

Field safety Notice

Regarding PT Owren's GHI131-10 SI, batch no 15446

Background to this message

After evaluations MediRox has confirmed that PT Owren's reagent batch 15446 develops precipitation after using the X1 reconstitution method.

Precipitation – where small opaque particles forms in the reagent – is a phenomenon known to occasionally occur in vials of GHI131 PT Owren's. The phenomenon is thought to be initiated by sediments from thromboplastin reacting with the reagent in the presence of CaCl_2 .

The phenomenon has not shown to have any effect on results, and is mainly considered to be a cosmetic deviation.

Precipitate typically occurs 1-4 days after reconstitution and only when using reconstitution method X1, where both diluent and CaCl_2 is added. Users that consume the reagent the same day as reconstitution, or use reconstitution method X2 where CaCl_2 is added to each sample individually, will not see the phenomena.

Actions required by end-users

The conclusion is that precipitation occurs more frequently than normal in batch 15446. The assessment is however that there is no patient risk to use the product; as described the phenomenon has not shown to have any effect on results.

However, it is a cosmetic issue and deviation from the normal, and we suggest all users to replace this batch. The replacement is free of charge and all required is to contact order@medirox.se and specify the number of kits you want to exchange.

For users preferring to continue using batch 15446, we recommend using X2 method. If using X1 reconstitution; use the reagent the same day as reconstitution. If using it over several days; visually inspect the reagent on a daily basis before use. Reagent with precipitate is not to be used.

Actions required by distributors

This FSN – field safety notice – is dispatched to all distributors of lot 15446 and must be re-distributed by the distributor to all users that have received vials from lot 15446.

We apologize for the inconvenience that this situation may cause. If you have any questions regarding this contact quality@medirox.se or order@medirox.se.

MediRox AB

Nyköping, May 23, 2016

Linda Östling
QA Manager

Robert Löfvenmark,
CEO