

AN 2022\_06-2

**ADVISORY NOTICE**

**Erba Protime**  
**Ref. No.: EHL00001 / EHL00002**  
**Pack size: 4 x 5 mL / 8 x 5 mL**

March 16, 2023  
 Dear Customers,

Serves this new AN 2022\_06-2 to rectify the previous AN 2022-06.

We hereby inform you that we are now launching our improve kit for determination of prothrombin time (PT). The following changes have been implemented in the kit.

**1. Change of composition**

The assay has been modified to improve reagent performance. Key details are outlined below:

- The principle of the determination is the same.
- Pack size has changed from 6 x 4 mL to 4 x 5 mL and from 10 x 4 mL to 8 x 5 mL.
- The assay procedure (volume of reagents, ration reagents/samples, wavelength...) is without any change.
- ECL instrument protocols have not been changed.

**2. New PT values for Erba Control N / N Plus and Erba Control P / P Plus**

Due to the change mentioned previously, you can expect different results in control plasma.

New values for Erba Control N / N Plus and Erba Control P / P Plus – see table bellow.

PT						
Control material	LOT	Unit	ECL 105/412		ECL 760	
			Value	Range	Value	Range
Erba Control N	2111014	sec	10.6	8.5 - 12.7	10.4	8.3 - 12.5
		%	104.8	78.6 - 130.9	116.6	87.5 - 145.8
		INR	0.88	0.75 - 1.01	0.88	0.75 - 1.01
	2202095	sec	10.4	8.3 - 12.5	10.1	8.1 - 12.1
		%	108.0	81.0 - 135.0	121.0	90.8 - 151.3
		INR	0.86	0.73 - 0.99	0.85	0.72 - 0.98
Erba Control N Plus	2104183 2104198	sec	10.7	8.6 - 12.8	10.6	8.5 - 12.7
		%	102.2	76.7 - 127.8	114.6	85.9 - 143.3
		INR	0.89	0.76 - 1.02	0.90	0.77 - 1.03

PT						
Control material	LOT	Unit	ECL 105/412		ECL 760	
			Value	Range	Value	Range
Erba Control P	2109006	sec	20.05	16.4 – 24.6	21.2	17.0 – 25.4
		%	48.2	36.2 – 60.3	49.7	37.3 – 62.1
		INR	1.64	1.39 – 1.89	1.83	1.56 – 2.10
	2202096	Sec	22.3	17.8 – 26.8	24.0	19.2 – 28.8
		%	39.0	29.3 – 48.8	42.3	31.7 – 52.9
		INR	1.93	1.64 – 2.25	2.08	1.77 – 2.39
Erba Control P Plus	2201100	sec	13.7	11.0 – 16.4	14.2	11.4 – 17.0
		%	71.3	53.5 – 89.1	80.7	60.5 – 100.9
		INR	1.16	0.99 – 1.33	1.21	1.03 – 1.39

Best regards,

Erba Lachema s.r.o.

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