

17 APRIL 2024

### **Urgent Field Safety Notice**

#### **YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70062452 / 70067451, Exp 31DEC2024)**

To the Attention of: Laboratories receiving YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70062452 / 70067451, Exp 31DEC2024), in Uganda, Senegal, Cameroon 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 70062452 / 70067451, Exp 31DEC2024) component Conjugate (Catalogue Number: YF-2 Lot 70061489).

This Field Safety Corrective Action has been issued for Conjugate (Catalogue Number: YF-2 component Lot 70061489), a component of the YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70062452 / 70067451, Exp 31DEC2024), that has shown low volume due to leakage of the component (YF-2) during transport.

Conjugate volume (YF-2 Lot 70061489) should be carefully confirmed prior to surveillance testing with YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70062452 / 70067451, Exp 31DEC2024). To ensure that 50 µL of Conjugate is present in the YF-2 vial, the vial should have 60 µL present as listed on the box. ATCC has confirmed the Conjugate volume (YF-2 Lot 70061489) after a customer complained that 2/20 vials were below the 50 µL volume required for testing. Please report YF-2 volume concerns immediately at the listed website or email: <https://www.atcc.org/federal-solutions/global-health-and-biodefense/yellow-fever-surveillance-kits> or email [yfkithelp@atcc.org](mailto:yfkithelp@atcc.org).

ATCC has completed a 100% volume check of YF-2 lot 70061489 inventory, retightened lids and added a parafilm seal to the lid-vial interface. The Instructions for Use have been updated to include a note to centrifuge the vials prior to opening. ATCC has reviewed the calibration records of our repeater pipettor that was used for dispensing, and it was correctly calibrated according to the preventative maintenance schedule.

If the YF MAC HD 1.0 Kit (YF-500, Lot 70062452 / 70067451, Exp 31DEC2024) Conjugate component (YF-2, Lot 70061489) does not contain enough material to perform one plate assay (50 µL), please evaluate the whether the remaining volume is useable. In addition to leaks, a loose lid may allow evaporation, which could affect the conjugate chemistry. If a YF-2 is not capped, evaporation of the material at room

temperature (23°C) and 50% humidity could occur at a rate of 4 µL per day. Please notify ATCC immediately regarding deviations from the minimum volume (50 µL).

Note: Endusers should use caution when pipetting to avoid volume losses on the outer wall of the tip which can have a large impact on small volumes.

In order to confirm the volume of the Conjugate (YF-2, Lot 70061489) the end user should:

1. Retrieve one YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70062452 / 70067451, Exp 31DEC2024) from 4°C storage (one kit = 240 tests).
2. Retrieve a calibrated pipette for pipetting 50 µL and appropriate-sized sterile tips.
3. Wearing proper PPE, remove the Conjugate vial (YF-2, lot 70061489) from each of the ten bags of components in the kit.
4. Place the 10 vials (one from each bag in one YF MAC HD 1.0 Kit) in a low-speed centrifuge and spin for 5-10 seconds to ensure the conjugate is not in the lid.
5. Pick up one vial, carefully open the lid, and confirm that there is liquid in the bottom of the vial and none in the lid or on the sides of the vial. It may be difficult to view due to the opaque vial.
6. Mount a sterile pipette tip and enter the vial, do not put the tip all the way to the bottom of the vial. Slowly take up 50 µL and insert the tip towards the vial bottom as the liquid fills the tip.
7. If the tip is filled, carefully and slowly inject the conjugate back into the vial.
8. Close the lid tightly and return YF-2 to its bag. YF-2 is light-sensitive, so it is important to perform the volume check and screw on the lid each time. Do not let YF-2 sit out with the lid off. When repacking each bag of test components, it is recommended that the vials be stored vertically.
9. **Steps 5 to 8 should be repeated for each vial of conjugate in the YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70062452 / 70067451, Exp 31DEC2024).**
10. Each YF MAC HD 1.0 Kit (Catalogue Number: YF-500) should be returned to 4°C storage once testing of the ten conjugate (YF-2) vials is completed.
11. **Steps 1 to 10 should be repeated for each YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70062452 / 70067451, Exp 31DEC2024).**
12. ATCC will provide additional YF-2 vials (sealed) to ensure that the volume required is available to complete testing.
13. 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.

For any questions please contact Heather Couch at [yfkithehelp@atcc.org](mailto:yfkithehelp@atcc.org).



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