bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

AESKU.Systems GmbH & Co. KG
Mikroforum Ring 3-5
Wendelsheim
55234
Germany

Holds Certificate Number: **MD 619746**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture, installation, servicing and distribution of in-vitro diagnostic instruments.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2014-10-22
Latest Revision Date: 2018-12-16

Effective Date: 2019-01-04
Expiry Date: 2022-01-03

...making excellence a habit.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

AESKU.DIAGNOSTICS GmbH & Co. KG
Mikroforum Ring 2
55234 Wendelsheim
Germany

Holds Certificate Number: **MD 619745**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development, manufacturing and distribution of in-vitro diagnostic test kits and in-vitro diagnostic reagents used in the diagnosis of autoimmune status and disease status.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2014-10-10
Latest Revision Date: 2018-11-28

Effective Date: 2017-06-14
Expiry Date: 2020-06-13

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Nuova Aptaca Srl Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

CERTIFIED COMPANY UNI EN ISO 9001 & UNI CEI EN ISO 13485

SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
07.10.2019

MADE IN ITALY

CODICE ARTICOLO: / *ITEM CODE:* **2120/SG**

DESCRIZIONE / *DESCRIPTION*

CONTENITORE GRADUATO PER URINE DA 150 ML
Tappo a vite inserito, in polietilene di colore rosso, che ne garantisce la perfetta tenuta con bordo zigrinato per una apertura e chiusura facile e sicura. Contenitore con superficie di scrittura. Ottima resistenza alle basse e alte temperature e buona resistenza agli agenti chimici. Prodotto in Polipropilene medicale (PP). Sterile, in confezione singola. Dispositivo Latex-Free e apirogeno. Conforme alla norma UNI EN 14254.

150 ML GRADUATED URINE CONTAINERS
Red inserted screw cap in polyethylene which guarantees the perfect leak-proof, with milled rim allowing a safe and easy opening/closing.
Container with writing surface. Excellent high and low temperatures resistance and chemical agents. Manufactured in medical PP. Sterile, individually wrapped. Latex free and pyrogen free device. Compliant with UNI EN 14254.

Prodotto con marchio CE - conforme alla Direttiva 98/79/CE e al D.lgs 332 del 08/09/2000

CE *Marked product* - *manufactured in compliance with 98/79/CE Directive and D.lgs 332 dtd 08/09/2000*

CARATTERISTICHE PRINCIPALI		*TECHNICAL FEATURES*
Stato microbiologico	**STERILE / *STERILE*** **RAGGI BETA / *BETA RAYS***	*Microbilogical status*
Materiale impiegato contenitore	POLIPROPILENE / *POLYPROPYLENE*	*Raw material – container*
Materiale impiegato tappo	POLIETILENE / *POLYETHYLENE*	*Raw material - cap*
Volume nominale contenitore (ml)	150	*Nominal volume container (ml)*
Scala graduata	MIN. 20ML – MAX 100ML	*Graduated scale*
Incrementi scala graduata (ml)	20	*Intervals graduated scale (ml)*
Temperature tollerate contenitore	MIN -10°C MAX +120°C	*Temperature range - container*
Temperature tollerate tappo	MIN -50°C MAX +80°C	*Temperature range - cap*
Dimensioni contenitore (mm)	Ø 58 X 72	*Dimensions - container (mm)*
Dimensione tappo (mm)	Ø 61 X 13	*Dimensions – cap (mm)*
Peso contenitore (gr.)	9,0	*Weight - container (gr.)*
Peso tappo (gr.)	5,8	*Weight – cap (gr.)*
Validità del prodotto	5 ANNI / *YEARS*	*Shelf life*

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DESTINAZIONE D'USO / *INTENDED PURPOSE*

La destinazione è quella di "DISPOSITIVO MEDICO DIAGNOSTICO IN VITRO" atto a contenere un campione biologico umano (urina) al fine di effettuare analisi diagnostiche di laboratorio. **Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.**
Classificazione Nazionale Dispositivi Medici (CND) > W05010203 (Contenitori per raccolta di urina).
Repertorio Nazionale dei Dispositivi Medici (RDM) > 1236972/R
Codice EDMA > 51021002 - Sterile urine containers

Intended purpose is "IN VITRO MEDICAL DEVICE" adapted to contain a human biological sample (urine) in order to perform diagnostic analysis laboratory. ***For professional use only.***
National classification of medical devices (CND - For Italian law) > *W05010203 (Urine collection, containers).*
Code EDMA > 51021002 - Sterile urine containers.

AVVERTENZE PER L'USO / *OPERATING INSTRUCTIONS*

Non avvicinare il dispositivo alla fiamma o a fonti di calore che lo potrebbero danneggiare.
Keep out of flame or heat sources which might damage the product

Non utilizzare il prodotto scaduto o con la confezione aperta
Do not use after expiry date or if packing is opened

Non riutilizzare: Dispositivo monouso
Do not re-use: Disposable device

Non variare la destinazione d'uso
Do not vary the intended purpose of the product

Prodotto non adatto ai bambini
Keep out of reach of children

Conservare in luogo asciutto, Temperatura min -10°C max +50°C
Store in dry place, Temperature range: min -10°C max +50°C

Smaltimento: utilizzare gli appositi D.P.I e smaltire secondo le normative vigenti
Disposal: use appropriate personal protective equipment and act according to applicable regulations

Prima dell'utilizzo con sostanze particolari consultare sul catalogo le tabelle di resistenza/compatibilità dei materiali.
Before use with particolar substance check the resistance / compatibility chart on our catalogue

IMBALLO / *PACKING*

Quantità (pz): *Quantity (pcs):*	250	Confezione interna (pz): *Internal packing (pcs):*	singola *individually*	QUANTITÀ MINIMA VENDIBILE *MINIMUM SALEABLE QUANTITY*	
Misura esterna scatola (cm): *External box dimensions (cm):*	35,5 x 55 x 45,7	Peso (Kg): *Weight (Kg):*	5,5	Volume (m^3): *Volume (m^3):*	0,089

SIMBOLI UTILIZZATI SULL'IMBALLO / *PACKING SYMBOLS*


Data di fabbricazione
Manufacturing date


Data di scadenza
Expiry date


Consultare i documenti accompagnatori
Please consult accompanying documents

Numero di lotto
Lot number


Monouso
Disposable

Sterilizzazione con radiazioni ionizzanti
Sterilization by ionizer rays

ITALCERT

CERTIFICATO N° 505SGQ04

CERTIFICATE N° 505SGQ04

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Commercializzazione di dispositivi medici e diagnostici in vitro. Commercializzazione di articoli da laboratorio

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Modifica *Modified Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2019-11-06	2020-10-29

Settore IAF 14 - 29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com - www.aptaca.com - www.vacucheck.com
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

CERTIFIED COMPANY UNI EN ISO 9001:2008 & UNI CEI EN ISO 13485:2012

DICHIARAZIONE DI CONFORMITA' CE

CE *DECLARATION OF CONFORMITY*

La sottoscritta Nuova Aptaca s.r.l.
The undersigned Nuova Aptaca s.r.l.

DICHIARA
DECLARES

Che il dispositivo medico diagnostico in vitro di seguito descritto:
That in vitro diagnostic medical devices described as follows:

CONTENITORI PER CAMPIONI BIOLOGICI

SPECIMEN CONTAINERS

PRODOTTI STERILI – *STERILE PRODUCTS*

(i cui codici di dettaglio sono riportati nell'allegato 1)
(which detailed codes are reported in Annex 1)

> **Sono conformi ai requisiti essenziali di cui all'allegato I della direttiva 98/79/CE del 27 ottobre 1998 recepita con il D.Lgs 332 del 08/09/2000.**
Are manufactured in compliance with essential requirements of Annex 1 of the 98/79/CE Directive dated 27Th October 1998 put into force by D.Lgs. 332 dated 08/09/2000.

> **I Dispositivi di cui all'Allegato 1 non rientrano nell'elenco A o B di cui all'Allegato II della Direttiva 98/79/CE.**
The devices as per Annex 1 do not do not fall under list A or B of annex II of the Directive 98/79/EC.

> **La presente dichiarazione è stata redatta in conformità all'Allegato III (escluso punto 6) della Direttiva 98/79/CE.**
The present Declaration was drafted in accordance with annex III to Directive 98/79/EC.

