



Ministerio de Salud  
Secretaría de Políticas, Regulación  
e Institutos  
A. N. M. A. T.

DISPOSICIÓN Nº 1912

BUENOS AIRES 17 MAR 2011

VISTO el expediente Nº 1-47-4944/10-1 del Registro de la Administración Nacional de Medicamentos Alimentos y Tecnología Médica y,

CONSIDERANDO:

Que por los presentes actuados la firma ROCHEM BIOCARE ARGENTINA S.A. solicita autorización para la venta a laboratorios de análisis clínicos del producto para diagnóstico de uso "in vitro" denominado FLEX PRIMARY ANTIBODIES / SON ANTICUERPOS POLICLONALES Y MONOCLONALES LISTOS PARA USAR, INDICADOS PARA SU USO EN INMUNOHISTOQUÍMICA, EN TÉCNICAS MANUALES O AUTOMATIZADAS CON LOS INSTRUMENTOS DAKO AUTOSTAINER, PARA LA DETECCIÓN DE ANTÍGENOS EN CÉLULAS NORMALES O PATOLÓGICAS , ver Listado de Productos en el ANEXO (3 páginas).

Que a fojas 590 consta el informe técnico producido por el Servicio de Productos para Diagnóstico uso In Vitro que establece que el producto reúne las condiciones de aptitud requeridas para su autorización.

Que la Dirección de Tecnología Médica ha tomado la intervención de su competencia.

Que se ha dado cumplimiento a los términos que establecen la Ley Nº 16.463, y Resolución Ministerial Nº 145/98 y Disposición A.N.M.A.T 2674/99.

Que la presente se dicta en virtud de las facultades conferidas por el Artículo 8º inciso 11) del Decreto 1490/92 y Decreto Nº 425/10.

Por ello;



Ministerio de Salud  
Secretaría de Políticas, Regulación  
e Institutos  
A. N. M. A. T.

DISPOSICIÓN N° 1912

EL INTERVENTOR DE LA ADMINISTRACIÓN NACIONAL DE  
MEDICAMENTOS, ALIMENTOS Y TECNOLOGÍA MÉDICA

DISPONE:

ARTÍCULO 1°.- Autorízase la venta a laboratorios de análisis clínicos del producto para diagnóstico de uso in Vitro denominado FLEX PRIMARY ANTIBODIES / SON ANTICUERPOS POLICLONALES Y MONOCLONALES LISTOS PARA USAR, INDICADOS PARA SU USO EN INMUNOHISTOQUÍMICA, EN TÉCNICAS MANUALES O AUTOMATIZADAS CON LOS INSTRUMENTOS DAKO AUTOSTAINER, PARA LA DETECCIÓN DE ANTÍGENOS EN CÉLULAS NORMALES O PATOLÓGICAS , ver Listado de Productos en el ANEXO (3 páginas), el que será elaborado por DAKO Denmark A/S (DINAMARCA) y DAKO North America Inc (USA) e importado terminado por la firma ROCHEM BIOCARE ARGENTINA S.A. en envases por 30 tests (1 vial x 6 ml) y 60 tests (1 vial x 12 ml), con una vida útil desde la fecha de elaboración de 12 (DOCE) meses almacenados entre 2-8°C, y que la composición se detalla a fojas 141.

57 ARTÍCULO 2°.- Acéptense los proyectos de rótulos y Manual de Instrucciones a fojas 550 a 588 debiendo constar en los mismos que la fecha de vencimiento es la declarada por el elaborador impreso en los rótulos de cada partida.

ARTÍCULO 3°.- Extiéndase el Certificado correspondiente.

ARTÍCULO 4°.- LA ADMINISTRACIÓN NACIONAL DE MEDICAMENTOS, ALIMENTOS Y TECNOLOGÍA MEDICA se reserva el derecho de reexaminar los métodos de control, estabilidad y elaboración cuando las circunstancias así lo determinen.



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DISPOSICIÓN N° 1912

ARTÍCULO 5°.- Anótese, gírese al Departamento de Registro a sus efectos, por Mesa de Entradas notifíquese al interesado y hágasele entrega de la copia de la presente Disposición junto con la copia de los proyectos de rótulos y del manual de instrucciones debidamente visados, y el certificado correspondiente. Remítase una copia de la presente Disposición y Certificado a la Dirección de Tecnología Médica. Cumplido, Archívese PERMANENTE.-

EXPEDIENTE N° 1-47- 4944/10-1

DISPOSICIÓN N°:

1912

Dr. OTTO A. ORSINGER  
SUB-INTERVENTOR  
A.N.M.A.T.



Ministerio de Salud  
Secretaría de Políticas, Regulación  
e Institutos  
A. N. M. A. T.

CERTIFICADO DE AUTORIZACION DE VENTA  
DE PRODUCTOS PARA DIAGNOSTICO DE USO IN VITRO

Expediente N°: 1-47-4944/10-1.-

Se autoriza a la firma ROCHEM BIOCARE ARGENTINA S.A. a comercializar los Productos para Diagnóstico de uso "in vitro" denominados FLEX PRIMARY ANTIBODIES / SON ANTICUERPOS POLICLONALES Y MONOCLONALES LISTOS PARA USAR, INDICADOS PARA SU USO EN INMUNOHISTOQUÍMICA, EN TÉCNICAS MANUALES O AUTOMATIZADAS CON LOS INSTRUMENTOS DAKO AUTOSTAINER, PARA LA DETECCIÓN DE ANTÍGENOS EN CÉLULAS NORMALES O PATOLÓGICAS , ver Listado de Productos en el ANEXO (3 páginas), en envases conteniendo 1 vial x 6 ml (30 tests) o 1 vial x 12 ml (60 tests). Se le asigna la categoría: Venta a laboratorio de Análisis clínicos por hallarse comprendido en las condiciones establecidas en la Ley 16.463, y Resolución M.S. y A.S. N° 145/98. Lugar de elaboración: DAKO Denmark A/S (DINAMARCA) y DAKO North America Inc (USA), ver anexo. Periodo de vida útil, desde la fecha de elaboración: 12 (DOCE) meses almacenados a 2-8°C. En las etiquetas de los envases, anuncios y Manual de instrucciones deberá constar PRODUCTO PARA DIAGNÓSTICO DE USO "IN VITRO" USO PROFESIONAL EXCLUSIVO AUTORIZADO POR LA ADMINISTRACION NACIONAL DE MEDICAMENTOS, ALIMENTOS Y TECNOLOGÍA MÉDICA.

