

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0964738	(X3) Date Survey Completed 04/05/2018
Name of Provider or Supplier Winfield Neurology Family Medicine	Street Address, City, State 125 Bob Lawrence Drive, Winfield, 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of documentation for the validation procedures for the DCA Vantage analyzer (used for Urine Microalbumin/Creatinine, a non-waived moderate-complexity test), patient test records, and an interview with Testing Personnel (TP #1), the surveyor determined the laboratory failed to ensure the verification of the manufacturer's performance specifications was performed, approved, signed and dated by the Laboratory Director before the instrument was used by the testing personnel for patient testing. The findings include: 1. During the entrance tour of the laboratory on 4/5/2018 at approximately 8:30 AM, TP #1 included Urine Microalbumin/Creatinine performed on the DCA Vantage on the test menu. [The laboratory had this instrument during the previous survey on 5/17/2016, however it was not in use at that time.] 2. A review of the DCA Vantage records revealed no documentation of validation procedures performed to verify the manufacturer's performance specifications. 3. A review of test records stored in the DCA Vantage revealed patient testing began on 6/13/2016. 4. During an interview on 4/5/2018 at 2:15 PM with TP #1, the surveyor explained new instruments required validation of precision, accuracy and reportable ranges of the tests as stated in the manufacturer's performance specifications, plus verification of the reference ranges for the laboratory's patient population. All validations must be reviewed and approved by the Laboratory Director before</p>

beginning patient testing. TP #1 stated they had purchased the instrument from another physician's office, and she did not think any validation studies had been performed on the analyzer. Thus the above noted findings were confirmed. .

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 a review of the maintenance procedures in the Operator's Manual for the DCA Vantage analyzer (used for Urine Microalbumin/Creatinine, a non-waived moderate-complexity test), a lack of maintenance records, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to perform and document the weekly and quarterly maintenance with the frequency required by the manufacturer for almost two years (from 6/13/2016 when patient testing began till the date of the survey on 4/5/2018). The findings include: 1. A review of the maintenance procedures for the DCA Vantage revealed documentation of the Optical Check performed on 7/20/2016 and 1/2/2017. There was no other documentation of maintenance for this analyzer. 2. A review of the Maintenance procedures on page 97 in the DCA Vantage Operator's Manual, revealed the following: "...Weekly Cleaning the on-board barcode reader window Cleaning the exterior Quarterly Removing and cleaning the cartridge spring and cartridge area Changing the air filter Optical Test" As needed procedures were also listed in the manual. 3. During an interview on 4/5 /2018 at 2:30 PM, the above procedures were reviewed with TP #1, who stated she performed some of the above maintenance, but had not documented it. Thus the above noted finding were confirmed. .

D5447

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on reviews of the quality control records for the DCA Vantage analyzer (used for Urine Microalbumin/Creatinine, a non-waived moderate-complexity test), patient test records and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure two levels of quality control (QC) were performed each day of patient testing in the absence of an optional IQCP (Individualized Quality Assurance Plan) in 2016 thru 2018. The findings include: 1. A review of the QC records for Urine Microalbumin/Creatinine on the DCA Advantage revealed the Testing Personnel had performed QC seven times in 2016, and ten times in 2017; there was no record of QC performed in 2018. A further review of the records revealed no evidence an optional IQCP had been implemented to allow decreased frequency in QC testing. 2. During an interview on 4/5/2018 at 2:15 PM, when asked

about the frequency of QC performed on the DCA Advantage, TP #1 stated testing personnel performed QC whenever prompted to do so by the analyzer. TP #1 was then asked if patient testing was performed on other days when QC was not tested. TP #1 answered, "I'm sure we do." When asked if an optional IQCP had been implemented by the laboratory in 2016, TP #1 stated she did not know what an IQCP was. 3. A review of results stored in the DCA Vantage revealed Urine Microalbumin/Creatinine testing on patient samples was performed on days when no QC was run as follows: A) 2016: 101 patient tests performed B) 2017: 106 patient tests performed C) 2018: 22 patient tests performed 4. During the exit interview on 4/5/2018 at approximately 4:00 PM, the surveyor explained that CLIA regulations required two levels of QC each day of patient testing. However if a laboratory chooses to follow a manufacturer's recommendation of performing QC less frequently, the laboratory had the option of implementing an IQCP for the tests. TP #1 stated she was not aware of the requirement to implement an IQCP to allow for decreased QC testing. Thus, the above noted findings were confirmed. .

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:
Based on a reviews of quality control (QC), maintenance and analyzer installation and validation records for the DCA Vantage analyzer (used for Urine Microalbumin /Creatinine, a non-waived moderate-complexity test), the Technical Consultant (also the Laboratory Director) failed to provide and document effective technical oversight of the laboratory in the following areas: A) Review of maintenance records to ensure maintenance on the DCA Vantage was performed and documented at the frequency specified by the manufacturer (Refer to D5429) B) Ensuring the development and implementation of an optional Individualized Quality Control Plan (IQCP) or two levels of QC each day of patient testing in 2016-2018 for Urine Microalbumin /Creatinine performed on the DCA Vantage (Refer to D5447) C) Ensuring the verification of the manufacturer's performance specifications was performed, approved, signed and dated before the DCA Vantage was used by the testing personnel for patient testing. (Refer to D5421 and D6040.) 2. During the exit summation on 4/5/2018 at 4:00 PM, these concerns were reviewed and confirmed with Testing Personnel #1. .

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
Based on a lack of documentation for the installation and validation procedures for the DCA Vantage analyzer (used for Urine Microalbumin/Creatinine, a non-waived moderate-complexity test), and an interview with Testing Personnel #1, the surveyor determined the Technical Consultant (also the Laboratory Director) failed to ensure

the verification of the manufacturer's performance specifications was performed, approved, signed and dated before the instrument was used by the testing personnel for patient testing. The findings include: 1. Refer to D5421. SURVEYOR:Laura T. Williams, BS, MT (ASCP)Licensure and Certification Surveyor