Rilasciato */ Released*
Canelli, 26.07.2015

Dulio BUONO
Responsabile Assicurazione Qualità

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com - www.aptaca.com - www.vacucheck.com
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE

Annex 1 to Declaration of Conformity 98/79/CE

COD.	DESCRIZIONE	*DESCRIPTION*
1011/E/SG	Contenitori per feci, 18ml, PS, tappo a pressione con paletta, con etichetta	*Faeces containers 18ml, PS, pressure cap and spoon, with label*
1011/E/SG/CS	Contenitori per feci, 18ml, PS, tappo a pressione con paletta, con etichetta, confezione singola	*Faeces containers 18ml, PS, pressure cap and spoon, with label, ind. wrapped*
1011/SG	Contenitori per feci, 18ml, PS, tappo a pressione con paletta	*Faeces containers 18ml, PS, pressure cap and spoon*
1011/SG/CS	Contenitori per feci, 18ml, PS, tappo a pressione con paletta, confezione singola	*Faeces containers 18ml, PS, pressure cap and spoon, ind. wrapped*
1012/SG	Contenitori per campioni biologici, 18ml, PS, tappo a pressione	*Specimen containers 18ml, PS, pressure cap*
1030/E/SG	Contenitori per urine 130ml, graduati, PS, tappo a pressione, confezione singola ed etichetta	*Graduated urine containers 130ml, PS, pressure cap, ind. wrapped, with label*
1030/E/TS	Contenitori per urine 130ml, graduati, PS, tappo a pressione, etichetta	*Graduated urine containers 130ml, PS, pressure cap, with label*
1030/MO/E/SG	Contenitori urina 130ml, in PP tappo a pressione, graduati, sterili, etichetta	*Graduated urine containers 130ml, PP, pressure cap, with label*
1030/MO/SG	Contenitori urina 130ml, in PP tappo a pressione, graduati, sterili	*Graduated urine containers 130ml, PP, pressure cap*
1030/SG	Contenitori per urine 130ml, graduati, PS, tappo a pressione, confezione singola	*Graduated urine containers 130ml, PS, pressure cap, ind. wrapped*
1030/TS	Contenitori per urina 120 ml ps t/press. ster.conf.multipla	*Graduated urine containers 130ml, PS, pressure cap*
1041/SG	Contenitori per campioni biologici, 30ml, PS, tappo a pressione	*Specimen containers 30ml, PS, pressure cap*
1050/E/SG	Contenitori per urine 150ml, graduati, PS, tappo a pressione, confezione singola ed etichetta	*Graduated urine containers 150ml, PS, pressure cap, ind. wrapped, with label*
1050/SG	Contenitori per urine 150ml, graduati, PS, tappo a pressione, confezione singola	*Graduated urine containers 150ml, PS, pressure cap, ind. wrapped*
1051/E/SG	Contenitori per urine 150ml, graduati, PS, tappo a pressione, con etichetta, confezione singola	*Graduated urine containers 150ml, PS, pressure cap, with label, ind. wrapped*
1051/S/SG/CS	Contenitori per espettorato, 60ml, PS, senza tappo a pressione, confezione singola	*Sputum containers 60ml, PS, without pressure cap, individually wrapped*
1051/SG	Contenitori per espettorato, 60ml, PS, tappo a pressione	*Sputum containers 60ml, PS, with pressure cap*
1051/SG/CS	Contenitori per espettorato, 60ml, PS, tappo a pressione, confezione singola	*Sputum containers 60ml, PS, with pressure cap, ind. wrapped*
1061/SG	Contenitori per campioni biologici, 35ml, PS, tappo a pressione	*Specimen containers 35ml, PS, pressure cap*
1061/SG/CS	Contenitori per campioni biologici, 35ml, PS, tappo a pressione, confezione singola	*Specimen containers 35ml, PS, pressure cap, ind. wrapped*
1070/E/SG	Contenitore modello "Bijou" in PS da 7ml, tappo a vite, non graduato, con etichetta, sterile	*"Bijou" containers in PS 7ml, screw cap, not graduated, with label, sterile*
1070/SG	Contenitore modello "Bijou" in PS da 7ml, tappo a vite, non graduato, sterile	*"Bijou" containers in PS 7ml, screw cap, not graduated, sterile*
1091	Contenitori per urine 150ml, graduati, PS, tappo a vite, confezione singola	*Graduated urine containers 150ml, PS, screw cap, ind. wrapped*
1091/E	Contenitori per urine 150ml, graduati, PS, tappo a vite, confezione singola ed etichetta	*Graduated urine containers 150ml, PS, screw cap, ind. wrapped, with label*
1211/E/SG	Contenitori per feci, 60ml, PS, tappo a pressione con paletta, con etichetta	*Faeces containers 60ml, PS, pressure cap and spoon, with label*
1211/E/SG/CS	Contenitori per feci, 60ml, PS, tappo a pressione con paletta, conf. singola e etichetta	*Faeces containers 60ml, PS, pressure cap and spoon, ind. wrapped, with label*
1211/SG	Contenitori per feci, 60ml, PS, tappo a pressione con paletta	*Faeces containers 60ml, PS, pressure cap and spoon*
1211/SG/CS	Contenitori per feci, 60ml, PS, tappo a pressione con paletta, confezione singola	*Faeces containers 60ml, PS, pressure cap and spoon, ind. wrapped*
1212/E/SG	Contenitori per campioni biologici, 60ml, PS, tappo a pressione, con etichetta	*Specimen containers 60ml, PS, pressure cap, with label*
1212/SG	Contenitori per campioni biologici, 60ml, PS, tappo a pressione	*Specimen containers 60ml, PS, pressure cap*
1212/SG/CS	Contenitori per campioni biologici, 60ml, PS, tappo a pressione, confezione singola	*Specimen containers 60ml, PS, pressure cap, ind. wrapped*
1230/E/SG	Contenitori per urine 200ml, graduati, PS, tappo a vite, confezione singola ed etichetta	*Graduated urine containers 200ml, PS, screw cap, ind. wrapped, with label*
1230/SG	Contenitori per urine 200ml, graduati, PS, tappo a vite, confezione singola	*Graduated urine containers 200ml, PS, screw cap, ind. wrapped*
1230/TS	Contenitori per urine 200ml, graduati, PS, tappo a vite	*Graduated urine containers 200ml, PS, screw cap*
1230SG	contenitori 200 ml ps tappo a vite ster. sing.	*Graduated urine containers 200ml, PS, screw cap*
12731/E/SG	Tanica per la raccolta delle urine nelle 24ore da 2.500ml, graduata, in PE, tappo a vite, etichetta	*24h urine collection tanks in PE, 2,500ml, graduated, screw cap, label*
12731/SG	Taniche per urine 24ore in PE, 2.500ml, sterili conf.singola,	*24h urine collection tanks in PE, 2,500ml, graduated, screw cap*

NUOVA APTACA s.r.l.
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P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE

Annex 1 to Declaration of Conformity 98/79/CE

COD.	DESCRIZIONE	*DESCRIPTION*
14142/SG	Contenitori in PP per pezzi chirurgici con tappo pressione	*Surgical specimen containers wide opening, 500ml, PE, with cap*
14142/SG/CS	Contenitori per pezzi chirurgici a bocca larga, 500ml, PE, con tappo, confezione singola	*Surgical specimen containers wide opening, 500ml, PE, with cap, ind. wrapped*
14143/SG/CS	Contenitori per pezzi chirurgici a bocca larga, 1.000ml, PE, con tappo, confezione singola	*Surgical specimen containers wide opening, 1.000ml, PE, with cap, ind. wrapped*
14144/SG/CS	Contenitori per pezzi chirurgici a bocca larga, 1.500ml, PE, con tappo, confezione singola	*Surgical specimen containers wide opening, 1.500ml, PE, with cap, ind. wrapped*
14150/SG/CS	Contenitori trasparenti per pezzi chirurgici 150ml, PP, tappo a pressione, conf. singola	*Surgical specimen transparent containers 150ml, PP, pressure cap, ind. wrapped*
14151/SG	Contenitori in PP per pezzi chirurgici con tappo a vite	*Surgical specimen transparent containers 250ml, PP, pressure cap*
14152/SG	Contenitori in PP per pezzi chirurgici con tappo a vite,	*Surgical specimen transparent containers 500ml, PP, pressure cap*
14155/SG	Contenitori trasparenti per pezzi chirurgici 250ml, PP, tappo a pressione	*Surgical specimen transparent containers 250ml, PP, pressure cap*
14155/SG/CS	Contenitori trasparenti per pezzi chirurgici 250ml, PP, tappo a pressione, conf. singola	*Surgical specimen transparent containers 250ml, PP, pressure cap, ind. wrapped*
14160/SG	Contenitori trasparenti per pezzi chirurgici 500ml, PP, tappo a pressione	*Surgical specimen transparent containers 500ml, PP, pressure cap*
14160/SG/CS	Contenitori trasparenti per pezzi chirurgici 500ml, PP, tappo a pressione, conf. singola	*Surgical specimen transparent containers 500ml, PP, pressure cap, ind. wrapped*
14170/SG/CS	Contenitori trasparenti per pezzi chirurgici 1.000 ml, PP, tappo a pressione, conf. singola	*Surgical specimen transparent containers 1,000 ml, PP, pressure cap, ind. wrapped*
14175/SG/CS	Contenitori trasparenti per pezzi chirurgici 2.300 ml, PP, tappo a pressione, conf. singola	*Surgical specimen transparent containers 2,300 ml, PP, pressure cap, ind. wrapped*
14180/SG/CS	Contenitori trasparenti per pezzi chirurgici 3.000 ml, PP, tappo a pressione, conf. singola	*Surgical specimen transparent containers 3,000 ml, PP, pressure cap, ind. wrapped*
14185/SG/CS	Contenitori trasparenti per pezzi chirurgici 5.000 ml, PP, tappo a pressione, conf. singola	*Surgical specimen transparent containers 5,000 ml, PP, pressure cap, ind. wrapped*
14190/SG/CS	Contenitori bianchi per pezzi chirurgici 5.500 ml, PP, tappo a pressione, conf. singola	*Surgical specimen white containers 5,500 ml, PP, pressure cap, ind. wrapped*
14192/SG/CS	Contenitori bianchi per pezzi chirurgici 2.500 ml, PP, tappo a pressione, conf. singola	*Surgical specimen white containers 2,500 ml, PP, pressure cap, ind. wrapped*
14195/SG/CS	Contenitori bianchi per pezzi chirurgici 11.000 ml, PP, tappo a pressione, conf. singola	*Surgical specimen white containers 11,000 ml, PP, pressure cap, ind. wrapped*
1560/SG	Contenitori per saliva 30 ml, in PP, tappo a vite,	*Autoclavable sputum collection container 30 ml, in PP, screw cap*
1630/E/SG	Contenitori da 250ml in PS, con tappo a vite in metallo e guarnizione, con etichetta	*Specimen containers 250ml in PS, with alluminium screw cap and gasket, with label*
1630/E/TS	Contenitori da 250ml in PS, con tappo a vite in metallo e guarnizione, con etichetta	*Specimen containers 250ml in PS, with alluminium screw cap and gasket, with label*
1630/SG	Contenitori da 250ml in PS, con tappo a vite in metallo e guarnizione	*Specimen containers 250ml in PS, with alluminium screw cap and gasket*
1630/TS	Contenitori da 250ml in PS, con tappo a vite in metallo e guarnizione	*Specimen containers 250ml in PS, with alluminium screw cap and gasket*
2030/E/SG	Contenitori campioni biologici 30ml,PP, tappo rosso inserito,	*Specimen containers 30ml, PP, screw cap, with label, ind. wrapped*
2030/SG	Contenitori per campioni biologici 30ml, PP, tappo a vite, confezione singola	*Specimen containers 30ml, PP, screw cap, ind. wrapped*
2030/TS	Contenitori per campioni biologici 30ml, PP, tappo a vite	*Specimen containers 30ml, PP, screw cap*
2040/E/SG	Contenitori per campioni biologici 60ml, PS, tappo a vite, confezione singola, con etichetta	*Specimen containers 60ml, PS, screw cap, ind. wrapped, with label*
2040/E/TS	Contenitori per campioni biologici 60ml, PS, tappo a vite, con etichetta	*Specimen containers 60ml, PS, screw cap, with label*
2040/EB/TS	Contenitori per campioni biologici 60ml, PS, tappo a vite bianco, con etichetta	*Specimen containers 60ml, PS, white screw cap, with label*
2040/EST/SG	Contenitori campioni biologici 60ml, PS, con tappo etichetta,	*Specimen containers 60ml, PS, white screw cap, with label*
2040/SG	Contenitori per campioni biologici 60ml, PS, tappo a vite, confezione singola	*Specimen containers 60ml, PS, screw cap, ind. wrapped*
2040/TS	Contenitori per campioni biologici 60ml, PS, tappo a vite	*Specimen containers 60ml, PS, screw cap*
2040/TS/70	Contenitori per campioni biologici 60ml, PS, tappo a vite, confezioni da 70 pcs	*Specimen containers 60ml, PS, screw cap, bags of 70 pcs*
2042/E/TS	Contenitori per feci da 60ml, PS, tappo a vite inserito e paletta, etichetta	*Faeces containers 60ml, PS, with inserted screw cap and spoon, label*
2042/SG	Contenitori per feci da 60ml, PS, tappo a vite inserito e paletta, confezione singola	*Faeces containers 60ml, PS, with inserted screw cap and spoon, individually wrapped*
2050/B/SG	Contenitori universali di colore blu da 60ml, in PP, non graduati, con tappo a vite, sterili	*60ml universal containers blue colour, in PP, not graduated, with screw cap, sterile*

