

<b>REF</b>	MRX170 Triple pack	4+4+2 x 1mL	<b>EXP</b> 2014-06	<b>LOT</b>	Triple pack	13197	<b>IVD</b>	For in Vitro Diagnostic Use In-vitro Diagnostikum In vitro diagnostisk produkt De uso diagnostico in vitro In vitro diagnostisk udstyr
	MRX171 Level 1	10x1 mL			Level 1	13194		
	MRX172 Level 2	10x1 mL			Level 2	13195		
	MRX173 Level 3	10x1 mL			Level 3	13196		

ASSAY AND REAGENT TYPE		Art MRX171 LOT 13194		Art MRX172 LOT 13195		Art MRX173 LOT 13196	
Product No/Product Name		Level 1		Level 2		Level 3	
		Mean	± 2SD	Mean	± 2SD	Mean	± 2SD
Prothrombin Time (PT)							
MediRox GHI131-10 Owrens PT	INR	1,05	N.A	2,54	N.A	3,56	N.A
20301800 HemosIL PT RecombiPlasTin 2G	INR	0,94	0,84-1,04	2,28	1,96-2,60	3,36	N.A
HemosIL PT Recombiplastin	INR	0,96	0,85-1,07	2,31	1,96-2,66	N.A	N.A
HemosIL PT-Fib HS Plus	INR	0,98	0,88-1,08	2,51	2,05-2,97	N.A	N.A
Roche STA Neoplastin plus	INR	0,95	0,85-1,05	2,70	2,29-3,11	N.A	N.A
Sclavo PT	INR	1,04	0,95-1,13	2,85	2,21-3,49	N.A	N.A
Siemens PT Innovin	INR	1,05	0,96-1,14	2,25	2,00-2,50	N.A	N.A
Siemens Thromborel S	INR	0,98	0,87-1,09	2,36	1,86-2,86	N.A	N.A
MediRox GHI131-10 Owrens PT	Seconds	26	N.A	65	N.A	93	N.A
20301800 HemosIL PT RecombiPlasTin 2G	Seconds	11	N.A	27	N.A	39	N.A

Thrombin Time (TT)		Mean	± 2SD	Mean	± 2SD	Mean	± 2SD
9758515 HemosIL Thrombin Time	Seconds	16,6	N.A	N.A	N.A	N.A	N.A

Activated Partial Thromboplastin time (APTT)		Mean	± 2SD	Mean	± 2SD	Mean	± 2SD
MediRox MRX930, MRX931 APTT	Seconds	30	N.A	64	N.A	83	N.A
20006300 HemosIL APTT-SP	Seconds	28	25-31	57	47-66	77	63-91
Hemosil SynthASil APTT	Seconds	31	27-36	51	39-63	N.A	N.A
Siemens APTT Pathrombin SL	Seconds	37	35-39	86	73-98	133	99-168
Siemens Actin FS	Seconds	33	28-39	62	48-76	N.A	N.A
Sclavo APTT	Seconds	32	31-33	66	60-72	N.A	N.A
Roche STA Cephascreen APTT	Seconds	33	31-34	58	56-60	N.A	N.A

Fibrinogen		Mean	± 2SD	Mean	± 2SD	Mean	± 2SD
20301800 HemosIL QFA Thrombin	mg/dl	272	242-303	157	127-187	103	N.A
HemosIL Fib-C	mg/dl	264	189-340	152	80-223	N.A	N.A
Siemens Thrombin	mg/dl	259	226-292	158	142-176	N.A	N.A
Siemens Multifibren U	mg/dl	280	211-348	204	142-266	N.A	N.A
Sclavo Fibrinogen	mg/dl	275	227-323	184	153-215	N.A	N.A
ROCHE STA Fibrinogen	mg/dl	284	257-310	175	162-187	N.A	N.A

Antithrombin III (ATIII)		Mean	± 2SD	Mean	± 2SD	Mean	± 2SD
MediRox MRX1200 Antithrombin Liquid	IU/mL	0,98	N.A	0,45	N.A	0,28	N.A
20030100 HemosIL Liquid Antithrombin	%	101	93-108	39	31-48	23	N.A
IL Antithrombin III Chromogenic	%	101	92-111	40	31-48	N.A	N.A
Siemens Innovance Antithrombin	%	103	85-121	42	28-56	N.A	N.A
Siemens Berichrom Antithrombin III	%	100	95-106	40	31-49	N.A	N.A
Sclavo Antithrombin	%	98	82-113	39	21-58	N.A	N.A

D-dimer		Mean	± 2SD	Mean	± 2SD	Mean	± 2SD
MediRox MRX143 D-dimer	mg/L DDU	0,36	N.A	0,96	N.A	2,47	N.A
MediRox MRX143 D-dimer	mg/L FEU <sup>[1]</sup>	0,72	N.A	1,92	N.A	4,94	N.A
20007700 HemosIL D-Dimer HS	ng/mL (DDU)	355	N.A	899	N.A	2473	N.A
20008500 HemosIL D-Dimer	ng/mL (DDU)	386	256-515	809	698-919	1906	N.A
Siemens Innovance D-Dimer	ng/mL (FEU)	1175	1071-1278	3144	2779-3509	N.A	N.A
Roche STA D-Dimer LIA	µg/mL (FEU)	0,644	0,468-0,820	1,62	1,48-1,76	N.A	N.A

**NOTE**

Note that the results for each independent laboratory may differ considerably depending on laboratory techniques, instrument settings and reagent depending factors. Therefore each laboratory should establish its own means and reference ranges and use those provided only as a guideline.

Mean values and ±2SD have been established by the usage of several instruments with separate calibration systems. Sample to sample variation should be significantly smaller than the given range. Refer to reagent insert for expected sample to sample variation.

N.A: Parameters are established using single instrument analysis, hence no ±2SD values are provided.

[1] MRX143 D-dimer levels are reported both as mg/L DDU and mg/L FEU. For a conversion to FEU a factor of 2 is generally used even if a stoichiometrical calibration would suggest a different factor. References: Fedde van der Graaf, Henk van der Borne, Marion van der Kolk, Piet J. de Wild, Ger W.T. Janssen, Stan H.M. van Uum. Exclusion of Deep Venous Trombosis with D-Dimer Testing. Bror Edlund, Torbjörn K. Nilsson. A proposed stoichiometrical calibration procedure to achieve transferability of D-Dimer measurements and to Characterize the performance of different methods.