Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0300393	02/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Coosa Valley Urology	16 South Douglas Avenue, Sylacauga, 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
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: Based on a review of Quality Control (QC) records for 2017 and 2018, a review of the patient tests log (instrument printouts) and interviews with Testing Personnel (TP) #1 and the office manager, the surveyor determined the laboratory failed to ensure QC material was not used beyond the expiration date for two months in 2017, when testing patient specimens for total Prostate Specific Antigen (PSA), Free PSA, and Testosterone on the Access 2. The findings include: 1. A review of the QC records for 2017 revealed Biorad QC material with lot numbers 40901 (Level 1) and 40903 (Level 3) expired 10/31/17; however were used with six patient runs in November and December of 2017. 2. On November 10, 2017, thirty-six (36) patient specimens were run, when the QC material was expired. On November 22, twenty-six patient specimens were run. On December 2, 8, 22 and 29, eighteen patients, twenty-two patients, nine patients, and thirty-seven patients were run respectively. The instrument printouts with the above dates indicated the QC material, which had expired on 10/31 /17, was in use for the above mentioned test runs. 3. Further review of the records, revealed TP #1 documented, when the technician realized the QC was expired, all specimens were retested. However, the testing personnel did not provide evidence or documentation of the repeated tests, nor any other patient remediation for the patient specimens tested, when out-dated QC material was used for testing. Further review of the instrument printouts revealed the lot number and expiration dates were changed in the instrument the first run of January 2018. 4. In an interview at 11:20 AM on 2/13 /2019, the surveyor inquired of TP #1 if the patient runs had been repeated. TP #1 stated the specimens were saved and the tests were repeated, after realizing the use of

	expired controls. TP #1 could not recall the date the repeat testing was done. TP #1 could provide no documentation of the repeated tests. At approximately 1:00 PM, the surveyor discussed the above noted findings with the office manager and TP #1.
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 Control (QC) and Quality Assurance (QA) records for 2017 and 2018, a review of the patient tests logs (instrument printouts) and interviews with Testing Personnel (TP) #1 and the office manager, the surveyor determined the laboratory failed to implement and document corrective actions for patients, after identifying expired QC material was used with patient test runs for total Prostate Specific Antigen (PSA), Free PSA, and Testosterone. This affected November and December of 2017 and potentially one hundred and forty-four patients. The findings include: 1. A review of the QC records for 2017 revealed Biorad QC material with lot numbers 40901 (Level 1) and 40903 (Level 3) expired 10/31/17; however were used with six patient runs in November and December of 2017. 2. On November 10, 2017, thirty-six (36) patient specimens were run, when the QC material was expired. On November 22, twenty-six patient specimens were run. On December 2, 8, 22 and 29, eighteen patients, twenty-two patients, nine patients, and thirty-seven patients were run respectively. The instrument printouts with the above dates indicated the QC material, which had expired on 10/31/17, was in use for the above mentioned test runs. 3. Further review of the records, revealed TP #1 documented, when the technician realized the QC was expired, all specimens were retested. However, the testing personnel did not provide evidence or documentation of the repeated tests, nor any other patient remediation for the patient specimens tested, when out-dated QC material was used for testing. Further review of the instrument printouts revealed the lot number and expiration dates were not changed until the first run of January 2018. 4. In an interview at 11:20 AM on 2/13/2019, the surveyor inquired of TP #1 if the patient runs had been repeated. TP #1 stated the specimens were saved and the tests were repeated, after realizing the use of expired controls. TP #1 could not recall the date the repeat testing was done. TP #1 could provide no documentation of the repeated tests. 5. A review of the QA records for 2017 and 2018 revealed the laboratory director had signed all monthly reports, where QC (corrective actions were reviewed for all QC problems to ensure resolutions prevent recurrence) and QA (remedial actions have been documented for the monthly reviews) categories were check-marked, and no problems were identified. 6. At approximately 1:00 PM on 2/13 /2019, the surveyor discussed the above noted findings with the office manager and TP #1.