

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D0087583	(X3) Date Survey Completed 03/28/2019
Name of Provider or Supplier Huggins Hospital	Street Address, City, State 240 South Main St, Wolfeboro, NH	
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 record review and staff interview, the laboratory failed to document that it checked the current batch of MacConkey with Sorbitol (SMAC) for sterility, its ability to support growth and produce biochemical responses used for the determination of sorbitol fermentation and a visual inspection of the batch received in February 2019. Findings include 1) Observation on 3/28/19 at 9:30 AM of the bacteriology storage refrigerator revealed two media plates of SMAC lot 474858. 2) Review on 3/28/19 of the laboratory's "Non-Exempt Media Quality Control 2019" log from January through March 2019 revealed no documentation that the current lot 474858 of SMAC had been visually checked for cracks or signs of deterioration, checked for sterility, checked for its ability to support growth of microorganisms that ferment sorbitol and microorganisms that do not ferment sorbitol. 3) Review on 3/28/19 of the shipping invoice for SMAC lot 474858 revealed the laboratory received 1 pack (of 10 plates) on 2/20/19. There was no documentation on the invoice of a visual inspection of SMAC media plates. 4) Interview on 3/28/19 at 9:45 AM with the General Supervisor (GS) confirmed the above findings. The GS revealed there is no quality assurance procedure to review the control log to ensure media has been checked prior to it's use.</p>

D5545

HEMATOLOGY

CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory's hematology control procedure failed to include instruction to perform two levels of control testing every 8 hours for nonmanual coagulation test systems in 2018 and 2019. Findings include: 1) Review on 3/28/2019 of the D-Dimer Procedure, last revised 1/18/2018, revealed the manufacturer's instruction to perform two levels of controls upon opening each new reagent cartridge kit. The laboratory did not develop an individualized quality control plan (IQCP) to support the alternative control procedures. 2) Review on 3/28/2019 of D-Dimer control testing from 1/1/19 to 3/28/19 revealed two levels of D-Dimer controls were run within 24 hours of patient testing. 2) Interview on 3/28/2019 at 12:45 PM with the Technical Supervisor (TS) confirmed the laboratory did not develop an IQCP to support the frequency of D-Dimer control testing outlined in the procedure and revealed the laboratory's practice was to perform control testing more frequent than the procedure required by performing them every 24 hours from patient testing.