

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D0342310	<b>(X3) Date Survey Completed</b>  11/20/2019
<b>Name of Provider or Supplier</b>  Noms Healthcare Eastern Ohio	<b>Street Address, City, State</b>  960 Windham Court Suite 1, Boardman, OH	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:                      **This is a repeat deficiency as cited on the 01/18/2018 routine, on-cite CLIA inspection** Based on record review and an interview with Technical Consultant (TC) #2, the laboratory failed to establish and follow written policies and procedures to assess the competency of TC#2, at a frequency determined by the laboratory, as specified in the personnel requirements in subpart M. All patient arterial blood gas (ABG) testing performed in this laboratory in 2018 and 2019 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Policy for Personnel Assessment" policy and procedure, provided on the date of the inspection, did not find any mention of the assessment of the TC based on the responsibilities of the position, at a frequency determined by the laboratory. 2. Review of the laboratory's Form CMS-209, approved, signed and dated by the Laboratory Director on 11/12/2019, revealed two individuals, including the Laboratory Director, listed and qualified by the Laboratory Director to function as TC. 3. Review of the laboratory's 2018 and 2019 competency assessment documentation, provided on the date of the inspection, did not find any assessment documentation for TC#2 based on the responsibilities of the TC position. 4. The Surveyor requested the laboratory's policy and procedure for the assessment of the TC and any competency assessment documentation for TC#2 based on the responsibilities of the position from TC#2. TC#2 confirmed the laboratory did not establish a policy and procedure for the assessment of the TC, did not assess the competency of TC#2 based on the</p>

responsibilities of the position, at a frequency determined by the laboratory and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 11/20/2019 at 8:55 AM.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

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.

This STANDARD is not met as evidenced by:

Based on record review and an interview with Technical Consultant (TC) #2, the laboratory failed to define criteria consistent with the manufacturer's instructions and document humidity conditions for reliable arterial blood gas (ABG) testing procedures on the OPTI Critical Care Analyzer. All patient ABG testing performed in this laboratory in 2018 and 2019 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Lab Policy Manual", provided on the date of the inspection, did not find any instructions to monitor and document humidity conditions consistent with manufacturer's operating specifications. 2. Review of the "OPTI Critical Care Analyzer" manufacturer's "Operating Parameters" revealed the following: "Relative Humidity Range 5%-95% (non-condensing)" %; percent 3. The Inspector requested the laboratory's policy and procedure for the humidity criteria consistent with the manufacturer's instructions and the humidity documentation from 2018 and 2019 from TC#2. TC#2 confirmed the laboratory did not establish a policy and procedure to monitor and document humidity criteria consistent with the manufacturer's instructions, did not monitor and document humidity in 2018 and 2019 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 11/20/2019 at 10:25 AM.