Factor VII Deficient Plasma

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

SUMMARY AND PRINCIPLE: Factor VII deficiency is a rare disorder inherited as an autosomal recessive trait that causes mild to severe bleeding.
Factor VII is synthesized in the liver and secreted as a single-chain glycoprotein. Tissue factor is an intrinsic membrane glycoprotein that is normally not exposed on the surface of intact blood vessels. When the vascular lumen is damaged, tissue factor is exposed and then binds to the small amounts of circulating factors VIIa and VII. This facilitates conversion of factor VII to factor VIIa. Factor VIIa bound to tissue factor in the presence of calcium and phospholipids facilitates the conversion of factor IX to factor IXa and factor X to factor Xa initiating the clotting cascade. [1,2]
Citrated patient plasma is diluted, added to a factor VII-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 FVII-deficient substrate. [3]

REAGENT: George King Factor VII deficient plasma (0700). No buffers or stabilizers have been added.

WARNING: Each individual donor plasma used in these products has been tested and found to be non-reactive for the presence of HBsAg and the antibody to HIV and HCV. 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.[4]

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 for 1.0 mL vials. Mix gently and keep cold 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 FVII 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 4 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) Coagulation instrument Plastic tubes / pipets

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. [5]

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. [6]

EXPECTED VALUES - GK Factor VII 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 - Adult normal reference range for FVII is generally reported in literature as 50-150%. However each laboratory should determine its own normal range.

PERFORMANCE CHARACTERISTICS - Precision was assessed in-house on two lots of GK FVII deficient plasma following CLSI EP5 guidelines. Multiple FVII 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 % FVII	Within Run %CV	Between Run %CV	Between Day %CV	Between Lots %CV	Total %CV
GK PNP	87.9	3.7	0.7	2.9	1.3	2.1
GK B-FACT	31.0	5.9	3.8	1.6	2.6	3.4
GK A-FACT	6.3	7.9	5.5	4.8	13.1	7.8

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.

References:

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3. Triplett, D, Harms, C. *Procedures for the Coagulation Laboratory Education Products Division, ASCP* 1981, p.36
4. Richmond JY. McKinney RW eds. "Biosafety in Microbiological and Biomedical Laboratories," US Dept. of Health and Human Services. Public Health Service, 4th Edition, 1999.
5. Kitchen, S, Olson J, Preston, F. Eric. Quality in Laboratory Hemostasis and Thrombosis. Blackwell Publishing 2009, pg 44.
6. 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

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