

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0301022	(X3) Date Survey Completed 10/21/2020
Name of Provider or Supplier Bbh Scn Princeton Pulmonology	Street Address, City, State 817 Princeton Ave Sw, Pob 2, Suite 199, Birmingham, AL	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records, personnel files, and an interview with the Laboratory Director, the laboratory failed to ensure the laboratory director signed attestation statements and ensure instrument printouts were retained. This was noted on two of the five 2019-2020 survey events reviewed. The findings include: 1. A review of the API PT attestation statements revealed Testing Personnel #1 had signed as the laboratory director for 2020 Events #2 and #3. 2. A review of the personnel files revealed Testing Personnel #1 had a high school diploma and cannot qualify as the Laboratory Director's designee. 3. A review of the PT records for the 2019 Event #2 and 2020 Event #1 surveys revealed no instrument printouts. The surveyor further noted printouts from other surveys were barely legible. 4. During an interview conducted on 10/21/2020 at 11:25 AM, the Laboratory Director confirmed the above noted findings.</p>

The Director further stated the laboratory had been unable to locate the missing instrument printouts, and she had noticed the printouts for other survey events were fading. .

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on a review of the Operator's Manual for the OPTI CCA-TS2 Arterial Blood Gas analyzer, a lack of maintenance records, and an interview with the Laboratory Director, the laboratory failed to document and perform maintenance as recommended by the manufacturer. The findings include: 1. A review of the Operator's Manual in section 7 Maintenance (pages 7.1 - 7.2) specified weekly, quarterly, and annual maintenance are required for the OPTI CCA-TS2. 2. There were no records available during the survey documenting maintenance had been performed. 3. During an interview conducted on 10/21/2020 at 11:30 AM, the Laboratory Director confirmed the laboratory had no maintenance records for the OPTI CCA-TS2. .

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 a review of the Operator's Manual for the OPTI CCA-TS2 Arterial Blood Gas analyzer, a lack of calibration records for the "tHb" (Hemoglobin) channel, and an interview with the Laboratory Director, the laboratory failed to ensure calibrations were performed every three months as recommended by the manufacturer. The findings include: 1. A review of the OPTI CCA-TS2 records revealed no tHb channel calibrations since patient testing started in March 2019. 2. A review of the OPTI CCA-TS2 Operator's Manual in Section 4 "CALIBRATION AND QUALITY CONTROL" revealed, "...calibration of the tHb channel is required every 3 months. This calibration is performed using the tHb calibration cassette ... The tHb calibration verifies the measurement optics and electronics and corrects any potential drift. ...". 3. During an interview conducted on 10/21/2020 at 11:02am, the Laboratory Director confirmed the tHb calibration had not been performed because the laboratory needed to order a tHb calibration cassette. .

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 a review of the Operator's Manual for the OPTI CCA-TS2 Arterial Blood Gas (ABG) analyzer, a lack of calibration verification records, and an interview with the Laboratory Director, the laboratory failed to perform calibrations verifications at least every six months as per CLIA regulations. The findings include: 1. A review of the OPTI CCA-TS2 records revealed no calibrations verification records since patient testing began in March 2019. 2. A review of the Operator's Manual for the OPTI CCA-TS2 revealed ABG cassettes are calibrated at the factory. When the ABG cassettes are used at the laboratory, the barcode is scanned, then a verification of the factory calibration and a "zero-point calibration" are automatically performed. Analytes calibrated with less than three calibrators must have a calibration verification performed every six months as per CLIA regulations. 3. During an interview at 9:45 AM on 10/21/2020, the Laboratory Director confirmed the laboratory had not performed any calibration verifications since March 2019. .

D5805

TEST REPORT

CFR(s): 493.1291(c)

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 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 reviews of patient results and interviews with the Laboratory Director and Testing Personnel #1, the laboratory failed to ensure patient reports included a second patient identifier. This was noted on two of two patient reports reviewed. The findings include: 1. On 10/21/2020 at 9:30 AM, the surveyor reviewed the "ABG & Lab" form which served as both the requisition and patient results reporting form. The surveyor reviewed results from Patient #1 and Patient #2; both reports included the patients' names, however the "Chart #" field was blank on both. 2. During an interview conducted on 10/21/2020 at 09:40 AM, the Laboratory Director and Testing Personnel #1 stated the EMR (Electronic Medical Record) did not have a chart number. The surveyor noted Patient #2 had a common name, and explained CLIA regulation required a second patient identifier to ensure positive patient identification. This can be an accession number, a date of birth, or any other unique identifier. SURVEYOR ID #32558 Licensure and Certification Surveyor