

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0342310	(X3) Date Survey Completed 01/18/2018
Name of Provider or Supplier Noms Healthcare Eastern Ohio	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<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: 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, as specified in the personnel requirements in subpart M. 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. 2. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 01/08/2018, revealed two individuals, including the Laboratory Director, listed and qualified by the Laboratory Director to function as TC. 3. Review of the laboratory's 2016, 2017 and 2018 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 responsibilities of the position, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/18/2018 at 8:35 AM.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p>

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on record review and an interview with Technical Consultant (TC) #2, the laboratory failed to verify the accuracy of the bicarbonate (HCO₃) testing procedures performed, that are not included in subpart I, at least twice annually. Findings Include: 1. Review of the laboratory's "Proficiency Testing Policy and Procedure", provided on the date of the inspection, did not find any mention of instructions for blind test accuracy verification (TAV) protocols for the HCO₃ testing procedures performed and reported on the OPTI CCA-TS AVL blood gas analyzer. 2. Review of six out of six of the laboratory's 2016 and 2017 American Association of Bioanalysts (AAB) proficiency testing (PT) records, provided on the date of inspection, did not find that the laboratory was enrolled in HCO₃ testing. 3. The Surveyor requested the laboratory's 2016 and 2017, twice annual, HCO₃ TAV records from TC#2. TC#2 confirmed that the laboratory did not enroll in HCO₃ testing via AAB or any other PT provider, did not conduct and document HCO₃ TAV at least twice annually and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/18/2018 at 10:12 AM.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on record review and an interview with Technical Consultant (TC) #2, the TC failed to evaluate and document the competency of one out of five of the testing personnel (TP) responsible for moderate complexity blood gas testing at least annually after the first year. Findings Include: 1. Review of the laboratory's "Policy for Personnel Assessment" policy and procedure, provided on the date of the inspection, found instructions to annually assess the competency of testing personnel, after the first year of testing. 2. Review of the laboratory's 2016, 2017 and 2018 competency assessment records did not find any 2016, 2017 and 2018 competency assessment documentation for TP#2. 3. The Surveyor requested the laboratory's 2016, 2017 and 2018 annual competency assessment records for TP#2 from TC#2. TC#2 confirmed that the laboratory did not follow their written policy and procedure to assess and document the competency of the TP, at least annually after the first year of testing patient specimens, as required, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/18/2018 at 8:35 AM.