Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0326986	11/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cumberland County Hospital	299 Glasgow Road, Burkesville, KY	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and staff interview on 11/06/2018, 11/07/2018, and 11/08 /2018, the laboratory failed to monitor and document external humidity for the performance of blood gases on the AVL OPTI CCA from 11/16/2016 through 11/07 /2018. Findings include: The Individualized Quality Control Plan (IQCP) written for the AVL OPTI CCA blood gas instrument included the daily monitoring of humidity under the Risk Assessment for performing blood gases Review of laboratory documentation for the blood gas analyzer failed to reveal daily recordings of humidity from 11/16/2016 through 11/07/2018. Testing personnel revealed in an interview at 9: 45 AM on 11/08/2018, the laboratory failed to have a system in place to ensure humidity readings were recorded daily.
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 review of quality control records and staff interview on 11/06/2018, 11/07/2018, and 11/08/2018, the laboratory failed to perform three levels of external controls every fifteen (15) days from 01/07/2017 to 11/01/2017 on the AVL OPTI CCA Blood Gas Analyzer. Findings include: Review of the Quality Control Plan adopted 11/16/2016, revealed three levels of external quality control are performed and recorded in the quality control log book every fifiteen (15) days and must be within acceptable range per manufacturer's packet insert. Review of laboratory records failed to reveal quality control documentation from 01/07/2017 thru 02/15/2017, 03/01/2017 thru 04/12/2017, and 10/01/2017 thru 11/01/2017. Interview with the General Supervisor at 9:45 AM on 11/08/2018, revealed the laboratory failed to have a system in place to ensure established policy was followed for the performance of external quality control on the blood gas analyzer.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and staff interview on 11/06/2018, 11/07/2018, and 11/08/2018, the laboratory failed to conduct annual reviews of their Individualized Quality Control Plan (IQCP)to identify and correct problems found with Risk Assessment monitors and/or the Quality Control Plan for 23 months since implementation 11/16/2016. Findings include: A review of the IQCP revealed an annual review would be conducted to ensure the analytical phase of testing was performed according to the established criteria implemented 11/16/2016. Record review revealed External Quality Control was not performed every fifteen (15) days from 01/07/2017 through 11/01/2017. Record review revealed humidity was not recorded from 11/16/2016 through 11/07/2018. Interview with the General Supervisor at 9:45 AM on 11/08/2018, revealed the laboratory failed to follow their written IQCP to identify problems, document corrective action to resolve problems, and update if necessary the Risk Assessment and modify the Quality Control Plan.