Factor X Deficient Plasma

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INTENDED USE - George King Factor X Deficient Plasma is citrated human plasma derived from congenital Factor X deficient donors and intended for use as a substrate in the quantitative determination of Factor X activity in citrated plasma using the clottable prothrombin time (PT) assay. Intended for *in vitro* diagnostic use only.

SUMMARY AND PRINCIPLE - Factor X is a vitamin K-dependent, liver-produced serine protease that serves a pivotal role in coagulation as the first enzyme in the common pathway to fibrin formation. Inherited factor X deficiency is a rare autosomal recessive bleeding disorder that is estimated to occur in 1:1,000,000 individuals. Acquired factor X deficiency is rare, but when it occurs it is usually in association with amyloidosis.[1]
Phenotype diagnosis is based on the concomitant prolongation of the prothrombin time and activated partial thromboplastin time.
Factor X activity is determined by using the modified prothrombin time (PT). Citrated patient plasma is diluted, added to a factor X-deficient substrate and a PT is performed. The % factor activity is interpolated using a reference curve with the same dilutions of a calibrator plasma and FX-deficient substrate. [2]

REAGENT -Factor X deficient plasma (1000) - no buffers or stabilizers have been added

WARNINGS - Each individual donor plasma used in these products has been tested by an approved method and found to be non-reactive for the presence of HBsAg and antibody to HIV. Anti-HCV positive, NAT negative donors have been identified. Because no known test method can offer complete assurance that these or other infectious agents are absent, this product should be handled at the **Biosafety Level 2** as recommended for any human blood-based product in the Centers for Disease Control/ National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories," 1999. [3]

PREPARATION - Place vial in 37° C. water bath until plasma is thawed. Exact time is determined by volume of plasma in vial - approximately 2-5 minutes in circulating water bath. Mix gently and keep on ice until ready to use.. Plasma must be discarded once thawed and used. ***DO NOT REFREEZE.***

STORAGE and STABILITY: Recommended storage: -70°C or below. Stability for FX deficient plasma is 3 years from the date of manufacture. Plasmas must remain frozen and will be stable until expiration date shown on vial. Remove plasma from dry ice packaging upon receipt and place in freezer overnight before use. (self-defrost freezer not recommended) Plasma is stable for 6 hours after being thawed when kept at refrigerated temperatures, and stable for 4 hours at room temperature.

PROCEDURE - Plasmas should be used as indicated by specific assay direction inserts for instrument and reagent system being used. See instrument manual and reagent direction insert for specific instructions regarding specimen preparation, procedure and limitations.

REAGENTS AND MATERIALS REQUIRED, NOT PROVIDED:

Calibration plasma		
Owren's Buffer or equivalent	Thromboplastin reagent	Quality Control (2 levels)
Plastic tubes / pipets	Coagulation instrument	

QUALITY CONTROL: Two levels of quality control (normal and abnormal) should be performed each 8 hours of operation in accordance with good laboratory practice. Each laboratory should establish its own mean and standard deviation and should establish a quality control program to monitor laboratory testing. [4]

SPECIMEN COLLECTION AND PREPARATION: Nine parts of freshly drawn venous blood is collected into one part trisodium citrate. Refer to CLSI Document H21-A5 for further instructions on specimen collection and handling. [5]

EXPECTED VALUES - GK Factor X Deficient Plasma has been tested at <1% factor activity. All other coagulation factors have been tested and found to be within the normal range

NORMAL REFERENCE RANGE -The normal range for FX activity in adults is 50-150% according to literature. However, each laboratory should determine is own normal range.

PERFORMANCE CHARACTERISTICS - Precision was assessed in-house on two lots of GK FX deficient plasma following CLSI EP5 guidelines. Multiple FX assays (n=80) were performed over 20 non-consecutive days on the ACL TOP 500 using a specific lot of RecombiPlasTin 2G and GK PNP (normal), GK B-FACT (borderline) and GK A-FACT (low abnormal) controls.

Sample Type	Sample mean % FX	Within Run %CV	Between Run %CV	Between Day %CV	Between Lots %CV	Total %CV
GK PNP	100.6	2.9	4.5	4.3	3.8	3.8
GK B-FACT	38.2	7.3	0	4.1	3.6	5.0
GK A-FACT	7.5	6.0	1.5	5.3	12.0	6.2

Acceptable (CV%: ≤ 10%) when using an optical instrument.

All studies were performed using an optical instrument. Validation studies would need to be performed by the end user if utilizing an instrument other than optical, ie. clotting, chromogenic and immunologic test methods.

BIBLIOGRAPHY

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4. Kitchen, S, Olson J, Preston, F. Eric. Quality in Laboratory Hemostasis and Thrombosis. Blackwell Publishing 2009, pg 44.
5. Clinical and Laboratory Standards Institute. Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation and Molecular Hemostasis Assays; Approved Guideline – Fifth Edition, CLSI Document H21-A5; Vol. 28 No.5

Revised 02/2017

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