Factor XI Deficient Plasma

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

SUMMARY AND PRINCIPLE - Factor XI (FXI) is a plasma glycoprotein that participates in the contact phase of blood coagulation (ie, the intrinsic pathway) Severe FXI deficiency is defined when the activity of FXI in plasma is less than 15%). The disorder is inherited as an autosomal recessive trait and although factor XI (FXI) deficiency has a particularly high incidence in Ashkenazi Jews, it is now frequently diagnosed in other ethnic groups.
The primary site of FXI synthesis is the liver. Patients with liver disease may therefore have decreased levels of FXI. FXI activity is low at birth and correlates with gestational age. [1,2]
Factor XI activity is determined by using the modified aPTT. Citrated patient plasma is diluted, added to a factor XI-deficient substrate and a PTT is performed. The % factor activity is interpolated using a reference curve with the same dilutions of a calibrator plasma and FXI-deficient substrate.[3]

REAGENT- George King Factor XI deficient plasmas (1100)- no buffers or stabilizers 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 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 in circulating 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 FXI 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 Coagulation instrument aPTT Reagent/ $CaCl_2$ Quality Control (2 levels) 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 FXI 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 Factor XI in adults 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 FXI deficient plasma following CLSI EP5 guidelines. Multiple FXI 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 % FXI	Within Run %CV	Between Run %CV	Between Day %CV	Between Lots %CV	Total %CV
GK PNP	104.0	2.3	1.1	2.7	2.7	2.2
GK B-FACT	42.6	4.6	0.9	3.7	1.0	2.5
GK A-FACT	9.7	5.6	2.0	2.0	1.5	2.8

Acceptable (CV%: $\leq$ 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

1. Salomon O, and Selligsohn, U, New observations on Factor XI deficiency, Haemophilia 2004, Oct 10; Suppl. 4: 184-7
2. Be'rube' Caroline, Factor XI Deficiency, UpToDate®
3. Triplett, Douglas A., MD, (ed) *Laboratory Evaluation of Coagulation*, Chicago, IL, American Society of Clinical Pathologists, 1982, pp. 358-361.
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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