NUOVA APTACA s.r.l.
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ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE

Annex 1 to Declaration of Conformity 98/79/CE

COD.	DESCRIZIONE	*DESCRIPTION*
2050/E/SG	Contenitori per campioni biologici 60ml, PP, tappo a vite, confezione singola, con etichetta	*Specimen containers 60ml, PP, screw cap, ind. wrapped, with label*
2050/E/TS	Contenitori per campioni biologici 60ml, PP, tappo a vite, con etichetta	*Specimen containers 60ml, PP, screw cap, with label*
2050/SG	Contenitori per campioni biologici 60ml, PP, tappo a vite, confezione singola	*Specimen containers 60ml, PP, screw cap, ind. wrapped*
2050/SG/C25	Contenitori per campioni biologici 60ml, PP, tappo a vite, confezione singola	*Specimen containers 60ml, PP, screw cap, ind. wrapped*
2050/SG/S	Contenitori per campioni biologici 60ml, PP, tappo a vite, confezione singola	*Specimen containers 60ml, PP, screw cap, ind. wrapped*
2050/TA/SG/20	Contenitori per campioni biologici 60ml, PP, tappo a vite azzurro, confezione da 20 pezzi	*Specimen containers 60ml, PP, light blue screw cap, bags of 20 pieces*
2050/TS	Contenitori per campioni biologici 60ml, PP, tappo a vite	*Specimen containers 60ml, PP, screw cap*
2052/E/SG	Contenitori per feci, 60ml, PP, tappo a vite con paletta, confezione singola, con etichetta	*Faeces containers 60ml, PP, screw cap and spoon, ind. wrapped, with label*
2052/E/TS	Contenitori per feci, 60ml, PP, tappo a vite con paletta, con etichetta	*Faeces containers 60ml, PP, screw cap and spoon, with label*
2052/SG	Contenitori per feci, 60ml, PP, tappo a vite con paletta, confezione singola	*Faeces containers 60ml, PP, screw cap and spoon, ind. wrapped*
2052/SG/25	Contenitori per feci da 60ml, PP, tappo inserito e paletta,	*Faeces containers 60ml, PP, screw cap and spoon*
2052/SG/C10	Contenitori per feci, 60ml, PP, tappo a vite con paletta, confezione singola	*Faeces containers 60ml, PP, screw cap and spoon, ind. wrapped*
2052/SG/C100	Contenitori per feci, 60ml, PP, tappo a vite con paletta, confezione singola	*Faeces containers 60ml, PP, screw cap and spoon, ind. wrapped*
2052/TS	Contenitori per feci, 60ml, PP, tappo a vite con paletta	*Faeces containers 60ml, PP, screw cap and spoon*
2062/E/SG	Contenitori per feci da 60ml, PP, tappo a vite con paletta, sterili, etichetta	*Faeces containers in PP 60ml, screw cap, with label, sterile*
2062/SG	Contenitori per feci da 60ml, PP, tappo a vite con paletta, sterili	*Faeces containers in PP 60ml, screw cap, sterile*
2072/E/SG	Contenitori per feci da 60ml, PS, tappo a vite con paletta, sterili, etichetta	*Faeces containers in PS 60ml, screw cap, with label, sterile*
2072/SG	Contenitori per feci da 60ml, PS, tappo a vite con paletta, sterili	*Faeces containers in PS 60ml, screw cap, sterile*
2120/B/SG	Contenitori urina 150ml, in PP tappo a vite bianco, graduati,	*Graduated urine containers 150ml, PP, screw cap, ind. wrapped*
2120/E/SG	Contenitori per urine 150ml, graduati, PP, tappo a vite, confezione singola ed etichetta	*Graduated urine containers 150ml, PP, screw cap, ind. wrapped, with label*
2120/E/TS	Contenitori per feci, 60ml, PP, tappo a vite con paletta, etichetta	*Faeces containers 60ml, PP, screw cap and spoon, with label*
2120/ES/SG	Contenitori per urine 150ml, graduati, PP, tappo a vite, confezione singola ed etichetta a parte	*Graduated urine containers 150ml, PP, screw cap, ind. wrapped, with label in a separate bag*
2120/H/SG	Contenitori per urine 150ml, graduati, PP, tappo a vite, confezione singola	*Graduated urine containers 150ml, PP, screw cap, ind. wrapped*
2120/SG	Contenitori per urine 150ml, graduati, PP, tappo a vite, confezione singola	*Graduated urine containers 150ml, PP, screw cap, ind. wrapped*
2120/SG/10	Contenitori per urine 150ml, graduati, PP, tappo a vite, confezione singola	*Graduated urine containers 150ml, PP, screw cap, ind. wrapped*
2120/SG/25	Contenitori per urine 150ml, graduati, PP, tappo a vite, confezione singola	*Graduated urine containers 150ml, PP, screw cap, ind. wrapped*
2120/SG/C10	Contenitori per urine 150ml, graduati, PP, tappo a vite, confezione singola	*Graduated urine containers 150ml, PP, screw cap, ind. wrapped*
2120/SG/C30	Contenitori per urine 150ml, graduati, PP, tappo a vite, confezione singola	*Graduated urine containers 150ml, PP, screw cap, ind. wrapped*
2120/SG/MI	Contenitori per urine 150ml, graduati, PP, tappo a vite, confezione singola	*Graduated urine containers 150ml, PP, screw cap, ind. wrapped*
2120/SG+1118	Contenitori per urine 150ml, graduati, PP, tappo a vite, confezione singola + etichette cod. 1118 non applicate	*Graduated urine containers 150ml, PP, screw cap, ind. Wrapped + labels cod. 1118 not applied*
2120/TA/SG	Contenitori per urine 150ml, graduati, PP, tappo a vite azzurro, confezione singola	*Graduated urine containers 150ml, PP, light blue screw cap, ind. wrapped*
2120/TS	Contenitori per urine 150ml, graduati, PP, tappo a vite	*Graduated urine containers 150ml, PP, screw cap*
2120/TSG	Contenitori per urine 150ml, graduati, PP, tappo a vite giallo	*Graduated urine containers 150ml, PP, yellow screw cap*
2220/E/SG	Contenitori per urine 200ml, graduati, PP, tappo a vite, con etichetta, confezione singola	*Graduated urine containers 200ml, PP, screw cap, ind. wrapped, with label*
2220/E/TS	Contenitori per urine 200ml, graduati, PP, tappo a vite, con etichetta	*Graduated urine containers 200ml, PP, screw cap, ind. wrapped*
2220/E/TSB	Contenitori per urine 200ml, graduati, PP, tappo a vite, con etichetta, con acido borico	*Graduated urine containers 200ml, PP, screw cap, ind. Wrapped, with boric acid*
2220/SG	Contenitori per urine 200ml, graduati, PP, tappo a vite, confezione singola	*Graduated urine containers 200ml, PP, screw cap, ind. wrapped*
2220/TS	Contenitori per urine 200ml, graduati, PP, tappo a vite,	*Graduated urine containers 200ml, PP, screw cap*
2250/E/SG	Contenitori per campioni biologici da 40ml, in PP, con etichetta	*40ml specimen containers in PP, with label*

