Factor XII Deficient Plasma

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INTENDED USE - George King Factor XII Deficient Plasma is citrated human plasma derived from congenital Factor XII Deficient donors and intended for use as a substrate in the quantitative determination of Factor XII activity based on the activated partial thromboplastin time. (APTT) assay. For *in vitro* diagnostic use only.

SUMMARY AND PRINCIPLE - Factor XII deficiency is a rare genetic blood disorder that causes prolonged clotting (coagulation) of blood in a test tube without the presence of prolonged clinical bleeding tendencies. It is caused by a deficiency of the factor XII (Hageman factor), a plasma protein (glycoprotein). The disorder is thought to be benign and usually presents no symptoms (asymptomatic); it is usually only accidentally discovered through pre-operative blood tests. When blood from a patient is subjected to a partial thromboplastin time test (PTT), a test measuring clotting time, it takes an abnormally long time for the blood to clot. [1] Citrated patient plasma is diluted, added to a factor XII-deficient substrate and an APTT is performed. The % factor activity is interpolated using a reference curve with the same dilutions of a calibrator plasma and FXII deficient substrate. [2]

REAGENT - George King Factor XII deficient plasma (1200)- no buffers or stabilizers have been added

WARNINGS - Each individual donor plasma used in these products has been tested 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 for 1.0 mL vials.. Mix gently and keep on cool 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 FXII 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
aPTT Reagent
Quality Control (2 levels)
Coagulation instrument
Plastic tubes / pipets
$CaCl_2$

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 XII 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 FXII 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 FXII deficient plasma following CLSI EP5 guidelines. Multiple FXII assays (n=80) were performed over 20 non-consecutive days on the ACL TOP 500 using a specific lot of SynthASil and GK PNP (normal), GK B-FACT (borderline) and GK A-FACT (low abnormal) controls.

Sample Type	Sample mean % FXII	Within Run %CV	Between Run %CV	Between Day %CV	Between Lots %CV	Total %CV
GK PNP	109.0	2.2	2.4	2.4	1.2	2.1
GK B-FACT	43.1	2.5	1.6	0.9	1.7	1.7
GK-A-FACT	7.5	9.3	3.1	3.3	2.7	4.6

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:

1. Coleman, Robert W. Factor XII Deficiency. NORD Nation Organization for Rare Disorders. Temple University School of Medicine. 2012
2. Triplett, D, Harms, C. *Procedures for the Coagulation Laboratory Education Products Division, ASCP* 1981, p.50
3. Richmond JY. McKinney RW eds. "Biosafety in Microbiological and Biomedical Laboratories," US Dept. of Health and Human Services. Public Health Service, 4th Edition, 1999.
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

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