

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0482488	<b>(X3) Date Survey Completed</b> 10/11/2021
<b>Name of Provider or Supplier</b> Collom & Carney Urology Clinic	<b>Street Address, City, State</b> 1902 Moores Lane, Texarkana, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, review of the QC package insert, CMS 116 application, and confirmed in an interview found that the laboratory failed to document revised expiration dates on opened QC bottles for one of one QC lot number in use for one of one test: urinalysis. The findings were: 1. Review of BioRad LiquiChek Urinalysis Control package insert (Ref 435) revealed under Storage and Stability "This product will be stable until the expiration date when stored unopened at 2 to 8C. Once the control is opened and stored tightly capped, all analytes will be stable for 30 days at 2 to 25C." 2. Surveyor's direct observation on 10/11/21 at 10:25 am in the lab revealed no revised expiration dates documented on the opened QC bottles for 1 of 1 QC lot number in use. Lot# 8770 Exp: 2022-07-31 Level 1 Lot# 87701 Exp: 2022-07-31 Level 2 Lot# 87702 Exp: 2022-07-31 3. Review of CMS 116 application signed by LD on 10/5/21 revealed the annual volume for urinalysis was 32812. 4. An interview with TP#6 on 10/11/21 at 10:05 am in the lab confirmed the</p>

above findings. TP#6 stated that she used the expiration dates on the bottles, not the revised expiration dates for opened QC bottles. Key: CMS=Center of Medicare and Medicaid QC=Quality Control LD=Laboratory Director TP=Testing personnel