BIOMEDICA DIAGNOSTICS

QuikCoag™ Thrombin Time

IVD For *In Vitro* Diagnostic Use

REF	Catalog Number	Quantity
	C.BMD.TT-01ML	10 x 1mL

INTENDED USE

QuikCoag Thrombin is a thrombin reagent (bovine) for use in the determination of the Thrombin Time in human plasma.

SUMMARY

The Thrombin Time assay is based on the ability of thrombin to catalyze the polymerization of fibrinogen into a fibrin clot. The mechanism involves the cleavage of peptides (fibrinopeptides A and B) from the amino-terminal ends of the alpha and beta chains of fibrinogen by the proteolytic action of thrombin. The resulting fibrin monomer molecules ultimately polymerize into a fibrin clot.

PRINCIPLE

The Thrombin Time assay is a qualitative screening assay used to detect abnormalities in this phase of coagulation. The assay is performed by adding a known quantity of low concentration thrombin reagent to a plasma specimen *in vitro* and measuring the time required for clot formation to occur. Abnormalities affecting this stage of coagulation include quantitative and qualitative alterations in fibrinogen, increased fibrinolytic activity causing variations in Fibrin(ogen) Degradation Products (FDP), and interferences with fibrinogen polymerization. The Thrombin Time assay is also sensitive to heparin and other circulating antithrombins.

REAGENT

The **QuikCoag Thrombin** reagent is a lyophilized preparation of bovine thrombin, calcium chloride, buffer, and stabilizers.

PRECAUTIONS

Do not ingest. Avoid contact with skin, eyes or clothing.

REAGENT PREPARATION

1. Reconstitute the contents of the vial with the specified volume of purified water.
2. Replace the stopper and thoroughly mix the vial contents. Let stand for no less than 15 minutes prior to use to assure complete hydration of the contents.

STORAGE AND STABILITY

Store reconstituted **QuikCoag Thrombin** at 2-8°C when not in use. The expiration date printed on the label indicates the date beyond which the unopened product should not be used. Signs of deterioration are reflected in quality control results outside the established laboratory range. After the reagent has been reconstituted, the product remains stable for 7 days if stored at 2-8°C, and 30 days if stored at -20°C.

SPECIMEN COLLECTION AND PREPARATION

No special preparation or fasting of the patient is necessary. Blood should be anticoagulated with sodium citrate dihydrate at a starting concentration of 3.2% or 3.8% (0.109 or 0.129 M). To assure accurate results, a ratio of nine parts blood to one part anticoagulant (9:1) should be used. Recommended procedures for the collection of diagnostic blood specimens for coagulation testing have been published by the National Committee for Clinical Laboratory Standards (NCCLS). Specimens that demonstrate visible hemolysis should not be used. The results obtained with plasma specimens that are icteric or lipemic should be interpreted with caution. **Plasma Storage:** Centrifuge capped specimens at 2500 x g for 15 minutes. If the plasma is to be frozen, remove from cells, then freeze rapidly (–20°C or lower) and thaw rapidly (37°C) to prevent denaturation of fibrinogen. It is recommended that testing be completed within the time limits specified in the following table.

Sample Storage Temperature	Test Within
22-24°C	2 hours
2-4 °C	4 hours
-20 °C	2 weeks
-70 °C	6 months

PROCEDURE

This procedure pertains to manual or semi-automated coagulation systems. Refer to your instrument manual for more detailed instrument specific instructions.

1. Ensure the reconstituted **QuikCoag Thrombin Time** is at room temperature.
2. Pipette 200 µL of test or control plasma into a test cuvette
3. Incubate at 37°C for 3 minutes.
4. Rapidly add 100 µL of the **QuikCoag Thrombin Time** reagent, simultaneously starting the timer.
5. Record the clotting time in seconds.

QUALITY CONTROL

Reliability of test results should be monitored within each run using normal and abnormal control fibrinogen control plasmas. Each laboratory should establish a control range to determine the allowable variation in day-to-day performance of each control plasma.

CALCULATION OF RESULTS

Calculate the mean clotting time of duplicate samples and controls. Differences between duplicate results should be less than 5%. Repeat the test if necessary. The clotting time in seconds is the patient's thrombin time.

EXPECTED VALUES

Clotting times are dependent upon numerous factors including temperature, water quality, pH, ionic strength, test system, specimen collection and preservation, and patient population. As a guide to the user, Thrombin Time data were obtained in 90 normal adults to establish a reference interval. Based on these results, the reference interval range was determined to be 8.5-11.9 seconds. This is only a guide to the user; specific Thrombin Time reference intervals should be established by each laboratory.

PERFORMANCE CHARACTERISTICS

Within-run precision studies on both normal and heparinized plasma and controls using **QuikCoag Thrombin Time** on hemostasis instrumentation gave Coefficients of Variation (CVs) of less than 3%. Day-to-day precision studies on normal and abnormal controls using similar instrumentation gave CVs of less than 5%. **QuikCoag Thrombin Time** was shown to be sensitive to fibrinogen levels as low as 75 mg/dl.

REFERENCES

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Symbols Key	
	Manufactured By
	Consult Instructions For Use
IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
	Expiration Date (YYYY.MM)
	Temperature Limitations
REF	Catalogue Number
CON	Contents
REC	Reconstitution Volume
	Biological Risks
EC REP	European Authorized Representative