

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0454833	(X3) Date Survey Completed 01/23/2019
Name of Provider or Supplier Chi Health Saint Mary's	Street Address, City, State 1301 Grundman Blvd, Nebraska City, NE	
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
D5477	<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: Based on review of patient worklogs, lack of documentation of media checks and an interview with the general supervisor on 1-23-19 at 1:45PM the laboratory failed to check each batch of media. Findings include: 1. Review of patient worklog from January 2019 revealed patient testing was performed using strep selective media. 2. No documentation could be presented on time of survey indicating end user quality control performed on media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response. 3. Interview with general supervisor confirmed end user checks had not been performed or an alternative Individualized Quality Control Plan (IQCP) had not been implemented for these checks.</p>