

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1018979	(X3) Date Survey Completed 11/17/2020
Name of Provider or Supplier Nowcare Medical Associates	Street Address, City, State 6632 Indian River Road - Suite 103, 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 on-site CLIA recertification survey was conducted at Nowcare Medical Associates on November 17, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on 11/2/2020 and virtual record review conducted on 11/13/2020. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D6047	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(i)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and an interview, the technical consultant (TC) failed to document annual competency assessments that included direct observation of Complete Blood Count (CBC) patient test performance for two (2) of three (3) testing personnel (TP) in the twenty-nine (29) months reviewed. Findings include: 1. During an entrance interview with the laboratory's office manager and technical consultant (TC) on 11/2/20, a review of the CMS 209 form revealed 3 TP responsible for moderate complexity CBC patient testing. 2. Review of the Abbott Emerald hematology competency assessment documentation from July 2018 to the date of the virtual record review on 11/13/20, a total of twenty-nine (29) months, revealed the laboratory's annual CBC competency assessments lacked required competency procedural element of direct observation of routine patient test performance (patient preparation, specimen handling, and analyzer testing) for TP A and TP B. The inspector noted that the competency assessment for TP A and TP B consisted of a check mark on a column header labeled "Competent" with no</p>

evaluation criteria described. (See Personnel Code Sheet.) 3. During the onsite tour on 11/17/20, the inspector requested to review additional competency documentation. The TC stated at approximately 3:00 PM: "The competency assessment check list for my role as TC and as the primary testing personnel does include six elements. We have not updated the competency records for other two staff members who run the Emerald instrument". 4. In an exit interview with the TC at approximately 3:30 PM, the above findings were confirmed.

D6048

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

The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.

This STANDARD is not met as evidenced by:
Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and an interview, the technical consultant (TC) failed to document annual competency assessments that included monitoring of the recording/reporting of Complete Blood Count (CBC) patient test results for two (2) of three (3) testing personnel (TP) in the twenty-nine (29) months reviewed. Findings include: 1. During an entrance interview with the laboratory's office manager and technical consultant (TC) on 11/2/20, a review of the CMS 209 form revealed 3 TP responsible for moderate complexity CBC patient testing. 2. Review of the Abbott Emerald hematology competency assessment documentation from July 2018 to the date of the virtual record review on 11/13/20, a total of twenty-nine (29) months, revealed the laboratory's annual assessments lacked required competency procedural element of monitoring of the recording/reporting of CBC test results for TP A and TP B. The inspector noted that the competency assessment for TP A and TP B consisted of a check mark on a column header labeled "Competent" with no evaluation criteria described. (See Personnel Code Sheet.) 3. During the onsite tour on 11/17/20, the inspector requested to review additional competency documentation. The TC stated at approximately 3:00 PM: "The competency assessment check list for my role as TC and as the primary testing personnel does include six elements. We have not updated the competency records for other two staff members who run the Emerald instrument". 4. In an exit interview with the TC at approximately 3:30 PM, the above findings were confirmed.

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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and an interview, the technical consultant (TC) failed to document annual competency assessments that included review of test results/worksheets, quality control (QC) records, or preventative maintenance for Complete Blood Count (CBC) patient test results for two (2) of three (3) testing personnel (TP) in the twenty-nine (29) months reviewed.

Findings include: 1. During an entrance interview with the laboratory's office manager and technical consultant (TC) on 11/13/20, a review of the CMS 209 form revealed 3 TP responsible for moderate complexity CBC patient testing. 2. Review of the Abbott Emerald hematology competency assessment documentation from July 2018 to the date of the virtual record review on 11/13/20, a total of twenty-nine (29) months, revealed the laboratory's annual CBC assessments lacked required competency procedural elements of review of test results/worksheets, quality control (QC) records, or preventative maintenance monitoring for TP A and TP B. The inspector noted that the competency assessment for TP A and TP B consisted of a check mark on a column header labeled "Competent" with no evaluation criteria described. (See Personnel Code Sheet.) 3. During the onsite tour on 11/17/20, the inspector requested to review additional competency documentation. The TC stated at approximately 3:00 PM: "The competency assessment check list for my role as TC and as the primary testing personnel does include six elements. We have not updated the competency records for other two staff members who run the Emerald instrument". 4. In an exit interview with the TC at approximately 3:30 PM, the above findings were confirmed.