Liquid Stable (LS) 2-Part HOMOCYSTEINE REAGENT

FHRWAU/FHRWR100/200/1000

REF

100 / 200 / 1000

R1 : 30mL, R2 : 5mL, Cal : 2 x 3mL
R1 : 60mL, R2 : 10mL, Cal : 2 x 3mL
R1 : 5 x 60mL, R2 : 5 x 10mL, Cal : 2 x 3mL

CE IVD en

WARNING: Specimens from patients who are on drug therapy involving S-adenosyl-methionine may show falsely elevated levels of homocysteine. Patients who are taking methotrexate, carbamazepine, phenytoin, nitrous oxide, anticonvulsants, or 6-azauridine triacetate, may have elevated levels of homocysteine due to their effect on the pathway. Refer to the LIMITATIONS FOR USE section in this assay package insert.

Revised September 2019

INTENDED USE

The Liquid Stable (LS) 2-Part Homocysteine Reagent is intended for *in vitro* quantitative determination of total homocysteine in human serum and plasma. The device can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia and homocystinuria.

PRINCIPLE OF THE ASSAY

This assay consists of two key steps:
Reduction: Dimerised homocysteine, mixed disulfide, and protein-bound forms of Homocysteine (HCY) in the sample are reduced to form free HCY by the use of tris [2-carboxyethyl] phosphine (TCEP).
Enzymatic Conversion: Free HCY is converted to cystathionine by the use of cystathionine beta-synthase (CBS) and excess serine. The cystathionine is then broken down to homocysteine, pyruvate and ammonia via cystathionine beta-lyase (CBL). Pyruvate is converted to lactate via lactate dehydrogenase (LDH) with nicotinamide adenine dinucleotide (NADH) as coenzyme. The rate of NADH conversion to NAD^+ (measured at A340 nm) is directly proportional to the concentration of homocysteine.

KIT COMPONENTS

REAG 1	1 x 30.0 mL, (100 test) 1 x 60.0 mL, (200 test) 5 x 60.0 mL (1000 test)	NADH (0.47 mM), LDH (38 KU/L), Serine (0.76 mM), Trizma Base 1-10%, Trizma Hydrochloride 1-10%, Sodium Azide < 1%. Reductant (TCEP:2.9 mM) **Ready-to-use**	
REAG 2	1 x 5.0 mL, (100 test) 1 x 10.0 mL, (200 test) 5 x 10.0 mL (1000 test)	Cycling Enzymes; CBS (0.748 KU/L) and CBL (16.4 KU/L) Sodium Azide < 1%. **Ready-to-use**	
CAL	1 x 3.0 mL (Blue Cap)	Homocysteine blank (0 µmol/L). **Ready-to-use**	
CAL	1 x 3.0 mL (Red Cap)	Homocysteine solution (28 µmol/L). **Ready-to-use**	

STANDARDISATION

The calibrators are traceable to NIST SRM 1955, confirmed by a designated measurement procedure (HPLC).

ITEMS REQUIRED BUT NOT PROVIDED

An analyzer capable of dispensing 2 reagents and measuring absorbance at 340 nm with temperature control (37˚C).
An Axis-Shield Homocysteine Control Kit (FHCY200) is sold separately and is available for use with the Liquid Stable (LS) 2-Part Homocysteine Reagent.

STORAGE OF REAGENTS, HANDLING AND PROCEDURAL NOTES

1. Store kit components at 2-8˚C and use until the expiry date on the labels. Do not use expired reagents. **DO NOT FREEZE REAGENTS**.
2. Reagents may be used on multiple occasions until the expiry date on the labels. Reagents **must** be returned to 2-8°C storage between use.
3. Do not mix different reagent kit lot numbers.
4. Do not expose Reagent 1 and Reagent 2 to light during on-board use.
5. Avoid contamination of reagents. Use a new disposable pipette tip for each reagent or sample manipulation.
6. Reagents should be clear of particulate material and should be discarded if they become turbid.