Certificado N°:

**006657**

ADMINISTRACION NACIONAL DE MEDICAMENTOS, ALIMENTOS Y  
TECNOLOGÍA MÉDICA.

Buenos Aires, 17 MAR 2011

Firma y sello

Dr. OTTO A. ORSINGER  
SUB-INTERVENTOR  
A.N.M.A.T.



Ministerio de Salud  
Secretaría de Políticas, Regulación  
e Institutos  
A. N. M. A. T.

CERTIFICADO DE AUTORIZACION DE VENTA  
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Certificado N°: **006657**

ADMINISTRACION NACIONAL DE MEDICAMENTOS, ALIMENTOS Y  
TECNOLOGÍA MÉDICA.

Buenos Aires, 17 MAR 2011

Firma y sello  
  
Dr. OTTO A. ORSINGER  
SUB-INTERVENTOR  
A.N.M.A.T.

## ANEXO – DISPOSICIÓN DE AUTORIZACION DE VENTA

Página 1 de 3

## FLEX PRIMARY ANTIBODIES - ROCHEM BIOCARE ARGENTINA S.A.

REF	NOMBRE DEL PRODUCTO	ORIGEN
IR001/ IS001	FLEX Polyclonal Rabbit Anti-Terminal Deoxynucleotidyl Transferase (TdT)	USA
IR002/ IS002	FLEX Polyclonal Guinea Pig Anti-Insulin	USA
IR051/ IS051	FLEX Monoclonal Mouse Anti-Human Cytokeratin HMW, Clone 34 BE12	USA
IR052/ IS052	FLEX Monoclonal Mouse Anti-Human Melanosome, Clone HMB-45	USA
IR053/ IS053	FLEX Monoclonal Mouse Anti-Human Cytokeratin, Clone AE1/AE3	USA
IR054/ IS054	FLEX Monoclonal Mouse Anti-Human Caldesmon, Clone h-CD	USA
IR055/ IS055	FLEX Monoclonal Mouse Anti-Human Wilms Tumor 1 Protein, Clone 6F-H2	USA
IR056/ IS056	FLEX Monoclonal Mouse Anti-Thyroid Transcription Factor, Clone 8G7G3/1	USA
IR057/ IS057	FLEX Monoclonal Mouse Anti-Human CD99, MIC2 Gene Product Ewing's Sarcoma Clon 12E7	USA
IR058/ IS058	FLEX Monoclonal Mouse Anti-Human Inhibin alpha, Clone R1	USA
IR059/ IS059	FLEX Monoclonal Mouse Anti-Human E-Cadherin, Clone NCH-38	USA
IR060/ IS060	FLEX Monoclonal Rabbit Anti-Human AMACR, Clone 13H4	USA
IR061/ IS061	FLEX Monoclonal Mouse Anti-Human Tyrosinase, Clone T311	USA
IR062/ IS062	FLEX Monoclonal Mouse Anti-Human CD15, Clone Carb-3	USA
IR066/ IS066	FLEX Monoclonal Mouse Anti-Human Smooth Muscle Myosin Heavy Chain, Clone SMMS-1	USA
IR067/ IS067	FLEX Monoclonal Mouse Anti-Myogenin Clone F5D	USA
IR068/ IS068	FLEX Monoclonal Mouse Anti-Human Progesterone Receptor, Clone PgR 636	USA
IR069/ IS069	FLEX Monoclonal Mouse Anti-Human CD1a, Clone 010	USA
IR072/ IS072	FLEX Monoclonal Mouse Anti-Human D2-40, Clone D2-40	USA
IR074/ IS074	FLEX Monoclonal Mouse Anti-Human Mammaglobin, Clone 304-1A5	USA
IR075/ IS075	FLEX Monoclonal Mouse Anti-Human Renal Cell Carcinoma Marker, Clone SPM314	USA
IR076/ IS076	FLEX Monoclonal Mouse Anti- Villin, Clone 1D2 C3	USA
IR077/ IS077	FLEX Monoclonal Mouse Anti-Human Gross Cystic Disease Fluid Protein-15, Clone 23A3	USA
IR080/ IS080	FLEX Monoclonal Mouse Anti-Human CDX-2, Clone DAK-CDX2	USA
IR081/ IS081	FLEX Monoclonal Rabbit Anti-Human, CD5 Clone SP19	USA
IR151/ IS151	FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor $\alpha$ , Clone SP1	USA
IR152/ IR152	FLEX Monoclonal Rabbit Anti-Human Cyclin D1, Clone SP4	USA
IR500/ IS500	FLEX Polyclonal Rabbit Anti-Human Alpha-1-Fetoprotein,	Dinamarca
IR502/ IS502	FLEX Polyclonal Rabbit Anti-Human Chromogranin A	Dinamarca
IR503/ IS503	FLEX Polyclonal Rabbit Anti-Human CD3	Dinamarca
IR504/ IS504	FLEX Polyclonal Rabbit Anti-S100	Dinamarca
IR505/ IS505	FLEX Polyclonal Rabbit Anti-Human Alpha-1-Antitrypsin	Dinamarca
IR506/ IS506	FLEX Polyclonal Rabbit Anti-Human Kappa Light Chains	Dinamarca
IR507/ IS507	FLEX Polyclonal Rabbit Anti-Human Lambda Light Chains	Dinamarca
IR508/ IS508	FLEX Polyclonal Rabbit Anti-Human Chorionic Gonadotropin	Dinamarca
IR509/ IS509	FLEX Polyclonal Rabbit Anti-Human Thyroglobulin	Dinamarca
IR510/ IS510	FLEX Polyclonal Rabbit Anti-Human IgA	Dinamarca
IR511/ IS511	FLEX Polyclonal Rabbit Anti-Human Myeloperoxidase	Dinamarca
IR512/ IS512	FLEX Polyclonal Rabbit Anti-Human IgG	Dinamarca
IR513/ IS513	FLEX Polyclonal Rabbit Anti-Human IgM	Dinamarca
IR515/ IS515	FLEX Polyclonal Rabbit Anti-Human Calcitonin	Dinamarca
IR517/ IS517	FLEX Polyclonal Rabbit Anti-Human IgD	Dinamarca

