

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D1035294	<b>(X3) Date Survey Completed</b>  12/07/2021
<b>Name of Provider or Supplier</b>  Brunswick Urgent Care	<b>Street Address, City, State</b>  3185 Route 27, Franklin Park, NJ	
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>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to ensure that all TP who performed Hematology and Chemistry tests participated in the Academy of Family Physician (AAFP) PT events in the calendar years 2020 and 2021. The finding includes: 1. A review of all PT events revealed that only two out of seventeen TP performed PT for all events in 2020 and 2021. 2. The TP #3 listed on CMS form 209 confirmed on 12/7 /21 at 11:33 am that PT events were not rotated between TP.</p>
<b>D2121</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to attain at least 80% or more for Hematology test performed on the Horiba ABX Micros 60 analyzer with the Academy of Family Physician (AAFP) in the 2021-A event. The finding includes: 1. The laboratory scored as follows in AAFP event 2021-A: a. 20% for Lymphocyte in percent, and Granulocyte Abs #. b. 40% for Lymphocyte Abs #. c. 60% Monocyte</p>

	<p>/Mixed in percent. 2. The TP #3 listed on CMS form 209 confirmed on 12/7/21 at 11:30 am the laboratory failed to achieve at least 80% for Hematology testing.</p>
<p><b>D2128</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to undertake appropriate training and employ technical assistance necessary to correct problems associated with PT failures performed on the Horiba ABX Micros 60 analyzer with the Academy of Family Physician (AAFP) in the 2021-A. The findings include: 1. There was no remedial action taken and documented for unacceptable Hematology results in event 2012-A with AAFP as follows: a. 20% for Lymphocyte in percent, and Granulocyte Abs #. b. 40% for Lymphocyte Abs #. c. 60% Monocyte/Mixed in percent. 2. The TP #3 listed on CMS form 209 confirmed on 12/7/21 at 11:30 am that corrective action was not documented for the unsatisfactory PT performance.</p>
<p><b>D5209</b></p>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP) the laboratory failed to follow its policies and procedures for assessing the competency of TP who perform routine chemistry testing performed on the Abbott i-stat analyzer in the calendar years 2020 and 2021. The findings include: 1. The CA was not performed on fourteen out of fourteen TP for the i-Stat in 2020 and 2021. 2. The laboratory CA policy stated that testing personnel are evaluated annually. 3. The TP #3 listed on the CMS form 209 confirmed on 12/7/21 at 10:20 am the laboratory did not use the follow the CA procedure.</p>
<p><b>D5401</b></p>	<p><b>PROCEDURE MANUAL</b> 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>

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to follow their PM Calibration Procedure for Hematology tests performed on the Horiba Micros 60 from 6/11/19 to the date of survey. The findings include: 1) The PM stated as follows: a. "5. Run reproducibility preferably using a fresh normal patient 10 times" b. "6. Calculate the coefficient of Variation to confirm that the following parameters are not greater than the following: WBC = 2.5%, RBC = 2.0%, HGB = 1.5%, HCT = 2.0%, HCT = 2.0%, PLT = 5.0%". c. "9. Verify Controls: Run all control levels" d. "10. Attach all paper work for documentation/inspection purposes". 2) The TP #3 listed on CMS form 209 confirmed on 12/7/21 at 11:45 am the PM was not followed.

**D5411**

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

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Manufacturers Package Insert (MPI), lack of Chemistry work records and interview with the Testing Personnel (TP), the laboratory failed to follow the MPI for i-STAT CHEM8+ Cartridges used for chemistry tests from January 2020 to the date of the survey. The finding includes: 1. The MPI stated the "The i-STAT quality control regimen comprises four aspects" aspect 3. "liquid materials are used to verify the performance of a batch of cartridges when they are first received or when storage conditions are in question.". 2. There was no documented evidence that the laboratory verified the performance of cartridges when they are first received. 3. The TP #3 listed on CMS form 209 confirmed on 12/7/21 at 11:10 am the laboratory did not follow the MPI.

**D5437**

CALIBRATION AND CALIBRATION VERIFICATION  
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:  
Based on surveyor review of Calibration Verification (CV) records, Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to perform and document Calibration procedures at least once every six months for

Hematology Tests performed on the Horiba ABX Micros 60 analyzer in the calendar year 2020. The findings include: 1. A review of CV records revealed that the laboratory performed CV once in the calendar year 2020. 2. The TP #34 of CMS form 209 confirmed on 12/7/21 at 10:30 am that the laboratory failed to perform and document CV once every six months.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on lack of Calibration Verification (CV) records and interview with the Testing Personnel (TP), the laboratory failed to perform and document CV procedures at least once every six months for Chemistry testing on the i-Stat analyzer in the calendar year 2020 and 2021. The TP #3 listed on CMS form 209 confirmed on 12/7/21 at 12:00 pm CV was not performed every six months.

**D5447**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records and interview with Testing Personnel (TP), the laboratory failed to perform and document two levels of external controls on each day of patient testing for CHEM8+ tests run on the i-Stat analyzer from January 2020 to the date of the survey. The findings include: 1. The laboratory reported CHEM8+ results but there was no documented evidence that QC

was performed every day of patient testing. 2. The laboratory performed approximately 36 CHEM8+ tests annually. 3. The TP #3 listed on CMAS form 209 confirmed on 12/7/21 at 11:20 am that two levels of QC were not run each day of patient testing.

**D5469**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of QC used for Chemistry tests performed on the i-Stat analyzer from January 2020 to the date of the survey. The finding includes: 1. i-Stat controls had no documented evidence that QC verification was performed. 2. The TP #3 listed on CMS from 209 confirmed on 12/7/21 at 11:00 am that assayed QC material was not verified before putting in use.

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(3)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on the lack of Performance Specification (PS) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that PS procedures for Chemistry tests performed on the iStat analyzer were adequate from 1 /20/20 to the date of survey. The TP #3 listed on CMS from 209 confirmed on 12/7/21 at 11:40 am that PS were not adequate.