

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1062238	(X3) Date Survey Completed 02/20/2019
Name of Provider or Supplier Baylor Scott & White The Heart Hospital -	Street Address, City, State 2813 South Mayhill Road, Denton, TX	
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Revisit 02/19/2019 through 02/20/2019 New condition level deficiency. Based on review of the CMS 155 report and College of American Pathologists (CAP) proficiency testing (PT) records, the laboratory failed to successfully participate in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the specialty of chemistry for the blood gas analyte pO2. Refer to D2096.</p>
D2088	ROUTINE CHEMISTRY

CFR(s): 493.841(b)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:

Revisit 02/19/2019 through 02/20/2019 New deficiency. Based on review of CMS 155 report, College of American Pathologists (CAP) proficiency testing (PT) records and in interview with staff, the laboratory failed to attain an overall testing event score of at least 80% for the specialty of chemistry for 1 of 3 events in 2018 (2018-1). Findings included: 1. Review of the CMS 155 report for the laboratory's PT scores 2018-1 revealed an overall testing event score of at least 80%, as follows: Event 1 - Routine Chemistry 36% 2. Review of CAP PT records for chemistry 2018 - 1 revealed an overall testing event score of 36%. 3. During an interview on 02/20/2019 at 5:00 pm, the Technical Consultant and Testing Person -2 confirmed the above findings.

D2096

ROUTINE CHEMISTRY

CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Revisit 02/19/2019 through 02/20/2019 New deficiency. Based on review of CMS 155 report, College of American Pathologists (CAP) proficiency testing (PT) records and in interview with staff, the laboratory failed to achieve satisfactory performance (80% score or greater) for the same analyte in two out of three testing events in the specialty of chemistry for the analyte pO₂. Two out of three unsatisfactory scores results in unsuccessful PT performance. Findings included: 1. Review of the CMS 155 report for the laboratory's PT scores in 2018 (Events 1 and 3) revealed unsatisfactory scores, as follows: Event 1 - pO₂ 0% Event 3 - pO₂ 60% 2. Review of CAP PT records for blood gases in 2018 revealed the following for Event 1 and 3 (AQ-A, AQ-C): Event 1 - PT company original evaluation included code "[24] = Incorrect response due to failure to provide a valid response" (04/10/2018). The scores for pH, pO₂, and pCO₂ were 0% (Unsatisfactory). Corrective action stated, "Self evaluation due to machine code not submitted." Event 3 - PT company original evaluation was dated 10/22/2018 and included a score for pO₂ of 60% (Unsatisfactory). Corrective action stated, "Based on the data collected the failures originally noted were due to tech error and not analyzer error." The unsatisfactory scores above resulted in unsuccessful PT performance for pO₂. 3. During an interview on 02/20/2019 at 5:00 pm, the Technical Consultant and Testing Person -2 confirmed the above findings.

D3031

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:
Revisit 02/19/2019 through 02/20/2019 New deficiency. Based on review of laboratory records and confirmed in interview, the laboratory failed to retain all package inserts for erythrocyte sedimentation rate (ESR) quality control (QC) material for 1 of 3 sets of lot numbers in 2018. Findings: 1. Review of ESR records revealed the laboratory failed to retain the package insert for the following QC lot: Level 1: Lot #72681380, expiration date 09/25/2018 Level 2: Lot # 72681381, expiration date 09/25/2018 2. During an interview on 02/20/2019 at 11:35 am, the technical consultant confirmed the laboratory failed to retain all ESR QC material package inserts.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

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:
Revisit 02/19/2019 through 02/20/2019 New deficiency. Based on review of the laboratory's test menu, College of American Pathologists (CAP) proficiency testing (PT) records, and in interview with staff, the laboratory failed to verify the accuracy of tests performed not included in subpart I of this part, at least twice annually (2018). Findings included: 1. Review of the laboratory's test menu revealed the following analytes were measured on the OPTI CCA - TS2 (installed 05/2018): pCO₂ pO₂ pH tHb SO₂ K⁺ (potassium) The laboratory was enrolled in CAP PT company for pCO₂, pO₂, pH, and K⁺. The laboratory was not enrolled in PT for tHb and SO₂ and did not verify accuracy of the non-regulated analytes, at least twice annually in 2018. 2. During an interview on 02/20/2019 at 5:00 pm, the Technical Consultant and Testing Person - 2 confirmed the above findings.

