



FOR USE WITH APTT REAGENTS

SUMMARY

Investigation of the coagulation system centers on the coagulation factors. The activity of these factors depends on specific surface receptors and phospholipids largely presented on the surface of the platelets and also by activated endothelium. The necessity for calcium in many of these reactions is frequently utilized to control their activity in Vitro.

The APTT test is useful for measuring the activity of the intrinsic pathway. In APTT test, plasma is first preincubated for a specific period of time with a contact activator resulting in the formation of factor XIa. However coagulation cascade does not proceed further in the absence of calcium. Recalcification with Calcium chloride (0.025 mol/l) initiates the coagulation cascade resulting in the formation of a stable fibrin clot. The APTT test is influenced by the concentration of calcium chloride used for assessment of the intrinsic pathway.

Calcium Chloride™ from Tulip is intended for use with APTT reagents.

PRESENTATION

REF	10633010	10633100
Calcium Chloride™	10 ml	10 x 10 ml
Pack Insert	1	1

REAGENT

Calcium Chloride™ is a ready to use solution standardized at 0.025 mol/l concentration for use with APTT reagents only.

REAGENT STORAGE AND STABILITY

The reagent must be stored at room temperature. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label. Do not use reagents after the expiry date.

PRINCIPLE

On activation of contact factors by the activator in the APTT reagents, Factor XIIa produced cleaves factor XI to XIa in the pre-incubation period. The partial thromboplastin time is then measured by adding appropriate amount of **Calcium Chloride™** (0.025 mol/l, prewarmed at 37°C), resulting in the formation of the clot.

PRECAUTIONS

1. In vitro diagnostic reagent for laboratory and professional use only. NOT FOR MEDICINAL USE.
2. Take every possible aseptic precaution to minimize contamination while drawing the reagent.
3. Avoid dipping contaminated pipettes / micropipette tips in the reagent vial. Ideally pour the required quantity for the days work into a sterile clean vial or test tube.
4. If the reagent vial develops turbidity, do not use the reagent as this would lead to erroneous results.

TEST PROCEDURE

Calcium Chloride™ must be used strictly adhering to the instructions described by the manufacturer of APTT reagents used for analysis.

NOTE

1. Incubate the required amount of **Calcium Chloride™** at 37°C after transferring it in a clean dry test tube. **DO NOT INCUBATE THE ENTIRE REAGENT VIAL.**
2. Prewarmed calcium chloride solution must be discarded at the end of the days work.

PERFORMANCE CHARACTERISTICS

The product has been evaluated by using with APTT reagents of two different manufacturers. Normal and abnormal control plasmas of the respective manufacturers were used as samples. The values obtained were within the expected range of the reagents used for analysis.

Calcium Chloride™ has also been evaluated by testing Plasmatrol HI and Plasmatrol HIII with Liquicelin-E®. The results obtained were within the expected range.

WARRANTY

This product is designed to perform as described on the label and the package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

(1) Dacie and Lewis, Practical Haematology, Ninth edition. (2) Data on file: Tulip Diagnostics (P) Ltd..

SYMBOL KEYS

	Temperature limitation		Manufacturer		Contains sufficient for <n> tests
	Use by		Consult Instructions for use		Production Site
	Date of Manufacture		Catalogue Number		This side up
	Batch Number/ Lot Number		<i>In vitro</i> Diagnostic Medical Device		Authorised Representative in the European Community

 **T TULIP DIAGNOSTICS (P) LTD.**



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