ELITech Clinical Systems SAS

REF: ICRP-XXXX

## <u>Instruction for use</u>: Consult Instruction for Use

## APPLICATION - ENVOY500 - PROPOSAL

This application is intended to serve as a guide for using the referenced ELITechGroup Reagent on this instrument system only. It is recommended that the user validate this application prior to routine use.

PRIMARY PARAMETERS		CHECK PARAMETERS		SECONDARY PARAMETERS SERUM*	
Code	CRP	Reagent limit (mABS)	3000	1 <sup>st</sup> Unit	mg/L
Bar-Code	Inactive	Curve Acceptance (%)	100	2 <sup>nd</sup> Unit **	Inactive
Code for Bar-Code	Inactive			Dynamic Blank	Inactive
Test Methodology	IMMUNO	SERUM*		Needle washes	3/3
Method	Sample Blank (A)	Low Test Limit (Conc)	0	Cuvette washes	3
Kind of Process	Cubic Spline	Test Limit (Conc)	190	Special wash	*
1 <sup>st</sup> Filter	340nm	Initial ABS (mABS)	0.000	Instrumental Factor	1.000
2 <sup>nd</sup> Filter	<no></no>	Final ABS (mABS)	3000	Shift	0.000
Reaction Direction	Increasing	Max ABS Delta (mABS)	1000	Reagent Blank	Every day
		Prozone Check	inactive	Decimals	1
REAGENTS					
Number of reagents	2	RE-RUN SERUM*		STANDARD PARAMETERS	
Reagent 1 Volume μL	250	Normal Range	Min Max	Timed Re-run	Inactive
Concentrated	Inactive	Man	[User defined]	Automatic Dilution	Inactive
Reagent 2 Volume μL	25	Woman	[User defined]	Reagent ABS	[Determined by Envoy
Concentrated	Inactive	Child	[User defined]	Number of Samples	6
SAMPLE		Re-run hyperactive	Inactive	Use Serum Pre- Dilution	Inactive
Name	<u>Serum</u>	Re-run pathological	Inactive	Pos.	[User defined]
Sample μL	16	Re-run out of curve "Above"	Inactive	Conc.	[User defined]
Pre-Dilution 1:	1	Re-run out of curve "Below"	Inactive	ABS	[Determined by Envoy
Dilution 1:	2			% last calibration	100
TIMES				Enable Auto Adjust	Inactive
Sample Starter	Inactive				
Delay Time (sec)	0 s				
Reading Time (sec)	10s				
Reagent 1 Incubation Time	300s				
Reagent 2 Incubation Time	240s				

<sup>\*</sup> Value input by operator.