

## 5-ENZYME Thrombin (Human)

REF 5D-60230

**For Research Use Only.**  
**Not for Use in Diagnostic Procedures.**  
**For *in vitro* use only.**

**Store at 2-8°C**  
**1 vial of 100 NIH**

English, last revision: 03-2023

### ORIGIN:

Prepared from a prothrombin complex concentrate extracted from human citrated plasma and fully activated in a purified system. Thrombin is then purified using an ion exchange chromatography and stabilised. It is a highly purified preparation, mainly in the  $\alpha$  form, with a specific activity  $\geq 1500$  NIH/mg.

### PRESENTATION:

Thrombin activity is reported in harmonized NIH or IU or USP units by reference to the WHO/NIBSC International Standard for Human Thrombin (01/580) (refer to "A reunification of the US ("NIH") and International Unit into a single standard for Thrombin", Longstaff *et al*, Thromb Haemost 2005, 93:261-6)). NIH is a clotting unit for thrombin activity.

Stabilised and lyophilised human Thrombin.

1 vial containing approximately 100 NIH of thrombin.

**This kit is for research use only and should not be used for patient diagnosis or treatment.**

### RECONSTITUTION:

Each vial must be restored with 1 mL distilled water, in order to get a concentration of about 100 NIH/mL. Dilute in the adequate buffer, if necessary.

### EXCIPIENTS:

Content per vial: Poly-Ethylene-Glycol 6000 (PEG-6000) (20mg), Sodium Chloride (6mg), Glycine (20mg), BSA (10mg), stabilizers.

### PURITY:

Human Thrombin has one major band of 35,000 daltons on SDS-PAGE.

### ACTIVITY:

Clotting time (at 4NIH/mL) on purified human Fibrinogen (4 mg/mL):  $8 \pm 3.5$  seconds.

Clotting time (at 10NIH/mL) on citrated human plasma pool:  $5 \pm 1$  second.

Chromogenic activity on 5-CHROM-38 Thrombin Chromogenic Substrate:  $\geq 0.75$ /min.NIH.mL.

Clotting activity determined in NIH (or IU).

Chromogenic activity on specific IIa substrates (expressed in nkats/ $\mu$ g) tested in the optimized conditions (0.05M Tris buffer at pH8.40, containing 0.30M NaCl). The exact activity in nkats/ $\mu$ g with 5-CHROM-38 Thrombin Chromogenic Substrate is reported on the analysis certificate for each lot.

### VIRAL SAFETY:

The human plasma used for Thrombin purification was tested with registered methods and found negative for HIV antibodies, HBs Ag and HVC antibodies. Bovine Serum Albumin (BSA) was prepared from bovine plasma, which was tested for the absence of infectious agents, and collected from animals free from BSE. However, no assay may warrant the total absence of infectious agents. Any product of biological origin must then be handled with all the required cautions, as being potentially infectious.

### USE:

For *in vitro* use only. All research studies and protocols where a source of highly purified human Thrombin is necessary.

**The results obtained should be for research purposes only and not used for patient diagnosis or treatment.**

### STABILITY:

#### Lyophilized:

- Until the expiration date printed on the kit.








**After reconstitution, in their original vial, and provided any contamination or evaporation is avoided:**

- 21 days at 2-8°C.
- 7 days at room temperature (18-25°C).
- 6 months frozen at -30°C or less

The stability of the reconstituted reagent should be checked under laboratory work conditions.

### SYMBOLS:

Symbols used and signs listed in the ISO 15223-1 standard, see symbol definitions below.

	Catalog number
	Batch code
	Expiration date
	Reconstitution volume
	YYYY-MM-DD Use by
	See instruction for use
	Temperature limitation

**Certificate of Analysis****5-ENZYME Thrombin (Human)****Vial of 100 NIH****REF** 5D-60230**LOT** XXX**EXP** XXX**Store at 2-8°C****Analytical Data | Specifications****Protein Content:**42.2 |  $\geq 30 \mu\text{g/vial}$ **SDS-PAGE (4-12 % acrylamide):**

35,000 daltons | 1 major band of about 35,000 daltons

**Clotting time** (tested on Fibrinogen):8.7 sec |  $8 \pm 3.5 \text{ sec.}$ **Thrombin concentration:**

108 NIH | 100 NIH +/- 10 NIH (IU\*)

\*1 NIH is equivalent to 1 international Unit (IU) ("A reunification of the US ("NIH") and international Unit into a single standard for Thrombin", Longstaff et al, Thromb Haemost 2005.93:261-6).**Chromogenic activity:** (on Ila substrate 5-CHROM-38 using at Ila for 4NIH/mL)A405: 1.513 | A405  $\geq 0.75$  /min.NIH.mL  
Activity: 1.2 /min.NIH.mL**Specific activity:**2901 NIH (or IU) /mg |  $\geq 1 500 \text{ NIH (or IU)/mg (clotting)}$   
5.26 nkats/ $\mu\text{g}$  |  $\geq 2 \text{ nkats}/\mu\text{g}$  (chromogenic on5-CHROM-38)  
2 nkats/ $\mu\text{g}$  |  $\geq 1 \text{ nkat/NIH (or nkats/IU)}$ **Batch homogeneity:**N = 25 - CV : 3.4 % | CV(OD)  $\leq 5\%$ **Conclusions:**

Date: XXX

 **Passed**  
 **Refused**