

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0301897	(X3) Date Survey Completed 07/06/2018
Name of Provider or Supplier Greene County Health System	Street Address, City, State 509 Wilson Avenue, Eutaw, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2016 - 2018 API (American Proficiency Institute) Proficiency Testing records and an interview with the Laboratory Manager (also the Testing Personnel), the laboratory failed to ensure attestation statements for 16 out of 23 surveys were signed by the Laboratory Director and testing personnel. The findings include: 1. A review of the API Proficiency Testing (PT) records revealed no signatures of the Laboratory Director (LD) (or designee) and/or the Testing Personnel (TP) on the attestation statements for the following surveys: A) 2016-Group #1 Chemistry, 2nd and 3rd Events : No LD B) 2016-Group #2 Chemistry, 1st, 2nd and 3rd Events : No LD C) 2016-Bacteriology, 3rd Event : No LD D) 2017-Hematology, 1st and 2nd Events: No LD E) 2017-Hematology, 3rd Event: No LD or TP F) 2017-Bacteriology, 1st and 2nd Events : No LD G) 2017-Chemistry, 1st and 3rd Events : No LD H) 2017-Chemistry, 2nd Event : No LD or TP I) 2018-Bacteriology, 1st Event : No LD J) 2018-Hematology, 1st Event: No LD or TP 2. In an interview on 7/6/2018 at 10:10 AM, the Laboratory Manager reviewed the PT records with the surveyor, and confirmed the above noted findings. .</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
 Based on a review of proficiency testing (PT) records and an interview with the Laboratory Manager (also the Testing Personnel), the surveyor determined the laboratory failed to either participate in proficiency testing or implement another method of semi-annual accuracy verification for four non-regulated Chemistry /Toxicology analytes, and eight analytes on the I-Stat used for back-up Chemistry testing in 2016-2107. The findings include: 1. A review of the API PT records revealed the laboratory failed to perform PT at least twice annually due to reagent shortages for four non-regulated Chemistry/Toxicology analytes, and eight analytes on the I-Stat used for back-up Chemistry testing, as follows: A) Phosphorus: 2016 #1 (Not performed-No reagent [NR]); 2016 #3 NR B) Troponin I: 2016 #1 NR; 2016 #3 NR C) Back-up tests performed on the I-Stat: TCO2 (Total Carbon Dioxide), Sodium, Potassium, Chloride, Glucose, Urea, Creatinine, and Ionized Calcium: 2016 #2 NR; 2016 #3 NR; 2017 #1 NR; 2017 #2 NR D) Acetaminophen: 2017 #2 NR; 2017 #3 NR E) Salicylate: 2017 #1 NR; 2017 #2 NR There was no evidence the laboratory had implemented an alternative method to ensure accuracy verification for the above analytes. 2. In an interview on 7/6/2018 at 10:10 AM, the Laboratory Manager reviewed the PT records with the surveyor, and explained the reagent shortages were due to monetary problems in the hospital. The Manager then confirmed they did not have another method of semi-annual accuracy verification. Thus, the above noted findings were confirmed.

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 the 2017 - 2018 API (American Proficiency Institute) Proficiency Testing records and an interview with the Laboratory Manager (also the Testing Personnel), the laboratory failed to document reviews of eight out of 23 of the returned survey evaluations results, and failed to document corrective action for six out of 24 surveys with results less than 100 % (percent). The findings include: 1. A review of the API Proficiency Testing records revealed no documentation of review (as indicated by the signature of the Laboratory Director or other designated personnel) of the returned evaluations for the following surveys: A) 2017 Hematology /Microscopy surveys-Events #1, #2, and #3 B) 2017 Bacteriology survey, Event #1 C) 2017 Chemistry and Toxicology surveys, Events #1 and #3 D) 2018 Bacteriology survey, Event #1 E) 2017 Hematology/Microscopy survey-Events #1 2. A review of the survey results revealed no documentation of investigation or corrective action for the following surveys with results less than 100%: A) 2016 Group #2 Chemistry-Event #3: Sodium and Chloride with failing scores of 0% each; Lipase and Potassium with 80% each B) 2017 Hematology/Microscopy-Event #3: Blood Cell Identification with a failing score of 40% and Wet Prep with a failing score of 0% C)2017 Chemistry and Toxicology-Event #1: Failing scores for Alkaline Phos (0%), Chloride (60%) and Digoxin (60%); Sodium with a score of 80% D) 2017 Chemistry and Toxicology-Event #2: Failing scores for Phosphorus (60%) and Lipase (20%); Amylase with a score of 80% E) 2017 Chemistry and Toxicology-Event #3: Failing scores 40% for Phosphorus and Sodium; HDL Cholesterol with a score of 80% F) 2017-Event #1 Chemistry with a score of 0% for the survey due to "Failure to participate", however the laboratory failed to perform an internal self-evaluation of

