



**HYPHEN BioMed**  
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A Company of Sysmex Group

**ANALYSIS CERTIFICATE**

**BIOPHEN HEPARIN Anti Ila (kinetics) - #221020**

**Lot : FE023814**

**QC Release : 18 MARS 2025**

**Expiration date: 2027-07-17**

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : Human Antithrombin	2 vials	30	FE023814	2027-07-18
R2 : Thrombin substrate	2 vials	30	FE023814	2027-07-17
R3 : Human Thrombin	2 vials	30	FE023814	2027-08-06
R4 : Reaction buffer	2 vials	30	FE023814	2027-07-18

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Analytical data	Specifications
<p><b>1. AT</b></p> <p>a. Reproducibility for AT concentration (AT chromogenic assay):</p> <p style="margin-left: 40px;">N: 5</p> <p style="margin-left: 40px;">AT : 257 %</p> <p style="margin-left: 40px;">CV: 3.8 %</p> <p>b. AT content per vial (anti-Xa activity chromogenic assay)</p> <p style="margin-left: 40px;">2.57 IU</p> <p>c. Indicative AT content per vial (A280nm/Lowry on raw material)</p> <p style="margin-left: 40px;">1000 µg</p> <p>d. SDS PAGE (on raw material)</p> <p style="margin-left: 40px;">1 major band of about 58,000 Da</p> <p>e. Absence of heparin</p>	<p>N ≥ 5</p> <p>≥ 100%</p> <p>≤ 5 %</p> <p>≥ 1 IU</p> <p>1 major band of about 58,000 Da</p> <p>Absence</p>
<p><b>2. Thrombin substrate (CS-01(38))</b></p> <p>a. Blank value (N ≥ 5)</p> <p style="margin-left: 40px;">Mean (A405) : 0.215</p> <p>b. Reproducibility for 0 IU/ml Heparin:</p> <p style="margin-left: 40px;">N: 5</p> <p style="margin-left: 40px;">Mean (A405): 2.167</p> <p style="margin-left: 40px;">CV: 0.7 %</p> <p>c. Indicative content per vial (raw material)</p> <p style="margin-left: 40px;">25 mg (about 45 µmol)</p> <p>d. HPLC analysis purity grade (raw material)</p> <p style="margin-left: 40px;">98 %</p> <p>e. Experimental molecular weight (raw material)</p> <p style="margin-left: 40px;">552.4 Da</p>	<p>A405 ≤ 0.30</p> <p>N ≥ 5</p> <p>indicative ≥ 1.80</p> <p>≤ 5 %</p> <p>≥ 95%</p> <p>553 ± 5 Da</p>
<p><b>3. Thrombin</b></p> <p>a. Reproducibility for 0 IU/ml Heparin:</p> <p style="margin-left: 40px;">N: 5</p> <p style="margin-left: 40px;">Mean (A405) : 2.157</p> <p style="margin-left: 40px;">CV: 1.6 %</p> <p>b. SDS PAGE (5% acrylamide) (on raw material)</p> <p style="margin-left: 40px;">1 major band of about 35,000 Da</p> <p>c. Indicative IIa content per vial (Lowry on raw material)</p> <p style="margin-left: 40px;">10.5 µg</p> <p>d. Indicative clotting activity per vial (clotting assay on raw material) (respectively to the WHO/NIBSC standard for h(IIa)</p> <p style="margin-left: 40px;">24 NIH (or IU)</p> <p>e. Indicative chromogenic activity per vial (on raw material) (chromogenic assay using CS-01(38))</p> <p style="margin-left: 40px;">28 nkats</p>	<p>N ≥ 5</p> <p>indicative ≥ 1.80</p> <p>≤ 5 %</p> <p>1 major band of about 35,000 Da</p>
<p><b>4. Reaction buffer</b></p> <p style="margin-left: 40px;">Volume: 21.0 ml</p> <p style="margin-left: 40px;">pH: 8.34</p> <p>Aspect: <input checked="" type="checkbox"/> Clear <input checked="" type="checkbox"/> Transparent</p>	<p>≥ 20 ml</p> <p>[8.30 - 8.50]</p> <p>Clear - Transparent</p>

*Jko*