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:
 Revisit 02/19/2019 through 02/20/2019 New deficiency. Based on review of the laboratory's policy, manufacturer's instructions, calibration verification, and in interview with staff, the laboratory failed to perform and document calibration verification for all OPTI CCA - TS2 analytes (07/2018, 01/2019). Findings included:
 1. The laboratory's policy for blood gas analysis did not include calibration verification procedures. Refer to D5403. 2. Review of the operator's manual (manufacturer's instructions) for OPTI CCA - TS2 (page 4-3) stated, "4.4 Calibration Verification: A calibration verification kit is available from OPTI Medical for all parameters except tHb and SO2. For calibration verification of tHb and SO2, OPTI Medical recommends testing whole blood against a reference analyzer." 3. The laboratory performed and documented calibration verification with OPTI Medical for all analytes except tHb and SO2 on 07/26/2018 and 01/17/2019. The laboratory did not follow manufacturer's instructions for "testing whole blood against a reference analyzer" to meet the calibration verification requirement of tHb and SO2. 4. During an interview on 02/20/2019 at 5:00 pm, the Technical Consultant and Testing Person 2 confirmed the above findings.

D5783

CORRECTIVE ACTIONS
 CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
 Revisit 02/19/2019 through 02/20/2019. This is a new deficiency. Based on direct observation, review of the laboratory policy, corrective action logs for the Beckman Coulter AU 680 chemistry analyzer, quality control (QC) data, patient test reports, and staff interview, the laboratory failed to have an effective system to document corrective action for unacceptable QC runs and patient remediation from the last acceptable QC run for routine chemistry testing for 50 of 92 days from 06/2018, 07/2018 and 08/2018. Findings included: 1. A tour of the laboratory on 02/19/2019 at 1330 hours revealed the laboratory utilized a Beckman Coulter AU680 (Serial Number 6014557) chemistry analyzer for testing the following analytes: Albumin (ALB) Alkaline Phosphate (ALP) Alanine Aminotransferase (ALT) Amylase (AMY) Aspartate Aminotransferase (AST) Blood Urea Nitrogen (BUN) Calcium (Ca) Cholesterol (Chol) Chloride (Cl) Carbon dioxide (CO2) Creatinine (Creat) Direct Bilirubin (DBili) Glucose (Glu) High Density Lipoprotein (HDL) Iron (Fe) Potassium (K) Low Density Lipoprotein (LDL) Lipase (Lip) Magnesium (Mag) Sodium (Na) Phosphate (Phos) Total Bilirubin (TBil) Total Protein (TP) Triglycerides (Trig) Prealbumin Vancomycin C-Reactive Protein (CRP) Hemoglobin A1C (HgbA1C) 2. The laboratory policy titled "Quality Control Program" stated, "QC is to be run following the manufacturer's instructions without modification. Following the manufacturer's instructions includes:4) Performing and documenting remedial action when errors or problems are identified. Remedial action involves