their results 3. In an interview on 7/6/2018 at 10:10 AM, the Laboratory Manager reviewed the PT records with the surveyor, and confirmed the above noted findings. .

D5400

ANALYTIC SYSTEMS

CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on reviews of calibration verification and quality control records, and interviews with the Laboratory Manager, the laboratory failed to: 1) Ensure a calibration verification of Sodium, Potassium and Chloride on the Vitros 350, and Arterial Blood Gas testing on the Abbott I-Stat was performed on every six months (Refer to D5439); 2.) Ensure a mechanism to monitor Chemistry/Toxicology and Hematology quality control (QC) shifts and trends over time was implemented and documented (Refer to D5441); 3) Ensure two levels of quality control (QC) were performed and documented on the Abbott I-Stat and Alere Triage each month of patient testing as per the IQCP (Individualized Quality Control Plan) (Refer to D5445); 4) Ensure at least two levels of Hematology QC were performed and within acceptable limits each day of patient testing (Refer to D5481); and 5) Implement effective quality assessment reviews to identify and correct problems identified in the analytical systems (D5791). .

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 a lack of calibration verification records for the Vitros 350 and the I-Stat, and an interview with the Laboratory Manager, the laboratory failed to perform and document calibration verifications every six months as required by the laboratory policy. The findings include: 1. A review of the calibration records for the Vitros 350 Chemistry analyzer revealed Sodium (Na), Potassium (K), and Chloride (Cl) are calibrated using two calibrators from Kit 2. Tests using less than three calibrators require a calibration verification (C/V) every six months. 2. A review of the records for the Vitros 350 revealed data from one calibration verification (C/V) performed on 5/25/2018. There were no records of C/V's for the Abbott I-Stat (used for Arterial Blood Gas testing). 3. During an interview on 7/6/2018 at 10:15 AM, the Laboratory Manager confirmed he had no other C/V records for the Vitros 350 or the I-Stat. He further explained the I-Stat was not currently in use because it needed a software update, and the analyzer failed the May 2018 C/V. When asked if any patient testing had been performed in the last year on the I-Stat, the Manager generated a report from the CPSI Laboratory Information System. The CPSI report showed 49 Arterial Blood Gases had been performed between August 2017 thru June 2018. Thus, the above noted findings were confirmed. 4. This is a repeat deficiency. .

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a lack of quality control documentation and an interview with the Laboratory Manager (also the Testing Personnel), the laboratory failed to implement and document a mechanism to monitor Chemistry/Toxicology and Hematology quality control (QC) shifts and trends over time. The findings include: 1. A review of the QC records for the Vitros 350 Chemistry analyzer revealed only the daily QC printouts were available for review. The laboratory had no mechanism to monitor QC shifts and trends over time. (Examples include printing Levi-Jennings charts periodically or submitting data to a QC company's Interlaboratory Quality Assurance Program [IQAP]). 2. A review of the QC records for the Sysmex XS 1000i Hematology analyzer revealed staff monitored their long-term QC performance by submitting their data to the Sysmex Insight IQAP until January 2017. Thereafter, only the daily QC printouts were available for review. The laboratory failed to implement another mechanism to monitor QC shifts and trends over time. 3. During an interview on 7/6/2018 at 11:55 AM the Laboratory Manager confirmed he had not had time to submit his Chemistry and Hematology QC data to the BioRad Unity or Sysmex Insight IQAP Programs. The Manager further stated he had not thought about trying to print Levi-Jennings charts. Thus the above noted findings were confirmed. 4. This is a repeat deficiency. .

