Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0303802	06/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Medical Center Barbour	820 W Washington Street, Eufaula, 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
D3035	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(ii) In addition, the laboratory must retain immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d). This STANDARD is not met as evidenced by: Based on a review of the Blood Banking records and an interview with the General Supervisor, the laboratory failed to document the lot numbers and expiration dates for the gel cards used for antibody screening since the previous survey (on 6/29/2016). The findings include: 1. During the entrance tour on 6/28/2018 at 9:30 AM, the General Supervisor included Antibody Screening using gel cards on the Blood Bank test menu. 2. A review of the Blood Bank records revealed the laboratory performed daily quality control on the antibody screen gel cards and other reagents, however the lot number and expiration dates of the cards was never documented. 3. During an interview with the General Supervisor on 6/28/2018 at 11:20 AM, the surveyor asked if the laboratory had a record of the lot numbers and expiry dates for gel cards in use for antibody screening for the last two years. The Supervisor referred to her records, and stated she had never noticed there was no place on the the Blood Bank QC log for the staff to record this information. Thus, the above noted finding were confirmed. .
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 Beckman Coulter UniCel DxH 800 Hematology analyzer calibration records, quality control records, and an interview with the General Supervisor, the laboratory failed to follow the manufacturer's instructions to verify calibrations by running quality controls (QC) for one out of three 2017 calibrations of the Hematology analyzer. The findings include: 1. A review of calibration records for the Beckman Coulter DxH 800 revealed the instrument was calibrated on 7/31/2017 at 7:54 AM. 2. A review of the QC records revealed three levels of QC were run between 7:08-7:15 AM on this date, however the General Supervisor was unable to provide documentation of QC performed after the calibration at 7:54 AM on this date. 3. A review of the Calibration guidelines (available on a CD provided with the instrument, and thru the internet) revealed, in "Chapter 11 Quality Assurance ... Calibrate with Coulter S-CAL Calibrator ... 12. Verify your calibration with controls. ..." 4. During an interview on 6/27/2018 at 2:55 PM, the General Supervisor confirmed she was unable to find records of QC performed after the 7/31/2018 calibration, since the analyzer does not store data from earlier QC lot numbers. The Supervisor further stated laboratory policy stated testing personnel were supposed to run QC after all calibrations, thus confirming the above noted findings. .
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of Microbiology records and an interview with the General Supervisor, the surveyor determined, the laboratory failed to document the sterility and appearance of the physical characteristics of the media, and to check each lot number for the ability to support growth, and as appropriate, select or inhibit specific organisms. The findings include: 1. During the initial tour of the laboratory on 6/27/2018 at approximately 9:30 AM, the General Supervisor provided a laboratory menu that included Urine, Wound, Sputum, Throat, and Blood Cultures performed on site. When asked about the procedure, the Supervisor explained the testing personnel set up the specimens on culture media (Blood, Chocolate, Mannitol, EMB [Eosin Methylene Blue], and Urine "Bi-plates" [Blood/MacConkey] agar); then bacterial growth had identification and sensitivities performed on the Vitek 2. 2. A review of the records in Microbiology revealed the facility routinely performed visual and sterility inspections on the Chocolate agar, and checked each new lot number of the media's ability to select and inhibit specific organisms. However there were no QC

	records for the other types of culture media. 3. A further review of the records revealed the staff documented the appearance of some lot numbers of media on the shipping invoices when received in the laboratory. However, some of the shipping invoices were missing (as evidenced by the fact that not all of the lot numbers of Chocolate media in the above QC records were listed on the retained shipping invoices). 4. During an interview on 6/28/2018 at 9:30 AM, the General Supervisor confirmed the testing personnel was not documenting visual inspections and sterility checks for all lot numbers and shipments of media because the laboratory did not always receive the invoices from the hospital's shipping department. The laboratory had only performed and documented the QC on the Chocolate agar because they thought this was all that was required. 5. As the interview continued the Supervisor was then asked if the laboratory performed on-site QC (for the Blood Mannitol, EMB, and "Bi-plates") to check each lot number for the ability to support growth, and as appropriate, select or inhibit specific organisms, or if they had implemented an optional IQCP (Individualized Quality Control Plan) in 2016 with a QC Plan (and other required elements) that specified the manufacturer's QC was acceptable. The supervisor stated the lab did ensure each lot number of Blood and Chocolate had the ability to support growth when they re-grew the QC organisms each week (with no documentation of the lot numbers of media used). However, there was no record of QC for the other media types, and there was no documentation the laboratory had implemented an optional IQCP for the culture media in 2016 after the previous survey. Thus the above noted findings were confirmed. .
