

Change Notification

Affected Product	Human Factor XIIIa, activated
Product number	T070
Change description	Specific activity is now > 2500 U/mg instead of > 3000 U/mg. Next retest date is now in 3 years instead of in 2 years.
Reason	Change of fluorescence spectrometer. Results of stability data.
Conformity assessment	The previous specification in regard to FXIIIa's specific activity was > 3000 U/mg. The Units are arbitrary relative fluorescence increase units measured in the DCC-assay (Dansylcadaverine incorporation into dimethylcasein). These relative units are specific to the fluorescence spectrometer used for the assay. The usage of a new fluorescence spectrometer resulted in a lower specific relative fluorescence increase for FXIIIa (T070). As a result, the new specification was set to > 2500 U/mg. The product and its quality did not change! Due to stability results the stability of T070 is increased to 3 years.
Measure	Specific activity specification is > 2500 U/mg. Next retest date is in 3 years. Changes are implemented starting with lots 2926aT070 and 2926bT070. The SOP for the production of T070 was updated. Customers are going to be notified about the change either via email or as notification on our website.
Note	This document is valid without a signature.