

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D1080421	<b>(X3) Date Survey Completed</b>  01/10/2023
<b>Name of Provider or Supplier</b>  Chi St Vincent Medical Group Hot Springs	<b>Street Address, City, State</b>  1707 Airport Road, Hot Springs, AR	
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>D5477</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Through a review of the Microbiology Policy and Procedure Manual and quality control (QC) documentation, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to perform microbiology (streptococcal culture) quality control on media plates prior to patient results being reported. Survey findings include: A. During a review of the Microbiology Policy and Procedure Manual it was revealed the policy for QC of Streptococcus cultures will be performed every day of testing and with each new lot of media utilized. B. Through a review of the Throat Culture Log for June, July, October, and December of 2022 it was determined that patient samples were reported prior to quality control being performed for new lots of media. Examples are as follows: Two of two patient samples were plated on lot 146045 media on 9/20/22. QC with 146045 media was not performed until 9/21/22. 9/27/22 four of five patient samples were plated on lot 146055 media. QC with 146055 media was not performed until 9/28/22. 10/11/22 one of six patient samples were plated on lot 147019 media. QC with 147019 media was not performed until 10/12/22. C. Through a review of the Throat Culture Log for December of 2022 it was determined that seven of seven patient samples were reported without QC being performed. D. In an interview at 1:23pm on 1/10/2023, laboratory employee #2 (as listed on the form CMS-209) confirmed the lab policy</p>

requires that microbiology quality control is performed daily when patient samples are being tested as well as with the utilization of new lots of media. They further stated that QC for microbiology was not performed properly on the dates listed above.