



DRG® Diabetes-antigen Control Serum (CTL-5132)



Revised 20 June 2008 (Vers. 6.0)



Directions for Use

INTENDED USE

The Diabetes-antigen Control is designed to be used as a two-level control for human insulin, C-peptide and proinsulin. It is manufactured from human serum and human insulin, C-peptide and proinsulin.

REAGENTS

Each DRG Diabetes-antigen Control contains 2 vials of lyophilized serum, each containing 0.5 ml after reconstitution. Values are found below.

PREPARATION OF REAGENT

Reconstitute each DRG Diabetes-antigen Control by adding 500 µl redistilled water to each vial. Replace the rubber stopper and allow to stand for 5 minutes. Gently swirl until contents are thoroughly mixed. Avoid foaming.

SHELF LIFE AND STORAGE

The expire date is stated below. Store the complete package at +2-8°C. Reconstituted Controls are stable for 1 week at +2 - 8°C or three months at -20°C. Avoid repeated freezing and thawing.

PROCEDURE

Perform the Insulin, C-peptide and Proinsulin assays according to the “Directions for Use”, handling DRG Diabetes-antigen Controls as patient samples.

WARNING! THIS KIT CONTAINS REAGENTS THAT MAY BE INFECTIOUS!

This kit contains reagents manufactured from human blood components. The source of material have been tested by immunoassay for hepatitis B surface antigen, antibodies for hepatitis C virus and for antibodies for HIV virus and found to be negative. Nevertheless, all recommended precautions for the handling of blood derivates should be observed. Please refer to HHS Publication no. (CDC) 88-8395 or corresponding local/national guide-lines on laboratory safety procedures.

TABLE OF VALUES

The following values only apply to the lot number and the expiry date mentioned below.

Control L Batch No. / Lot No.: 15558 Exp. date: 2011-05-02

Method	Mean Value	Range	Units
DRG Insulin ELISA (EIA-1825)	7.7	6.3 – 9.2	mU/L
DRG C-peptide ELISA spec	543	443 - 644	pmol/L
DRG Proinsulin ELISA	7.0	4.6 – 9.5	pmol/L
DRG Iso Insulin (EIA-2336)	9.1	7.3 – 10.9	mU/L

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USA:

Control H Batch No. / Lot No.: 15558 Exp. date: 2011-05-02

Method	Mean Value	Range	Units
DRG Insulin ELISA (EIA-1825)	56.9	52.6 – 61.2	mU/L
DRG C-peptide ELISA spec	1903	1614 - 2193	pmol/L
DRG Proinsulin ELISA	47.7	41.9 – 53.5	pmol/L
DRG Iso Insulin (EIA-2336)	57.6	45.7 – 69.5	mU/L

The values given are only applicable to DRG assays.
If used with other methods, different values may be obtained.

WARRANTY

The performance data presented here was obtained using the procedure indicated. Any change or modification in the procedure not recommended by DRG may affect the results, in which event DRG disclaims all warranties expressed, implied or statutory, including the implied warranty of merchantability and fitness for use. DRG and its authorized distributors, in such event, shall not be liable for damages indirect or consequential.

Symbols used with DRG ELISAs








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
	European Conformity	CE-Konformitätskennzeichnung	Conformité aux normes européennes	Conformidad europea	Conformità europea
	In vitro diagnostic device	In-vitro-Diagnostikum	Usage Diagnostic in vitro	Para uso Diagnóstico in vitro	Per uso Diagnostica in vitro
	For research use only	Nur für Forschungszwecke		Sólo para uso en investigación	
	Catalogue number	Katalog-Nr.	Numéro de catalogue	Número de catálogo	Numero di Catalogo
	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	Temperature de conservation	Temperatura de conservación	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeitsdatum	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Legal Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
Distributed by	Distributor	Distributeur	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	
	Conformidade com as	Europeaisk	Europeisk	Ευρωπαϊκή	

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	normas europeias	overensstemmelse	överensstämmelse	Συμμόρφωση
	Diagnóstico in vitro	In vitro diagnostik	Diagnostik in vitro	in vitro διαγνωστικό
				
	Catálogo n.º	Katalognummer	Katalog nummer	Αριθμός καταλόγου
	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	Förvaringstemperatur	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..