WARNINGS AND SAFETY PRECAUTIONS

1. Reagent 1 and Reagent 2 contain sodium azide which can react with lead or copper plumbing to form highly explosive metal azides. On disposal, flush with large quantities of water to prevent azide build-up.
2. Material safety data sheets are available upon request from Axis-Shield.

REAG 1 REAG 2	EUH032	Contact with acids liberates very toxic gases.

Caution: Federal law restricts this device to sale by or on the order of a physician

ASSAY PROCEDURE

- Programme instrument using appropriate instrument protocols.
- Load reagents and samples onto the instrument as instructed.
- Run assay.

SPECIMEN COLLECTION AND HANDLING

1. Serum (collected in serum or serum separator tubes) and plasma (collected in potassium EDTA or lithium heparin tubes) may be used for the measurement of homocysteine.
   However, it is not recommended to use individual patient results from serum, heparinized plasma and EDTA plasma interchangeably.[11] Additionally matrix differences between serum and serum separator tubes and plasma tubes have been reported.[1]
   To minimize increases in homocysteine concentration from synthesis by red blood cells, process specimens as follows:
   - Place all specimens (serum and plasma) on ice after collection and prior to processing. Serum may clot more slowly and the volume may be reduced.[2]
   - All specimens may be kept on ice for up to 6 hours prior to separation by centrifugation.[1]
   - Separate red blood cells from serum or plasma by centrifugation and transfer to a sample cup or other clean container.

   Note: Specimens not placed on ice immediately may exhibit a 10-20% increase in homocysteine concentration.[3]
2. If the assay will be performed within 2 weeks after collection, the specimen should be stored at 2-8˚C. If the testing will be delayed more than 2 weeks, the specimen should be stored frozen at -20˚C or colder. Specimens have been shown to be stable at -20˚C for 8 months. Mix specimens thoroughly after thawing. Avoid multiple freeze-thawing. [1,2]
3. Specimens containing particulate matter (fibrin, red blood cells, or other matter) and visibly lipaemic specimens should not be used with the assay. Results from these specimens may be inaccurate.

QUALITY CONTROL PROCEDURES

Maintenance and calibration of the instrument must be performed according to the manufacturer's instructions. Assayed control materials with values for homocysteine in both the normal and abnormal ranges should be tested to validate reagent performance. Users should demonstrate that they obtain performance specifications for precision and reportable range of test results comparable to those established by the manufacturer before reporting patient test results.

EXPECTED VALUES

The reference range should be determined by each laboratory. HCY concentrations in healthy individuals varies with age, gender, geographical areas and genetic factors. Scientific literature reports reference values for adult male and females between 5-15 µmol/L[2,4,5]. A reference range among an elderly population (> 60 years) is 5-20 µmol/L.[6] In countries with folic acid fortification programmes, reduced levels of HCY may be observed.[7,8] As a point of reference the ranges quoted above may be used until the laboratory has analysed a sufficient number of specimens to determine its own reference range.

LIMITATIONS OF USE

1. In Vitro Diagnostic Use. For professional use only.
2. The linear range of the Liquid Stable (LS) 2-Part Homocysteine Reagent when run as directed is 1-46 µmol/L for the BECKMAN COULTER AU400 and COBAS Integra 800; 2-46 µmol/L for the ROCHE Hitachi 917 and ROCHE Modular P and 2-44 µmol/L for the BECKMAN COULTER AU480, AU680 and AU5800.
3. Specimens >46 µmol/L should be diluted 1 part specimen to 2 parts Cal 0 µmol/L or 1 part specimen to 9 parts Cal 0 µmol/L as appropriate.
4. Cystathionine is measured with homocysteine, but in the general population the cystathionine level (0.065 to 0.3 µmol/L) has a negligible effect. In very rare cases, end stage renal disease and patients with severe metabolic disturbances, cystathionine levels may rise dramatically and in severe cases cause greater than 20% interference.[9,10]
5. Hydroxylamine, present in several iron reagents may carryover (reagent probe or reaction cuvette) and cause falsely low results. Routine rinsing procedures are not adequate to eliminate this problem in most cases. Possible solutions would include special washing protocols, changing to an iron assay that used ascorbic acid as reductant or running iron and homocysteine assays on separate instruments.
6. Carbamazepine, methotrexate, phenytoin, nitrous oxide, or 6-azauridine triacetate may affect the homocysteine concentration.[1]
7. Note: Specimens from patients who are on drug therapy involving S-adenosyl-methionine may show falsely elevated levels of homocysteine. Patients who are taking methotrexate, carbamazepine, phenytoin, nitrous oxide, anticonvulsants, or 6-azauridine triacetate, may have elevated levels of homocysteine due to their effect on the pathway.
8. Specimens containing particulate matter (fibrin, red blood cells, or other matter) and visibly lipaemic specimens should not be used with the assay. Results from these specimens may be in accurate.

