Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0304677	11/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Tanner Medical Center East Alabama	1032 Main Street South, Wedowee, 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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing records, and interviews with testing personnel #8 [also the supervisor of the Arterial Blood Gas Unit (ABG)], the technical and general supervisors and laboratory director, the surveyor determined the laboratory failed to implement and document corrective actions for unacceptable results obtained on ABG proficiency testing for three events. This affected Events #1 and #2 of 2017 and Event #3, 2018, three of five testing events reviewed by the surveyor. The findings include: 1. The laboratory scored 80 % (percent) for pCO2 (ABG, Carbon Dioxide) for Event #1, 2017. TP #8 documented no corrective actions to be taken. 2. For Event #2, 2017, the laboratory's results for pCO2, pO2 (Oxygen) and pH (Hydrogen ions) for specimen BG-10 were found to be unacceptable by API. The laboratory failed to implement and document corrective actions for these unacceptable results (less than 100 %). 3. A review of proficiency testing records for Event #3, 2018 revealed the laboratory was given a "Failure to Participate" by API and scored zero percent for the ABGs. A review of the records revealed the laboratory performed proficiency testing on the correct samples; however submitted the results for the incorrect kit (worksheet). The laboratory submitted results for the verification kit, instead of the proficiency testing kit. Because results were submitted for the verification kit, no results were submitted for the proficiency testing kit. The laboratory did not implement nor document corrective actions to ensure correct and timely submission of proficiency testing results. 4. The laboratory's self-evaluation of Event #3, 2018 (Failure to Participate) resulted in an 80 % score for pO2. The laboratory failed to implement and document corrective actions for this less than 100 % score. 5. In an interview on 11/27/18 at 12:50 PM, TP #8 stated she performed the proficiency testing on the correct samples, but submitted the results for

	the incorrect kit (the verification kit), resulting in no submission of results for the proficiency testing samples. 6. In the exit interview on 11/28/18, the surveyor discussed the requirements for corrective actions for unacceptable and non-graded proficiency testing results with the laboratory director and the general and technical supervisors.
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 a review the policy and procedure (ABG 3.1,2,3) for the ISTAT, a review of the installation records, a review of quality control records for Arterial Blood Gases (ABGs), a lack of documentation of an IQCP (Individualized Quality Control Plan), a telephone interview with a manger for the hospital, and an interview with testing personnel (TP) #8, the surveyor determined the laboratory failed to perform testing of at least two levels of quality control for ABGs on each day of patient testing. The findings include: 1. On 11/27/18, the surveyor reviewed the policy, titled Arterial Blood Gas Lab - Quality Control (ABG 3.1,2,3), pages 1 through 3, which included the following: "ISTAT: ...Liquid QC is to be run every 30 days or with a new cartridge lot number or for a remedial action to address a problem. A CalVer is to be run every 6 months..." 2. During a telephone interview on 11/27/18, one of the mangers at the hospital stated the laboratory had an IQCP for the ISTAT, and it could be reviewed in the electronic system. According to this manager the quality control for ABGs were run with each lot change of cartridges or at least every thirty days. 3. The installation records for the laboratory equipment revealed the ISTAT was installed and validated in June of 2017. 4. At 1:30 PM on 11/28/18, the surveyor requested to review the laboratory's IQCP for ABGs. 5. A review of the quality control records revealed two levels of external, liquid quality control were tested once a month from January 2018 through November 28, 2018, with the controls being run twice in June. 6. At 1:58 PM on 11/28/18, TP #8, after contacting the parent company (hospital), stated the laboratory did not have an IQCP. The general supervisor was present during this interview. 7. Patient testing of ABGs occurred throughout this time-frame. 8. During the exit interview on 11/28/18 at approximately 2:30 PM, the quality control requirements for Chemistry testing, in the absence of an IQCP, were discussed with the general and technical supervisors and the laboratory director.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of installation and validation records for Chemistry and

