

Change of storage temperature range on the labels for Gibco sera

FAQs

Will you be changing the operating temperature range of your freezers?

No. While the storage temperature range on Gibco™ serum labels has traditionally been stated as –5 to –20°C, our freezers are set to operate at around –15 to –20°C globally, which complies with both the old and the new temperature ranges on the labels. Accordingly, we do not need to change our freezer set points or operating ranges. This label change will not affect the product composition or quality standards that we have in place today. All serum products will continue to be manufactured under our current global quality management systems.

Will you be changing the way sera are shipped to customers?

No, the new temperature range applies to the storage of sera only and does not impact our shipping processes already in place, which ensure that the product remains frozen using dry ice, wet ice, or active refrigeration as appropriate.

Does this change affect the shelf life of sera?

No. Existing studies on shelf life have been performed in our freezers under usual operational conditions. There are no alterations to our storage or shipping processes associated with this change. Our shelf-life studies remain current.

Will you be changing anything else associated with the manufacturing process?

No, the only change will be to update the associated documentation such as the Certificate of Analysis (CoA), other appropriate labels, and information on the Web.

Why are you making the change?

The current United States Pharmacopeia (USP) and European Pharmacopoeia (EP) guidelines for monographs for serum refer to a storage temperature of ≤–10°C. While our actual storage practices have complied with this range previously, this change ensures that the storage temperature range on the label and CoA is consistent with USP and EP requirements.

Find out more at thermofisher.com/gibcolabelchanges