

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2042485	(X3) Date Survey Completed 07/08/2019
Name of Provider or Supplier North Central Florida Neurodiagnostic Services Llc	Street Address, City, State 12076 Technology Ave, Alachua, FL	
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
D0000	An unannounced complaint survey (CCR #2019007677) was conducted at NCF Diagnostics & DNA Technologies on 7/8/19. NCF Diagnostics & DNA Technologies was found not in compliance with the 42 CFR Part 493, Requirements for Laboratories.
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency test records and interview with staff, the laboratory failed to perform proficiency testing in the same manner as patient testing. Findings Include: The review of proficiency test record and procedure manual showed that NCF Diagnostics & DNA Technologies developed an internal proficiency testing program. The laboratory's policy titled "Proficiency Testing Policies" states "Participate in CAP or other PT programs including split sample testing with another laboratory or by two different technologists. Perform the procedure exactly like processing for a patient specimen. All PT testing should be integrated into the routine workload and PT samples handled just like patient sample without any variation." The records of the split testing states "DNA and RNA extracted from patient samples are split into two separate aliquots. One aliquot was used by one Technologist to perform PT tests. Another aliquot of the same sample was used by another Technologist to</p>

perform PT tests. The test results were compared and percentage identical positive and negative detection were scored." A document titled "NCF Diagnostics and DNA Technologies Proficiency Testing Results" states "We have developed a Proficiency Test in our lab to meet CLIA requirements. Five well characterized DNA and RNA collected from patients are split into two separate sample. The split sample are provided two separate Medical Technologists. They performed the Proficiency Tests for five different pathogen panels that we have developed (RespiraPath, WoundPath, NailPath, Uripath, and Gastropath). Five samples were selected and used for this Proficiency Testing. These Proficiency Testing will be performed every four months and three times per year. The Proficiency results generated by the two testing personnel are compared and the PT test score percentage calculated for all pathogen tests (positives and negatives)." The interview with the general supervisor on 7/8/19 at 4:00pm confirmed that split sample testing was between two technologists and results were compared before determining if the event passed and this was not how patient testing was performed.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to follow their procedures to document semi-annual and annual competency evaluations for four of nine Technologist's records reviewed (Technologists #3, #5, #6, #8, and #9) for two of two years reviewed (2017-2018). Findings include: Review of the competency evaluation for Technologist #3 showed a hire date of 4/24/18 and the semi-annual competency evaluation was performed on 6/30/18. Review of the competency evaluation for Technologist #5 showed a hire date of 6/01/17 and the semi-annual competency evaluation was performed on 7/01/17. Review of the competency evaluation for Technologist #6 showed a hire date of 3/14/18 and the semi-annual competency evaluation was performed on 6/30/18. Review of the competency evaluation for Technologist #8 showed a hire date of 5/22/18 and had no documentation of a semi-annual or annual competency. Review of the competency evaluation for Technologist #9 showed a hire date of 4/19/18 and the semi-annual competency evaluation was performed on 6/30/18. The review of the laboratory's policy and procedure for Competency Evaluation states "1. All new employees will have an assessment of their competency to perform specific tasks documented on a competency check list at 6 and 12 months after their hire date and annually thereafter". The interview on 7/8/19 at 12:30pm with the Technical Supervisor confirmed the competency assessments were not performed according to the written procedure's timeline.

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in

493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on review of the laboratory procedure manual, patient test runs, and interview with the General Supervisor, the laboratory failed to perform quality control each day of patient testing (Refer to D5455). .

D5455

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(v)(g)

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-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to ensure a positive quality control was performed with each test run for four of four days reviewed. Findings include: The review of the test runs performed on 4/1/19, 4/30/19, 6/5/19, and 6/19/19 showed that no positive pathogen controls were performed for each amplification procedure. The interview on 7/8/19 with the General Supervisor at 4:30pm confirmed no positive quality controls were performed because the laboratory wanted to "avoid contamination". The policy titled "DNA Sequencing Procedure" states to "Start with a no DNA negative control, a positive control DNA from the lab collection and a genomic DNA from patient sample". The policy titled "Quality Management Plan" states "A negative No DNA Water control and a positive variant homozygous or heterozygous genomic DNA control should be included for each allele-amplification in each run. If positive control is not available for a marker, then negative control alone should be used. For quantitative assay, control materials at more than one concentration should be included for each run."