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com - www.aptaca.com - www.vacucheck.com
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE

Annex 1 to Declaration of Conformity 98/79/CE

COD.	DESCRIZIONE	*DESCRIPTION*
2250/SG	Contenitori per campioni biologici da 40ml, in PP	*40ml specimen containers in PP*
2420/E/SG	Contenitori per urine 150ml, graduati, PP, tappo a vite e tappino prelievo campioni, con etichetta, conf. singola	*Graduated urine containers 150ml, PP, screw cap and plug, with label, ind. wrapped*
2420/SG	Contenitori per urine 150ml, graduati, PP, tappo a vite e tappino prelievo campioni, conf. singola	*Graduated urine containers 150ml, PP, screw cap and plug, ind. wrapped*
2440/E/SG	Contenitori per campioni biologici 60ml, PS, tappo a vite, confezione singola, con etichetta	*Specimen containers 60ml, PS, screw cap, ind. wrapped, with label*
2440/SG	Contenitori per campioni biologici 60ml, PS, tappo a vite, confezione singola	*Specimen containers 60ml, PS, screw cap, ind. wrapped*
2442/E/SG	Contenitori per feci, 60ml, PS, tappo a vite con paletta, con etichetta, confezione singola	*Faeces containers 60ml, PS, screw cap and spoon, with label, individually wrapped*
2442/SG	Contenitori per feci, 60ml, PS, tappo a vite con paletta, confezione singola	*Faeces containers 60ml, PS, screw cap and spoon, ind. wrapped*
2450/E/SG	Contenitori per campioni biologici 60ml, PP, tappo a vite, confezione singola, con etichetta	*Specimen containers 60ml, PP, screw cap, ind. wrapped, with label*
2450/E/TS	Contenitori per campioni biologici 60ml, PP, tappo a vite, con etichetta	*Specimen containers 60ml, PP, screw cap, with label*
2450/SG	Contenitori per campioni biologici 60ml, PP, tappo a vite, confezione singola	*Specimen containers 60ml, PP, screw cap, ind. wrapped*
2450/SG/100	Contenitori per campioni biologici 60ml, PP, tappo a vite, confezione singola	*Specimen containers 60ml, PP, screw cap, ind. wrapped*
2450/TS	Contenitori per campioni biologici 60ml, PP, tappo a vite	*Specimen containers 60ml, PP, screw cap*
2452/E/SG	Contenitori per feci, 60ml, PP, tappo a vite con paletta, con etichetta, confezione singola	*Faeces containers 60ml, PP, screw cap and spoon, with label, individually wrapped*
2452/E/TS	Contenitori per feci, 60ml, PP, tappo a vite con paletta, con etichetta	*Faeces containers 60ml, PP, screw cap and spoon, with label*
2452/SG	Contenitori per feci, 60ml, PP, tappo a vite con paletta, confezione singola	*Faeces containers 60ml, PP, screw cap and spoon, ind. wrapped*
2452/SG/100	Contenitori per feci da 60ml, PP, tappo inserito e paletta,	*Faeces containers 60ml, PP, screw cap and spoon*
2580/B/SG	Contenitori campioni biologici 25ml PS, tappo inserito bianco	*Specimen containers 25ml, PS, screw cap*
2580/E/SG	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta	*Specimen containers 25ml, PS, screw cap, with label*
2580/E/SG/B	Contenitori per campioni biologici 25ml, PS, tappo a vite bianco, con etichetta	*Specimen containers 25ml, PS, white screw cap, with label*
2580/E/SG/CS	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta, in conf. singola	*Specimen containers 25ml, PS, screw cap, with label, individually wrapped*
2580/E/SG/CS/W	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta, in conf. singola	*Specimen containers 25ml, PS, screw cap, with label, individually wrapped*
2580/E/TS	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta	*Specimen containers 25ml, PS, screw cap, with label*
2580/E/TS/W	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta	*Specimen containers 25ml, PS, screw cap, with label*
2580/EB/TS	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta bianca	*Specimen containers 25ml, PS, screw cap, with white label*
2580/EB/TS/W	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta bianca	*Specimen containers 25ml, PS, screw cap, with white label*
2580/EST/SG	Contenitori campioni biologici 25ml, PS, con tappo e con	*Specimen containers 25ml, PS, screw cap*
2580/SG	Contenitori per campioni biologici 25ml, PS, tappo a vite	*Specimen containers 25ml, PS, screw cap*
2580/SG/CS	Contenitori per campioni biologici 25ml, PS, tappo a vite, confezione singola	*Specimen containers 25ml, PS, screw cap, ind. wrapped*
2580/TB/SG/CS	Contenitori per campioni biologici 25ml, PS, tappo a vite bianco, confezione singola	*Specimen containers 25ml, PS, white screw cap, ind. wrapped*
2580/TS	Contenitori per campioni biologici 25ml, PS, tappo a vite	*Specimen containers 25ml, PS, screw cap*
2580/TS/W	Contenitori per campioni biologici 25ml, PS, tappo a vite	*Specimen containers 25ml, PS, screw cap*
2588/E/SG	Contenitori per feci, 25ml, PS, tappo a vite con paletta, con etichetta	*Faeces containers 25ml, PS, screw cap and spoon, with label*
2588/E/SG/CS	Contenitori per feci, 25ml, PS, tappo a vite con paletta, confezione singola, con etichetta	*Faeces containers 25ml, PS, screw cap and spoon, ind. wrapped, with label*
2588/E/SG/CS/W	Contenitori per feci, 25ml, PS, tappo a vite con paletta, confezione singola, con etichetta	*Faeces containers 25ml, PS, screw cap and spoon, ind. wrapped, with label*
2588/E/TS	Contenitori per feci, 25ml, PS, tappo a vite con paletta, con etichetta	*Faeces containers 25ml, PS, screw cap and spoon, with label*
2588/E/TS/W	Contenitori per feci, 25ml, PS, tappo a vite con paletta, con etichetta	*Faeces containers 25ml, PS, screw cap and spoon, with label*
2588/EB/TS	Contenitori per feci, 25ml, PS, tappo a vite con paletta, con etichetta bianca	*Faeces containers 25ml, PS, screw cap and spoon, with white label*

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com - www.aptaca.com - www.vacucheck.com
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE

Annex 1 to Declaration of Conformity 98/79/CE

COD.	DESCRIZIONE	*DESCRIPTION*
2588/EB/TS/W	Contenitori per feci, 25ml, PS, tappo a vite con paletta, con etichetta bianca	*Faeces containers 25ml, PS, screw cap and spoon, with white label*
2588/SG	Contenitori per feci, 25ml, PS, tappo a vite con paletta	*Faeces containers 25ml, PS, screw cap and spoon*
2588/SG/CS	Contenitori per feci, 25ml, PS, tappo a vite con paletta, confezione singola	*Faeces containers 25ml, PS, screw cap and spoon, ind. wrapped*
2640/E/SG	Contenitori da 60ml in PS, con tappo a vite in metallo e guarnizione, con etichetta	*Specimen containers 60ml in PS, with alluminium screw cap and gasket, with label*
2640/E/TS	Contenitori da 60ml in PS, con tappo a vite in metallo e guarnizione, con etichetta	*Specimen containers 60ml in PS, with alluminium screw cap and gasket, with label*
2640/SG	Contenitori da 60ml in PS, con tappo a vite in metallo e guarnizione	*Specimen containers 60ml in PS, with alluminium screw cap and gasket*
2640/TS	Contenitori da 60ml in PS, con tappo a vite in metallo e guarnizione	*Specimen containers 60ml in PS, with alluminium screw cap and gasket*
2680/E/SG	Contenitori per campioni biologici 25ml, PP, tappo a vite, con etichetta	*Specimen containers 25ml, PP, screw cap, with label*
2680/E/SG/CS	Contenitori per campioni biologici 25ml, PP, tappo a vite, con etichetta, conf. singola	*Specimen containers 25ml, PP, screw cap, with label, individually wrapped*
2680/E/TS	Contenitori per campioni biologici 25ml, PP, tappo a vite, con etichetta	*Specimen containers 25ml, PP, screw cap, with label*
2680/EB/TS	Contenitori per campioni biologici 25ml, PP, tappo a vite, con etichetta bianca	*Specimen containers 25ml, PP, screw cap, with white label*
2680/EST/SG	Contenitori campioni biologici 25ml, PP, tappo inserito ed	*Specimen containers 25ml, PP, screw cap*
2680/SG	Contenitori per campioni biologici 25ml, PP, tappo a vite	*Specimen containers 25ml, PP, screw cap*
2680/SG/CS	Contenitori per campioni biologici 25ml, PP, tappo a vite, confezione singola	*Specimen containers 25ml, PP, screw cap, ind. wrapped*
2680/TS	Contenitori per campioni biologici 25ml, PP, tappo a vite	*Specimen containers 25ml, PP, screw cap*
2688/E/SG	Contenitori per feci, 25ml, PP, tappo a vite con paletta, con etichetta	*Faeces containers 25ml, PP, screw cap and spoon, with label*
2688/E/SG/CS	Contenitori per feci, 25ml, PP, tappo a vite con paletta, con etichetta, confezione singola	*Faeces containers 25ml, PP, screw cap and spoon, with label, ind. wrapped*
2688/E/TS	Contenitori per feci, 25ml, PP, tappo a vite con paletta, con etichetta	*Faeces containers 25ml, PP, screw cap and spoon, with label*
2688/SG	Contenitori per feci, 25ml, PP, tappo a vite con paletta	*Faeces containers 25ml, PP, screw cap and spoon*
2688/SG/CS	Contenitori per feci, 25ml, PP, tappo a vite con paletta, confezione singola	*Faeces containers 25ml, PP, screw cap and spoon, ind. wrapped*
5024/E/SG	Bottiglie per la raccolta delle urine nelle 24 ore, 2.500ml, PE, con etichetta	*Sampling bottles for 24 hours urine collection, graduated, 2.500ml, PE, with label*
5024/SG	Bottiglie per la raccolta delle urine nelle 24 ore, graduate, 2.500ml, PE	*Sampling bottles for 24 hours urine collection, graduated, 2.500ml, PE*
5120/SG	Contenitore per urine in PP da 120ml, tappo con sistema di prelievo sottovuoto, sterile in confezione singola	*120 ml urine containers in PP, with screw cap with device for vacuum tube, sterile individually wrapped*
5120/TS	Contenitore per urine in PP da 120ml, tappo con sistema di prelievo sottovuoto, sterile	*120 ml urine containers in PP, with screw cap with device for vacuum tube, sterile*

