

Certificate of Analysis

CONGENITAL FACTOR VIII DEFICIENT PLASMA WITH INHIBITOR

Article no.: FVIII-CON-IP
Lot / Exp.: xxx-xxx / xxxx-xx-xx
Description: Citrated human plasma from a donor deficient for Factor VIII
Donor no.: xxxx
Presentation: Frozen congenital plasma in 1 mL aliquots.
Preparation: Thaw vials in 37°C water bath for 5 minutes.
Storage: Frozen deficiency plasma should be stored at - 40 to - 80°C until expiration date stated on vial label. Once thawed, plasma is stable for 4 hours at 2-8°C in original vial.

Specifications:

PARAMETER	RESULT
FACTOR VIII (ACTIVITY)	<1%
INHIBITOR SCREEN	Positive
INHIBITOR ACTIVITY	81 BU (Bethesda Units)

Human plasma was tested and found negative by FDA accepted methods for Anti-HIV 1/O/2 Ab, HBsAg, Syphilis (RPR), HBC Ab, HIV-1 RNA, HCV RNA and HBV DNA.

Donors are screened and found negative for CJD (Creutzfeld-Jakob Disease).

Nevertheless, the plasma should be handled by personnel trained in the proper procedures for handling potential viral contaminants.

For Research Use Only. Not for Use in Diagnostic Procedures.