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## ANEXO – DISPOSICIÓN DE AUTORIZACION DE VENTA

## FLEX PRIMARY ANTIBODIES - ROCHEM BIOCARE ARGENTINA S.A.

REF	NOMBRE DEL PRODUCTO	ORIGEN
IR519/ IS519	FLEX Polyclonal Rabbit Anti-Human Gastrin	Dinamarca
IR521/ IS521	FLEX Polyclonal Rabbit Anti-Herpes Simplex Virus Type 1	Dinamarca
IR523/ IS523	FLEX Polyclonal Rabbit Anti-Helicobacter Pylori	Dinamarca
IR524/ IS524	FLEX Polyclonal Rabbit Anti-Glial Fibrillary Acidic Protein	Dinamarca
IR526/ IS526	FLEX Polyclonal Rabbit Anti-Human Carcinoembryonic Antigen	Dinamarca
IR527/ IS527	FLEX Polyclonal Rabbit Anti-Human Von Willbrand Factor	Dinamarca
IR602/ IS602	FLEX Monoclonal Mouse Anti-Human CD30, Clone Ber-H2	Dinamarca
IR604/ IS604	FLEX Monoclonal Mouse Anti-Human CD20cy, Clone L26	Dinamarca
IR605/ IS605	FLEX Monoclonal Mouse Anti-Human Amyloid A, Clone mc1	Dinamarca
IR606/ IS606	FLEX Monoclonal Mouse Anti-Human Desmin, Clone D33	Dinamarca
IR607/ IS607	FLEX Monoclonal Mouse Anti-Human Neurofilament Protein, Clone 2F11	Dinamarca
IR608/ IS608	FLEX Monoclonal Mouse Anti-Human CD21, Clone 1F8	Dinamarca
IR609/ IS609	FLEX Monoclonal Mouse Anti-Human CD68, Clone KP1	Dinamarca
IR610/ IS610	FLEX Monoclonal Mouse Anti-Human CD31, Endothelial Cell, Clone JC70A	Dinamarca
IR611/ IS611	FLEX Monoclonal Mouse Anti-Human Smooth Muscle Actin, Clone 1A4	Dinamarca
IR612/ IS612	FLEX Monoclonal Mouse Anti-Human Neuron Specific Enolase, Clone BBS/NC/VI-H14	Dinamarca
IR613/ IS613	FLEX Monoclonal Mouse Anti-Human CD68, Clone PG-M1	Dinamarca
IR614/ IS614	FLEX Monoclonal Mouse Anti-Human BCL2 Oncoprotein, Clone 124	Dinamarca
IR615/ IS615	FLEX Monoclonal Mouse Anti-Human Cytokeratin 19, Clone RCK108	Dinamarca
IR616/ IS616	FLEX Monoclonal Mouse Anti-Human p53 Protein, Clone DO-7	Dinamarca
IR618/ IS618	FLEX Monoclonal Mouse Anti-Human Cytokeratin 18, Clone DC 10	Dinamarca
IR619/ IS619	FLEX Monoclonal Mouse Anti-Human Cytokeratin 7, Clone OV-TL 12/30	Dinamarca
IR620/ IS620	FLEX Monoclonal Mouse Anti-Cytokeratin 17, Clone E3	Dinamarca
IR621/ IS621	FLEX Monoclonal Mouse Anti-Human CD79α, Clone JCB117	Dinamarca
IR622/ IS622	FLEX Monoclonal Mouse Anti-Human Carcinoembryonic Antigen, Clone II-7	Dinamarca
IR623/ IS623	FLEX Monoclonal Mouse Anti-Human CD8, Clone C8/144B	Dinamarca
IR624/ IS624	FLEX Monoclonal Mouse Anti-Human Hepatocyte, Clone OCH1E5	Dinamarca
IR625/ IS625	FLEX Monoclonal Mouse Anti-Human BCL6 Protein, Clone PG-B6p	Dinamarca
IR626/ IS626	FLEX Monoclonal Mouse Anti-Human Ki-67 Antigen, Clone MIB-1	Dinamarca
IR627/ IS627	FLEX Monoclonal Mouse Anti-Human Calretinin, Clone DAK-Calret 1	Dinamarca
IR628/ IS628	FLEX Monoclonal Mouse Anti-Human CD56, Clone 132C3	Dinamarca
IR629/ IS629	FLEX Monoclonal Mouse Anti-Human Epithelial Membrane Antigen, Clone E29	Dinamarca
IR630/ IS630	FLEX Monoclonal Mouse Anti-Human Vimentin, Clone V9	Dinamarca
IR632/ IS632	FLEX Monoclonal Mouse Anti-Human CD34, Clone QBEnd 10	Dinamarca
IR633/ IS633	FLEX Monoclonal Mouse Anti-Human Melan-A, Clone A103	Dinamarca
IR635/ IS635	FLEX Monoclonal Mouse Anti-Pneumocystis Jiroveci, Clone 3F6	Dinamarca
IR636/ IS636	FLEX Monoclonal Mouse Anti-Human CD43, Clone DF-T1	Dinamarca
IR637/ IS637	FLEX Monoclonal Mouse Anti-Human Epithelial Antigen, Clone Ber-EP4	Dinamarca
IR640/ IS640	FLEX Monoclonal Mouse Anti-Human Mast Cell Tryptase, Clone AA1	Dinamarca
IR641/ IS641	FLEX Monoclonal Mouse Anti-Human CD246, ALK Protein, Clone ALK1	Dinamarca
IR642/ IS642	FLEX Monoclonal Mouse Anti-Human CD138, Clone MI15	Dinamarca
IR643/ IS643	FLEX Monoclonal Mouse Anti-Human CD7, Clone CBC.37	Dinamarca
IR644/ IS644	FLEX Monoclonal Mouse Anti-Human MUM1 Protein, Clone MUM1p	Dinamarca
IR647/ IS647	FLEX Monoclonal Mouse Anti-Human CD57, Clone TB01	Dinamarca

**ANEXO - CERTIFICADO DE AUTORIZACION DE VENTA**      *Página 3 de 3*  
**FLEX PRIMARY ANTIBODIES - ROCHEM BIOCARE ARGENTINA S.A.**