Dr.ssa Lidia BUONO
Responsabile Assicurazione Qualità

Ленпипет Блэк 30-300 мкл, восьмиканальный

Описание

Дозатор пипеточный многоканальный Ленпипет серии Блэк переменного объема 30-300 мкл производства компании Thermo Fisher Scientific. Серия пипеточных дозаторов Ленпипет производится на заводе в Санкт-Петербурге. Все пипеточные дозаторы калибруются на заводе при температуре +20 С, использую дистиллированную воду. Однако для работы с вязкими жидкостями или с жидкостями другой температуры возможно потребуется дополнительная калибровка. Для самостоятельной калибровки Вам потребуются аналитические весы с точностью до 3 знака после запятой, дистиллированная вода помещение без сквозняков и температурный режимом +20 С, при относительной влажности воздуха 65%. Полная последовательность операции калибровки пипеточного дозатора можно прочесть в инструкции к дозатору.

Дозатор пипеточный серии Блэк полностью автоклавируем в течении 20 мин (2 атм), имеет цветовую кодировку для разных объемов, выполнен из химически стойких материалов, объем дозирования четко отображается на дисплее, прост и надежен в использовании. Выпускаются 2 модели многоканальный дозаторов серии Блэк с диапазонами 5-50 мкл и 30-300 мкл.

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Сертификат №:
59878-2009-AQ-MCW-FINAS

Дата начальной сертификации:
20 декабря 2000

Действителен:
21 июня 2018 - 31 августа 2021

Настоящим удостоверяется, что система менеджмента организации:

АО «ТЕРМО ФИШЕР САЙЕНТИФИК»

Кубинская, д.73, литер А, корпус 1, Санкт-Петербург, Российская Федерация, 196240

была признана соответствующей стандарту:
ISO 9001:2015

Настоящий сертификат действителен для следующей области:
ПРОИЗВОДСТВО ДОЗАТОРОВ ПИПЕТОЧНЫХ И СПЕЦИАЛЬНОГО ДИАГНОСТИЧЕСКОГО ПЛАСТИКА.

Место и дата:
Москва, 21 июня 2018

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT
IAF
FINAS
Finnish Accreditation Service
S001 (EN ISO/IEC 17021)

От выпускающего офиса:
DNV GL – Business Assurance
Трехпрудный переулок 9, стр. 2, Москва, Российская Федерация

S. Grubine

Сергей Грубин
Представитель руководства

Невыполнение условий Договора на сертификацию делает данный Сертификат недействительным.
Аккредитованный офис: DNV GL BUSINESS ASSURANCE FINLAND OY AB, Keilasatama 5, 02150 Espoo, Finland. TEL:+358 10 292 4200.
assurance.dnvgl.com

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2012

The National Standards Authority of Ireland certifies that:

Monobind Inc.
100 North Pointe Drive
Lake Forest, CA 92630
USA

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

The Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Device Immunoassays, and Related Reagent Products and Equipment

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4585)

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Susan Murphy
European Medical Device
Operations Manager

Registration Number: MD19.4585
Certification Granted: May 18, 2010
Effective Date: Oct 29, 2017
Expiry Date: Oct 28, 2020

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800

Annex to Certificate Number: MD19.4585

Scope of Registration:

The Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Device Immunoassays, and Related Reagent Products and Equipment

Activity	Location
Headquarters, Design, Manufacture	Monobind Inc. 100 North Pointe Drive Lake Forest, CA 92630 USA File No.: MD19.4585
Manufacture, Design	Monobind Inc. 103 North Pointe Drive Lake Forest, CA 92630 USA File No.: MD19.4585/A

Verified by:
Operations Manager

ПолітехМед

МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ
Державне українське об'єднання «Політехмед»
Орган з оцінки відповідності
Conformity assessment body
Ukrainian State Association «Politechmed»
UA.TR. 101

№ 000146

Сертифікат відповідності
Certificate of Conformity

№ UA.TR.101-326.430/СУ-1-2018
Дата реєстрації 12.11.2018 р.
Термін дії до 11.11.2021 р.

ОРГАН З ОЦІНКИ ВІДПОВІДНОСТІ «ДУО «ПОЛІТЕХМЕД»

ЦИМ ЗАСВІДЧУЄ, ЩО СИСТЕМА УПРАВЛІННЯ ЯКІСТЮ

ТОВАРИСТВА З ОБМЕЖЕНОЮ ВІДПОВІДАЛЬНІСТЮ
«СПЕЦТЕХОСНАСТКА»
Україна, 51921, м. Кам'янське, Дніпропетровської обл., вул. Васильєвська, 122,
ЄДРПОУ 13429839.

Місце виробництва

ТОВАРИСТВО З ОБМЕЖЕНОЮ ВІДПОВІДАЛЬНІСТЮ
«СПЕЦТЕХОСНАСТКА»
Україна, 51921, м. Кам'янське, Дніпропетровської обл., вул. Васильєвська, 122

ОЦІНЕНА ТА СЕРТИФІКОВАНА НА ВІДПОВІДНІСТЬ ВИМОГАМ
ДСТУ ISO 9001:2015
(ISO 9001:2015 IDT)
«Системи управління якістю. Вимоги»

У НАСТУПНИХ СФЕРАХ ДІЯЛЬНОСТІ:
ПРОЕКТУВАННЯ, ВИРОБНИЦТВО ТА РЕАЛІЗАЦІЯ МЕДИЧНОЇ ПРОДУКЦІЇ:

Контейнери лабораторні пластикові для біологічних матеріалів,
Скарифікатор – спис

Рішення щодо надання сертифікату відповідності від 12.11.2018 р. №326.430/СУ.РС
Контроль відповідності сертифікованої системи управління якістю вимогам зазначених стандартів здійснюється шляхом наглядових аудитів, періодичність яких регламентується програмою

Р. Картавцев

Підпис М.П.
Генеральний директор
ДУО «Політехмед»
Керівник Органу з оцінки відповідності

DECLARATION OF CONFORMITY

1) Manufacturer *(Name, department)*: **Monobind Inc.**

Address: **100 North Pointe, LAKE FOREST, CA 92630. UNITED STATES**

and

2) European authorized representative: **CEpartner4U BV,**

Address**: ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS**;
(on product labels printed as:
CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS Tel.: +31 (0)6 516 536 26;
or as: CEpartner4U, 3951DB; 13. NL tel: +31 (0)6 – 516.536.26)

3) Product(s) *(name, type or model/batch number, etc.)*:

Immunoassay products; **ELISA**, **CLIA**, **Control,** **Instruments** (see appendix)

4) The product(s) described above is in conformity with:

Document No.	Title	Edition / Date of issue
L 331; 98/79/EC	In-Vitro-Diagnostic Directive	1998-10-27

5) Additional information *(conformity procedure, Notified Body, CE certificate, etc.)*:

Conformity assessment procedure for CE marking: IVD Directive, Annex III

Lake Forest, USA;2011-09-27 ---------- A Shatola ----------

Tony Shatola; QA Director, Monobind Inc.

(Place & date of issue (yyyy-mm-dd)) *(name, function and signature of manufacturer)*

Maarn, NL; 2011-09-27 ----------

Olga Teirlinck; Consultant, CEpartner4U BV

(Place & date of issue (yyyy-mm-dd)) *(name; function and signature of authorized representative)*

