Pooled Normal Plasma from Single Donor Normal Plasmas

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INTENDED USE – George King Pooled Normal Plasma is intended to be used as a normal control for the one-stage prothrombin time assay and the activated partial thromboplastin time (aPTT) assay. It may also be used as the normal pooled plasma for mixing studies in the determination of a prolonged protime (PT) and/or aPTT.
For *in vitro* diagnostics only

SUMMARY AND PRINCIPLE - The PT and aPTT are routinely used as screening tests to access coagulation abnormalities caused by inherited or acquired factor deficiency or circulating anticoagulants, (lupus anticoagulant, FVIII Inhibitor, etc.).
Mixing studies are one of the most common tests performed in the laboratory. They are instrumental in determining which pathway will be used to identify the cause for a prolonged Prothrombin (PT) or Activated Partial Thromboplastin Time (aPTT).
In order to perform a mixing study either or both the PT/aPTT screening assays must exceed the upper limit of a laboratory's defined reference range. The test that results in a prolongation will be the test system used for the mixing study.
At its fundamental, the mixing study utilizes the normal pooled plasma that interacts with patient plasma to either correct a factor deficiency or be affected by an abnormality in the patient plasma.
The classical mixing study uses one part patient citrated platelet poor plasma and one part normal pooled plasma. Immediately after preparation a 1:1 mix is tested in the test system that was originally prolonged. A 1:1 mix discriminates between factor deficiencies and inhibitors if initial clotting times are significantly prolonged. [1]

REAGENT - Fresh frozen citrated human plasma from 30 or more carefully screened normal donors. Each lot of George King Pooled Normal plasma (PNP-0010) is tested and confirmed to contain normal levels of coagulation factors and fibrinogen. Each lot of PNP is screened and found negative for presence of lupus anticoagulant. [2]
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 (Hepatitis B Surface Antigen), antibodies to HIV and anti-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. [3]

PREPARATION - Place vial in 37° C. water bath until plasma is thawed. Exact time is determined by volume of plasma used - approximately 2-5 minutes for 1.0 mL vials. Plasma must be discarded once thawed and used. ***DO NOT REFREEZE*.**

STORAGE and STABILITY: Recommended storage: -70°C or below. Stability for PNP 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. If PNP is used for mixing studies plasma may be stored at -20 ˚C for up to 3 months. Plasma is stable for 4 hours after being thawed when kept at refrigerated temperatures, and stable for 4 hours at room temperature. Do not use self-defrosting freezer.

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: Thromboplastin Reagent aPTT Reagent / $CaCL^2$ Quality Control (2 levels) Coagulation instrument Owren's Buffer or equivalent 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.[4]

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 - Results should fall within the protime and aPTT normal ranges that have been established by the laboratory.

PERFORMANCE CHARACTERISTICS - Precision was assessed in-house on two lots of GK Pooled Normal Plasma (PNP) plasma following CLSI EP5 guidelines. Multiple protime and aPTT's (n=80) were performed over 20 non-consecutive days on the ACL TOP 500 using a specific lot of RecombiPlasTin 2G and SynthASil.

Sample Type PNP	Sample mean (sec)	Within Run %CV	Between Run %CV	Between Day %CV	Between Lots %CV	Total %CV
PT	11.5	1.5	1.2	1.7	0.2	1.2
aPTT	33.8	2.0	2.8	2.1	0.4	1.8

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.

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

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