REF	NOMBRE DEL PRODUCTO	ORIGEN
IR648/ IS648	FLEX Monoclonal Mouse Anti-Human CD10, Clone 56C6	Dinamarca
IR649/ IS649	FLEX Monoclonal Mouse Anti-Human CD4, Clone 4B12	Dinamarca
IR650/ IS650	FLEX Monoclonal Mouse Anti-Human B-Cell Specific Activator Protein, Clone DAK-PAX5	Dinamarca
IR651/ IS651	FLEX Monoclonal Mouse Anti-Human CD2, Clone AB75	Dinamarca
IR652/ IS652	FLEX Monoclonal Mouse Anti-Human Nucleophosmin, Clone 376	Dinamarca
IR653/ IS653	FLEX Monoclonal Mouse Anti-Human ZAP-70, Clone 2F3.2	Dinamarca
IR654/ IS654	FLEX Monoclonal Mouse Anti-Human Estrogen Receptor $\alpha$ Clone 1D5	Dinamarca
IR656/ IS656	FLEX Monoclonal Mouse Anti-Human CD19, Clone LE-CD19	Dinamarca
IR700/ IS700	FLEX Monoclonal Mouse Anti-Human Muscle Actin, Clone HHF35	Dinamarca
IR701/ IS701	FLEX Monoclonal Mouse Anti-Human CA 125, Clone M11	Dinamarca
IR702/ IS702	FLEX Monoclonal Mouse Anti-Human $\beta$ -Catenin, clone $\beta$ -Catenin-1	Dinamarca
IR751/ IS751	FLEX Monoclonal Mouse Anti-Human CD45, Leucocyte Common Antigen, Clone 2B11+PD7/26	Dinamarca
IR753/ IS753	FLEX Monoclonal Mouse Anti-Epstein-Barr Virus, LMP, Clone CS.1-4	Dinamarca
IR776/ IS776	FLEX Monoclonal Mouse Anti-Synaptophysin, Clone SY38	Dinamarca
IR777/ IS777	FLEX Monoclonal Mouse Anti-Human Cytokeratin 20, Clone Ks20.8	Dinamarca
IR779/ IS779	FLEX Monoclonal Mouse Anti-Human Placental Alkaline Phosphatase, Clone 8A9	Dinamarca
IR780/ IS780	FLEX Monoclonal Mouse Anti-Human Cytokeratin 5/6, Clone D5/16 B4	Dinamarca
IR800/ IS800	FLEX Monoclonal Rabbit Anti-Human CD23, Clone SP23	Dinamarca
IR600/ IS600	Universal Negative Control Rabbit *	USA
IR750/ IS750	Universal Negative Control Mouse *	USA

\* PRESENTACIONES: 120 tests, 24 ml/ 60 tests, 12 ml

**1912**

**DR. OTTO A. ORSINGER**  
**SUB-INTERVENTOR**  
**A.N.M.A.T.**



**ANEXO - CERTIFICADO DE AUTORIZACION DE VENTA**      Página 2 de 3  
**FLEX PRIMARY ANTIBODIES - ROCHEM BIOCARE ARGENTINA S.A.**

REF	NOMBRE DEL PRODUCTO	ORIGEN
IR519/ IS519	FLEX Polyclonal Rabbit Anti-Human Gastrin	Dinamarca
IR521/ IS521	FLEX Polyclonal Rabbit Anti-Herpes Simplex Virus Type 1	Dinamarca
IR523/ IS523	FLEX Polyclonal Rabbit Anti-Helicobacter Pylori	Dinamarca
IR524/ IS524	FLEX Polyclonal Rabbit Anti-Glial Fibrillary Acidic Protein	Dinamarca
IR526/ IS526	FLEX Polyclonal Rabbit Anti-Human Carcinoembryonic Antigen	Dinamarca
IR527/ IS527	FLEX Polyclonal Rabbit Anti-Human Von Willbrand Factor	Dinamarca
IR602/ IS602	FLEX Monoclonal Mouse Anti-Human CD30, Clone Ber-H2	Dinamarca
IR604/ IS604	FLEX Monoclonal Mouse Anti-Human CD20cy, Clone L26	Dinamarca
IR605/ IS605	FLEX Monoclonal Mouse Anti-Human Amyloid A, Clone mc1	Dinamarca
IR606/ IS606	FLEX Monoclonal Mouse Anti-Human Desmin, Clone D33	Dinamarca
IR607/ IS607	FLEX Monoclonal Mouse Anti-Human Neurofilament Protein, Clone 2F11	Dinamarca
IR608/ IS608	FLEX Monoclonal Mouse Anti-Human CD21, Clone 1F8	Dinamarca
IR609/ IS609	FLEX Monoclonal Mouse Anti-Human CD68, Clone KP1	Dinamarca
IR610/ IS610	FLEX Monoclonal Mouse Anti-Human CD31, Endothelial Cell, Clone JC70A	Dinamarca
IR611/ IS611	FLEX Monoclonal Mouse Anti-Human Smooth Muscle Actin, Clone 1A4	Dinamarca
IR612/ IS612	FLEX Monoclonal Mouse Anti-Human Neuron Specific Enolase, Clone BBS/NC/VI-H14	Dinamarca
IR613/ IS613	FLEX Monoclonal Mouse Anti-Human CD68, Clone PG-M1	Dinamarca
IR614/ IS614	FLEX Monoclonal Mouse Anti-Human BCL2 Oncoprotein, Clone 124	Dinamarca
IR615/ IS615	FLEX Monoclonal Mouse Anti-Human Cytokeratin 19, Clone RCK108	Dinamarca
IR616/ IS616	FLEX Monoclonal Mouse Anti-Human p53 Protein, Clone DO-7	Dinamarca
IR618/ IS618	FLEX Monoclonal Mouse Anti-Human Cytokeratin 18, Clone DC 10	Dinamarca
IR619/ IS619	FLEX Monoclonal Mouse Anti-Human Cytokeratin 7, Clone OV-TL 12/30	Dinamarca
IR620/ IS620	FLEX Monoclonal Mouse Anti-Cytokeratin 17, Clone E3	Dinamarca
IR621/ IS621	FLEX Monoclonal Mouse Anti-Human CD79 $\alpha$ , Clone JCB117	Dinamarca
IR622/ IS622	FLEX Monoclonal Mouse Anti-Human Carcinoembryonic Antigen, Clone II-7	Dinamarca
IR623/ IS623	FLEX Monoclonal Mouse Anti-Human CD8, Clone C8/144B	Dinamarca
IR624/ IS624	FLEX Monoclonal Mouse Anti-Human Hepatocyte, Clone OCH1E5	Dinamarca
IR625/ IS625	FLEX Monoclonal Mouse Anti-Human BCL6 Protein, Clone PG-B6p	Dinamarca
IR626/ IS626	FLEX Monoclonal Mouse Anti-Human Ki-67 Antigen, Clone MIB-1	Dinamarca
IR627/ IS627	FLEX Monoclonal Mouse Anti-Human Calretinin, Clone DAK-Calret 1	Dinamarca
IR628/ IS628	FLEX Monoclonal Mouse Anti-Human CD56, Clone 132C3	Dinamarca
IR629/ IS629	FLEX Monoclonal Mouse Anti-Human Epithelial Membrane Antigen, Clone E29	Dinamarca
IR630/ IS630	FLEX Monoclonal Mouse Anti-Human Vimentin, Clone V9	Dinamarca
IR632/ IS632	FLEX Monoclonal Mouse Anti-Human CD34, Clone QBEnd 10	Dinamarca
IR633/ IS633	FLEX Monoclonal Mouse Anti-Human Melan-A, Clone A103	Dinamarca
IR635/ IS635	FLEX Monoclonal Mouse Anti-Pneumocystis Jiroveci, Clone 3F6	Dinamarca
IR636/ IS636	FLEX Monoclonal Mouse Anti-Human CD43, Clone DF-T1	Dinamarca
IR637/ IS637	FLEX Monoclonal Mouse Anti-Human Epithelial Antigen, Clone Ber-EP4	Dinamarca
IR640/ IS640	FLEX Monoclonal Mouse Anti-Human Mast Cell Tryptase, Clone AA1	Dinamarca
IR641/ IS641	FLEX Monoclonal Mouse Anti-Human CD246, ALK Protein, Clone ALK1	Dinamarca
IR642/ IS642	FLEX Monoclonal Mouse Anti-Human CD138, Clone MI15	Dinamarca
IR643/ IS643	FLEX Monoclonal Mouse Anti-Human CD7, Clone CBC.37	Dinamarca
IR644/ IS644	FLEX Monoclonal Mouse Anti-Human MUM1 Protein, Clone MUM1p	Dinamarca
IR647/ IS647	FLEX Monoclonal Mouse Anti-Human CD57, Clone TB01	Dinamarca