Appendix

Date: 2011-09-26

Device types	Item# ELISA	Item# CLIA	Item# Control	Item# Instrument	EDMS code	Risk Class	Certificate #	First date of CE-marking
Thyroid								
T3 – Triidothyronine	125-300	175-300			12.04.01.05.00	Low		2005-11-11
fT3 – Free Triidothyronine	1325-300	1375-300			12.04.01.01.00	Low		2005-11-11
T4 – Thyroxine	225-300	275-300			12.04.01.07.00	Low		2005-11-11
fT4 – Free Thyroxine	1225-300	1275-300			12.04.01.02.00	Low		2005-11-11
TSH – Thyrotropin	325-300	375-300			12.04.01.11.00	Low		2005-11-11
Rapid TSH – Rapid Thyrotropin	6025-300	6075-300			12.04.01.11.00	Low		2010-06-29
T3U – Triidothyronine Uptake	525-300	575-300			12.04.01.06.00	Low		2005-11-11
TBG – Thyroxine-Binding Globulin	3525-300	3575-300			12.04.01.09.00	Low		2005-11-11
Tg – Thyroglobulin	2225-300	2275-300			12.04.01.08.00	Low		2005-11-11
T3, T4 & TSH – Triidothyronine, Thyroxine & Thyrotropin Combo (VAST)	8025-300	8075-300			12.04.01.01.00	Low		2005-11-11
T3 – Triidothyronine (SBS)	8125-300	8175-300			12.04.01.01.00	Low		2010-06-29
T4- Thyroxine (SBS)	8225-300	8275-300			12.04.01.01.00	Low		2010-06-29
fT3, fT4 & TSH – Free Triidothyronine, Free Thyroxine & Thyrotropin Combo (VAST)	7025-300	7075-300			12.04.01.01.00	Low		2010-06-29
Neonatal Thyroid & Genetics								
NTSH – Neonatal Thyrotropin	3425-300	3475-300			12.04.01.90.00	Low		2005-11-11
NT4 – Neonatal Thyroxine	2625-300	2675-300			12.04.01.12.00	Low		2005-11-11
N 17OHP – Neonatal 17 OH Progesterone	5525-300				12.05.01.07	Low		2008-02-01
Biotinidase	8825-300				12 07 02 90 00	Low		2011-09-26
AutoImmune Thyroid								
Anti-Tg – Anti-Thyroglobulin Antigen	1025-300	1075-300			12.10.03.04.00	Low		2005-11-11
Anti-TPO – Anti-Thyroperoxidase Antigen	1125-300	1175-300			12.10.03.01.00	Low		2005-11-11
Fertility & Prenatal								
LH – Lutropin	625-300	675-300			12.05.01.05.00	Low		2005-11-11
FSH – Follitropin	425-300	475-300			12.05.01.04.00	Low		2005-11-11
PRL – Prolactin	725-300	775-300			12.05.01.08.00	Low		2005-11-11
PRL – Prolactin Sequential	6025-300	6075-300			12.05.01.08.00	Low		2005-11-11
hCG – Human Chorionic Gonadotropin	825-300	875-300			12.05.02.05.00	Low		2005-11-11
Rapid hCG – Rapid Human Chorionic Gonadotropin	3325-300				12.05.02.05.00	Low		2005-11-11
FSH, LH, hCG, sPRL Combo (VAST)	8325-300	8375-300			12.05.01.90.00	Low		2006-08-24
AFP, hCG, uE3 Combo (VAST)	8525-300	8575-300			12.05.01.90.00	Low		2010-06-29
Steroid								
Cortisol	3625-300	3675-300			12.06.02.04.00	Low		2005-11-11
DHEA-S – Dehydroepiandrosterone sulfate	5125-300	5175-300			12.05.01.02.00	Low		2010-06-29
DHEA - Dehydroepiandrosterone	7425-300	7475-300			12.05.01.02.00	Low		2011-09-26

Device types	Item# ELISA	Item# CLIA	Item# Control	Item# Instrument	EDMS code	Risk Class	Certificate #	First date of CE-marking
E2 – Estradiol	4925-300	4975-300			12.05.01.03.00	Low		2010-06-29
uE3 – Estriol, Unconjugated	5025-300	5075-300			12.05.02.02.00	Low		2010-06-29
Progesterone	4825-300	4875-300			12.05.01.06.00	Low		2010-06-29
Testosterone	3725-300	3775-300			12.05.01.10.00	Low		2007-11-01
Free Testosterone	5325-300	5375-300			12.05.01.10.00	Low		2010-06-29
17OHP - 17-Hydroxyprogesterone	5225-300	5275-300			12.05.01.07.00	Low		2010-06-29
17OHP - 17-Hydroxyprogesterone Ext. Range	9925-300	9975-300			12.05.01.07.00	Low		2010-10-18
Vitamin D3 – 25-Hydroxyvitamin D3	7725-300	7775-300			12.06.03.10.00	Low		2011-09-26
Growth & Bone Metabolism								
hGH - Human Growth Hormone	1725-300	1775-300			12.06.04.02.00	Low		2005-11-11
PTH - Parathyroid Hormone	7825-300	7875-300			12.06.03.13.00	Low		2011-09-26
Diabetes								
Insulin	2425-300	2475-300			12.06.01.03.00	Low		2005-11-11
Insulin Rapid	5825-300				12.06.01.03.00	Low		2010-06-29
C-peptide	2725-300	2775-300			12.06.01.01.00	Low		2005-11-11
Insulin & C-peptide Combo (VAST)	7325-300	7375-300			12.06.01.03.00	Low		2005-11-11
Cardiac Markers								
CKMB – Circulating Creatine Kinase (MB)	2925-300	2975-300			12.13.01.02.00	Low		2005-11-11
CTnI – Troponin I	3825-300	3875-300			12.13.01.07.00	Low		2005-11-11
DIG – Digoxin	925-300	975-300			12.08.01.01.00	Low		2005-11-11
HS-CRP – High Sensitivity C-Reactive Protein	3125-300	3175-300			12.13.01.90.00	Low		2005-11-11
Myoglobin	3225-300	3275-300			12.13.01.05.00	Low		2005-11-11
Infectious Diseases								
IgG – Anti/H. Pylori	1425-300	1475-300			15.01.04.03.00	Low		2005-11-11
IgM – Anti/H. Pylori	1525-300	1575-300			15.01.04.03.00	Low		2005-11-11
IgA – Anti/H. Pylori	1625-300	1675-300			15.01.04.03.00	Low		2005-11-11
Cancer Markers								
AFP – Alpha-Fetoprotein	1925-300	1975-300			12.03.90.01.00	Low		2005-11-11
CA 125 Ovarian Cancer Antigen	3025-300	3075-300			12.03.01.06.00	Low		2005-11-11
CA 15-3 Breast Cancer Antigen	5625-300	5675-300			12.03.01.02.00	Low		2010-06-29
CA 19-9 - Pancreatic Cancer Antigen	3925-300	3975-300			12.03.01.03.00	Low		2005-11-11
CEA – Carcinoembryonic Antigen	1825-300	1875-300			12.03.01.31.00	Low		2005-11-11
CEA - Carcinoembryonic Antigen Next Generation	4625-300	4675-300			12.03.01.31.00	Low		2010-06-29
fβhCG – Free Beta Human Chorionic Gonadotropin	2025-300	2075-300			12.03.01.90.00	Low		2005-11-11
Allergy & Anemia								
Ferritin	2825-300	2875-300			12.07.01.02.00	Low		2005-11-11
Folate	7525-300	7575-300			12.07.01.03.00	Low		2010-06-29
IgE – Immunoglobulin E	2525-300	2575-300			12.02.01.02.00	Low		2005-11-11
sTfR - Transferrin Soluble Receptor	8625-300	8675-300			12.07.01.06.00	Low		2010-06-29
Vitamin B12	7625-300	7675-300			12.07.02.04.00	Low		2011-09-26

Miscellaneous Controls								
Anti-Tg & Anti-TPO – Positive & Negative - Anti-Thyroglobulin, Anti-Thyroperoxidase			AIT-101		12.50.01.16.00	Low		2010-06-29
High Level Fertility Control – Single Level – Progesterone, Estradiol, Human Chorionic Gonadotropin			FC-300		12.50.01.16.00	Low		2010-06-29
Maternal Control – Tri Level - Human Chorionic Gonadotropin, Free Beta Human Chorionic Gonadotropin Subunit, Alpha Feta Protein, Estriol			MC-300		12.50.01.16.00	Low		2010-06-29
Thyroglobulin Control – Tri Level			TG-300		12.50.01.16.00	Low		2010-06-29
H. Pylori IgG Control – Positive & Negative			HPy-IgG-300		12.50.01.16.00	Low		2010-06-29
Miscellaneous Instruments								
IC hardware + dedicated accessories + software – Autoplex ELISA Analyzer & CLIA Processor				IN006	21.02.10.01	Low		2010-06-29
IC hardware + dedicated accessories + software – Lumax Chemiluminescence Strip Reader				IN001	21.02.10.01	Low		2006-08-24
IC hardware + dedicated accessories + software – Neo-Lumax Chemiluminescence Strip Reader				IN010	21.02.10.01	Low		2011-09-26
IC hardware + dedicated accessories + software – Impulse 2 Chemiluminescence Strip Reader				IN005	21.02.10.01	Low		2006-08-24
IC hardware + dedicated accessories + software – Impulse 3 Chemiluminescence Strip Reader				IN007	21.02.10.01	Low		2010-06-29
IC hardware + dedicated accessories + software – Lumax96 Chemiluminescence Plate Reader				IN004	21.02.10.01	Low		2007-03-01
IC hardware + dedicated accessories + software – LuMatic Chemiluminescence Plate Reader				IN008	21.02.10.01	Low		2011-09-26
IC hardware + dedicated accessories + software – Eldex 3.8 ELISA Strip Reader				IN003	21.02.10.01	Low		2007-09-10
IC hardware + dedicated accessories + software – Neo-Eldex ELISA Strip Reader				IN009	21.02.10.01	Low		2011-09-26
IC hardware + dedicated accessories + software – Mircoplate Washer				IN002	21.02.10.01	Low		2010-06-29

Monobind Inc.
The World Resource for Diagnostic Products

www.monobind.com

100 North Pointe Drive
Lake Forest, CA 92630

TEL 949.951.2665
FAX 949.951.3539

Orange County, California, January 10, 2020

IM Global Biomarketing Group - Moldova SRL,
Tighina str.65,office 607
MD-2001,Chisinau, Republic of Moldova

Commercialization Agreement

To Whom It May Concern:

We, Monobind Inc., an ISO 13485 certified company specializing in the research, development and manufacturing of in vitro diagnostic products for clinical and research application, located at 100 North Pointe Drive, Lake Forest, California 92630 USA;

Hereby authorizes and entitles IM Global Biomarketing Group from Moldova legally registered at Tighina str.65,office 607 MD-2001,Chisinau to effect clinical trials and evaluation of goods, registration of the goods at Health Ministry of Moldova, receive certificate of registration and conclude an agreement on consulting and examination of the documents needed for the registration in Moldova.

