DRG® Homocysteine Controls (EIA-3329)

Revised 23 Feb. 2010 rm (Vers. 4.0) **RUO in the USA**

Please use only the valid version of the package insert provided with the kit.

Intended Use

Control Kit for Homocysteine is intended to be used as an assayed quality control serum when used for the quantitative measurement of total L-homocysteine in human serum or plasma.

Summary and Principle

The use of quality control material is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. Three levels of control are available to allow performance monitoring within the clinical range.

Contents

3 vials (1.5 mL each) contain L-homocysteine in processed human serum in the following concentration ranges:

			CONTROL L	CONTROL M	CONTROL H
	PRODUCT CODE	UNITS	RANGE	RANGE	RANGE
Homocysteine ELISA	EIA-2925	µmol/L	5.6-8.4	10.0-15.0	20.0-30.0

Precautions

For In Vitro Use.
The controls contain human sourced and potentially infectious components.
Components sourced from human blood have been tested and found to be non-reactive for Hepatitis B Surface Antigen (HBsAg), HIV-1 Antigen (HIVAg) or HIV-1 RNA, HCV antibody,HIV-1/2 antibody, HTLV-1/2 antibody and Hepatitis B core Antibody (HBc) No known test method can offer complete assurance that products derived from human sources will not transmit infection. Therefore all human sourced materials should be considered potentially infectious. It is recommended that these materials be handled in accordance with Biosafety Level 2[1] or local/national guidelines on laboratory safety procedures. Controls contain <0.10% sodium azide as preservative.

([1] US Department of Health and Human Services, Biosafety in Microbiological and Biomedical Laboratories, Fifth Edition. Washington, DC: US Government Printing Office January 2007.)

Storage and Stability

The Control Kit for Homocysteine ELISA must be stored refrigerated (2-8 °C). The controls are stable until the expiration date when stored and handled as directed. Do not use past expiration date.

Procedure and Handling

Each control should be treated as a patient sample and run in accordance with the instructions accompanying the instrument, kit or reagent being used.
Before sampling, allow the control to reach room temperature (18-25ºC) and swirl gently before use to ensure homogeneity. Return the control to storage at 2-8ºC immediately after use.
Dispose of any discarded materials in accordance with local waste management regulations.

Assignment of values

Individual laboratory means should fall within the corresponding acceptable range. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by test method modifications. It is recommended that each laboratory establishes its own mean and acceptable ranges and use those provided only as a guide.

Limitations

This product must not be used past the expiration date.
If there is evidence of microbial contamination or excessive turbidity in the product discard the vial.
This product is not intended for use as a calibrator.

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Symbols used with DRG Assays

Symbol	English	Deutsch	Français	Español	Italiano
	Consult instructions for use	Gebrauchsanweisung beachten	Consulter les instructions d'utilisation	Consulte las instrucciones de uso	Consultare le istruzioni per l'uso
CE	European Conformity	CE-Konfirmitäts-kennzeichnung	Conformité aux normes européennes	Conformidad europea	Conformità europea
IVD	In vitro diagnostic device	In-vitro-Diagnostikum	Usage Diagnostic in vitro	Para uso Diagnóstico in vitro	Per uso Diagnostica in vitro
RUO	For research use only	Nur für Forschungszwecke	Seulement dans le cadre de recherches	Sólo para uso en investigación	Solo a scopo di ricerca
REF	Catalogue number	Katalog-Nr.	Numéro de catalogue	Número de catálogo	Numero di Catalogo
LOT	Lot. No. / Batch code	Chargen-Nr.	Numéro de lot	Número de lote	Numero di lotto
	Contains sufficient for <n> tests/	Ausreichend für "n" Ansätze	Contenu suffisant pour "n" tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	Storage Temperature	Lagerungstemperatur	Température de conservation	Temperatura de conservación	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeits-datum	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Legal Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
Distributed by	Distributor	Vertreiber	Distributeur	Distribuidor	Distributore
Content	Content	Inhalt	Conditionnement	Contenido	Contenuto
Volume/No.	Volume / No.	Volumen/Anzahl	Volume/Quantité	Volumen/Número	Volume/Quantità

Symbol	Portugues	Dansk	Svenska	Ελληνικά
	Consulte as instruções de utilização	Se brugsanvisning	Se bruksanvisningen	Εγχειρίδιο χρήστη
CE	Conformidade com as normas europeias	Europaeisk overensstemmelse	Europeisk överensstämmelse	Ευρωπαϊκή Συμμόρφωση
IVD	Diagnóstico in vitro	In vitro diagnostik	Diagnostik in vitro	in vitro διαγνωστικό
RUO				
REF	Catálogo n.º	Katalognummer	Katalog nummer	Αριθμός καταλόγου
LOT	No do lote	Lot nummer	Batch-nummer	Αριθμός Παρτίδος
		Indeholder tilstrækkeligt til "n" test	Innehåller tillräckligt till "n" tester	Περιεχόμενο επαρκές για «n» εξετάσεις
	Temperatura de conservação	Opbevarings-temperatur	Förvaringstempratur	Θερμοκρασία αποθήκευσης
	Prazo de validade	Udløbsdato	Bäst före datum	Ημερομηνία λήξης
	Fabricante	Producent	Tillverkare	Κατασκευαστής
Distributed by				
Content	Conteúdo	Indhold	Innehåll	Περιεχόμενο
Volume/No.	Volume/Número	Volumen/antal	Volym/antal	Όγκος/αριθ..