

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0246260	(X3) Date Survey Completed 05/23/2023
Name of Provider or Supplier Coastal Children's Clinic	Street Address, City, State 218 Stonebridge Square, Havelock, NC	
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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of performance verification records and interview with TP #4, 5/23 /23, the laboratory failed to demonstrate verification of precision on the Medonic M series hematology analyzer. Findings: Review of performance verification records for the Medonic M series hematology analyzer revealed the verification was performed by a technical representative on June 8, 2022. The performance verification failed to include operator and day-to-day run variances to demonstrate verification of precision. Interview with TP #4 at approximately 10:20 a.m. confirmed the technical representative performed all performance verification testing on June 8, 2022. She stated they were told by the technical representative that this was all that was needed.</p>
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</p>

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 review of laboratory procedure, review of 2021, 2022 and 2023 quality control (QC) records for Select Strep Agar (SSA) media and interview with testing personnel (TP #4) 5/18/23, the laboratory failed to ensure QC for the SSA media included an organism that was inhibited by the SSA media for 29 of 29 months reviewed. Findings: Review of laboratory procedure "Throat Culture for Identification of Group A Beta-Hemolytic Streptococci" revealed "3. Controls Cryobeads will be used to create a stock culture of Strep. pyo. and E. faecalis from the preordered specimens....When controls need to be run, a single Cryobead for each control is removed from the freezer and inoculated on a non-selective plate as per package instructions. This plate is then used to create a positive and negative control plate on our normal selective plates.". The E. Faecalis organism used for the "negative" control plate is not inhibitory for SSA media and cannot be used as a "negative" control. Review of 2021, 2022 and 2023 QC records for the SSA media revealed the laboratory had performed QC using Streptococcus Pyogenes and Enterococcus faecalis, both organism are selective for SSA media. There was no documentation the laboratory had also performed QC using an organism that was inhibitive for SSA media. Interview with TP #4 at approximately 11:00 a.m. confirmed the laboratory did not include an organism that was inhibited by the SSA media for use as QC. She stated they have always done the QC for the SSA media in this way and no one has ever told them there was a problem with it.