

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D0086553	(X3) Date Survey Completed 12/14/2023
Name of Provider or Supplier Weeks Medical Center	Street Address, City, State 173 Middle St, Lancaster, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, testing personnel failed to follow control procedures for the blood culture identification panel testing in November and December of 2023. Findings include: 1. Review on 12/14/2023 of the lab's procedure titled "Individualized Quality Control Plan Nanosphere Verigene Gram Positive and Gram Negative Nucleic Acid Test" effective 2/19/2021 revealed on page 8 instruction to perform a positive and negative control monthly after opening a new lot of identification panels. 2. Review on 12/14/2023 of control logs from September through December 2023 for the blood culture identification panels performed on the Nanosphere Verigene instrument revealed control testing failed to meet acceptable criteria in November and December. Further review revealed in November attempts to resolve control issues were made by repeat analysis were unsuccessful in obtaining acceptable control results. No attempts for resolving December's control failures were documented. 3. Interview on 12/14/2023 at 9:15 a.m. with Testing Personnel confirmed the above findings.</p>
D5545	<p>HEMATOLOGY CFR(s): 493.1269(b)(d)</p> <p>(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</p>

section.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory (lab) failed to perform D-Dimer control testing every 8 hours from June to December 2023. Findings include: 1. Review on 12/13/2023 of the lab's procedure titled "Vidas D-Dimer Exclusion II Assay (DEX2)", effective 3/13/2020, revealed instruction to perform two levels of D-Dimer control testing every 24 hours. The lab did not have an Individualized Quality Control Plan (IQCP) to support this procedure. 2. Review on 12/13/2023 of patient test logs and quality control logs for D-Dimer testing performed 6/1/2023 through 12/11/2023 revealed 13 of 181 patient tests had been performed without control testing in the previous 8 hours. It was also revealed that 4 of the 13 patient D-Dimer tests without control testing in the previous 8 hours also did not have control testing in the previous 24 hours. 3. Interview on 12/13/2023 at 11:15 a.m. with the Technical Supervisor confirmed the above findings.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory's (lab) quality assessment procedures failed to identify failures in Bacteriology and Hematology testing from June through December 2023. Findings include: 1. Review on 12/13/2023 of D-Dimer control records from 6/1/2023 to 12/11/2023 revealed daily control testing was not performed in accordance with the lab's procedure on 4 days. Reference D5545. 2. Review on 12/14/2023 of blood culture panel control testing performed on the Nanosphere Verigene (Verigene) instrument from 9/1/2023 to 12/15/2023 revealed monthly control testing was not performed in accordance with the lab's procedure in November and December. Reference D5401. 3. Interview on 12/14/2023 at 11:00 a.m. with the Technical Supervisor revealed current monthly review of control testing records did not include verifying that control testing is performed each day of patient testing and did not include review of monthly control testing performed on the Verigene.