Hematology analyzers, a review of quality control records, a lack of documentation, and interviews with the general supervisor, technical supervisor and laboratory director, the surveyor determined the laboratory director failed to ensure the laboratory established and maintained a quality assessment program to assure routine monitoring of quality control, as well as retention of records. The laboratory director also failed to ensure quality control for Arterial Blood Gases (ABGs) were tested at least every day of patient testing in the absence of an Individualized Quality Control Plan (IQCP). The findings include: 1. Upon tour of the laboratory on 11/27/18 at 9:35 AM, the general manager stated the Chemistry and Hematology and Coagulation instruments were new and installed in August of 2017. The instruments included: a Unicel DxC 600i for routine Chemistry, Endocrinology, and Toxicology testing; DxH 600 for Hematology testing (Complete Blood Cell Counts); and a Stago for Coagulation testing. 2. A review of the installation and validation records revealed all of the above noted instruments were installed in August of 2017. 3. At 10:36 AM on 11/28/18, the surveyor requested to review Hematology quality control records for the DxH 600. The general supervisor stated the quality controls would have to be reviewed on the instrument monitors for Hematology and Chemistry, due to the controls were not printed, but maintained electronically for a two year period. The general supervisor further stated she realized in August of 2018, the Chemistry quality control maintained electronically were altered each time the means were adjusted. Therefore, the ranges would not be reflective of the quality controls in use on the dates prior to August of 2018, when she began to print the quality control data logs. At this time, the surveyor requested to review Hematology quality control, beginning with November of 2017 (when patient testing began at the new laboratory). At this time, the surveyor asked if the general supervisor had monitored the quality control on a routine frequency and documented quality assurance records, which may be reviewed by the surveyor. The general supervisor stated during the period prior to printing the quality control, she monitored the quality control weekly on the instrument, however did not document the quality assurance activities. At 11:00 AM, because the staff were unable to provide the quality control records on the monitor for Hematology as requested, the surveyor asked if the staff could possibly print five months of quality control for review (November 2017 - March 2018), whenever the controls could be located on the flashdrive. Of the time-frame requested, the laboratory was able to provide Hematology quality control records (three levels) for December 9, 2017 - May 15, 2018. November 2017 was never provided for review, and the lab was not able to recall the quality control values. 4. A review of random days of quality controls for the DxC 600i (Chemistry analyzer) for June and July of 2018 revealed of the two levels of quality control tested each day, at least one of the levels appeared out-of-range, sometimes greater than three standard deviations. However, these ranges were not reflective of the acceptable ranges, due to the shifting of the ranges whenever the means were adjusted. 5. At 12:16 PM, the surveyor asked the general supervisor for documentation of each time the means were adjusted. The general supervisor did not provide this documentation. At this time, the general supervisor stated the ranges for Lipase changed with each lot and changed significantly. The general supervisor confirmed the validity of the quality control, prior to August of 2018, could not be determined by a review at this time. 6. The laboratory director, technical supervisor and general supervisor did not identify the lack of sufficient quality control testing of ABGs, in the absence of an IQCP. The laboratory failed to perform at least two levels of quality control each day of patient testing for ABGs, when no IQCP had been established to reduce the frequency of testing the quality control to at least once a month. 7. The above noted findings were discussed during the exit interview with the laboratory director and general and technical supervisors on 11/28/18 at 2:30 PM.

D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of personnel records, an interview with testing personnel #8 [also the supervisor of the Arterial Blood Gas unit (ABG)], and interviews with the technical and general supervisors and laboratory director, the surveyor determined the laboratory director failed to ensure one of nine testing personnel, who perform ABGs was trained, prior to allowing the personnel to perform patient testing. This affected testing personnel (TP #16), one of sixteen total testing personnel for the laboratory. The findings include: 1. The personnel records for TP #16, whose date of hire was documented as October 2018, did not include training documentation. The personnel was listed on the CMS Personnel Form (#209) as one of the testing personnel who perform ABG testing. 2. At 12:50 PM on 11/27/18, the surveyor asked the supervisor of the ABG unit (TP #8) to provide training documentation for TP #16, as well as educational credentials for several laboratory testing personnel. TP #8 stated the employee (TP #16) was new, since October of 2018. TP #8 further stated TP #16 had been checked-off (trained), and was performing patient testing. TP #8 further stated the training records for TP #16 were in HR (Human Resources) for review. 3. On the second day of the survey, 11/28, at 1:30 PM, the surveyor asked if the training records for TP #16 had been returned from HR for the surveyor's review. TP #8 stated the training records could not yet be provided for the surveyor's review. 4. In the exit interview at 2:30 PM on 11/28/18, the surveyor discussed the missing training record for TP #16 with the laboratory director and the technical and general supervisors. Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor