

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0313702	(X3) Date Survey Completed 08/01/2018
Name of Provider or Supplier Baptist Memorial Medical Group Inc -Utim And Tmg	Street Address, City, State 8040 Wolf River Blvd Suite 102, Germantown, TN	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the maintenance records for the Sysmex XN 2000 instrument, and interview with the laboratory supervisor, the laboratory failed to retain background counts for the Sysmex XN 2000 instrument for 2 years in 2016 and 2017. The findings include: 1. Observation of the laboratory on August 1, 2018 at 8:30 am revealed the Sysmex XN 2000 instrument in use for patient testing for performance of complete blood count (CBC). 2. Review of the maintenance records for the Sysmex XN 2000 instrument revealed that the background counts for the Sysmex XN 2000 instrument are stored in the instrument database. The last retrievable background count was for January 18, 2017. 3. Interview with the laboratory supervisor on August 1, 2018 at 4:30 pm confirmed the laboratory failed to retain background counts for two years for the Sysmex XN 2000 instrument in 2016 and 2017.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p>

This STANDARD is not met as evidenced by:

Citation #1 Based on review of the laboratory's policy titled "Quality Assurance Management Plan", the laboratory's 2016, 2017 and 2018 proficiency testing evaluation reports from the laboratory's proficiency testing provider-Medical Laboratory Evaluation (MLE), and interview with the laboratory supervisor, the laboratory failed to follow the Quality Assurance Management Plan for evaluation of proficiency testing in 2016, 2017, and 2018 for 7 of 7 proficiency testing events. The findings include: 1. Review of the laboratory's policy titled "Quality Assurance Management Plan" revealed the following statements under the section titled "Proficiency Testing": "We will carefully evaluate all results in a timely manner. Any unacceptable, unsatisfactory or unsuccessful grade will result in an investigation to determine cause and a corrective action if needed." "If a challenge is not graded for any reason the challenge will be self graded using the data in the summary book." 2. Review of the MLE 2016 event two proficiency testing evaluation report revealed the following: Neutrophils percent-sample # MX-8 graded as unacceptable-no corrective action for unacceptable score; ALT/SGPT-sample #s CH-6, CH-7, CH-8, CH-9, CH-10-Not graded-no self-evaluation of results. 3. Review of the MLE 2016 event three proficiency testing evaluation report revealed the following: Neutrophils percent-sample # MX-11 graded as unacceptable-no corrective action for unacceptable score; Lymphocytes percent-sample # MX-11 graded as unacceptable-no corrective action for unacceptable score; ALT/SGPT-sample # CH-15-graded as unacceptable-no corrective action for unacceptable score; Amylase-sample # CH-12-graded as unacceptable-no corrective action for unacceptable score. 4. Review of the MLE 2017 event one proficiency testing evaluation report revealed the following: Triglyceride-sample # CH-3-Not graded-no self-evaluation of results. 5. Review of the MLE 2017 event two proficiency testing evaluation report revealed the following: CO2-sample # CH-6-graded as unacceptable-no corrective action for unacceptable score. 6. Review of the MLE 2017 event three proficiency testing evaluation report revealed the following: Hematocrit-sample # MX-12 scored as unacceptable with no corrective action for unacceptable score; LDL Cholesterol-Calculated-sample #s CH-12 and CH-13 scored as unacceptable with no corrective action for unacceptable scores; NT-proBNP sample numbers CK-13, CK-14, CK-15 scored as Not Graded with no self-evaluation of results. 7. Review of the MLE 2018 event one proficiency testing evaluation report revealed the following: Albumin-sample # CH-3 scored as unacceptable-no corrective action for unacceptable score; Testosterone sample # SC-1 scored as unacceptable-no corrective action for unacceptable score. 8. Review of the MLE 2018 event two proficiency testing evaluation report revealed the following: Troponin I sample # CK-10 scored as Not Graded-no self-evaluation of results. 9. Interview with the laboratory supervisor on August 1, 2018 at 1:00 pm confirmed the laboratory failed to follow policy for evaluation of proficiency testing when it did not perform corrective action for unacceptable scores or perform self-evaluation of non-graded scores in 2016, 2017, and 2018 for 7 of 7 proficiency testing events.

Citation #2 Based on review of the laboratory's policy titled "Quality Assurance Management Plan", the documents used for reviewing quality control for the Sysmex XN 2000 instrument used for performing complete blood count (CBC) patient testing, interview with Sysmex technical assistance center employee and interview with the laboratory supervisor, the laboratory's quality assessment was ineffective when it failed to review daily quality control for the Sysmex XN 2000 CBC instrument in 2016, 2017, and 2018. The findings include: 1. Review of the laboratory's policy titled "Quality Assurance Management Plan" revealed the following statement: "We will evaluate our Quality Control Program for calibration and control data for each test method used in the lab."

2. Review of the documents used for quality control review for the Sysmex XN 2000 CBC instrument revealed monthly review performed using only the Sysmex Interlaboratory Quality Assurance Program (IQAP) reports. 3. Interview by phone on August 6, 2018 at 3:30 pm with a Sysmex technical assistance center representative confirmed that the IQAP reports are a comparison of the laboratory's cumulative mean and standard deviation and how those values compare with their peers using the same instruments. The program does not evaluate the raw data against the laboratory's expected quality control ranges for acceptability. 4. Interview by phone on August 7, 2018 at 12:30 pm with the laboratory supervisor confirmed the laboratory is using the IQAP reports from Sysmex as the final quality control review, is not reviewing the daily quality control, and their quality assessment process for the Sysmex XN2000 CBC instrument was not effective in 2016, 2017, and 2018.

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 observation of the laboratory, review of the manufacturer calibrator package insert, the manufacturer operator manual and interview with the laboratory supervisor, the laboratory failed to verify the calibration of the Tosoh G8 instrument using at least a minimal, mid-point and maximum value near the upper limit of the range at least every 6 months in 2016, 2017, and 2018. The findings include: 1. Observation of the laboratory on August 1, 2018 at 8:30 am revealed the Tosoh G8 instrument in use for patient testing for hemoglobin A1c. 2. Review of the Hemoglobin A1c calibrator package insert for lot ZS7001 revealed that calibration is performed using only 2 calibrators with calibrator values of 5.7% and 10.9%. 3. Review of the manufacturer operator manual for the Tosoh G8 instrument revealed a measuring range of 4.0 - 16.9%, and a calibration performed using two points for the Hemoglobin A1c. 4. Interview with the laboratory supervisor on August 1, 2018 at 5:00 pm confirmed that the laboratory failed to verify the calibration of the Hemoglobin A1c performed on the

Tosoh G8 instrument when it did not perform additional calibration verification studies using at least 3 levels that spanned the reportable range of the instrument in 2016, 2017, and 2018.