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(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--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a lack of Quality Control (QC) records for the Abbott I-Stat and Alere Triage, patient data in the CPSI Laboratory Information System (LIS), and an interview with the Laboratory Manager (also the Testing Personnel), the surveyor determined the laboratory failed to ensure two levels of quality control (QC) were performed and documented each month of patient testing as per the IQCP (Individualized Quality Control Plan) which was implemented after the previous survey in 2016. The findings include: 1. A review of the QC Plans in the IQCP's for the I-Stat and Triage (implemented by the laboratory after the previous survey in 2016) revealed testing personnel should perform two levels of QC every 30 days, and with each new lot number of reagents. 2. A review of the QC records for the I-Stat (used for Cardiac [Troponin I and CK-MB Isoenzymes] and D-Dimer testing) revealed instrument printouts for two levels of QC on Cardiac cartridges dated: 11/21/16, 1/31/17, 6/3/17, 6/28/17, 1/28/18, and 2/24/18. There was also documentation of two levels of QC performed on the D-Dimer cartridges dated 1/30/18 and 2/22/18. Other instrument printout were observed in a plastic sleeve in no particular order. There were no records of QC performed on the I-Stat. 3. During an interview on 7/6/2018 at 12:20 PM, the Laboratory Manager was asked if he was prompted by the Triage to perform QC every 30 days, and with each new lot number of cartridges, and if he had documentation of the QC results. The Manager reviewed the analyzer and stated the automatic 30-day prompt in the Triage had been turned off, so he had not been remembering to perform QC every 30 days. The surveyor then reviewed the QC data from the Triage binder, and asked if he was able to find QC run for some of the missing months in 2016 - 2018. The Manager stated the missing QC data might be in the binder, however he did not have time to organize it. 4. During a later interview on 7/6/2018 at 1:05 PM, the surveyor requested QC records for the I-Stat. The Laboratory Manager stated he had been unable to locate any I-Stat QC. He further explained the I-Stat was not currently in use because it needed a software update, and it had failed the C/V he performed in May 2018. When asked if any patient testing had been performed in the last year on the Triage and I-Stat, the Manager generated a report from the CPSI Laboratory Information System. The CPSI report showed 49 Arterial Blood Gases had been performed between August 2017 thru June 2018; 411 Cardiac tests were performed August-December 2017, and March-July 2018 on the Triage; 81 D-Dimers had been performed August-December 2017, and March-July 2018. Thus the above noted findings were substantiated. 5. This is a repeat deficiency.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the Sysmex XS 1000i Hematology analyzer quality control (QC) record, and an interview with the Laboratory Manager (also the Testing Personnel), the laboratory failed to ensure at least two levels of Hematology QC were performed and within acceptable limits before patient testing began. This was noted on two days of patient CBC (Complete Blood Count) testing in June 2018. The findings include: 1. A review of the June 2018 Hematology QC records revealed two days of patient testing without at least two levels of QC within acceptable ranges as follows: A) 6/29/2018: Only the Normal level of QC was performed; 16 patient CBC's tested B) 6/30/2018: No QC was performed; six patient CBC's tested 2. During an interview on 7/6/2018 at 11:55 AM the Laboratory Manager reviewed his records and stated he was very busy and had missed performing two levels of QC on the above dates; he then confirmed the number of patient CBC's that had been performed. .

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 lack of quality assurance documentation and an interview with the Laboratory Manager (also the Testing Personnel), the surveyor determined the laboratory failed to implement effective quality assessment reviews to identify and correct problems identified in the analytical systems. The findings include: 1. During an interview on 7/6/2018 at 1:15 PM, when asked if he had any documentation of quality assurance activities for the last two years, the Laboratory Manager explained the previous Laboratory Manager may have performed QA, however he had been unable to locate her records. When asked if he had documented his own QA reviews, the current Manager stated he had no time except to review his daily quality control results. There was no QA plan in place to assess, monitor and correct problems in: A) Proficiency Testing (Refer to D2009, D5217 and D5221) B) Calibration verifications on the Vitros 350 and I-Stat (Refer to D5439) C) Quality Control procedures on the Vitros 350, I-Stat, Alere Triage and Sysmex XS1000i (Refer to D5441, D5445 and D5481.) D) Lack of sufficient personnel (Refer to D6028.) 2. During the exit summation with the Laboratory Manager and Hospital Administrator on 7/6/2018 at 1:45 PM, this concern was reviewed and confirmed. 3. This is a repeat deficiency. .

