

## Reference ranges for routine haemostasis

**Date: 29/8/24**

Reference ranges for **routine** haemostasis assay have been reviewed and harmonised across all Synnovis labs as they now all use the same methodology and reagents at GSTT/KCH (DH&PRUH) and Synnovis Hub Laboratories.

Changes to the ranges have been discussed and approved by Laboratory Haematology consultants and scientific staff. Please see the **Table 1** for the new Harmonised adult reference ranges which also includes paediatric reference ranges (where applicable). Any future **major** changes in decision limits we will be adding comments to the reported results to aid your interpretation.

There are some key changes that we would like to highlight as follows.

### Coagulation Screening Tests:

- Marginal changes been made to both lower and upper limits in regards to the routine screening tests i.e. PT/APTT, associated ratios INR/APTR respectively and Thrombin Time, Clauss Fibrinogen and PT and APTT 50:50 mix studies.
- Paediatric reference ranges will be reported for screening tests including D-Dimer.

### D-Dimer Assay:

- **Major** changes to D-Dimer assay and associated reporting units. Currently GSTT and Hub sites are reporting result in **mg/mL FEU** (short for Fibrinogen Equivalent Units) and going forward all Synnovis sites will be reported to **ng/mL FEU**.
- D-Dimer value of 0.50 mg/mL FEU in future will be reported as 500 ng/mL FEU.
- D-Dimer reference cut off values at GSTT will continue to the current age- related limits (see below).

Test	Age/ Legal Sex	Reference Range		Reporting Units
		Lower Limit	Upper Limit	
D-Dimer	Day 1 – 12 Years	≤312		ng/mL FEU
	>12 Years	≤550		
D-Dimer reported at (St Thomas' Hospital)	<60 Years	≤500		
	<70 Years	≤600		
	<80 Years	≤700		
	<90 Years	≤800		
	>90 Years	≤900		

- KCH (DH&PRUH) and Hub laboratory will report to <550 ng/mL FEU in patients >12 years of age and <312 ng/mL FEU for paediatrics.

### DOAC Assays:

- Ranges for DOAC assays been provided with expected peak and trough for direct oral anticoagulant concentration when on therapeutic doses.

As part of the transition to harmonised ranges we have taken the opportunity to review the **critical** limits for telephone action that we currently use. Some changes will be made that will

bring us into line with national guidelines for communicating critical results and with other Haemostasis departments within Synnovis. Refer to table 2 for the harmonised critical limits.

If you have any concerns or queries, please do not hesitate to contact us via our main email address:

**Table 1:** Harmonised reference ranges.

Test	Age/ Legal Sex	Reference Range		Reporting Units
		Lower Limit	Upper Limit	
Prothrombin Time (PT)/ PT 50:50 Mix	Day 1 – Day 91	8.2	14.1	Seconds
	Day 91 – 12 Years	9.6	11.8	
	>12 years	9.7	12.0	
INR Ratio	All ages	0.8	1.2	Ratio
APTT/ APTT 50:50 Mix	Day 1 – Day 4	29.0	51.5	Seconds
	Day 5 – Day 21	28.0	55.0	
	Day 22 – Day 84	28.0	50.0	
	Day 85 – Day 175	28.0	45.0	
	Day 176 – 1 Year	28.0	40.0	
	01 year– 12 years	26.0	38.0	
	>12 Years	21.0	29.0	
APTT Ratio	All ages	0.8	1.2	Ratio
Thrombin Time	Day 1 – 12 Years	9.2	15.0	Seconds
	>12 Years	14.0	18.0	
Fibrinogen	Day 0 – 12 Years	1.7	4.0	g/L
	>12 Years	1.7	4.9	
Reptilase Time	All ages	20.6	23.2	Seconds
D-Dimer	Day 1 – 12 Years	≤312		ng/mL FEU
	>12 Years	≤550		
D-Dimer reported at (St Thomas' Hospital)	<60 Years	≤500		
	<70 Years	≤600		
	<80 Years	≤700		
	<90 Years	≤800		
	>90 Years	≤900		

