

ADVISORY NOTICE

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

Dear Customers,

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 (Quick method).
- 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 (Plus) and Erba Control P (Plus)

Because of the new supplier of product component, you can expect different results in control plasma.

New values for Erba Control N (Plus) and Erba Control P (Plus) – see table.

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	22.0 – 26.4
		%	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.
Technical Product Management

Brno, 28th March 2022

Erba Lachema s.r.o.

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