

Helena Biosciences Notification:

SAS Free Kappa IEF Kit: REF 102208; SAS Free Lambda IEF Kit: REF 102209

URGENT FIELD SAFETY NOTICE

NC476

Electrophoresis Division

GEP070 25 March 2021

Dear Colleague,

Further to customer feedback regarding the performance of the SAS Free Kappa IEF Kit: REF 102208 and SAS Free Lambda IEF Kit: REF 102209, it has been confirmed that the following products have been inappropriately labelled:

SAS Free Kappa IEF Kit, LOT: 11779995; Expiry: 10/2022

SAS Free Lambda IEF Kit, LOT: 11780001; Expiry: 10/2022

As such, and as an **immediate** measure we are asking users to carry out the following actions:

- Cease use of the product immediately
- Quarantine any open or unused packs immediately
- Confirm total number of packs used and total number held in inventory for return to Helena
- The use of this product as part of a panel of tests for information purposes only suggests that it has no direct affect on any clinical decisions made as a direct result of the use of the affected product. If this material has been used in order to make clinical decisions as a direct result of this material alone, please report immediately to the most appropriate Clinical Lead and Helena Biosciences Europe directly.
- Confirm in writing to Helena no later than 31st March 2022 that the above actions have been carried out supplying the additional supporting information requested.

Our investigations are concluded with respect to Root Cause Analysis. Contact will be made in order to return affected goods under Helena MRA procedure. Notification to the appropriate Regulatory Authority has been actioned simultaneously. Replacement product is available on request.

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