| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 01D0304677 | 09/01/2021 |
| **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 |
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| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the 2019 - 2021 API (American Proficiency Institute) proficiency testing (PT) records and an interview with the Respiratory Therapy (RT) Supervisor, the laboratory failed to ensure attestation statements for four out of eight surveys were signed by the Laboratory Director (LD) and Testing Personnel (TP). The findings include: 1. A review of the API Arterial Blood Gas PT records revealed attestation statements did not include the signatures of the Laboratory Director (LD) and and the Testing Personnel (TP) for the following surveys: A) 2019-Event #1: No signature of the LD B) 2019-Event #2: No signature of the LD or the TP C) 2020-Event #1: No signature of the LD D) 2020-Event #2: No signature of the LD 2. In an interview on 9/1/2021 at 1:10 PM, the RT Supervisor reviewed the PT records with the surveyor, and confirmed the above noted findings. . |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of Hematology records and an interview with the Laboratory |

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| | Manager, the laboratory failed to retain documentation of daily CBC (Complete Blood Counts) quality controls (QC) performed on the Beckman Coulter DxH 600 Hematology analyzer from 11/28/2018 thru 8/19/2020. The findings include: 1. A review of the Beckman Coulter (B-C) DxH 600 Hematology analyzer QC records revealed the laboratory had retained the B-C Interlaboratory Quality Assurance Reports (peer group evaluations) for each CBC QC lot number from December 2018 thru to the current 2021 report, however there was no documentation of the daily CBC QC before 8/20/2020. 2. In an interview in 8/31/2021 at 10:15 AM, the Laboratory Manager explained a B-C technical representative had advised her to store the daily QC data on a USB (Universal Serial Bus) drive. However, the Supervisor stated she had failed to review the USB contents until recently, and realized the data was "gibberish", and possibly corrupted. When she contacted B-C, the representative stated they only retained the QC for each laboratory for a one-year period. The Laboratory Supervisor was only able to obtain the QC from 8/20/2020 to the current date; all previous data was lost. . |
| **D3037** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(4)<br><br>Proficiency testing records. Retain all proficiency testing records for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records and interviews with the Laboratory Manager, and the Respiratory Therapy Supervisor, the surveyor determined the laboratory failed to retain all PT records from the previous survey on 11/28/2018. This affected two of two 2018 surveys performed by the main laboratory (and not reviewed during the previous CLIA survey), and one of eight 2019-2021 surveys performed in Respiratory Therapy. The findings include: 1. A review of the API PT records revealed the main laboratory failed to retain the program forms, attestation statement, instrument printouts, and documentation of review for the 2018 Event #3 Immunohematology (Blood Bank), and the 2018 Event #3 Hematology surveys. 2. In an interview on 8/31/2021 at 10:30 AM, the Laboratory Manager stated she had recently discarded the 2018 PT records due to a lack of space. The surveyor explained the laboratory must retain all PT records that were not reviewed during the previous survey. 3. A review of the API Blood Gas surveys performed in the Respiratory Therapy (RT) Department revealed the laboratory had failed to retain the program forms and the instrument printouts for the 2020 Event #1 survey. 4. In an interview on 9/1/2021 at 1:10 PM, the RT supervisor stated he was not employed until after the above survey event, and was unable to locate any other records. . |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on reviews of personnel files and an interview with the Respiratory Therapy Supervisor (also Testing Personnel #2), the laboratory failed to implement policies |

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| | and procedures ensuring inclusion of all six of the minimal regulatory requirements for assessment of competency of testing personnel performing Arterial Blood Gas (ABG) analyses, since the previous survey on 11/28/2018. The findings include: 1. A review of the Form CMS-209 (Laboratory Personnel Report) revealed eleven testing personnel who performed ABG's in the Respiratory Therapy Department. 2. A review of the on-line Health Stream evaluation checklist, "Respiratory Therapy Annual ABG Competency Checklist" revealed an evaluation with the following categories: "Specimen Collection", "Arterial Punctures", "Safety and Infection Control", "Professional Activities", and "QC/PT [Quality Control/ Proficiency Testing]". The Evaluator indicated "Yes" next to each "Task", and the assessment was electronically signed by Testing Personnel #1 (as listed on the Form CMS-209). 3. During an interview on 9/1/2021 at approximately 1:20 PM, the surveyor reviewed the assessment with Testing Personnel #2 (with Testing Personnel #1 present) and explained the electronic assessment does not include all six of the minimal regulatory requirements for assessment of competency as per CLIA standards. The assessment concentrated on the pre-analytical aspects of collecting the ABG specimen. Only #9 (under Specimen Collection), "Demonstrates the ability of operating, maintaining and troubleshooting the ABG machines", and #1 under "QC/PT", "Participates in monthly external QC, CAP, and other proficiency testing" covered aspects of analytical competency. There was also no indication of how the assessment was made (direct observation, documentation or other means). 4. As the interview continued on 9/1 /2021 at 1:30 PM, the surveyor provided the CMS booklet, "What Do I Need to Do to Assess Personnel Competency?", and reviewed the minimal regulatory requirements for assessment of competency, and noted the current assessment did not include the following: 1) "Direct observation of routine patient test performance..."; the current records did not specify whether the Evaluator actually observed the testing personnel performing patient testing. 2) "Monitoring the recording and reporting of test results"; there was no documentation of this assessment. ... 4) "Direct observation of performance of instrument maintenance and function checks"; the current records did not specify whether the Evaluator actually observed the testing personnel performing this task. ... 6) "Assessment of problem solving skills"; there was no indication of how this skill was assessed. The surveyor further explained the competencies should also be reviewed/approved by the Laboratory Technical Consultant or the Laboratory Director. The Respiratory Therapy Supervisor confirmed the electronic competency assessment did not include all regulatory requirements. . |
| **D5447** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(i)(g)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on reviews of the Hematology quality control (QC) records, and an interview with the General Supervisor, the laboratory failed to perform at least two levels of QC each day of patient testing. The surveyor noted one day in 2020 when the laboratory failed to perform QC prior to testing and reporting patient CBC's (Complete Blood Counts). The findings include: 1. A review of the 2020 monthly cumulative QC records for the Beckman Coulter DxH 600 Hematology analyzer revealed no |

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| | documentation of QC on 12/27/2020. 2. During an interview on 9/1/2021 at 10:10 AM, the surveyor reviewed the records with the General Supervisor who confirmed there was no QC performed on 12/27/2020. The surveyor then asked if any patient CBC's were performed that day; the Supervisor reviewed patient reports, and at 10:40 AM stated six patient CBC's were run. SURVEYOR ID#32558 Licensure and Certification Surveyor |