This is also to confirm that IM Global Biomarketing Group is the exclusive distributor our AccuBind® ELISA and AccuLite® CLIA products and accessories in Moldova. IM Global Biomarketing Group is authorized to promote and supply our products, to contract for their delivery and take part in tenders with our products.

This authorization is valid until January 1, 2021.

On behalf of the Monobind Inc.

Alicia Jerome Volkov
Marketing Director
Monobind Inc.

Monobind Inc.
Lake Forest, CA 92630, USA

AccuBind
ELISA Microwells

β-Human Chorionic Gonadotropin (hCG) Test System

Product Code: 825-300

1.0 INTRODUCTION

Intended Use: The Quantitative Determination of Chorionic Gonadotropin (hCG) Concentration in Human Serum by a Microplate Enzyme Immunoassay, Colorimetric

2.0 SUMMARY AND EXPLANATION OF THE TEST

Human chorionic gonadotropin (hCG) concentration increases dramatically in blood and urine during normal pregnancy. hCG is secreted by placental tissue, beginning with the primitive trophoblast, almost from the time of implantation, and serves to support the corpus luteum during the early weeks of pregnancy. hCG or hCG similar glycoproteins can also be produced by a wide variety of trophoblastic and nontrophoblastic tumors. The measurement of hCG, by assay systems with suitable sensitivity and specificity has proven great value in the detection of pregnancy and the diagnosis *of early* pregnancy disorders.

According to the literature, hCG is detectable as early as 10 days after ovulation, reaching 100 mIU/ml by the first missed period. At the time for the next ovulation, the hCG level is 200 mIU/ml (approximately 28 days after conception).[1] A peak of 50,000 or even 100,000 mIU/ml is attained by the third month, then a gradual decline is observed.[2,3]

In this method, hCG calibrator, patient specimen or control is first added to a streptavidin coated well. Biotinylated monoclonal and enzyme labeled antibodies (directed against distinct and different epitopes of hCG) are added and the reactants mixed. Reaction between the various hCG antibodies and native hCG forms a sandwich complex that binds with the streptavidin coated to the well.

After the completion of the required incubation period, the enzyme-chorionic gonadotropin antibody bound conjugate is separated from the unbound enzyme-chorionic gonadotropin conjugate by aspiration or decantation. The activity of the enzyme present on the surface of the well is quantitated by reaction with a suitable substrate to produce color.

The employment of several serum references of known chorionic gonadotropin levels permits construction of a dose response curve of activity and concentration. From comparison to the dose response curve, an unknown specimen's activity can be correlated with chorionic gonadotropin concentration.

3.0 PRINCIPLE

Immunoenzymometric assay (TYPE 3):
The essential reagents required for an immunoenzymometric assay include high affinity and specificity antibodies (enzyme and immobilized), with different and distinct epitope recognition, **in excess,** and native antigen. In this procedure, the immobilization takes place during the assay at the surface of a microplate well through the interaction of streptavidin coated on the well and exogenously added biotinylated monoclonal anti-hCG antibody. Upon mixing monoclonal biotinylated antibody, the enzyme-labeled antibody and a serum containing the native antigen, reaction results between the native antigen and the antibodies without competition or steric hindrance to form a soluble sandwich complex. The interaction is illustrated by the following equation:

$$^{Enz}Ab_{(x\text{-}hCG)} + Ag_{hCG} + {}^{Btn}Ab_{(m)} \underset{k_{-a}}{\overset{k_a}{\rightleftharpoons}} {}^{Enz}Ab_{(m)} - Ag_{hCG} - {}^{Btn}Ab_{(m)}$$

$^{Btn}Ab_{(m)}$ = Biotinylated Monoclonal Antibody (Excess Quantity)
Ag_{hCG} = Native Antigen (Variable Quantity)
$^{Enz}Ab_{(x\text{-}hCG)}$ = Enzyme labeled Antibody (Excess Quantity)
$^{Enz}Ab_{(hCG)}$- Ag_{hCG}- $^{Btn}Ab_{(m)}$ = Ag-Antibodies Sandwich complex
k_a = Rate Constant of Association
k_{-a} = Rate Constant of Dissociation

Simultaneously, the complex is deposited to the well through the high affinity reaction of streptavidin and biotinylated antibody. This interaction is illustrated below:
$^{Enz}Ab_{(x\text{-}hCG)}$-$Ag_{hCG}$-$^{Btn}Ab_{(m)}$ + $Streptavidin_{CW} \Rightarrow$ immobilized complex
$Streptavidin_{CW}$ = Streptavidin immobolized on well
Immobilized complex = sandwich complex bound to the well

After equilibrium is attained, the antibody-bound fraction is separated from unbound antigen by decantation or aspiration. The enzyme activity in the antibody-bound fraction is directly proportional to the native antigen concentration. By utilizing several different serum references of known antigen values, a dose response curve can be generated from which the antigen concentration of an unknown can be ascertained.

4.0 REAGENTS

Materials Provided:

A. hCG Calibrators – 1 ml/vial - Icons A-F
Six (6) vials of references for hCG Antigen at levels of 0(**A**), 5(**B**), 25(**C**), 50(**D**), 100(**E**) and 250(**F**) mIU/ml. Store at 2-8°C. A preservative has been added.
Note: The calibrators, human serum based, were calibrated using a reference preparation, which was assayed against the WHO 3rd IS (75/537).

B. hCG Enzyme Reagent – 13 ml/vial - Icon Ⓔ
One (1) vial containing enzyme labeled affinity purified antibody, biotinylated monoclonal mouse IgG in buffer, dye, and preservative. Store at 2-8°C.

C. Streptavidin Coated Plate – 96 wells – Icon ⇓
One 96-well microplate coated with streptavidin and packaged in an aluminum bag with a drying agent. Store at 2-8°C.

D. Wash Solution Concentrate – 20 ml/vial - Icon
One (1) vial containing a surfactant in buffered saline. A preservative has been added. Store at 2-8°C.

E. Substrate A – 7ml/vial - Icon S[A]
One (1) vial containing tetramethylbenzidine (TMB) in buffer. Store at 2-8°C.

F. Substrate B – 7ml/vial - Icon S[B]
One (1) vial containing hydrogen peroxide (H_2O_2) in buffer. Store at 2-8°C.

G. Stop Solution – 8ml/vial - Icon STOP
One (1) vial containing a strong acid (1N HCl). Store at 2-8°C.

H. Product Instructions.

Note 1: Do not use reagents beyond the kit expiration date.
Note 2: Avoid extended exposure to heat and light. **Opened reagents are stable for sixty (60) days when stored at 2-8°C. Kit and component stability are identified on the label.**
Note 3: Above reagents are for a single 96-well microplate

4.1 Required But Not Provided:

1. Pipette(s) capable of delivering 0.025 and 0.050ml (25 & 50µl) volumes with a precision of better than 1.5%.
2. Dispenser(s) for repetitive deliveries of 0.100 and 0.350ml (100 & 350µl) volumes with a precision of better than 1.5%.
3. Microplate washers or a squeeze bottle (optional).
4. Microplate Reader with 450nm and 620nm wavelength absorbance capability.
5. Absorbent Paper for blotting the microplate wells.
6. Plastic wrap or microplate cover for incubation steps.
7. Vacuum aspirator (optional) for wash steps.
8. Timer.
9. Quality control materials

5.0 PRECAUTIONS

For In Vitro Diagnostic Use
Not for Internal or External Use in Humans or Animals

All products that contain human serum have been found to be non-reactive for Hepatitis B Surface Antigen, HIV 1&2 and HCV Antibodies by FDA licensed reagents. Since no known test can offer complete assurance that infectious agents are absent, all human serum products should be handled as potentially hazardous and capable of transmitting disease. Good laboratory procedures for handling blood products can be found in the Center for Disease Control / National Institute of Health, "Biosafety in Microbiological and Biomedical Laboratories," 2nd Edition, 1988, HHS Publication No. (CDC) 88-8395.

Safe Disposal of kit components must be according to local regulatory and statutory requirement.

6.0 SPECIMEN COLLECTION AND PREPARATION

The specimens shall be blood, serum in type and the usual precautions in the collection of venipuncture samples should be observed. For accurate comparison to established normal values, a fasting morning serum sample should be obtained. The blood should be collected in a plain redtop venipuncture tube without additives or anti-coagulants. Allow the blood to clot. Centrifuge the specimen to separate the serum from the cells.

In patients receiving therapy with high biotin doses (i.e. >5mg/day), no sample should be taken until at least 8 hours after the last biotin administration, preferably overnight to ensure fasting sample.

Samples may be refrigerated at 2-8°C for a maximum period of five (5) days. If the specimen(s) cannot be assayed within this time, the sample(s) may be stored at temperatures of -20°C for up to 30 days. Avoid use of contaminated devices. Avoid repetitive freezing and thawing. When assayed in duplicate, 0.05 ml (50µl) of the specimen is required.

7.0 QUALITY CONTROL

Each laboratory should assay controls at levels in the low, normal and elevated range for monitoring assay performance. These controls should be treated as unknowns and values determined in every test procedure performed. Quality control charts should be maintained to follow the performance of the supplied reagents. Pertinent statistical methods should be employed to ascertain trends. Significant deviation from established performance can indicate unnoticed change in experimental conditions or degradation of kit reagents. Fresh reagents should be used to determine the reason for the variations.

