

**Supplier:** Svizera Europe B.V

**Subject:** Update on supply delays for Ziehl Neelsen and Auramine microscopy kits

**Cause of supply delays:** Ziehl Neelsen and Auramine microscopy kits that are transported as Dangerous Goods have been facing supply chain challenges since 2023. While changes in EU sustainability policy and updates to IATA regulations on the transportation of Dangerous Goods have improved their alignment with In Vitro Diagnostic Medical Device Regulation (IVDR), they are also more stringent and—for the supplier—have resulted in:

- The need to navigate frequent updates to the regulations on dangerous cargo.
- A shortage of packaging material classified as Dangerous Goods.
- An increase in time used to prepare/pack dangerous cargo.

**Extent of supply delays:** Delays vary based on the quantity ordered. Expected delays will be communicated with each order.

**Expected duration of supply delays:** It is expected that the IATA regulations updates for Dangerous Goods will continue throughout 2024. The effect of these changes on the delivery lead time will be evaluated and communicated to the client for each order.

**Update as of 24 May 2024:** Svizera Europe B.V informed GDF that they are on track with an additional production line for Dangerous Goods and an additional provider of packaging material to increase their production capacity. However, new regulations have been established in 2024 that restrict the quantities packed per inner packaging to a minimum of 1 liter. These restrictions particularly affect kits shipped via passenger airfreight.

The GDF microscopy kits presently contain 6 liters each of ZN carbol-fuchsin stain solution, ZN Acid-Alcohol decolorization solution, Auramine Acid alcohol decolorisation solution, Auramine Methylene blue counterstaining solution, and either ZN Methylene blue counterstaining solution or Carbolic Auramine stain solution. Microscopy kits also contain other reagents, as well as several consumables. Additionally, each box has specific packaging rules, including around how taping, inner packaging, and labelling must be carried out according to the new regulations. The individual packaging of each reagent bottle and the increasingly stringent packaging rules have led to long delays in finishing packing the microscopy kits for passenger airfreight, as well as to an overpack kit box of considerable size and weight.

To mitigate the delay, the microscopy kits can be delivered as Cargo Air Only, as this option has less stringent regulation. But unfortunately, not all destinations have the Cargo Air Only option.

**GDF mitigation actions:**

- GDF requests client countries to plan and place orders as early as possible and notify GDF immediately of any concerns around insufficient stock to meet program needs.
- GDF will prioritize available products to avoid stockouts in country programmes whenever possible.

- GDF is working with clients to split orders into multiple, smaller shipments to address immediate client needs.
- GDF is working to check if the Cargo Air Only option is available when the client wishes to switch to this option.

**Contact Information:** For additional information, or if you need support with order planning, please contact either the GDF Country Supply Officer for your programme or [gdf@stoptb.org](mailto:gdf@stoptb.org).

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**Date of last update:** 03 June 2024

**Status:** Open