS6-A) survey revealed no documentation of results review with corrective action (if required). 2. During an interview and review of the PT records on 7/6/2021 at 2:35 PM, the Collections Supervisor confirmed the above noted findings, stating the Laboratory Director had not had a chance to print the documents from the CAP website. .

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on a review of personnel files and an interview with Testing Personnel (TP) #1, the Technical Consultant (who also serves as the Laboratory Director) failed to perform and document semi-annual competency evaluations (due in 2019) on two of two testing personnel. The findings include: 1. A review of personnel files revealed no competency evaluations for TP #1 or #2. Documentation of training on both testing personnel was reviewed during the previous survey 2/27/2019. TP #1 was trained on the Beckman Coulter AU 480 on 8/17/2018, and TP #2 was trained on 2/11/2019. The semi-annual competency evaluations for both employees was due in 2019. 2. During an interview on 4/6/2021 at 12:35 PM, TP #1 stated no competencies had been performed on the testing personnel because "[name of the Laboratory Director] did not tell me this was required."

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on a review of personnel files and an interview with Testing Personnel (TP) #1, the Technical Consultant (who also serves as the Laboratory Director) failed to perform and document two annual competency evaluations (for the 2019-2021 period)

on two of two testing personnel. The findings include: 1. A review of personnel files revealed no competency evaluations for TP #1 or #2. Documentation of training on both testing personnel was reviewed during the previous survey 2/27/2019. TP #1 was trained on the Beckman Coulter AU 480 on 8/17/2018, and TP #2 was trained on 2/11/2019. The annual competency evaluations for TP #1 were due in August 2019 and 2020; the annual evaluations for TP #2 were due in February 2020 and 2021. 2. During an interview on 4/6/2021 at 12:35 PM, TP #1 stated no competencies had been performed on the testing personnel because "[name of the Laboratory Director] did not tell me this was required." SURVEYOR ID#32558 Licensure and Certification Surveyor