

AN 2022_08

ADVISORY NOTICE

Erba Thrombin Reagent

Ref. No.: EHL00006

Pack size: 4 x 5 ml

Dear Customers,

We hereby inform you that we are innovating a kit for determination of fibrinogen (FIB). The following changes have been made to the set.

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 (Claus method).
- Pack size has changed from 10 x 2 mL to 4 x 5 mL.
- The assay procedure (volume of reagents, ration reagents/samples, wavelength,...) is **without** any change.
- ECL instrument protocols **have not been** changed.
- The change in composition will result in slightly different clotting times. Local reference ranges should be reviewed before the introduction of the new reagent lots.

2. New FIB values for Erba Control N (Plus) and Erba Control P (Plus)

Because of changed composition, you can expect different results in control plasma.

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

Control material	LOT	Unit	FIB			
			ECL 105/412		ECL 760	
			Value	Range	Value	Range
Erba Control N	2111014 2112012	g/L	2.98	2.54 – 3.43	3.16	2.69 – 3.64
	2012044 2009054	g/L	3.16	2.69 – 3.63	3.34	2.84 – 3.84
	2101118 2011152	g/L	2.94	2.50 – 3.38	3.20	2.72 – 3.68
	2202095 2202097 2203067	g/L	2.94	2.50 – 3.38	3.26	2.77 – 3.75
Erba Control N (Plus)	2104111 2010012 2010022 2102088 2104116	g/L	3.24	2.76 – 3.73	3.38	2.87 – 3.89
	2104198 2104183 2201032 2104137 2104187 2108028 2201052	g/L	2.79	2.38 – 3.21	3.05	2.59 – 3.51
Erba Control P	2009047	g/L	2.93	2.49 – 3.37	3.13	2.66 – 3.59

	2102116 2011153 2012121	g/L	2.76	2.35 – 3.18	2.86	2.43 – 3.29
	2012119 2102083	g/L	2.79	2.37 – 3.21	2.86	2.43 – 3.29
	2112013 2108062 2108096 2112011	g/L	2.45	2.08 – 2.82	2.68	2.27 – 3.08
	2109006 2109011 2109025 2109026	g/L	2.74	2.33 – 3.15	2.97	2.52 – 3.41
	2202096 2202098 2203039	g/L	2.86	2.43 – 3.29	3.26	2.77 – 3.74
Erba Control P (Plus)	2011194 2010013 2011199 2101027 2103033 2106056 2106054	g/L	1.68	1.43 – 1.94	1.54	1.31 – 1.77
	2201100 2112058 2112086 2203037	g/L	1.78	1.51 – 2.04	1.65	1.41 – 1.90

Control lots produced later than March 2022 already have the value for Fibrinogen of the new formulation listed in its Value sheet.

The first batch with a new composition is No:2302076 will be available from 03/2023.

Best regards,

Erba Lachema s.r.o.
Technical Product Management

Brno, 15th February 2023

Erba Lachema s.r.o.
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