Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0648630	10/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Crittenden Community Hospital	520 West Gum, Marion, 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
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview on 10/08/2019, 10/09/2019, and 10/10/2019, the laboratory failed to perform and document a positive reactivity for each substrate tested on the Microscan Identification Panels when new lot numbers were received and put into use. Findings include: 1. Review of quality control documentation for the NUC 73 Gram Negative Identification Panels failed to include a positive reaction for the H2S and TDA substrates. 2. Review of quality control documentation for the PBPC 20 Gram Positive Breakpoint Combo Panels failed to include a positive reaction for the ARA, INU, and RAF substrates. The general supervisor acknowledged in an interview at 10:00 AM on 10/09/2019, the laboratory failed to have a system in place to ensure a positive reactivity was confirmed for all substrates tested on the Microscan Identification Panels prior to patient testing.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its

	ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview on 10/08/2019, 10/09/2019, and 10/10/2019, the laboratory failed to check each new batch of Blood Agar Plates, MacConkey Plates, Hektoen, and MacConkey II with Sorbital for sterility prior to use for patient testing. Findings include: 1. Review of the Microbiology Policy and Procedure Manual revealed the Microbiology Quality Control Policy states "Perform sterility check of the media by incubating one plate overnight." 2. Review of quality control documentation failed to reveal results for sterility on new batches of media prior to patient testing. The general supervisor acknowledged in an interview at 10:00 AM on 10/09/2019, the laboratory failed to have a system in place to ensure the policy for sterility was followed when new batches of media was received.