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a lack of Quality Control (QC) records for body fluid cell counts performed manually on the hemocytometer, and an interview with General Supervisor, the laboratory failed to ensure testing personnel documented and performed at least one level of QC in duplicate each eight hours before performing patient testing in 2016 - 2018. The findings include: 1. During the entrance tour on 6/27/2018 at approximately 9:30 AM, the General Supervisor included manual cell counts (using a hemocytometer) on Cerebral Spinal Fluid (CSF) on the Hematology test menu. 2. During the second day of the survey on 6/28/2018 at 11:30 AM, the surveyor requested QC records for manual cell counts on body fluids; the General Supervisor stated the laboratory did not do any QC when performing manual cell counts. The surveyor explained QC in duplicate was required by CLIA whenever manual cell counts on body fluids were performed to ensure the accuracy of the test performance. When asked how many patient tests were performed since the previous survey (on 6 /29/2016), the Supervisor printed a report from the Laboratory Information System, and stated 31 patient CSF cell counts were performed. Thus the above noted findings were confirmed. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)

	(a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of quality assurance documentation and interviews with the General Supervisor, the surveyor determined the laboratory failed to implement and perform effective quality assessment reviews to identify and correct problems identified in the analytical systems. The findings include: 1. A review of quality assurance documentation revealed the laboratory performed quality assurance activities, however the reviews were inadequate to discover and perform corrective action in a timely manner for problems found during the survey in the following areas: A) A review of the the Beckman Coulter (B/C) IQAP (Interlaboratory Quality Assurance Program) report used to assess monthly Quality Control (QC) results from the B/C DxH 800 Hematology analyzer revealed, the General Supervisor signed her review of the reports each month. However a review of five consecutive reports from 4 /22 thru 8/21/2017 revealed the RBCs (Red Blood Cells) and related RBC parameters (such as Hemoglobin and calculated indices) had indications of a problem evidenced by the low calculated CVI (Content Validity Index) and SDI (Standard Deviation Index) statistical evaluations. Additional evidence of a problem with the RBC related parameters included a failing score of 40% for MCV (Mean Corpuscular Volume) on the first proficiency testing event in 2017 performed on 3/29/2017. However, the laboratory failed to investigate the cause of the underlying problems or perform corrective action to resolve the issue. B) A review of calibration records revealed the laboratory failed to ensure testing personnel verified calibrations on the Hematology analyzer by running quality controls as specified by the manufacturer's instructions and laboratory policy. (Refer to D5437.) C) A review of Microbiology records revealed the laboratory failed to document the sterility and appearance of the physical characteristics of the media, and failed to check each lot number for the ability to support growth, and as appropriate, select or inhibit specific organisms (in the absence of an optional Individualized Quality Control Plan). (Refer to D5477.) D) A lack of QC records revealed the laboratory failed to insure QC was performed in duplicate each eight hours of patient testing when manual cell counts were performed on Cerebral Spinal Fluid. (Refer to D5543.) 2. During an interview on 6/28/2018 at 1:50 PM the problems revealed in the IQAP reports were discussed with the General Supervisor, who confirmed she had not investigated the multiple statistical outages. During the exit summation on 6/28/2018 at approximately 2:45 PM, the surveyor's concerns that the lab processes were not being regularly reviewed for problems and missing QC performance was discussed and confirmed with the General Supervisor. SURVEYOR: Laura T. Williams, BS, MT (ASCP)Licensure and Certification Surveyor