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## FLEX PRIMARY ANTIBODIES - ROCHEM BIOCARE ARGENTINA S.A.

REF	NOMBRE DEL PRODUCTO	ORIGEN
IR001/ IS001	FLEX Polyclonal Rabbit Anti-Terminal Deoxynucleotidyl Transferase (TdT)	USA
IR002/ IS002	FLEX Polyclonal Guinea Pig Anti-Insulin	USA
IR051/ IS051	FLEX Monoclonal Mouse Anti-Human Cytokeratin HMW, Clone 34 $\beta$ E12	USA
IR052/ IS052	FLEX Monoclonal Mouse Anti-Human Melanosome, Clone HMB-45	USA
IR053/ IS053	FLEX Monoclonal Mouse Anti-Human Cytokeratin, Clone AE1/AE3	USA
IR054/ IS054	FLEX Monoclonal Mouse Anti-Human Caldesmon, Clone h-CD	USA
IR055/ IS055	FLEX Monoclonal Mouse Anti-Human Wilms Tumor 1 Protein, Clone 6F-H2	USA
IR056/ IS056	FLEX Monoclonal Mouse Anti-Thyroid Transcription Factor, Clone 8G7G3/1	USA
IR057/ IS057	FLEX Monoclonal Mouse Anti-Human CD99, MIC2 Gene Product Ewing's Sarcoma Clon 12E7	USA
IR058/ IS058	FLEX Monoclonal Mouse Anti-Human Inhibin alpha, Clone R1	USA
IR059/ IS059	FLEX Monoclonal Mouse Anti-Human E-Cadherin, Clone NCH-38	USA
IR060/ IS060	FLEX Monoclonal Rabbit Anti-Human AMACR, Clone 13H4	USA
IR061/ IS061	FLEX Monoclonal Mouse Anti-Human Tyrosinase, Clone T311	USA
IR062/ IS062	FLEX Monoclonal Mouse Anti-Human CD15, Clone Carb-3	USA
IR066/ IS066	FLEX Monoclonal Mouse Anti-Human Smooth Muscle Myosin Heavy Chain, Clone SMMS-1	USA
IR067/ IS067	FLEX Monoclonal Mouse Anti-Myogenin Clone F5D	USA
IR068/ IS068	FLEX Monoclonal Mouse Anti-Human Progesterone Receptor, Clone PgR 636	USA
IR069/ IS069	FLEX Monoclonal Mouse Anti-Human CD1a, Clone 010	USA
IR072/ IS072	FLEX Monoclonal Mouse Anti-Human D2-40, Clone D2-40	USA
IR074/ IS074	FLEX Monoclonal Mouse Anti-Human Mammaglobin, Clone 304-1A5	USA
IR075/ IS075	FLEX Monoclonal Mouse Anti-Human Renal Cell Carcinoma Marker, Clone SPM314	USA
IR076/ IS076	FLEX Monoclonal Mouse Anti- Villin, Clone 1D2 C3	USA
IR077/ IS077	FLEX Monoclonal Mouse Anti-Human Gross Cystic Disease Fluid Protein-15, Clone 23A3	USA
IR080/ IS080	FLEX Monoclonal Mouse Anti-Human CDX-2, Clone DAK-CDX2	USA
IR081/ IS081	FLEX Monoclonal Rabbit Anti-Human, CD5 Clone SP19	USA
IR151/ IS151	FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor $\alpha$ , Clone SP1	USA
IR152/ IR152	FLEX Monoclonal Rabbit Anti-Human Cyclin D1, Clone SP4	USA
IR500/ IS500	FLEX Polyclonal Rabbit Anti-Human Alpha-1-Fetoprotein,	Dinamarca
IR502/ IS502	FLEX Polyclonal Rabbit Anti-Human Chromogranin A	Dinamarca
IR503/ IS503	FLEX Polyclonal Rabbit Anti-Human CD3	Dinamarca
IR504/ IS504	FLEX Polyclonal Rabbit Anti-S100	Dinamarca
IR505/ IS505	FLEX Polyclonal Rabbit Anti-Human Alpha-1-Antitrypsin	Dinamarca
IR506/ IS506	FLEX Polyclonal Rabbit Anti-Human Kappa Light Chains	Dinamarca
IR507/ IS507	FLEX Polyclonal Rabbit Anti-Human Lambda Light Chains	Dinamarca
IR508/ IS508	FLEX Polyclonal Rabbit Anti-Human Chorionic Gonadotropin	Dinamarca
IR509/ IS509	FLEX Polyclonal Rabbit Anti-Human Thyroglobulin	Dinamarca
IR510/ IS510	FLEX Polyclonal Rabbit Anti-Human IgA	Dinamarca
IR511/ IS511	FLEX Polyclonal Rabbit Anti-Human Myeloperoxidase	Dinamarca
IR512/ IS512	FLEX Polyclonal Rabbit Anti-Human IgG	Dinamarca
IR513/ IS513	FLEX Polyclonal Rabbit Anti-Human IgM	Dinamarca
IR515/ IS515	FLEX Polyclonal Rabbit Anti-Human Calcitonin	Dinamarca
IR517/ IS517	FLEX Polyclonal Rabbit Anti-Human IgD	Dinamarca



