

DRG® Diabetes Antigen Control (Rat/Mouse) (CTL-4783)

Revised 12 Feb. 2008

For Veterinary Use Only

1 INTENDED USE

The Diabetes Antigen Control (Low, Medium, High) Rat/Mouse is designed to be used as a three-level control for DRG Ultrasensitive Mouse, Ultrasensitive Rat, Mouse, Rat Insulin ELISA kits and DRG Rat C-peptide.

It is manufactured from human serum and insulin.

For DRG assays the control levels are suitable in each method as stated in the table below.

Method	Control		
	Low	Medium	High
Ultrasensitive Mouse Insulin ELISA EIA-3440	Only 50 µL assay	x	Only 5 µL assay
Ultrasensitive Rat Insulin ELISA EIA-2943	Only 50 µL assay	x	Only 5 µL assay
Mouse Insulin ELISA EIA-3439		x	x
Rat Insulin ELISA EIA-2048		x	x
Rat C-Peptide ELISA EIA-4767	x	x	x

2 REAGENTS

Each Diabetes Antigen Control (Low, Medium, High) Rat/Mouse contains 3 vials of lyophilized serum, each containing 0.5 mL after reconstitution.

Values are found below.

3 PREPARATION OF REAGENTS

Reconstitute each Diabetes Antigen Control (Low, Medium, High) Rat/Mouse 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.

4 SHELF LIFE AND STORAGE

The expiry date is stated below. Store the complete package at 2-8°C.

Reconstituted Controls are stable for 2 week at 2-8°C or three months at -20°C.

Avoid repeated freezing and thawing.

DRG® Diabetes Antigen Control (Rat/Mouse) (CTL-4783)

Revised 12 Feb. 2008

For Veterinary Use Only

5 PROCEDURE

Perform the Insulin ELISA assays (Ultrasensitive Mouse, Ultrasensitive Rat, Mouse, Rat and Rat C-peptide ELISA) according to the "Instructions for Use", handling the Diabetes Antigen Control (Low, Medium, High) Rat/ Mouse as 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 derivatives should be observed. Please refer to HHS Publication No. (CDC) 88-8395 or corresponding local/national guidelines on laboratory safety procedures.

6 TABLE OF VALUES

The concentrations of the control values were determined in 4 replicates on twelve occasions, performed in three days by four different technicians.

The range is determined as: target value $\pm$ 3 SD (obtained from the twelve analysis)

Control Low Batch No./Lot No.: 15954 Exp.date: 2011-12-04

	Target value	Range	Units
Ultrasensitive Mouse Insulin ELISA EIA-3440, 50 µL	0,12	0,10-0,15	µg/L
Ultrasensitive Rat Insulin ELISA EIA-2943, 50 µL	0,08	0,05-0,11	µg/L
Rat C-Peptide ELISA EIA-4767	307	237-377	pmol/L

DRG® Diabetes Antigen Control (Rat/Mouse) (CTL-4783)

Revised 12 Feb. 2008

For Veterinary Use Only

Control Medium Batch No./Lot No.: 15955

Exp.date: 2011-12-04

	Target value	Range	Units
Ultrasensitive Mouse Insulin ELISA EIA-3440, 5 µL	0,72	0,61-0,83	µg/l
Ultrasensitive Mouse Insulin ELISA EIA-3440, 50 µL	0,71	0,66-0,76	µg/L
Ultrasensitive Rat Insulin ELISA EIA-2943, 5 µL	0,58	0,51-0,64	µg/L
Ultrasensitive Rat Insulin ELISA EIA-2943, 50 µL	0,55	0,46-0,63	µg/L
Mouse Insulin ELISA EIA-3439	0,72	0,61-0,83	µg/L
Rat Insulin ELISA EIA-2048	0,58	0,51-0,64	µg/L
Rat C-Peptide ELISA EIA-4767	1244	1087-1401	pmol/L

DRG® Diabetes Antigen Control (Rat/Mouse) (CTL-4783)

Revised 12 Feb. 2008

For Veterinary Use Only

Control High Batch No./Lot No.: 15956 Exp.date: 2011-12-04

	Target value	Range	Units
Mouse Insulin ELISA EIA-3439	3,67	3,07-4,28	µg/L
Ultrasensitive Mouse Insulin ELISA EIA-3440, 5 µL	3,67	3,07-4,28	µg/L
Rat Insulin ELISA EIA-2048	3,28	3,04-3,51	µg/L
Ultrasensitive Rat Insulin ELISA EIA-2943, 5 µL	3,28	3,04-3,51	µg/L
Rat C-peptide ELISA EIA-4767	2204	1881-2526	pmol/l

The values given are only applicable to the lot number and the expiry date mentioned in the table and to assays mentioned in the table.

If used with other methods, different values may be obtained.

Good practice dictates that each laboratory establishes its own expected range of values.

7 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.

DRG® Diabetes Antigen Control (Rat/Mouse) (CTL-4783)

Revised 12 Feb. 2008

For Veterinary Use Only

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
	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	Seulement dans le cadre de recherches	Sólo para uso en investigación	Solo a scopo di ricerca
	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	Température 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	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	
	Conformidade com as normas europeias	Europaeisk overensstemmelse	Europeisk överensstämmelse	Ευρωπαϊκή 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..	