ELITechGroup
EMPOWERING IVD
ELITech Clinical Systems SAS

BILIRUBIN TOTAL 4+1

REF : BITO-XXXX

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

Code	BILi T
Bar-Code	Inactive
Code for Bar-Code	Inactive
Test Methodology	BILI Total
Method	Sample Blank A
Kind of Process	Linear
1st Filter	546
2nd Filter	700
Reaction Direction	Increasing

REAGENTS

Number of reagents	2
Reagent 1 Volume µL	280
Concentrated	Inactive
Reagent 2 Volume µL	70
Concentrated	Inactive

SAMPLE

	Serum	Urine
Name	Bilirubin Total	
Sample µL	18	N/A
Pre-Dilution 1:	1	N/A
Dilution 1:	1	N/A

TIMES

Sample Starter	Inactive
Delay Time (sec)	0
Reading Time (sec)	10
Reagent 1 Incubation Time	300
Reagent 2 Incubation Time	390

CHECK PARAMETERS

Reagent limit (mABS)	xxx
Curve Acceptance (%)	100

RE-RUN SERUM

Test Limit (Conc)	25.00
Low Test Limit (Conc)	0.25
Initial ABS (mABS)	N/A
Final ABS (mABS)	N/A
Max ABS Delta (mABS)	N/A
Prozone Check	Inactive

Normal Range	Min	Max
Man	xxx	xxx
Woman	xxx	xxx
Child	xxx	xxx

Re-run hyperactive	Inactive
Re-run pathological	Inactive

RE-RUN URINE

Test Limit (Conc)	N/A
Low Test Limit (Conc)	N/A
Initial ABS (mABS)	N/A
Final ABS (mABS)	N/A
Max ABS Delta (mABS)	N/A
Prozone Check	Inactive

Normal Range	Min	Max
Man	N/A	N/A
Woman	N/A	N/A
Child	N/A	N/A

Re-run hyperactive	N/A
Re-run pathological	N/A

SECONDARY PARAMETERS

1st Unit Serum	mg/dL
2nd Unit Serum	Inactive
1st Unit Urine	N/A
2nd Unit Urine	Inactive
Dynamic Blank	Active
Needle washes	3/3
Cuvette washes	3
Additional wash	Inactive
Instrumental Factor	1.000
Shift	0.000
Reagent Blank	Every day
Decimals	2

STANDARD PARAMETERS

Factor	[Determinated by Calibration]
Minimum	xxx
Maximum	xxx
Number of Samples	1
Max Var.(%)	10
Timed Re-run	xxx/xxx
N.replicates	3
Reagent ABS	[Determined by Envoy]
Pos.	xxx
Conc.	xxx
ABS	[Determined by Envoy]
% last calibration	100

xxx Value input by operator.