**ANEXO – DISPOSICIÓN DE AUTORIZACION DE VENTA**

**FLEX PRIMARY ANTIBODIES - ROCHEM BIOCARE ARGENTINA S.A.**

REF	NOMBRE DEL PRODUCTO	ORIGEN
IR648/ IS648	FLEX Monoclonal Mouse Anti-Human CD10, Clone 56C6	Dinamarca
IR649/ IS649	FLEX Monoclonal Mouse Anti-Human CD4, Clone 4B12	Dinamarca
IR650/ IS650	FLEX Monoclonal Mouse Anti-Human B-Cell Specific Activator Protein, Clone DAK-PAX5	Dinamarca
IR651/ IS651	FLEX Monoclonal Mouse Anti-Human CD2, Clone AB75	Dinamarca
IR652/ IS652	FLEX Monoclonal Mouse Anti-Human Nucleophosmin, Clone 376	Dinamarca
IR653/ IS653	FLEX Monoclonal Mouse Anti-Human ZAP-70, Clone 2F3.2	Dinamarca
IR654/ IS654	FLEX Monoclonal Mouse Anti-Human Estrogen Receptor $\alpha$ Clone 1D5	Dinamarca
IR656/ IS656	FLEX Monoclonal Mouse Anti-Human CD19, Clone LE-CD19	Dinamarca
IR700/ IS700	FLEX Monoclonal Mouse Anti-Human Muscle Actin, Clone HHF35	Dinamarca
IR701/ IS701	FLEX Monoclonal Mouse Anti-Human CA 125, Clone M11	Dinamarca
IR702/ IS702	FLEX Monoclonal Mouse Anti-Human $\beta$ -Catenin, clone $\beta$ -Catenin-1	Dinamarca
IR751/ IS751	FLEX Monoclonal Mouse Anti-Human CD45, Leucocyte Common Antigen, Clone 2B11+PD7/26	Dinamarca
IR753/ IS753	FLEX Monoclonal Mouse Anti-Epstein-Barr Virus, LMP, Clone CS.1-4	Dinamarca
IR776/ IS776	FLEX Monoclonal Mouse Anti-Synaptophysin, Clone SY38	Dinamarca
IR777/ IS777	FLEX Monoclonal Mouse Anti-Human Cytokeratin 20, Clone Ks20.8	Dinamarca
IR779/ IS779	FLEX Monoclonal Mouse Anti-Human Placental Alkaline Phosphatase, Clone 8A9	Dinamarca
IR780/ IS780	FLEX Monoclonal Mouse Anti-Human Cytokeratin 5/6, Clone D5/16 B4	Dinamarca
IR800/ IS800	FLEX Monoclonal Rabbit Anti-Human CD23, Clone SP23	Dinamarca
IR600/ IS600	Universal Negative Control Rabbit *	USA
IR750/ IS750	Universal Negative Control Mouse *	USA

\* PRESENTACIONES: 120 tests, 24 ml/ 60 tests, 12 ml

**1912**

*Dr. Otto A. Orsinger*  
**Dr. OTTO A. ORSINGER**  
 SUB-INTERVENTOR  
 A.N.M.A.T.

**ANEXO - CERTIFICADO DE AUTORIZACION DE VENTA**      Página 1 de 3  
**FLEX PRIMARY ANTIBODIES - ROCHEM BIOCARE ARGENTINA S.A.**

