

Instruction for use :
 Consult Instruction for Use

APPLICATION - ENVOY500 / 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	
Code	BILi D		Reagent limit (mABS)	xxx		1st Unit Serum	mg/dL
Bar-Code	Inactive		Curve Acceptance (%)	100		2nd Unit Serum	Inactive
Code for Bar-Code	Inactive		RE-RUN SERUM			1st Unit Urine	N/A
Test Methodology	BILI Direct		Test Limit (Conc)	10.55		2nd Unit Urine	Inactive
Method	Sample Blank A		Low Test Limit (Conc)	0.08		Dynamic Blank	Active
Kind of Process	Linear		Initial ABS (mABS)	N/A		Needle washes	3/3
1st Filter	546		Final ABS (mABS)	N/A		Cuvette washes	3
2nd Filter	N/A		Max ABS Delta (mABS)	N/A		Additional wash	Inactive
Reaction Direction	Increasing		Prozone Check	Inactive		Instrumental Factor	1.000
REAGENTS			Normal Range	<u>Min</u>	<u>Max</u>	Shift	0.000
Number of reagents	2		Man	xxx	xxx	Reagent Blank	Every day
Reagent 1 Volume µL	280		Woman	xxx	xxx	Decimals	2
Concentrated	Inactive		Child	xxx	xxx	STANDARD PARAMETERS	
Reagent 2 Volume µL	70		Re-run hyperactive	Inactive		Factor	[Determined by Calibration]
Concentrated	Inactive		Re-run pathological	Inactive		Minimum	xxx
SAMPLE			RE-RUN URINE			Maximum	xxx
Name	Serum	Urine	Test Limit (Conc)	N/A		Number of Samples	1
Sample µL	35	N/A	Low Test Limit (Conc)	N/A		Max Var.(%)	10
Pre-Dilution 1:	1	N/A	Initial ABS (mABS)	N/A		Timed Re-run	xxx/xxx
Dilution 1:	1	N/A	Final ABS (mABS)	N/A		N.replicates	3
TIMES			Max ABS Delta (mABS)	N/A		Reagent ABS	[Determined by Envoy]
Sample Starter	Inactive		Prozone Check	Inactive		Pos.	xxx
Delay Time (sec)	0		Normal Range	<u>Min</u>	<u>Max</u>	Conc.	xxx
Reading Time (sec)	10		Man	N/A	N/A	ABS	[Determined by Envoy]
Reagent 1 Incubation Time	300		Woman	N/A	N/A	% last calibration	100
Reagent 2 Incubation Time	50		Child	N/A	N/A		
			Re-run hyperactive	N/A			
			Re-run pathological	N/A			

xxx Value input by operator.