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on a review of the 2017 - 2018 API (American Proficiency Institute) Proficiency Testing records and an interview with the Laboratory Manager (also the Testing Personnel), the Laboratory Director failed to ensure the laboratory documented reviews of 8 out of 23 of the returned survey evaluations, and documented corrective action for 6 out of 24 surveys with results less than 100 % (percent). The Director further failed to ensure the laboratory participated in proficiency testing or implement another method of semi-annual accuracy verification for four non-regulated Chemistry/Toxicology analytes, and eight analytes on the I-Stat used for back-up Chemistry testing in 2016-2107. (Refer to D5217 and D5221.) .

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on reviews of Quality Control (QC) records for the Sysmex XS 1000i Hematology analyzer, the Abbott I-Stat and the Alere Triage, patient data in the CPSI Laboratory Information System (LIS), and an interview with the Laboratory Manager (also the Testing Personnel), the Laboratory Director failed to ensure: 1) at least two levels of Hematology QC were run and were within acceptable limits before patient testing began on two days of patient CBC (Complete Blood Count) testing in June 2018. (Refer to D5481.) 2) two levels of quality control (QC) were performed and documented for the Abbott I-Stat and the Alere Triage each month of patient testing as per the IQCP (Individualized Quality Control Plan). (Refer to D5445.) 3) a mechanism to monitor Chemistry and Hematology quality control (QC) shifts and trends over time was implemented and documented. (Refer to D5441.) .

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a lack of quality assurance documentation and an interview with the

Laboratory Manager (also the Testing Personnel), the surveyor determined the Laboratory Director failed to ensure the laboratory implemented effective quality assessment reviews to identify and correct problems identified in the analytical systems. (Refer to D5791.) .

D6028

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(10)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:

Based on a review of the Testing Personnel listed on the Form CMS-209, a review of laboratory processes, and an interview with the Laboratory Manager (also Testing Personnel #1), the Laboratory Director failed to ensure the laboratory had sufficient staff available to perform and document required quality control, calibration verification, and quality assurance procedures for accurate and reliable test performance. The findings include: 1. A review of the Form CMS-209 revealed two testing personnel (TP), with TP #1 also listed as the Technical Consultant. Personnel records revealed TP #1 had been employed since before the previous survey; TP #2 was recently hired on 6/27/2018 and was still in training. 2. A review of laboratory processes revealed many deficiencies related to a lack of staff, including: A) Proficiency Testing: a) Failure to review all API Proficiency Testing (PT) records to ensure attestation statements were signed by the testing personnel and Laboratory Director b) Failure to perform PT or implement an alternative method of accuracy verification; and c) Failure to perform and document corrective actions for PT results less than 100% (Refer to D2009, D5217 and D5221) B) Failure to perform Calibration verifications on the Vitros 350 and I-Stat (Refer to D5439) C) Failure to perform and document Quality Control procedures on the Vitros 350, I-Stat, Alere Triage, and Sysmex XS1000i (Refer to D5441, D5445 and D5481.) D) Failure to perform routine Quality Assurance activities to ensure accurate and reliable test performance and implement corrective actions when required (Refer to D5791.) 3. During an interview on 7/6/2018 at 11:50 AM, when asked about staffing for the laboratory, the Laboratory Manager explained he was the only person in the laboratory from 4/28 /2017 thru 6/27/2018 except for one testing personnel who worked approximately every other weekend up until 4/1/2018. Then from 4/2 - 6/27/2018, he was the only personnel in the laboratory. When asked if the Laboratory Director or other personnel made on-site visits to review the laboratory records, the Manager stated no one else made on-site visits. He stated the Director was only available by phone and only reviewed their proficiency testing results on line. Thus the above noted findings were confirmed. SURVEYOR:Laura T. Williams, BS, MT (ASCP)Licensure and Certification Surveyor