REF	NOMBRE DEL PRODUCTO	ORIGEN
IR001/ IS001	FLEX Polyclonal Rabbit Anti-Terminal Deoxynucleotidyl Transferase (TdT)	USA
IR002/ IS002	FLEX Polyclonal Guinea Pig Anti-Insulin	USA
IR051/ IS051	FLEX Monoclonal Mouse Anti-Human Cytokeratin HMW, Clone 34 BE12	USA
IR052/ IS052	FLEX Monoclonal Mouse Anti-Human Melanosome, Clone HMB-45	USA
IR053/ IS053	FLEX Monoclonal Mouse Anti-Human Cytokeratin, Clone AE1/AE3	USA
IR054/ IS054	FLEX Monoclonal Mouse Anti-Human Caldesmon, Clone h-CD	USA
IR055/ IS055	FLEX Monoclonal Mouse Anti-Human Wilms Tumor 1 Protein, Clone 6F-H2	USA
IR056/ IS056	FLEX Monoclonal Mouse Anti-Thyroid Transcription Factor, Clone 8G7G3/1	USA
IR057/ IS057	FLEX Monoclonal Mouse Anti-Human CD99, MIC2 Gene Product Ewing's Sarcoma Clon 12E7	USA
IR058/ IS058	FLEX Monoclonal Mouse Anti-Human Inhibin alpha, Clone R1	USA
IR059/ IS059	FLEX Monoclonal Mouse Anti-Human E-Cadherin, Clone NCH-38	USA
IR060/ IS060	FLEX Monoclonal Rabbit Anti-Human AMACR, Clone 13H4	USA
IR061/ IS061	FLEX Monoclonal Mouse Anti-Human Tyrosinase, Clone T311	USA
IR062/ IS062	FLEX Monoclonal Mouse Anti-Human CD15, Clone Carb-3	USA
IR066/ IS066	FLEX Monoclonal Mouse Anti-Human Smooth Muscle Myosin Heavy Chain, Clone SMMS-1	USA
IR067/ IS067	FLEX Monoclonal Mouse Anti-Myogenin Clone F5D	USA
IR068/ IS068	FLEX Monoclonal Mouse Anti-Human Progesterone Receptor, Clone PgR 636	USA
IR069/ IS069	FLEX Monoclonal Mouse Anti-Human CD1a, Clone 010	USA
IR072/ IS072	FLEX Monoclonal Mouse Anti-Human D2-40, Clone D2-40	USA
IR074/ IS074	FLEX Monoclonal Mouse Anti-Human Mammaglobin, Clone 304-1A5	USA
IR075/ IS075	FLEX Monoclonal Mouse Anti-Human Renal Cell Carcinoma Marker, Clone SPM314	USA
IR076/ IS076	FLEX Monoclonal Mouse Anti- Villin, Clone 1D2 C3	USA
IR077/ IS077	FLEX Monoclonal Mouse Anti-Human Gross Cystic Disease Fluid Protein-15, Clone 23A3	USA
IR080/ IS080	FLEX Monoclonal Mouse Anti-Human CDX-2, Clone DAK-CDX2	USA
IR081/ IS081	FLEX Monoclonal Rabbit Anti-Human, CD5 Clone SP19	USA
IR151/ IS151	FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor $\alpha$ , Clone SP1	USA
IR152/ IR152	FLEX Monoclonal Rabbit Anti-Human Cyclin D1, Clone SP4	USA
IR500/ IS500	FLEX Polyclonal Rabbit Anti-Human Alpha-1-Fetoprotein,	Dinamarca
IR502/ IS502	FLEX Polyclonal Rabbit Anti-Human Chromogranin A	Dinamarca
IR503/ IS503	FLEX Polyclonal Rabbit Anti-Human CD3	Dinamarca
IR504/ IS504	FLEX Polyclonal Rabbit Anti-S100	Dinamarca
IR505/ IS505	FLEX Polyclonal Rabbit Anti-Human Alpha-1-Antitrypsin	Dinamarca
IR506/ IS506	FLEX Polyclonal Rabbit Anti-Human Kappa Light Chains	Dinamarca
IR507/ IS507	FLEX Polyclonal Rabbit Anti-Human Lambda Light Chains	Dinamarca
IR508/ IS508	FLEX Polyclonal Rabbit Anti-Human Chorionic Gonadotropin	Dinamarca
IR509/ IS509	FLEX Polyclonal Rabbit Anti-Human Thyroglobulin	Dinamarca
IR510/ IS510	FLEX Polyclonal Rabbit Anti-Human IgA	Dinamarca
IR511/ IS511	FLEX Polyclonal Rabbit Anti-Human Myeloperoxidase	Dinamarca
IR512/ IS512	FLEX Polyclonal Rabbit Anti-Human IgG	Dinamarca
IR513/ IS513	FLEX Polyclonal Rabbit Anti-Human IgM	Dinamarca
IR515/ IS515	FLEX Polyclonal Rabbit Anti-Human Calcitonin	Dinamarca
IR517/ IS517	FLEX Polyclonal Rabbit Anti-Human IgD	Dinamarca

**ANEXO - CERTIFICADO DE AUTORIZACION DE VENTA**      Página 2 de 3  
**FLEX PRIMARY ANTIBODIES - ROCHEM BIOCARE ARGENTINA S.A.**

