

Certificate of Analysis

FACTOR VIII CONGENITAL DEFICIENT PLASMA WITH INHIBITOR

Article no.: FVIII-CON-IP-1
Lot / Exp.: xxxxxx / xxxx-xx
Description: Citrated human plasma from a donor deficient for Factor VIII
Donor no.: CC-15604
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 below - 60°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	1.0 BU (Bethesda Units)

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

THE DONOR IS HISTORICALLY KNOWN TO BE POSITIVE FOR HCV ANTIBODIES.

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.