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June 8, 2026

Subject: Discontinuation of ORTHO® HCV Version 3.0 ELISA Test System at the Maine Health and Environmental Testing Laboratory

Dear Valued Client,

This notice is to inform you that the Maine Health and Environmental Testing Laboratory (HETL) will be discontinuing the **ORTHO® HCV Version 3.0 ELISA Test System** for Hepatitis C virus IgG antibody (HCV IgG Ab) screening. The manufacturer has ceased production of this test kit, and no additional reagent lots are available for purchase.

HETL's remaining inventory of ORTHO® HCV Version 3.0 ELISA reagents will **expire on August 5, 2026**. As a result, **HETL will no longer be able to perform HCV IgG Ab screening after this date**. All specimens received on or after August 5, 2026, requiring this assay will be unable to be processed.

In preparation for this discontinuation, HETL conducted an extensive review of available replacement assays. While several comparable HCV serology kits exist, they are proprietary to closed, manufacturer-specific instrumentation platforms. These systems are not compatible with HETL's open-access serology analyzer and therefore cannot be adopted within our current testing infrastructure.

We recognize the importance of HCV screening and surveillance and are actively evaluating long-term options to restore in-house testing capacity. In the interim, we encourage clients to review alternative testing arrangements, including referral to external laboratories offering FDA-cleared HCV serology assays.

HETL will provide additional updates as they become available. If you have questions regarding this transition or need assistance identifying interim testing resources, please contact our Serology Section at (207) 287-1722.

Thank you for your understanding and continued partnership in supporting public health in Maine.

Sincerely,

Handwritten signature of Trevor J. Rivard in blue ink.

Trevor J. Rivard
CLIA General Supervisor, Virology/Serology/STI

Handwritten signature of Dr. Daniel Jones in blue ink.

Dr. Daniel Jones
CLIA Laboratory Director