

15 MARCH 2024

Urgent Field Safety Notice

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

To the Attention of: Laboratories receiving YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70062452, 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, Exp 31DEC2024) component Yellow Fever Antigen (Catalogue Number: YF-12 Lot 70061500).

This Field Safety Corrective Action has been issued for Yellow Fever Antigen (Catalogue Number: YF-12 component Lot 70061500), a component of the YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70062452, Exp 31DEC2024), that has shown poor performance in the assay due to storage of the component (YF-12) at -20°C. prior to kit assembly.

Surveillance testing with Yellow Fever Antigen (Catalogue Number: YF-12 Lot 70061500) in YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70062452, Exp 31DEC2024) may lead to false negative results. During ATCC testing of the Yellow Fever Antigen (Catalogue Number: YF-12 Lot 70061500) after customer complaint the internal positive control was below the > 0.6 specification 2/8 times or 25%. It is recommended that the YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70062452, Exp 31DEC2024) not be used with the current lot of Yellow Fever Antigen (Catalogue Number: YF-12 Lot 70061500).

ATCC has produced and validated a new lot of Yellow Fever Antigen (Catalogue Number: YF-12 Lot 70067133) which has been validated with all components of YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70062452, Exp 31DEC2024) and has passed all quality control checks. ATCC will provide the new lot of Yellow Fever Antigen (Catalogue Number: YF-12 Lot 70067133) to all customers to replace the faulty Yellow Fever Antigen (Catalogue Number: YF-12 Lot 70061500) originally packaged in YF MAC HD 1.0 Kit Lot 70062452 expiring on 31DEC2024. Replacement of the YF-12 component with the new validated YF-12 Lot 70067133 does not affect the original expiration date of the YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70062452), which remains Exp 31DEC2024. ATCC plans to distribute the replacement vials March 25 through April 1st, 2024.

Within 72 hours of receipt of Yellow Fever Antigen (Catalogue Number: YF-12 Lot 70067133) the following procedure for replacement of the Yellow Fever Antigen (YF-12 Lot 70061500) with the new lot of Yellow Fever Antigen (Catalogue Number: YF-12 Lot 70067133) is recommended.

1. Retrieve one YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70062452, Exp 31DEC2024) from 4°C storage (one kit = 240 tests).
2. Retrieve the Yellow Fever Antigen (YF-12, lot 70061500) from each of the ten bags of components in the kit and discard it in a sharps container (Biosafety Level 1).
3. Add the new Yellow Fever Antigen (YF-12, Lot 70067133) to each of the ten kit component bags.
4. **Re-label the kit with a new label displaying the new Kit Lot number (Lot 70067451). It is recommended for end-user to document such change of lot in their internal inventory management and quality assurance and documentation system.** Note that a new YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70067451, Exp 31DEC2024) outer label will be provided, please place the new label sticker (YF-500, Lot 70067451, Exp 31DEC2024) on the box covering the original label (YF-500, Lot 70062452, Exp 31DEC2024).
5. **Steps 1 to 4 should be repeated for each kit received (one kit = 240 tests).**
6. A Certificate of Testing for YF MAC HD 1.0 Kit (Catalogue Number: YF-500, Lot 70067451, Exp 31DEC2024) will also be provided. Please review the Certificate of Testing.
7. To ensure YF MAC HD 1.0 Kit (Catalogue Number: YF-500) is performing as expected, please routinely monitor the performance of the assay through systematic use of internal and external controls.
8. 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 yfkithelp@atcc.org.



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