

Important message to Customers,

Regarding

Diluent GHI154, batch no 11171,12012

Diluent GHI154-2, batch no 11340 and 12094

CaCl₂ GHI155-2 batch no 12092

CaCl₂ GHI155-5 batch no 12011

Above Diluent and CaCl₂ is used for reconstitution of MediRox Owrens PT.

By commercial reasons we have decided to replace above lot numbers since investigations have confirmed that vials may contain a volume less than specified. Evaluations indicates a low fill level in less than 2% of the lot population.

The assessment is that there is no patient health risk using the product, but it may cause difficulties with abnormal controls and should therefore not be used. In case you have no possibility of replacing the product you can use it, provided that correct reconstitution volume first is verified.

MediRox will compensate all customers with new products upon contact. For replacement or questions please contact MediRox on order@medirox.se.

MediRox AB

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Linda Östling
QA Manager

Robert Löfvenmark,
CEO