



STATE OF WASHINGTON

DEPARTMENT OF HEALTH

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March 31, 2022

RE: Department of Health Approval to Use Expired Reagent Antigen Test Kits

Dear DOH Partners,

During the COVID-19 pandemic, various components of the testing supply chain (e.g. test kits, reagents, swabs) have become temporarily unavailable. This has led to periods of supply scarcity and instances of stockpiling. The testing supply chain remains vulnerable to surges in COVID-19 transmission, concurrent changes in supply and demand, and variable access to resources. Due to these continued constraints and ongoing high levels of demand, Department of Health (DOH) has determined the use of expired but functional COVID-19 antigen tests is warranted and necessary.

The Centers for Medicare & Medicaid Services (CMS) has acknowledged the issue of expired pandemic supplies and has released, "Guidance for the Use of Expired SARS-CoV-2 Tests," on December 10, 2020, ([Guidance for the Use of Expired SARS-CoV-2 Tests](#)). 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." The guidance goes on to state that: "If doing so deviates from the test manufacturer's authorized instructions for use, the use would not be authorized under the EUA and should not be represented as such." Thus, these expired supplies may be used, but with an acknowledgment that their use deviates from authorization. The guidance also states that: "When in-date reagents are unavailable, it may become necessary to frame written policies for their temporary use beyond their expiration dates until non-expired supplies become available. Under no circumstances, however, should a laboratory adopt policies that would allow for the regular use of expired reagents." Thus, DOH may write temporary policies to allow the use of these expired supplies, which would naturally terminate once a stable supply chain is re-established. For test platforms, these policies would rest upon functional quality controls.

Testing supply expiration dates have been set according to how long each supply and component are expected to be stable. Many COVID-19 testing supplies are set to expire quickly due to manufacturers performing under short study times on stability. Many of these tests have integrated quality control

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indicators, which can also be used to determine if an expired item can reliably be used. The scope of this document encompasses only antigen tests supplies that include an integrated quality control indicator and does not apply to molecular/PCR testing supplies.

Sincerely,

A handwritten signature in blue ink, appearing to read "J. Davis", with a stylized flourish at the end.

Jerrod Davis

Assistant Secretary

Division of Disease Control & Health Statistics

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