RESULTS

The results are calculated automatically and are presented in µmol/L.
Ensure results are multiplied by the correct dilution factor.

VER: 2016/01

PERFORMANCE DATA

Data presented were generated on the BECKMAN COULTER AU systems (AU400, AU480, AU680, AU5800), COBAS INTEGRA 800, ROCHE Hitachi 917 and ROCHE Modular P systems. Results may vary depending on the system used. Other instrument protocols are available. It is the responsibility of the user to verify performance. See www.homocysteine.org.uk or contact the manufacturer.

Accuracy:

A correlation study was performed to a comparator device based on guidance from NCCLS document EP9-A2[12]. The specimens tested gave the statistical values (95% confident intervals) as summarized below:

Instrument System	Specimen Range (µmol/L)	No of Specimens (n)	Slope	Y-Intercept	Correlation coefficient (r)
BECKMAN COULTER AU400	6.5 – 49.0	94	0.99	0.17	1.00
BECKMAN COULTER AU480	8.5 – 45.1	99	0.97	-0.68	1.00
BECKMAN COULTER AU680	8.5 – 45.1	98	0.97	-0.22	1.00
BECKMAN COULTER AU5800	8.5 – 45.1	99	0.98	-0.75	1.00
COBAS Integra 800	6.3 – 48.4	100	0.97	-0.16	1.00
ROCHE Hitachi 917	8.2 – 45.6	100	0.97	0.49	0.99
ROCHE Modular P	5.7 – 47.1	96	0.94	-0.22	1.00

Precision:

A 20-day study was performed based on guidance from NCCLS document EP5-A2[13] using two reagent lots and a stored calibration curve. Results (*rounded to 1 decimal place*) per system are summarized below for each level tested (n=80).

	BECKMAN COULTER *AU400*			BECKMAN COULTER *AU480*		
Sample	Mean µmol/L	Within Run CV%	Total CV%	Mean µmol/L	Within Run CV%	Total CV%
Panel 1	7.0	1.9	3.3	10.54	3.1	3.5
	7.0	2.2	4.4	11.00	6.5	8.4
Panel 2	36.0	1.3	2.5	28.71	0.9	2.0
	35.5	1.1	2.3	28.20	0.6	2.1
Panel 3	48.3	1.1	2.0	37.63	0.9	2.6
	47.7	1.0	2.2	36.98	0.6	2.5
Low Control	6.3	2.6	4.4	6.73	1.1	3.1
	6.3	2.1	4.1	6.51	2.5	3.4
Medium Control	12.3	1.5	3.0	12.74	1.4	1.9
	12.2	1.3	3.2	12.43	1.8	2.4
High Control	25.5	1.5	2.5	26.13	0.9	1.8
	25.3	1.6	2.9	25.66	0.7	1.8

