

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2000903	(X3) Date Survey Completed 05/17/2018
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 the Nowcare- First Colonial on May 17, 2018 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:
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 review of proficiency testing (PT) records, Laboratory Personnel Report form (CMS 209), and interviews, the laboratory failed to rotate proficiency testing among the three (3) testing personnel for four (4) of the six (6) events reviewed. Findings include: 1. The review of the American Proficiency Institute (API) hematology PT records revealed that the same testing personnel, TP A, performed all three (3) events in 2017 and the first event in 2018. (See attached personnel code list.) 2. An interview with the primary testing personnel at approximately 11:00 AM and review of the CMS 209 laboratory personnel form revealed three (3) testing personnel performing testing in 2017 and up to the date of survey on May 17, 2018. 3. An interview with the primary testing personnel and quality support specialist at approximately 12:00 PM confirmed that the laboratory failed to rotate the API PT events among all 3 testing personnel in 2017 and for the first event in 2018.</p>
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p>

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on the review of the policy and procedures, quality control records, personnel competency assessments, and interviews, the laboratory director did not delegate, in writing, the job duties and responsibilities of technical consultant (TC) to the individual performing the duties of TC from January 1, 2017 at the date of survey on May 17, 2018. Findings include: 1. Review of the quality control records in the specialties hematology and competency assessments performed in 2017 revealed that TP A was performing duties of TC in the calendar year of 2017 and up to the date of survey in 2018. 2. Review of the policy and procedure manuals revealed no documentation of the delegation of duties of TC, in writing, by the laboratory director to the TP A. The inspector requested to review the above-mentioned documentation. The documentation was not available for review. 3. An interview with the primary testing personnel and quality support specialist at approximately 12:00 PM confirmed that the laboratory director did not delegate the job duties and responsibilities of TC to the individual that was performing the duties of TC in 2017 and up to the date of survey on May 17, 2018.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on the review of the testing personnel (TP) records, and interviews, the technical consultant failed to include the review of laboratory worksheets, proficiency testing records, quality control records or instrument maintenance records as part of the competency assessments performed on two (2) of the two (2) TP in 2016 and 2017. Findings include: 1. Review of the available testing personnel competency assessments for 2016 and 2017 revealed that the competency assessments records for TP B and C failed to include the review of laboratory worksheets, proficiency testing records, quality control records or instrument maintenance records for TP B and C. (See attached list.) 2. An interview with the primary testing personnel and quality support specialist at approximately 12:00 PM confirmed that the technical consultant failed to include the above-specified monitors of competency assessment for the TP B and C in 2016 and 2017.