

13 JUN 2024

Urgent Field Safety Notice

YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70065611 / Exp 28FEB2025)

To the Attention of Laboratories receiving YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70065611 Exp 28FEB2025), in Central African Republic, Benin, Ghana, Mali, Togo and CDC Fort Collins, CO, USA.

YF MAC-HD 1.0 Kit is a qualitative ELISA-based assay for detecting IgM antibodies against yellow fever virus in human serum, it is a research use only (RUO) product intended for yellow fever surveillance. It should be used by trained laboratory personnel in a laboratory setting. The results of this assay are qualitative and should be used in the context of laboratory surveillance detection of anti-yellow fever IgM antibodies in human serum where IgM results should be confirmed according to applicable laboratory guidelines.

This notice is in regard to YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70065611 Exp 28FEB2025) component 10x Wash Buffer (Catalogue Number: YF-1 Lot 70061488).

This Field Safety Corrective Action has been issued for 10x Wash Buffer (Catalogue Number: YF-1 component Lot 70061488), a component of the YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70065611 Exp 28FEB2025), that has shown volume leakage during transport.

10x Wash Buffer volume (YF-1 Lot 70061488) should be carefully confirmed prior to surveillance testing with YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70065611 Exp 28FEB2025) to ensure that 100mL of 10x Wash Buffer is present in the bottle. ATCC has confirmed the 10x Wash Buffer volume (YF-1 Lot 70061488) after a customer complained that 2/30 bottles had leaked during shipment.

ATCC has completed a 100% volume check of YF-1 lot 70061488 inventory, retightened lids and added parafilm to the lid-vial interface prior to heat sealing with shrink wrap.

If the YF MAC HD 1.0 Kit (YF-500, Lot 70065611 Exp 28FEB2025) 10x Wash Buffer component (YF-1, Lot 70061488) appears to have leaked, please notify ATCC immediately at yfkithelp@atcc.org, then refer to volume indicators on the side of the bottle. An excessive volume of Wash Buffer is provided in each bottle, so if the volume present is ≥ 65 mL, then there is still sufficient volume to run a plate. Dilute the remaining 10x Wash Buffer with distilled water 1:10 and use as instructed. If there is not enough volume to complete one plate per bottle (<65 mL), please assess if spare volume can be taken from other bottles of the same lot supplied in the kit box that have not leaked. If the sum total of 10x Wash Buffer is insufficient, please contact ATCC to receive additional YF-1 (10x Wash Buffer).

In case you observe any irregularities while using the assay, kindly contact us immediately using the email address below while providing a clear description of your observation.



Credible leads to Incredible™

YF-500

For any questions please contact Heather Couch at yfkithep@atcc.org.

A handwritten signature in black ink that reads "Heather Couch".

Heather Couch, PhD, PMP®
PROGRAM MANAGER II

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