troubleshooting the assay system using appropriate QC data, and fixing the problem. Repeat the analytical run. If the QC is now within acceptable limits, patient results may be reported. If QC is still unacceptable, the next steps include instrument recalibration, new controls, new reagents, and instrument. The assay must be brought into range before patient results can be reported. It is important that all remedial steps be documented. If patient results are delayed due to an assay problem, the laboratory must notify the appropriate individual." 3. Review of the "Monthly QC Summary" for 06/2018, 07/2018 and 08/2018 revealed the following entries: June 2; Iron QC out; new lot of rgt on board; no patients run today June 3; Iron QC still out June 4; Iron & DBil out Iron bad calibration DBili old QC June 5; Iron, Phos, Mag, ALP- New QC affects results June 6; Lipase out-new reagent no patient testing done today June 7; DBil & Lipase out; no patient testing done June 8; DBil & Lipase out; no patient testing done June 9; DBil & Lipase out; no patient testing done June 10; Dbil & Lipase out; no patients run June 11; DBil & Lipase out- changed mean of DBil-Lipase Recal no patients run with these analytes June 15; Iron, Phos, BUN, -Rerun Iron, Phos in, BUN recal -in June 16; Phos, DBil, TBil, out-Rerun-Phos passed; calibrated and run w/new QC- DBil & TBil passed June 22; HDL, CO2, TBil rerun pass, Chol, TP, ALT, LDL, ALB, Creat -rerun fail-recal June 23; Creat & TP failed QC- recal & rerun June 27; Creat- Bad Cal- recal pass July 4; HDL cal out, reran mixed and passed July 11; CO2 out-reran fail-recal fail-new QC fail-mix QC rerun pass July 13; HgbA1C- Cal fail-no pts run July 14; TBil out-reran-recal failed-new rgt-passed July 18; Creat, Iron, BUN, Glu, Phos- bad cal- made new cal- pass July 20; HgbA1C-Recal-open new QC July 21; Probe error-cleaned probe; CO2 and Lip QC out-new QC passed July 22; Sodium & Cl- outliers-recal'd serum ISE-passed July 24; HDL-old reagent-replace-passed July 28; CO2 calibration failed-new cal aliquot-passed August 4; Chol August 5; Alb, Alt, Trig, -multiple issues-no patient specimens run August 6; Alb, Chol, Glu, Mag, Phos August 7; Chol, Glu, Phos, Alb, Creat August 8; Iron August 9; Iron August 10; Glu August 12; Na, Chol, Iron, Alb August 13; Alt, Na, Chol, Iron August 14; Chol, Glu August 15; ALP, Glu, Phos, DBil, TBil, Trig August 17; Na, Chol August 19; Trig QC error, Cal & new QC -passed August 20; HDL, Chol, Iron August 21; Chol, Iron August 22; Trig, Lip August 23; Iron August 24; Alb August 25; Chol, TP, Trig, Iron, Alb August 26; Trig, Alb August 27; Chol, Gluc August 28; Iron August 29; Na, DBil, Iron, BUN August 30; Phos, Trig August 31; Glu These entries did NOT indicate which level(s) of control was unacceptable and did NOT include detailed remedial steps performed to bring QC within acceptable limits. "No patients run" for the specific date was noted on the log but the laboratory failed to document patient remediation from the last acceptable QC run if more than a remix /rerun of QC material was performed. The laboratory was asked to provide documentation of patient remediation from the last acceptable QC run. No documentation was provided. 4. The following is random review sample of patients tested that required remediation from the last acceptable QC run: Patient 3597; TP, ALT, ALB, Creat tested 06/21/2018; QC failures occurred 06/22/2018 for these analytes; no documentation of remediation Patient 3602; TP, Creat tested on 06/22 /2018; QC failures occurred 06/23/2018 for these analytes; no documentation of remediation Patient 3633; CO2 tested on 07/27/2018; QC failures occurred 07/28 /2018 for this analyte; no documentation of remediation Patient 3624; CO2 tested on 07/27/2018; QC failures occurred 07/28/2018 for this analyte; no documentation of remediation Patient 3629; CO2 tested on 07/27/2018; QC failures occurred 07/28 /2018 for this analyte; no documentation of remediation Patient 3636; CO2 tested on 07/27/2018; QC failures occurred 07/28/2018 for this analyte; no documentation of remediation 5. In an interview on 02/19/2019 at 1405, the laboratory manager confirmed the above findings. Word Key: Rgt=reagent Recal=Recalibration