

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2089348	(X3) Date Survey Completed 05/13/2021
Name of Provider or Supplier Bowtie Medical Ohio	Street Address, City, State 29001 Cedar Rd #103, Lyndhurst, 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
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 record review and an interview with the Laboratory Director (LD), the Technical Consultant (TC) failed to include direct observation of routine patient test performance, patient preparation, specimen handling, processing, and testing in the evaluation of the competency of Testing Personnel (TP) #2. All patients tested under the subspecialty of virology from 10/05/2020 to 05/13/2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure titled " BowTie Medical Ohio-Lyndhurst Lab Personnel Competency Assessment Policy" approved and signed by the Laboratory Director on 05/18/2021 and provided on the date of the inspection found the following statement: "5.1.1 Competency Assessment ...1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing." 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 01/06/2021, revealed two individuals indicated as TP. 3. The inspector requested the laboratory's 2020 competency assessment records for TP#2 that included direct observation of routine patient test performance, patient preparation, specimen handling, processing, and testing from the LD. The LD provided a problem solving quiz titled "LAB.GEN.001#1" for TP#2. The LD was unable to provide the requested documentation on the date of inspection. The interview occurred on 05/13/2021 at 10:20 AM.</p>
D6048	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(ii)</p>

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 record review and an interview with the Laboratory Director (LD), the Technical Consultant (TC) failed to include monitoring of the recording and reporting of test results in the evaluation of the competency of Testing Personnel (TP) #2. All patients tested under the subspecialty of virology from 10/05/2020 to 05/13/2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure titled "BowTie Medical Ohio-Lyndhurst Lab Personnel Competency Assessment Policy" approved and signed by the Laboratory Director on 05/18/2021 and provided on the date of the inspection found the following statement: "5.1.1 Competency Assessment ...2. Monitoring the recording and reporting of test results." 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 01/06/2021, revealed two individuals indicated as TP. 3. The inspector requested the laboratory's 2020 competency assessment records for TP#2 that included monitoring of the recording and reporting of test results from the LD. The LD provided a problem solving quiz titled "LAB.GEN.001#1" for TP#2. The LD was unable to provide the requested documentation on the date of inspection. The interview occurred on 05/13/2021 at 10:20 AM.

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 record review and an interview with the Laboratory Director (LD), the Technical Consultant (TC) failed to include the review of intermediate test results or worksheets, quality control (QC) records and preventive maintenance records in the evaluation of the competency of Testing Personnel (TP) #2. All patients tested under the subspecialty of virology from 10/05/2020 to 05/13/2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure titled "BowTie Medical Ohio-Lyndhurst Lab Personnel Competency Assessment Policy" approved and signed by the Laboratory Director on 05/18/2021 and provided on the date of the inspection found the following statement: "5.1.1 Competency Assessment ...3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records." 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 01/06/2021, revealed two individuals indicated as TP. 3. The inspector requested the laboratory's 2020 competency assessment records for TP#2 that included the review of intermediate test results or worksheets, quality control (QC) records and preventive maintenance records from the LD. The LD provided a problem solving quiz titled "LAB.GEN.001#1" for TP#2. The LD was unable to provide the requested documentation on the date of inspection. The interview occurred on 05/13/2021 at 10:20 AM.

D6050

TECHNICAL CONSULTANT RESPONSIBILITIES

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

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Laboratory Director (LD), the Technical Consultant (TC) failed to include the direct observation of performance of instrument maintenance and function checks in the evaluation of the competency of Testing Personnel (TP) #2. All patients tested under the subspecialty of virology from 10/05/2020 to 05/13/2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure titled " BowTie Medical Ohio-Lyndhurst Lab Personnel Competency Assessment Policy" approved and signed by the Laboratory Director on 05/18/2021 and provided on the date of the inspection found the following statement: "5.1.1 Competency Assessment ...4. Direct observations of performance of instrument maintenance and function checks." 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 01/06/2021, revealed two individuals indicated as TP. 3. The inspector requested the laboratory's 2020 competency assessment records for TP#2 that included the direct observation of performance of instrument maintenance and function checks from the LD. The LD provided a problem solving quiz titled "LAB.GEN.001#1" for TP#2. The LD was unable to provide the requested documentation on the date of inspection. The interview occurred on 05/13/2021 at 10:20 AM.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES

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

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Laboratory Director (LD), the Technical Consultant (TC) failed to include the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in the evaluation of the competency of Testing Personnel (TP) #2. All patients tested under the subspecialty of virology from 10/05/2020 to 05/13/2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure titled " BowTie Medical Ohio-Lyndhurst Lab Personnel Competency Assessment Policy" approved and signed by the Laboratory Director on 05/18/2021 and provided on the date of the inspection found the following statement: "5.1.1 Competency Assessment ...5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples." 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 01/06/2021, revealed two individuals indicated as TP. 3. The inspector requested the laboratory's 2020 competency assessment records for TP#2 that included the assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples from the LD. The LD provided a problem solving quiz titled "LAB.GEN.001#1" for TP#2. The LD was unable to

provide the requested documentation on the date of inspection. The interview occurred on 05/13/2021 at 10:20 AM.