	BECKMAN COULTER *AU680*			BECKMAN COULTER *AU5800*		
Sample	Mean µmol/L	Within Run CV%	Total CV%	Mean µmol/L	Within Run CV%	Total CV%
Panel 1	10.76	2.8	3.0	10.53	1.5	3.3
	10.65	3.0	3.6	10.53	2.6	3.2
Panel 2	28.90	1.2	1.6	28.58	0.8	1.8
	28.67	1.5	2.5	28.42	1.0	1.7
Panel 3	37.78	0.7	1.4	37.65	0.9	2.1
	37.90	0.7	1.8	37.55	0.8	1.5
Low Control	6.96	2.4	2.4	6.49	3.6	4.7
	6.79	2.3	3.1	6.70	2.2	2.7
Medium Control	13.03	1.0	1.5	12.52	1.8	1.8
	12.76	1.6	1.7	12.57	1.4	2.1
High Control	26.38	0.9	1.6	25.87	1.0	1.6
	26.19	1.2	1.5	25.69	1.2	1.3

	COBAS Integra 800			*ROCHE Hitachi 917*			*ROCHE Modular P*		
Sample	Mean µmol/L	Within Run CV%	Total CV%	Mean µmol/L	Within Run CV%	Total CV%	Mean µmol/L	Within Run CV%	Total CV%
Panel 1	8.5	1.9	2.7	6.6	2.4	5.3	6.4	3.3	6.8
	8.5	1.7	3.3	6.7	2.0	4.2	6.4	2.7	6.6
Panel 2	35.5	0.9	1.6	34.1	0.9	2.6	33.9	1.7	2.8
	35.5	1.1	2.1	34.1	0.6	1.8	33.9	2.1	2.9
Panel 3	45.6	0.9	1.9	44.1	0.8	2.3	45.7	1.1	2.0
	45.5	0.9	2.7	44.0	0.6	1.9	45.6	1.0	2.0
Low Control	6.0	2.6	2.9	5.5	2.3	5.5	6.0	4.9	5.7
	6.0	2.4	4.4	5.5	3.0	4.6	6.2	4.0	5.0
Medium Control	11.2	1.4	1.9	11.2	1.4	3.7	11.8	1.9	3.1
	11.2	1.4	3.1	11.3	1.4	2.9	11.9	1.9	3.2
High Control	23.4	1.1	1.7	24.1	1.4	3.3	24.3	1.2	1.9
	23.4	1.2	2.0	24.2	0.9	2.4	24.5	1.0	2.4

Dilution Linearity

Instrument System	Measuring Range (µmol/L)	Recovery[a] (%)	Mean Recovery[b] (%)
BECKMAN COULTER AU400	1 - 46	91 to 104	100 ± 11
BECKMAN COULTER AU480	2- 44	93 to 99	100 ± 3
BECKMAN COULTER AU680	2- 44	98 to 103	100 ± 3
BECKMAN COULTER AU5800	2- 44	97 to 100	100 ± 3
COBAS Integra 800	1 - 46	98 to 102	100 ± 13
ROCHE Hitachi 917	2 - 46	100 to 109	100 ± 11
ROCHE Modular P	2 - 46	93 to 105	100 ± 10

[a]Range of percent (%) recovery data for samples diluted across the measuring range of the systems used.
[b]Mean % recovery for out-of-range when diluted into the range.

Limit of Detection

The limit of detection (LOD) of each system was determined according to NCCLS document EP17-A.[14] LOD values (µmol/L) are tabulated below.

BECKMAN COULTER AU400	BECKMAN COULTER AU480	BECKMAN COULTER AU680	BECKMAN COULTER AU5800	COBAS Integra 800	ROCHE Hitachi 917	ROCHE Modular P
0.33	0.39	0.54	0.59	0.43	1.2	0.6

On-board Reagent Stability

Reagents are stable when stored on-board as detailed below (in days);

BECKMAN COULTER AU400	BECKMAN COULTER AU480	BECKMAN COULTER AU680	BECKMAN COULTER AU5800	COBAS Integra 800	ROCHE Hitachi 917	ROCHE Modular P
30 d	30 d	30 d	30 d	30 d	7 d	30 d

Calibration Curve Stability

The calibration curve is stable on the BECKMAN COULTER AU400, Cobas Integra 800, ROCHE Hitachi 917 and ROCHE Modular P systems for up to 30 days.

