

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0655961	(X3) Date Survey Completed 08/19/2019
Name of Provider or Supplier Belmont Community Hospital	Street Address, City, State 4697 Harrison Street, Bellaire, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based of policy and procedures review, document review, and interviews with the Chief Technician and Administrative Laboratory Director, laboratory personnel failed to follow the written procedure manual for Proficiency Testing (PT) samples on three out of three test events. Findings include: 1. Review of the laboratory policy manual, "Policy Number: Laboratory 4.1, Subject: Proficiency Testing", approved by the Laboratory Director 03/29/2017, section 3.0 states, "CAP surveys are mailed to the laboratory and then distributed to the appropriate department." 2. Review of the College of American Pathology (CAP) shipping labels revealed the following address: "Wheeling Hospital, 1 Medical Park, Wheeling, WV 26003" 3. The Chief Technician and Administrative Laboratory Director both confirmed three out of three PT samples were shipped to the above laboratory location and documented as received by the receiving department, then transported to the survey location for testing. The Laboratory Administrative Director stated the survey location did not have a receiving department or area to accept shipments. The interviews occurred on 08/19/2019 at 11:47 AM.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and</p>

identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and interviews with the Administrative Laboratory Director and the Chief Technician, the laboratory failed to include the correct name and address of the laboratory location where the blood gas testing was performed on three out of three final test reports reviewed. This deficient practice had the potential to affect all patients tested under the specialty of chemistry. Findings Include: 1. Review of three out of three test reports revealed the following address: Wheeling Hospital Affiliated Laboratories 1 Medical Park, Wheeling, WV 26003 Edward Adamovich, MD, Director 2. The Administrative Laboratory Director and the Chief Technician confirmed the name and address of the laboratory location where the testing was performed was not correct. The interview occurred on 08/19/2019 at 12:45 PM.

D5807

TEST REPORT

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Administrative Laboratory Director, the laboratory failed to report the correct pH normal range values for two out of two male patient test reports reviewed. This deficient practice had the potential to affect all male patients tested under the specialty of chemistry. Findings include: 1. Review of the laboratory's policy and procedure titled "BGAS03.005-CH, Table 7.2 Normal Ranges", revealed the following ranges: Parameter Male Normal Range Female Normal Range pH 7.34 - 7.44 7.35 - 7.45 2. Review of two male blood gas test reports and one female blood gas test report found the normal pH value range listed as 7.35 - 7.45. 3. An interview with the Laboratory Administrative Director, confirmed the male pH normal ranges listed on the test reports was wrong. The interview occurred 08/19/2019 at 12:55 PM.