REF	NOMBRE DEL PRODUCTO	ORIGEN
IR519/ IS519	FLEX Polyclonal Rabbit Anti-Human Gastrin	Dinamarca
IR521/ IS521	FLEX Polyclonal Rabbit Anti-Herpes Simplex Virus Type 1	Dinamarca
IR523/ IS523	FLEX Polyclonal Rabbit Anti-Helicobacter Pylori	Dinamarca
IR524/ IS524	FLEX Polyclonal Rabbit Anti-Glial Fibrillary Acidic Protein	Dinamarca
IR526/ IS526	FLEX Polyclonal Rabbit Anti-Human Carcinoembryonic Antigen	Dinamarca
IR527/ IS527	FLEX Polyclonal Rabbit Anti-Human Von Willbrand Factor	Dinamarca
IR602/ IS602	FLEX Monoclonal Mouse Anti-Human CD30, Clone Ber-H2	Dinamarca
IR604/ IS604	FLEX Monoclonal Mouse Anti-Human CD20cy, Clone L26	Dinamarca
IR605/ IS605	FLEX Monoclonal Mouse Anti-Human Amyloid A, Clone mc1	Dinamarca
IR606/ IS606	FLEX Monoclonal Mouse Anti-Human Desmin, Clone D33	Dinamarca
IR607/ IS607	FLEX Monoclonal Mouse Anti-Human Neurofilament Protein, Clone 2F11	Dinamarca
IR608/ IS608	FLEX Monoclonal Mouse Anti-Human CD21, Clone 1F8	Dinamarca
IR609/ IS609	FLEX Monoclonal Mouse Anti-Human CD68, Clone KP1	Dinamarca
IR610/ IS610	FLEX Monoclonal Mouse Anti-Human CD31, Endothelial Cell, Clone JC70A	Dinamarca
IR611/ IS611	FLEX Monoclonal Mouse Anti-Human Smooth Muscle Actin, Clone 1A4	Dinamarca
IR612/ IS612	FLEX Monoclonal Mouse Anti-Human Neuron Specific Enolase, Clone BBS/NC/VI-H14	Dinamarca
IR613/ IS613	FLEX Monoclonal Mouse Anti-Human CD68, Clone PG-M1	Dinamarca
IR614/ IS614	FLEX Monoclonal Mouse Anti-Human BCL2 Oncoprotein, Clone 124	Dinamarca
IR615/ IS615	FLEX Monoclonal Mouse Anti-Human Cytokeratin 19, Clone RCK108	Dinamarca
IR616/ IS616	FLEX Monoclonal Mouse Anti-Human p53 Protein, Clone DO-7	Dinamarca
IR618/ IS618	FLEX Monoclonal Mouse Anti-Human Cytokeratin 18, Clone DC 10	Dinamarca
IR619/ IS619	FLEX Monoclonal Mouse Anti-Human Cytokeratin 7, Clone OV-TL 12/30	Dinamarca
IR620/ IS620	FLEX Monoclonal Mouse Anti-Cytokeratin 17, Clone E3	Dinamarca
IR621/ IS621	FLEX Monoclonal Mouse Anti-Human CD79α, Clone JCB117	Dinamarca
IR622/ IS622	FLEX Monoclonal Mouse Anti-Human Carcinoembryonic Antigen, Clone II-7	Dinamarca
IR623/ IS623	FLEX Monoclonal Mouse Anti-Human CD8, Clone C8/144B	Dinamarca
IR624/ IS624	FLEX Monoclonal Mouse Anti-Human Hepatocyte, Clone OCH1E5	Dinamarca
IR625/ IS625	FLEX Monoclonal Mouse Anti-Human BCL6 Protein, Clone PG-B6p	Dinamarca
IR626/ IS626	FLEX Monoclonal Mouse Anti-Human Ki-67 Antigen, Clone MIB-1	Dinamarca
IR627/ IS627	FLEX Monoclonal Mouse Anti-Human Calretinin, Clone DAK-Calret 1	Dinamarca
IR628/ IS628	FLEX Monoclonal Mouse Anti-Human CD56, Clone 132C3	Dinamarca
IR629/ IS629	FLEX Monoclonal Mouse Anti-Human Epithelial Membrane Antigen, Clone E29	Dinamarca
IR630/ IS630	FLEX Monoclonal Mouse Anti-Human Vimentin, Clone V9	Dinamarca
IR632/ IS632	FLEX Monoclonal Mouse Anti-Human CD34, Clone QBEnd 10	Dinamarca
IR633/ IS633	FLEX Monoclonal Mouse Anti-Human Melan-A, Clone A103	Dinamarca
IR635/ IS635	FLEX Monoclonal Mouse Anti-Pneumocystis Jiroveci, Clone 3F6	Dinamarca
IR636/ IS636	FLEX Monoclonal Mouse Anti-Human CD43, Clone DF-T1	Dinamarca
IR637/ IS637	FLEX Monoclonal Mouse Anti-Human Epithelial Antigen, Clone Ber-EP4	Dinamarca
IR640/ IS640	FLEX Monoclonal Mouse Anti-Human Mast Cell Tryptase, Clone AA1	Dinamarca
IR641/ IS641	FLEX Monoclonal Mouse Anti-Human CD246, ALK Protein, Clone ALK1	Dinamarca
IR642/ IS642	FLEX Monoclonal Mouse Anti-Human CD138, Clone MI15	Dinamarca
IR643/ IS643	FLEX Monoclonal Mouse Anti-Human CD7, Clone CBC.37	Dinamarca
IR644/ IS644	FLEX Monoclonal Mouse Anti-Human MUM1 Protein, Clone MUM1p	Dinamarca
IR647/ IS647	FLEX Monoclonal Mouse Anti-Human CD57, Clone TB01	Dinamarca

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**FLEX PRIMARY ANTIBODIES - ROCHEM BIOCARE ARGENTINA S.A.**

REF	NOMBRE DEL PRODUCTO	ORIGEN
IR648/ IS648	FLEX Monoclonal Mouse Anti-Human CD10, Clone 56C6	Dinamarca
IR649/ IS649	FLEX Monoclonal Mouse Anti-Human CD4, Clone 4B12	Dinamarca
IR650/ IS650	FLEX Monoclonal Mouse Anti-Human B-Cell Specific Activator Protein, Clone DAK-PAX5	Dinamarca
IR651/ IS651	FLEX Monoclonal Mouse Anti-Human CD2, Clone AB75	Dinamarca
IR652/ IS652	FLEX Monoclonal Mouse Anti-Human Nucleophosmin, Clone 376	Dinamarca
IR653/ IS653	FLEX Monoclonal Mouse Anti-Human ZAP-70, Clone 2F3.2	Dinamarca
IR654/ IS654	FLEX Monoclonal Mouse Anti-Human Estrogen Receptor $\alpha$ Clone 1D5	Dinamarca
IR656/ IS656	FLEX Monoclonal Mouse Anti-Human CD19, Clone LE-CD19	Dinamarca
IR700/ IS700	FLEX Monoclonal Mouse Anti-Human Muscle Actin, Clone HHF35	Dinamarca
IR701/ IS701	FLEX Monoclonal Mouse Anti-Human CA 125, Clone M11	Dinamarca
IR702/ IS702	FLEX Monoclonal Mouse Anti-Human $\beta$ -Catenin, clone $\beta$ -Catenin-1	Dinamarca
IR751/ IS751	FLEX Monoclonal Mouse Anti-Human CD45, Leucocyte Common Antigen, Clone 2B11+PD7/26	Dinamarca
IR753/ IS753	FLEX Monoclonal Mouse Anti-Epstein-Barr Virus, LMP, Clone CS.1-4	Dinamarca
IR776/ IS776	FLEX Monoclonal Mouse Anti-Synaptophysin, Clone SY38	Dinamarca
IR777/ IS777	FLEX Monoclonal Mouse Anti-Human Cytokeratin 20, Clone Ks20.8	Dinamarca
IR779/ IS779	FLEX Monoclonal Mouse Anti-Human Placental Alkaline Phosphatase, Clone 8A9	Dinamarca
IR780/ IS780	FLEX Monoclonal Mouse Anti-Human Cytokeratin 5/6, Clone D5/16 B4	Dinamarca
IR800/ IS800	FLEX Monoclonal Rabbit Anti-Human CD23, Clone SP23	Dinamarca
IR600/ IS600	Universal Negative Control Rabbit *	USA
IR750/ IS750	Universal Negative Control Mouse *	USA

\* PRESENTACIONES: 120 tests, 24 ml/ 60 tests, 12 ml

7912

**Dr. OTTO A. ORSINGER**  
**SUB-INTERVENTOR**  
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