

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2000903	(X3) Date Survey Completed 03/04/2020
Name of Provider or Supplier Nowcare - First Colonial	Street Address, City, State 1168 First Colonial Road-Suite 100, Virginia Beach, VA	
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 announced CLIA recertification survey was conducted at NowCare-First Colonial on March 4, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a tour, review of procedures, daily temperature/environment logs, manufacturer's user guides, lack of documentation, and interviews, the laboratory failed to monitor the daily relative humidity percent (%) to ensure manufacturer's operating and storage requirements were followed for one (1) chemistry and one (1) hematology analyzer utilized for patient Basic Metabolic Panel (BMP) and Complete Blood Count (CBC) testing for twenty-two (22) of 22 months reviewed. Findings include: 1. During a tour of the laboratory at approximately 10:00 AM, the inspector noted: Abbott iSTAT analyzer system, Serial Number (SN) 353327, in use for BMP chemistry testing; Abbott Emerald, SN 030609-000686, in use for CBC hematology testing; Thermco Products Hygro-Thermometer, SN 2949, in use for monitoring laboratory room humidity. 2. Review of the laboratory's procedures revealed Quality Assurance protocols that outlined daily monitoring of environmental conditions. The</p>

clinical coordinator and lead testing personnel stated at approximately 11:30 AM on 03/04/20: "All of our NowCare laboratory personnel monitor temperatures of the lab room, refrigerators, freezers, and humidity levels daily". 3. Review of the daily temperature/environmental logs from 05/01/18 to 03/04/20, revealed no record of humidity monitoring. The inspector requested to review documentation of the monitoring. No records were available for review. The primary testing personnel stated at approximately 12:00 PM on 03/04/20: "I have discussed the lack of recording with the technical consultant. The staff do observe the humidity reading on the Thermco each day but have not been recording on the charts". 4. Review of the two (2) analyzers' user guides revealed the following operating requirement: iSTAT manufacturer's technical specifications stated "environmental conditions for running instrument is humidity levels less than 80% non-condensing"; Emerald manufacturer's guide stated "Environmental Specifications: relative humidity range is 80% maximum". 5. In an exit interview with the clinical coordinator and primary testing personnel on 3/4/20 at approximately 12:45 PM the above findings were confirmed.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
 Based on a review of the laboratory's Center for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), personnel files, lack of documentation, and interviews, the laboratory director (LD) failed to document competency assessment for the technical consultant (TC) in calendar year 2018. Findings: 1. Review of the laboratory's CMS 209 form revealed that the LD identified technical consultant ("TC A") as also responsible for non-waived hematology testing during the twenty-two (22) months reviewed. (See Personnel Code Sheet.) 2. Review of the laboratory's personnel files revealed no competency assessment documentation for TC A in 2018. The inspector requested to review the competency assessment documentation. The lead testing personnel and clinical coordinator stated at approximately 10:30 AM on 3/4/20: "We most likely have competency documents at one of our other facilities or in files boxed up here". The clinical coordinator was unable to locate the competency documents. 3. In an exit interview with the clinical coordinator and primary testing personnel on 3/4/20 at approximately 12:45 PM the above findings were confirmed.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform

test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the technical consultant (TC) failed to document hematology competency assessment for one (1) testing personnel (TP) in calendar year 2018. Findings include: 1. Review of the CMS 209 personnel form revealed that the laboratory director (LD) identified a TC and three (3) TP as responsible for performing non-waived hematology patient testing during the twenty-two (22) months reviewed. 2. Review of personnel records revealed no Abbott Emerald hematology competency assessment for TP A in calendar year 2018. The inspector requested to review the documentation. The clinical coordinator stated at approximately 11:30 AM on 3/4/20: "The tech is no longer working in the lab but we should have that record for 2018. I should be able to find it". No records were made available for review. (See Personnel Code Sheet.) 3. In an exit interview with the clinical coordinator and primary testing personnel on 3/4/20 at approximately 12:45 PM the above findings were confirmed.