Test	Therapeutic Range		Units
	Lower Limit	Upper Limit	
INR Ratio (Vitamin K Anticoagulants)	2.0	4.0	Ratio
Anti-Xa (UFH)	0.3	0.7	IU/mL
Anti-Xa (Enoxaparin)	Therapeutic enoxaparin administered once daily, peak target 0.8-1.2 IU/mL & trough target <0.3IU/mL.		IU/mL
Anti-Xa (Tinzaparin)	The Therapeutic peak target anti-Xa activity for Tinzaparin is 0.5-1.0 IU/mL		IU/mL
Anti-Xa (Dalteparin)	Therapeutic dalteparin administered once daily: Peak target range 0.7-1.2 IU/mL & Trough target <0.2 IU/mL.		IU/mL
Anti-Xa (Fondaparinux)	Therapeutic peak target anti-Xa activity is 0.8-1.2 µg/mL.		µg/mL
Anti-Xa (Danaparoid)	Therapeutic peak target anti-Xa activity for Danaparoid is 0.5-0.8 IU/mL		IU/mL
Anti-Xa (Rivaroxaban)	Stroke prevention in NVAf 20mg od, expected peak 249 (184-343) ng/mL, trough 44 (12-137) ng/mL. PE/VTE: 20mg od, expected peak 270 (189-419) ng/mL, trough 26 (6-87) ng/mL Values: Mean (5-95 <sup>th</sup> percentile).		ng/mL
Anti-Xa (Apixaban)	Stroke prevention in NVAf 5mg bid, expected peak 171 (91-321) ng/mL, trough 103 (41-230) ng/mL. PE/VTE: 5mg bid, expected peak 132 (59-302) ng/mL, trough 63 (22-177) ng/mL Values: Median (5-95 <sup>th</sup> percentile).		ng/mL
Anti-Xa (Edoxaban)	Stroke prevention in NVAf 60mg od, expected peak 170 (125-245) <sup>a</sup> ng/mL, trough 36 (19-62) <sup>b</sup> ng/mL. PE/VTE: 60mg od, expected peak 234 (149-317) <sup>b</sup> ng/mL, trough 19 (10-39) <sup>b</sup> ng/mL <sup>a</sup> : Median (1.5 x interquartile range) <sup>b</sup> : Median (interquartile range).		ng/mL

Test	Therapeutic Range		Units
	Lower Limit	Upper Limit	
Anti-IIa (Dabigatran)	Stroke prevention in NVAf 150mg bd, expected peak 175 (117-275) ng/mL, trough 91 (61-143) ng/mL. PE/VTE: 150mg bd, expected peak 175 (117-275) ng/mL, trough 60 (39-95) ng/mL. Values: Mean (25-75 <sup>th</sup> percentile).		ng/mL
Anti-IIa (Argatroban)	Therapeutic peak target for Argatroban is 0.5-1.25ug/mL.		ug/mL

**Table:** Harmonised Critical Limits.

Test	Harmonised critical phoning limit	Patient details
PT/INR Sec	≥15.0	Patient >12 years of age with no history
PT/INR Ratio	≥1.4	Patient >12 years of age with no history
APTT Sec	≥34.0	Patient >12 years of age with no history
APTT Ratio	≥1.4	Patient >12 years of age with no history
INR on warfarin Ratio	≥5.0	Known VKA. Escalation to Kings College Hospital Anti-coagulation/ Haematology SpR.
	≥6.0	Known VKA. Escalation to Guys ad St Thomas Anticoagulation/ Haematology SpR.
Fibrinogen g/L	≤1.0	All incidences
D-Dimer ng/L FEU	≥550	Patient >12 years of age with no history
D-Dimer reported at (St Thomas' Hospital)	≥500	Patient >12 <60 yrs
	≥600	Patient <70 yrs
	≥700	Patient <80 yrs
	≥800	Patient <90 yrs
	≥900	Patient >90 yrs
	≥350	Patient <12 yrs
Anti Xa UFH IU/mL	≥1.5	All incidences
Anti Xa Enoxaparin	≥1.5	All incidences

Test	Harmonised critical phoning limit	Patient details
Anti Xa Tinzaparin	≥1.5	All incidences
Anti Xa Dalteparin	≥1.5	All incidences
Anti Xa Danaparoid	≥1.5	All incidences
Factor Assays	≤30	Patient with no history
ADAMTS13	<20	All incidences