Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0468598	07/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pat Walker Health Center, University Of Ar, Fayett	Pat Walker Health Center, University Of Arkansas, Fayetteville, AR	

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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Through observation, review of manufacturer's package insert, and interview it was determined that the laboratory failed to ensure that reagents were not used in performing testing past their date of expiration for one of one bottles of 10% Potassium Hydroxide and one of one vials of Free T4 substrate. Findings follow: 1. The laboratory failed to ensure that one of one bottles of 10% Potassium Hydroxide that had exceeded its expiration date was not used in KOH testing. A. On a tour of the laboratory on 7/18/18 at approximately 13:15, one of one bottles of 10% Potassium Hydroxide lot # 5773-00 with an expiration date of APR-2018 was observed adjacent to the microscope in the Women's Clinic testing area. B. In an interview on 7/18/18 at approximately 13:15, the general supervisor identified as number 3 on the CMS 209 form confirmed that the Potassium Hydroxide was in use for patient testing and had exceeded its expiration date. 2. The laboratory failed to ensure that one of one vials of Free T4 substrate was not used for testing after it had exceeded its date of expiration. A. Review of the manufacturer's package insert for the Free T4 substrate revealed that after reconstituting the substrate is stable at refrigerator temperature for seven days. B. On a tour of the laboratory on 7/19/18 at approximately 14:00, one of one vial of Free T4 substrate lot # 1X60053 with a hand written in use date of of 7/6/18 was observed in the laboratory refrigerator (13 days after the in use date). C. In an interview on 7/19 /18 at approximately 14:30, the general supervisor identified as number 3 on the CMS 209 form confirmed that the Free T4 substrate was in use and had exceeded its expiration date.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Through review of manufacturer's package inserts, Sysmex instrument control result summaries, three months of Levey-Jennings Reports for July 2017, November 2017 and March 2018, and interview it was determined that the laboratory failed to establish target mean and ranges for three of three levels of Sysmex e-CHECK XS hematology control material and failed to establish establish the mean target for two of two levels of Alfa Wassermann chemistry controls. Findings follow: 1. The laboratory did not establish their mean target and acceptable ranges for Sysmex e-CHECK XS hematology controls. A. Review of all three levels of the manufacturer's package insert for Sysmex e-CHECK XS hematology controls reveals that "the mean values obtained on e-CHECK XS should be within the expected ranges" and "these expected ranges should not be used as QC file limits". B. Review of all three levels of the Sysmex instrument control result summaries for July 2017, Novemebr 2017, and March 2018 reveal that target mean values for complete blood cell analysis were set identical to the target mean values listed in the manfacturer's package insert and expected range values were not established or set in the instrument. C. Review of the laboratory information system Levey-Jennings report for July 2017, November 2017, and March 2018 revealed that mean target values for complete blood cell analysis were identical to the target mean listed on the manufacturer's package insert and the expected ranges were identical to the range of means listed on the manufacturer's package insert. D. In an interview on 7/18/18 at approximately 1545, the technical consultant identified as number 1 on the CMS 209 report confirmed that the mean target values and expected ranges listed on the manufacturer's pacakge insert were set as target values and acceptable ranges in the laboratory information system and used to evaluate quality control results for acceptability of complete blood count controls. 2. The laboratory did not establish their own mean target value for both levels of Alfa Wassermann Chemistry Controls.. A. Review of the manufacturer's package insert for the Alfa Wassermann Chemistry Controls revealed that "each laboratory should establish its own mean and precision parameters". B. Review of the Levey-Jennings Report in the laboratory information system for Alfa Wassermann Chemistry Controls for July 2017, November 2017, and March 2018 for ten analytes (Albumin, AST, Amylase, BUN, Creatinine, Glucose, Lipase, Sodium, Free T4, and Triglycerides) revealed that mean target values set in the laboratory information system Levey-Jennings report for all analytes for all three months were identical to the mean value listed on the manfacturer's package insert. C. In an interview on 7/19/18 at approximately 1400, the technical consultant identified as number 1 on the CMS 209

	form confirmed that the mean target values set in the laboratory information system were identical to the target values on the manufacturer's package insert.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Through review of the laboratory's policy and procedure for quality control, quality control Levey-Jennings reports for March 2018, corrective action log, patient result reports, lack of documentation and interview it was determined that the laboratory failed to evaluate patient results back to the last successful quality control performance for one of one patient tested on 3/13/18 after quality control for Lipase failed to meet the laboratory's accetable criteria on 3/14/18. Findings follow: A. Review of the laboratory's quality control policy and procedure revealed that quality control results are deemed unacceptable if two of two levels of quality control are outside acceptable limits or if one level is outisde of acceptable limits on two successive runs. B. Review of the laboratory's Levey-Jennings report for March 2013 revealed that on 3/14/18 level 1 quality control material lot # 1231UNCM with an accepable range of 23 to 41 for lipase analysis was resulted 21 at 10:01, and 21 at 10: 22 before an acceptable reading of 37 at 11:30. C. . Review of the laboratory's Levey-Jennings report for March 2013 revealed that on 3/14/18 level 2 quality control material lot # 937UECM with an accepable range of 135 to 157 for lipase analysis was resulted 133 at 10:03, and 130 at 10:23 before an acceptable reading of 149 at 11: 30. D. Review of the corrective action log revealed that on 3/14/18 the entry for Lipase stated "recalibrated, rerun", which indicates a change in the test system which may have affected prior patient results. E. Review of patient results revealed that a Lipase test was performed and reported on patient, identified as patient number 1 on a separate patient identification list, was reported as 42 on 3/13/18 at 11:27. F. Upon request, the laboratory was unable to provide documentation that the patient's lipase result on 3/13/18 was evaluated after failure of quality control results to meet acceptable limits on 3/14/18. E. In an interview on 7/19/18 at approximately 1500, the technical consultant identified as number 1 on the CMS 209 report confirmed that quality control for lipase failed to meet the laboratory's acceptable limits on 3/14/18, that recalibration was a change in the test system and that the patient result performed and reported on 3/13/18 was not evaluated.