The calibration curve is stable on the other AU systems tested for up to 14 days as verified on the AU5800.

Carryover:

The carryover is less than the limit of detection on all the systems tested.

Specimen Types:

The specimen collection tubes verified for use are EDTA and lithium heparin plasma tubes, serum and Serum Separator tubes. Other specimen collection tubes have not been tested. Serum (collected in serum or Serum Separator tubes) and plasma (collected in potassium EDTA or lithium heparin tubes) may be used for the measurement of homocysteine. It is the responsibility of the operator to verify that the correct tubes are used. However it is not recommended to use individual patient results from serum, heparinized plasma and EDTA plasma interchangeably.[11] Additionally matrix differences between serum, Serum Separator tubes and plasma tubes have been reported.[1]

EDTA samples can be stored on board the instrument for 3 hours, other have not been tested.

Analytical Specificity:

The specificity was assessed on the BECKMAN COULTER AU400 based on guidance from CLSI EP7-A2[15] for the interfering substances tabulated below:

Interfering Substance	Interfering Substance Concentration	% Interference
Bilirubin	20 mg/dL	≤ ±10
Haemoglobin	500 mg/dL	≤ ±10
Red Blood Cell	0.4%	≤ ±10
Triglyceride (Intralipid solution)	500 mg/dL	≤ ±10
Glutathione	1000 µmol/L	≤ ±10
Methionine	800 µmol/L	≤ ±10
Cysteine	200 µmol/L	≤ ±10
Pyruvate	1250 µmol/L	≤ ±10

Samples with raised protein levels show >10% difference compared to results obtained from normal samples and should be avoided. None of these substances interfered significantly in the assay.

LITERATURE REFERENCES

1. Fiskerstrand T, Refsum H, Kvalheim G, et al. Homocysteine and Other Thiols in Plasma and Urine: Automated Determination and Sample Stability. Clin Chem 1993;39:263-271
2. Ueland PM, Refsum H, Stabler SP, et al. Total Homocysteine in Plasma or Serum: Methods and Clinical Applications. Clin Chem 1993;39:1764-1779
3. Ueland PM, Refsum H. Plasma Homocysteine, A Risk Factor for Vascular Disease: Plasma Levels in Health, Disease, and Drug Therapy. *J Lab Clin Med* 1989;114:473-501
4. Nehler MR, Taylor LM Jr, Porter JM. Homocysteinemia as a Risk Factor for Atherosclerosis: A Review. *Cardiovascular Pathol* 1997;6:1-9
5. Lussier-Cacan S, Xhignesse M, Piolot A, *et al.* Plasma Total Homocysteine in Healthy Subjects: Sex-Specific Relation with Biological Traits. *Am J Clin Nutr* 1996;64:587-593
6. Clarke R, Woodhouse P, Ulvik A, *et al.* Variability and Determinants of Total Homocysteine Concentrations in Plasma in an Elderly Population. *Clin Chem* 1998;44:102-107
7. Jacques PF, Selhub J, Bostom AG, *et al.* The Effect of Folic Acid Fortification on Plasma Folate and Total Homocysteine Concentrations. *N Engl J Med* 1999;340:1449-1454
8. Lawrence JM, Petitti DB, Watkins M and Umekubo MA. Trends in Serum Folate after Food Fortification. *The Lancet* 1999;354:915-916
9. Herrmann W, Schorr H, Obeid R, *et al.* Disturbed Homocysteine and Methionine Cycle Intermediates S-adenosylhomocysteine and S-adenosylmethionine are Related to Degree of Renal Insufficiency in Type 2 Diabetes. *Clin Chem* 2005:51;1-7
10. Obeid R, Kuhlmann MK, Kohler H, *et al.* Response of Homocysteine, Cystathionine, and Methylmalonic Acid to Vitamin Treatment in Dialysis Patients. *Clin Chem* 2005;51:196-201
11. Refsum H, Smith AD, Ueland PM, *et al.* Facts and recommendations about total homocysteine determinations:an expert opinion. Clin Chem 2004;50(1):3-32
12. National Committee for Clinical Laboratory Standards. *Method Comparison and Bias Estimation using Patient Samples; Approved Guideline-Second Edition.* NCCLS document EP9-A2. Wayne, PA: NCCLS, 2002
13. National Committee for Clinical Laboratory Standards. *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition.* NCCLS Document EP5-A2, Wayne, PA: NCCLS, 2004
14. National Committee for Clinical Laboratory Standards. *Protocols for the Determination of Limits of Detection and Limits of Quantitation; Approved Guideline*. NCCLS Document EP17-A. Wayne, PA: NCCLS, 2004.
15. Clinical Laboratory Standards Institute. Interference Testing in Clinical Chemistry; Approved Guideline–Second Edition. CLSI Document EP7-A2. Wayne, PA: CLSI, 2005.

