APPLICATION PROCEDURE

REF	Cont.		
908510	**4 x 20 ml**	3 x 20 ml	Reagent 1
	(78 ml)	1 x 18 ml	Reagent 2
908520	**4 x 10 ml**	3 x 10 ml	Reagent 1
	(39 ml)	1 x 9 ml	Reagent 2

Additionally offered:

909560SV	1 x 1 ml	Homocysteine Calibrator 0 µM
909561SV	1 x 1 ml	Homocysteine Cal./Ctrl. approx. 10 µM
909562SV	1 x 1 ml	Homocysteine Cal./Ctrl. approx. 33 µM
905620	4 x 1 ml	Homocysteine Control Set (4 levels)
908550	5 x 1 ml	Homocysteine Calibrator Set (5 levels)

BT 2000/3000 Targa

Double reagent application

Test Type		Fixed Time With Start
Serum Starter		(Not Active)
Filters	(A/B)	340 / 700
Units		µmol/l
Test Method		Multi Point
Test Methodology		UV
Number Of Needle Washes		2 / 2
Delay Time	(Sec)	0
Reagent Inc.	(Sec)	180 / 150
Reading Time	(Sec)	360
Reaction Limit	(mABS)	700
Max ABS Delta	(mABS)	1500
Reagent Limit	(mABS)	1000
Reagents A/B	(µl)	240 / 65
Reaction Direction		Decreasing
Reagent Diluent		1:1
Initial ABS	(mABS)	2000
Curve Acceptance		100%
Cross Contamination Map		(Not Active)
Automatic Profile		(Not Active)
Rerun Reagent BLK	H: M	00:00
Dynamic Blank		(Not Active)
Pathological Repetition		(Not Active)

SERUM PARAMETERS

Test's Name		Homocysteine
Sample Volume	(µl)	13
Dilution Ratio		1:2
Test Limit		60.0
Min. Max. M.		3.0 /27.0
Min. Max. F.		3.0 /27.0
Min. Max. B.		3.0 /27.0

URINE PARAMETERS

Test's Name	
Urine Volume (µl)	
Test Limit	
Min. Max. M.	---/ ---
Min. Max. F.	---/ ---
Min. Max. B.	---/ ---
Auto Dilution	Not Active
Multi Factor	1
Units Factors	1

SAMPLE: Fresh serum, heparin or EDTA plasma (Discard hemolysed, turbid or severely lipemic specimens.
Centrifuge blood samples immediately after collection!
The Homocysteine in the sample is stable at room temperature 4 days, at 0-8C° several weeks, at – 20C° > 1year.

REFERENCE VALUES
Serum: Men 6.0 – 15.0 µmol/l, Women 3.0 – 12.0 µmol/l
Reference values should be used as a guide only. It is recommended that each laboratory should establish its own reference ranges for patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

CALCULATION:
All values of the determined samples are referred to the generated calibration curve.

CALIBRATION: Use kit REF 620 to create the standard calibration curve. The Standard value is lot dependent. The standard value is indicated in the insert of kit REF 620. The calibrators must be placed on the sample plate observing progressive increase of concentrations.
Standard Calibration Curve:

STD # 1	STD # 2	STD # 3	STD # 4	STD # 5
Level Zero	Level 1	Level 2	Level 3	Level 4

REAGENT STORAGE AND STABILITY
The data is printed in "Manual Methodology" insert in the kit

PREPARATION OF REAGENTS
The reagents are liquid and ready to use.

QUALITY CONTROLS:
Suggested Calibrators and Control Sample:
Calibrator REF 620,, Controls are included in kit

Application data stated in this sheet should be considered as indicative even if coming from routine tests made with Biotecnica's automatic analyzers. They are not validated in accordance with the directive 98/79-CE. Each laboratory is responsible for confirming the validity of indicated data through a Quality Control procedure.

BT 1000//BT Plus series		BT 2500 / BT 3500	
Double reagent application			
Code for BAR_ CODE		Inactive	Inactive
Test Methodology		UV	
Method		Fixed Time	Fixed Time
Kind Of Process		Multi Point	Multi Point
Filters		340 / 700	340 / 700
Reaction Direction		Decreasing	Decreasing
Reagent #1	(µl)	240	200
Reagent # 2	(µl)	65	54
Sample Starter		Inactive	Inactive
Delay Time	(sec)	0	0
Incubation Time	(sec)	180 / 150	180 / 150
Reading Time	(sec)	360	360
Unit Serum		µmol/l	µmol/l
Unit Urine			
Number Of Needle Washes		2 / 2	2 / 2
Number Of Cuvette Washes		2	2
Dynamic Blank		Inactive	Inactive
Reagent Blank		Every Day	Every Day
Reagent Limit	(mABS)	1000	1000
Curves Acceptance	(%)	100	100
SERUM PARAMETERS			
Name		Homocysteine	
Sample	(µl)	13	10.8
Pre-Dilution		1	1
Dilution			
Factor		2	2
Limit Test	(Conc.)	60.0	60.0
Initial ABS	(mABS)	2000	2000
Final ABS	(mABS)	700	700
Max ABS Delta	(mABS)	1500	1500
Check Prozona	(mABS)	Inactive	Inactive
Instrumental Factor		1	1
Shift		0.000	0.000
Re-run Hyperactive		Active	Active
Re-run Pathological		Inactive	Inactive
RE-run out of curve " Above"		Active	Active
Re-run out of curve "Below"		Inactive	Inactive
Normal Range			
Men		3.0 /27.0	
Women		3.0 /27.0	
Children		3.0 /27.0	
URINE PARAMETERS			
Name			
Sample	(µl)	3	3
Pre-Dilution		1	1
Diluizione			
Factor		1	1
Limit Test	(Conc.)		
Initial ABS	(mABS)		
Final ABS	(mABS)		
Max ABS Delta	(mABS)		
Check Prozona	(mABS)	Inactive	Inactive
Instrumental Factor		1	1
Shift		0.000	0.000
Re-run Hyperactive		Inactive	Inactive
Re-run Pathological		Inactive	Inactive
RE-run out of curve " Above"		Inactive	Inactive
Re-run out of curve "Below"		Inactive	Inactive
Normal Range			
Men			
Women			
Children			

INTERFERENCES
The data is printed in "Manual Methodology" insert in the kit.

LINEARITY
The data is printed in "Manual Methodology" insert in the kit. The declared data can be obtained with the instrument under optimal conditions of use.

ANALYTICAL PERFORMANCE: The data is printed in "Manual Methodology" insert in the kit. The declared data can be obtained with the instrument under optimal conditions of use.

NOTE
- Avoid reagent exposure to heating, direct sunlight, contamination and evaporation.
In case of complaint or quality control request, indicate the lot number of the package or the lot number of the individual components.

WASTE MANAGEMENT: Dispose of in accordance with local official regulations.

	Consult accompanying documents		Consult instructions for use		Manufactured by DIALAB GmbH
	Biological risks		Do not dispose of in environment		Rev01. 09.04.2010