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PUBLIC HEALTH ADVISORY

To: All Health Care

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Subject: Extending the Use of Rapid Antigen Testing Supplies

Date / Time: Friday, November 12, 2021 at 1:05PM

Pages: 2

Priority: Normal

Message ID: 2021PHADV024

Extending the Use of Rapid Antigen Testing Supplies

I. Background

During the COVID-19 pandemic, various components of the testing supply chain (*e.g.*, test kits, reagents, swabs) have been in short supply. Though the testing supply chain has stabilized, it remains vulnerable to increases in COVID-19 transmission, such as the one Maine is experiencing now.

II. Expiration Date Extension

The Maine Center for Disease Control and Prevention (Maine CDC) currently has 92,160 rapid antigen test kits in its warehouse with expiration dates in January and February 2022. In addition, Maine CDC recently distributed tens of thousands of kits with expiration dates in November and December 2021 to facilities across the state, and some of these will not be used before these expiration dates. The U.S. Centers for Medicare & Medicaid Services (CMS) has acknowledged the issue of expired pandemic supplies and released <u>Guidance for the Use of Expired SARS-CoV-2 Tests</u> on December 10, 2020. This guidance states, "during the COVID-19 public health emergency, in order to address the concern over COVID-19 reagent and swab supply problems, CMS will allow laboratories to use expired COVID-19 test kits, reagents, and swabs."

In light of this Guidance, Maine CDC is adopting a temporary policy to allow the use of expired but functional COVID-19 rapid antigen tests to allow Maine to continue its focus on alleviating the impact of COVID-19. This temporary policy applies only to rapid antigen tests, not to other testing supplies. This temporary policy will be in place until further notice.

Facilities in possession of rapid antigen tests may continue to use those tests after the expiration date, consistent with the CMS Guidance. Such tests should be used in accordance with their authorized instructions for use.

III. Additional Information

Testing supply expiration dates are set according to manufacturers' testing and reflect the duration for which each supply is reasonably expected to be stable. For many COVID-19 testing supplies, expiration dates are brief because there has only been a short period of time during which the manufacturer has been able to study testing supply stability. The Maine CDC has distributed more than 719,000 rapid antigen tests (including Abbott BinaxNOW and AccessBio CareStart) to facilities since October 2020.

Maine is working to secure additional testing supplies with a longer shelf life but has not yet received supplies to replace expired inventory and to meet current demand. Because of national shortages of rapid antigen tests, we anticipate a supply increase will appear in the first quarter of 2022. Therefore, the use of expired but functional pandemic supplies is necessary at this time.