ASSAY PROTOCOLS

ENSURE THAT THE USER DEFINED* ASSAY PROCEDURE PARAMETERS ENTERED MATCH EXACTLY THOSE LISTED FOR THE SYSTEM OF USE.

OTHER INSTRUMENT PROTOCOLS ARE AVAILABLE PLEASE REFER TO www.homocysteine.org.uk. OR CONTACT THE MANUFACTURER.

BECKMAN COULTER AU400 – PROCEDURE PARAMETERS

Test No. [*]	Name [HCY]	Type [Ser.]	
Sample Volume:	[16.5] µL	Diluent Volume:	[0.0] µL
Pre-Dilution Factor:	[1]		
Reagent 1 Volume:	[250] µL	Diluent Volume:	[0.0] µL
Reagent 2 Volume:	[25] µL	Diluent Volume:	[0.0] µL
Wavelength Pri:	[340] nm		
Wavelength Sec:	[380] nm		
Reaction Method:	RATE1		
Reaction Slope	[-]		
Point 1	Fst [15]		
	Lst [27]		
Point 2	Fst [ ]		
	Lst [ ]		
Linearity	[100]%		
No-Lag-Time	[No]		
Min. OD		Max. OD	
L [-2.0]		H [2.5]	
Reagent OD Limit	Fst L [ ]	Fst H [ ]	
	Lst L [ ]	Lst H [ ]	
Dynamic Range:	L [1.0]	H [46.0]	
Correlation Factor:	A [1.0]	B [0.0]	
Onboard Stability Period:		[30]	
Calibration Specific:			
	Point	OD	Conc
	1 [*]	[ ]	[0.0]
	2 [*]	[ ]	[**]
	Calibration Type:		[AA]
	Formula:	[Y=AX+B]	

*User Defined **Enter Values on Calibrator Vials

BECKMAN COULTER AU480 / AU680– PROCEDURE PARAMETERS

Test No. [*]	Name [HCY]	Type [Ser.]	
Sample Volume:	[10] µL	Diluent Volume:	[0.0] µL
Pre-Dilution Factor:	[1]		
Reagent 1 Volume:	[155] µL	Diluent Volume:	[0.0] µL
Reagent 2 Volume:	[16] µL	Diluent Volume:	[0.0] µL
Wavelength Pri:	[340] nm		
Wavelength Sec:	[380] nm		
Reaction Method:	RATE1		
Reaction Slope	[-]		
Point 1	Fst [15]		
	Lst [27]		
Point 2	Fst [ ]		
	Lst [ ]		
Linearity	[25]%		
No-Lag-Time	[Yes]		
Min. OD		Max. OD	
L […]		H […]	
Reagent OD Limit	Fst L [-2.0]	Fst H [2.5]	
	Lst L [-2.0]	Lst H [2.5]	
Dynamic Range:	L [2.0]	H [44.0]	
Correlation Factor:	A [1.0]	B [0.0]	
Onboard Stability Period:		[30]	
LIH Influence Check		[No]	
Calibration Specific:			
	Point	OD	Conc
	1 [*]	[ ]	[0.0]
	2 [*]	[ ]	[**]
	Calibration Type:		[AA]
	Formula:	[Y=AX+B]	
Stability	Reagent Blank [30] day	Calibration [14] Day	

