

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D0882248	(X3) Date Survey Completed 11/16/2022
Name of Provider or Supplier Weeks Medical Center	Street Address, City, State 173 Middle Street, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and staff interview, the laboratory failed to follow manufacturer's instructions for performing urinalysis quality control testing and maintenance of the GeneXpert Xpress test system used for SARS-CoV-2 nucleic acid amplification test (NAAT) and failed to maintain test SARS-CoV-2 test records in 2021 and 2022. Findings include: Observation on 11/15/2022 at 9:20 a.m. of the emergency department revealed an open bottle of urine Multistix 10SG with an open date of 7/5/21 and expiration date of 4/30/22 and 1 GeneXpert Xpress with 2 of the sample doors open in the soil utility room. Interview with Director of the Emergency Department on 11/15/2022 at 9:15 a.m. revealed that they do not do quality control on urine Multistix 10SG or maintenance on the GeneXpert Xpress. Interview with Lab Manager on 11/16/2022 at 10:15 a.m. revealed lab does not do maintenance on the GeneXpert Xpress in the emergency department. Record Review on 11/16/2022 revealed a urinalysis on 11/09/2022 and a SARS-CoV-2 NAAT on 11/12/2022 were performed in the emergency department. Review on 11/16/2022 of the GeneXpert Xpress User 's Guide, (P/N 302-5609 Rec A) February 2021, Figure 5-1. Maintenance Log revealed daily, weekly, monthly, quarterly, yearly and as necessary maintenance checks are required. Review further revealed instruction to refer to Chapter 5 (maintenance) in the operator manual for detailed procedure. Review on 11/16/2022 of the GeneXpert Xpress instruction for use (IFU) revealed any record pertaining to this emergency use authorization (EUA) test system must be maintained until otherwise notified by the Food and Drug Administration (FDA). Review on 11/16/22 of the Multistix 10 SG manufacturer ' s instructions revealed instruction to perform</p>

control testing when opening a new bottle of test strips and every 30 days. Interview with Director of the Emergency Department on 11/16/2022 at approximately 11:00 a. m. confirmed the facility had no policy for urinalysis quality control or GeneXpert Xpress maintenance in the emergency department. The Director of the Emergency Department revealed SARS-CoV-2 test results are recorded on the accession label and sent to the hospital's main lab for reporting; the emergency department did not maintain the test records. Interview with the Lab Manager on 11/16/2022 at approximately 11:30 a.m. confirmed the receipt of the test results on the accession labels but could provide the original or copies of the test record provided by the emergency department.