*User Defined **Enter Values on Calibrator Vials

BECKMAN COULTER AU5800– PROCEDURE PARAMETERS

Test No. [*]	Name [HCY]	Type [Ser.]	
Sample Volume:	[7.5] µL	Diluent Volume:	[0.0] µL
Pre-Dilution Factor:	[1]		
Reagent 1 Volume:	[115] µL	Diluent Volume:	[0.0] µL
Reagent 2 Volume:	[12] µL	Diluent Volume:	[0.0] µL
Wavelength Pri:	[340] nm		
Wavelength Sec:	[380] nm		
Reaction Method:	RATE1		
Reaction Slope	[-]		
Point 1	Fst [15]		
	Lst [27]		
Point 2	Fst [ ]		
	Lst [ ]		
Linearity	[25]%		
No-Lag-Time	[Yes]		
Min. OD		Max. OD	
L [ ]		H [ ]	
Reagent OD Limit	Fst L [-2.0]	Fst H [2.5]	
	Lst L [-2.0]	Lst H [2.5]	
Dynamic Range:	L [2.0]	H [44.0]	
Correlation Factor:	A [1.0]	B [0.0]	
Onboard Stability Period:		[30]	
LIH Influence Check		[No]	
Calibration Specific:			
	Point	OD	Conc
	1 [*]	[ ]	[0.0]
	2 [*]	[ ]	[**]
	Calibration Type:		[AA]
	Formula:	[Y=AX+B]	
Stability	Reagent Blank [30] day	Calibration [14] Day	

*User Defined **Enter Values on Calibrator Vials

ROCHE HITACHI 917 – PROCEDURE PARAMETERS

Test: HCY*	Type: Ser/PI
ANALYZE	
Assay time/Point	[2 Point End]/[10]/[19] [34] [0] [0]
Wave (2nd/Primary)	[376]/[340]
S. Vol (Normal)	[16.5]
Reagent (R1) T1	[250] [0] [000000]
Reagent (R2) T2	[0] [0] [000000]
Reagent (R3) T3	[25] [0] [000000]
Abs. Limit	[32000] [Decrease] 2 Tests
Prozone Limit	[-32000] [0] [Lower]
Cell Detergent	[Detergent 1]
CALIB	
Calibration Type	[Linear]
Point	[2]
Span Point	[2]
Weight	[0]
Auto Calibration	
2 Point	[168]
SD Limit	[100]
Duplicate Limit	[10%] [32000 Abs]
Sensitivity Limit	[-99999] [99999]
S1 Abs limit	[-32000] [32000]
RANGE	
Application Code*	[ ] Unit [µmol/L]
Control Interval*	[ ]
Instrument Factor	(Y=aX+b) a=[1.0] b=[0.0]
Technical Limit	[2.0] [46.0]
Repeat Limit*	[-99999] [99999]
OTHERS	
<Standard>	(1) (2)
Calibration Code*	[ ] [ ]
Concentration**	[0.00] [**]
Position*	[ ] [ ]
Sample Volume	[16.5] [16.5]

*User Defined **Enter Values on Calibrator Vials

ROCHE MODULAR ANALYTICS <P> – PROCEDURE PARAMETERS

Test: HCY*	Type: Ser/Pl
ANALYZE	
Assay time/Point	[2 Point End]/[10]/[19] [34] [0] [0]
Wave (2nd/Primary)	[376]/[340]
S. Vol (Normal)	[16.5]
Reagent (R1) T1	[250] [0] [000000]
Reagent (R2) T2	[0] [0] [000000]
Reagent (R3) T3	[25] [0] [000000]
Abs. Limit	[32000] [Decrease] 2 Tests
Prozone Limit	[-32000] [0] [Lower]
Cell Detergent	[Detergent 1]
CALIB	
Calibration Type	[Linear]
Point	[2]
Span Point	[2]
Weight	[0]
Auto Calibration	
2 Point	[720]
SD Limit	[100]
Duplicate Limit	[10%] [32000 Abs]
Sensitivity Limit	[-99999] [99999]
S1 Abs limit	[-32000] [32000]
RANGE	
Application Code*	[ ] Unit [µmol/L]
Control Interval*	[ ]
Instrument Factor	(Y=aX+b) a=[1.0] b=[0.0]
Technical Limit	[2.0] [46.0]
Repeat Limit*	[-99999] [99999]
OTHERS	
<Standard>	(1) (2)
Calibration Code*	[ ] [ ]
Concentration**	[0.00] [**]
Position*	[ ] [ ]
Sample Volume	[16.5] [16.5]

*User Defined **Enter Values on Calibrator Vials

KEY TO SYMBOLS USED

IVD	*In vitro* Diagnostic Medical Device		Use by
REF	Catalogue number	LOT	Batch code
REAG 1	Kit component: reagent	CAL	Kit component: Calibrator
	Consult instructions for use		Manufacturer
+2°C +8°C	Storage conditions		Store in the dark
Rx Only	For Prescription Use Only		

COBAS INTEGRA 800 – PROCEDURE PARAMETERS

GENERAL		
Test:	Test ID:	8-643
	Short Name:	HCYS
	Long Name:	Homocysteine
	Test No.:	643
	Version No.	87A.00
General	Test Class:	Substrate
	Default Sample Type:	Serum
	Measurement Mode:	Abs
	Clot Detection:	Enabled
CALIBRATION		
	Selected Calibrator:	User Defined
Calibrator Editor:	Short Name:	CHCY
	Long Name;	HCYS Calibrator
	Version No.:	87A.00
Calibrator Definitions:	No. of Standards	2
	Replicate:	Duplicate
	Sequence:	No Interval
	BOD Action:	None
DILUENT		
	Selected Pre-diluent:	None
	Selected Diluent:	None
PIPETTING		
Sample & Control Definitions:	Pre-dilution:	Disabled
Pipetting Parameter	Reaction Mode:	R1-S-SR
	Pipetting Depth:	Normal
Pipetting Volumes	S:	Specimen: 10.00 µL Water: 4.00 µL
	R1:	Reagent: 140 µL Water: 0 µL
	SR:	Reagent: 14 µL Water: 2 µL
CASSETTE		
Cassette	Cassette ID:	87-6340-0
	Short Name:	HCYS
	Long Name:	Homocysteine
	Version:	87A.00
Development channel COBAS c pack	No. of tests:	100
	Container B:	Empty – Volume (mL): 0.00
	Container A:	R1 – Volume (mL): *
	Container C:	R2 – Volume (mL): *
Mixing	By BOD:	Disabled
On-board Stability	On-board Stability:	Enabled-Time to use: 30 days
CALCULATION		
General	ABS Calculation Model:	Kinetic
	Wavelength L1:	340 nm
	Wavelength L2:	378 nm
	Reaction Direction:	Decrease
	Calculation Point	First: 58 Last: 98
	Standard Unit:	umol/L
Calibration:	Curve Direction Check:	Off
	Calculation Model:	Linear Regression
CHECKS		
	Reagent Range:	Low Limit: Disabled High Limit: Disabled
	Test Range:	Low Limit: 1.0 High Limit: 46.0
	Kinetic:	Linearity Limit: Disabled
	Replicate Deviation:	Disabled
	Activity:	None
	Antigen Excess:	Disabled
	Lin Reg Curve Range:	Disabled

*User defined

Axis-Shield Diagnostics Ltd.,
The Technology Park,
Dundee, DD2 1XA, UK
Tel: +44 (0) 1382 422000
Fax: +44 (0) 1382 422088
email: axd.axis-shield@alere.com
Web: www.axis-shield.com

EC Authorized Representative:

Medical Device Safety Service GmbH (MDSS)
Schiffgraben 41,
30175 Hannover,
Germany

Tel.: + (49) 511 6262 8630
Fax: + (49) 511 6262 8633

VER: 2019/09