8.0 REAGENT PREPARATION

1. **Wash Buffer**
   Dilute contents of wash concentrate to 1000ml with distilled or deionized water in a suitable storage container. Store diluted buffer at 2-30°C for up to 60 days.
2. **Working Substrate Solution** – Stable for one year
   Pour the contents of the amber vial labeled Solution 'A' into the clear vial labeled Solution 'B'. Place the yellow cap on the clear vial for easy identification. Mix and label accordingly. Store at 2 - 8°C.

Note1: Do not use the working substrate if it looks blue.
Note 2: Do not use reagents that are contaminated or have bacteria growth.

9.0 TEST PROCEDURE

Before proceeding with the assay, bring all reagents, serum reference calibrators and controls to room temperature (20-27°C).
*****Test Procedure should be performed by a skilled individual or trained professional*****

1. Format the microplate wells for each serum reference calibrator, control and patient specimen to be assayed in duplicate. **Replace any unused microwell strips back into the aluminum bag, seal and store at 2-8°C**
2. Pipette 0.025 ml (25µl) of the appropriate serum reference calibrator, control or specimen into the assigned well.
3. Add 0.100 ml (100µl) of hCG-Enzyme Reagent to all wells.
4. Swirl the microplate gently for 20-30 seconds to mix and cover.
5. Incubate 60 minutes at room temperature.
6. Discard the contents of the microplate by decantation or aspiration. If decanting, blot the plate dry with absorbent paper.
7. Add 0.350ml (350µl) of wash buffer (see Reagent Preparation Section), decant (tap and blot) or aspirate. Repeat two (2) additional times for a total of three (3) washes. **An automatic or manual plate washer can be used. Follow the manufacturer's instruction for proper usage. If a squeeze bottle is employed, fill each well by depressing the container (avoiding air bubbles) to dispense the wash. Decant the wash and repeat two (2) additional times.**
8. Add 0.100 ml (100µl) of working substrate solution to all wells (see Reagent Preparation Section). **Always add reagents in the same order to minimize reaction time differences between wells**

DO NOT SHAKE THE PLATE AFTER SUBSTRATE ADDITION

9. Incubate at room temperature for fifteen (15) minutes.
10. Add 0.050ml (50µl) of stop solution to each well and gently mix for 15-20 seconds). **Always add reagents in the same order to minimize reaction time differences between wells**
11. Read the absorbance in each well at 450nm (using a reference wavelength of 620-630nm to minimize well imperfections) in a microplate reader. **The results should be read within thirty (30) minutes of adding the stop solution.**

10.0 CALCULATION OF RESULTS

A dose response curve is used to ascertain the concentration of Human chorionic gonadotropin (hCG) in unknown specimens.

1. Record the absorbance obtained from the printout of the microplate reader as outlined in Example 1.
2. Plot the absorbance for each duplicate serum reference versus the corresponding hCG concentration in mIU/ml on linear graph paper (do not average the duplicates of the serum references before plotting).
3. Draw the best-fit curve through the plotted points.
4. To determine the concentration of hCG for an unknown, locate the average absorbance of the duplicates for each unknown on the vertical axis of the graph, find the intersecting point on the curve, and read the concentration (in mIU/ml) from the horizontal axis of the graph (the duplicates of the unknown may be averaged as indicated). In the following example, the average absorbance (1.745) intersects the dose response curve at (157 mIU/ml) hCG concentration (See Figure 1).

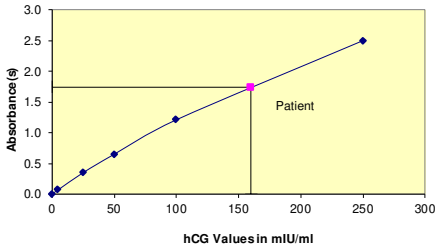
Note: Computer data reduction software designed for ELISA assays may also be used for the data reduction. If such software is utilized, the validation of the software should be ascertained.

EXAMPLE 1

Sample I.D.	Well Number	Abs (A)	Mean Abs (B)	Value (mIU/ml)
Cal A	A1	0.002	0.004	0
	B1	0.005		
Cal B	C1	0.073	0.071	5
	D1	0.069		
Cal C	E1	0.340	0.350	25
	F1	0.360		
Cal D	G1	0.637	0.650	50
	H1	0.663		
Cal E	A2	1.223	1.212	100
	B2	1.199		
Cal F	C2	2.518	2.502	250
	D2	2.486		
Ctrl 1	E2	0.075	0.076	**5.8**
	F2	0.077		
Ctrl 2	G2	0.280	0.290	**21.9**
	H2	0.301		
Patient	A3	1.736	1.745	**157**
	B3	1.754		

*The data presented in Example 1 and Figure 1 are for illustration only and **should not** be used in lieu of a dose response curve prepared with each assay.

Figure 1



11.0 Q.C. PARAMETERS

In order for the assay results to be considered valid the following criteria should be met:

1. The absorbance (OD) of calibrator 'F' should be ≥ 1.8.
2. Four out of six quality control pools should be within the established ranges.

12.0 RISK ANALYSIS

The MSDS and Risk Analysis Form for this product are available on request from Monobind Inc.

12.1 Assay Performance

1. It is important that the time of reaction in each well is held constant to achieve reproducible results.
2. Pipetting of samples should not extend beyond ten (10) minutes to avoid assay drift.
3. Highly lipemic, hemolyzed or grossly contaminated specimen(s) should not be used.
4. If more than one (1) plate is used, it is recommended to repeat the dose response curve.
5. The addition of substrate solution initiates a kinetic reaction, which is terminated by the addition of the stop solution. Therefore, the substrate and stop solution should be added in the same sequence to eliminate any time-deviation during reaction.
6. Plate readers measure vertically. Do not touch the bottom of the wells.
7. Failure to remove adhering solution adequately in the aspiration or decantation wash step(s) may result in poor replication and spurious results.
8. Use components from the same lot. No intermixing of reagents from different batches.
9. Patient specimens with hCG concentrations above 250 mIU/ml may be diluted with normal male serum (hCG < 1 mIU/ml) and re-assayed. The sample's concentration is obtained by multiplying the result by the dilution factor.
10. Accurate and precise pipetting, as well as following the exact time and temperature requirements prescribed are essential. Any deviation from Monobind IFU may yield inaccurate results.
11. All applicable national standards, regulations and laws, including, but not limited to, good laboratory procedures, must be strictly followed to ensure compliance and proper device usage.
12. It is important to calibrate all the equipment e.g. Pipettes, Readers, Washers and/or the automated instruments used with this device, and to perform routine preventative maintenance.
13. Risk Analysis- as required by CE Mark IVD Directive 98/79/EC - for this and other devices, made by Monobind, can be requested via email from Monobind@monobind.com.

12.2 Interpretation

1. ***Measurements and interpretation of results must be performed by a skilled individual or trained professional.***
2. Laboratory results alone are only one aspect for determining patient care and should not be the sole basis for therapy, particularly if the results conflict with other determinants.
3. The reagents for the test system have been formulated to eliminate maximal interference; however, potential interaction between rare serum specimens and test reagents can cause erroneous results. Heterophilic antibodies often cause these interactions and have been known to be problems for all kinds of immunoassays (Boscato LM, Stuart MC. 'Heterophilic antibodies: a problem for all immunoassays' Clin. Chem. 1988:3427-33). For diagnostic purposes, the results from this assay should be in combination with clinical examination, patient history and all other clinical findings.For valid test results, adequate controls and other parameters must be within the listed ranges and assay requirements.
4. If test kits are altered, such as by mixing parts of different kits, which could produce false test results, or if results are incorrectly interpreted, Monobind shall have no liability.
5. If computer controlled data reduction is used to interpret the results of the test, it is imperative that the predicted values for the calibrators fall within 10% of the assigned concentrations.
6. False positive results may occur in the presence of a wide variety of trophoblastic and nontrophoblastic tumors that secrete hCG. Therefore, the possibility of an hCG secreting neoplasia should be eliminated prior to diagnosing pregnancy.
7. Also, false positive results may be seen when assaying specimens from individuals taking the drugs Pergonal* and Clomid**. Additionally Pergonal will often be followed with an injection of hCG.
8. Spontaneous microabortions and ectopic pregnancies will tend to have values which are lower than expected during a normal pregnancy while somewhat higher values are often seen in multiple pregnancies.[5,6,7]
9. Following therapeutic abortion, detectable hCG may persist for as long as three to four weeks. The disappearance rate of hCG, after spontaneous abortion, will vary depending upon the quantity of viable residual trophoblast.[4,5,6,7]
10. **A hCG value alone is not of diagnostic value** and should only be used in conjunction with other clinical manifestations (observations) and diagnostic procedures.

*Pegonal is a registered trademark of Serono Laboratories, Inc.
**Clomid is a registered trademark of Merriell-National Laboratories

13.0 EXPECTED RANGES OF VALUES

A study of an apparent normal adult population was undertaken to determine expected values for the HCG AccuBind® ELISA Test System. The mean (X) values, standard deviations (**σ**) and expected ranges (±2**σ**) are presented in Table 1.

TABLE I
Expected Values for the hCG ELISA Test System
(In mIU/ml - 3rd IS 75/537)

Number	25
Mean	2.9
Standard Deviation	1.4
Expected Ranges (±2σ)	0.1 - 5.7

Expected levels for hCG during normal pregnancy (3) are listed in Table 2.

TABLE 2
Expected Values for hCG levels (3rd IS 75/537)
during normal pregnancy (in mIU/ml)

1st week	**10 - 30**
2nd week	30 - 100
3rd week	100 - 1000
4th week	1,000 -10,000
2nd & 3rd month	30,000 - 100,000
2nd trimester	10,000 - 30,000
3rd trimester	5,000 - 15,000

It is important to keep in mind that establishment of a range of values which can be expected to be found by a given method for a population of "normal"-persons is dependent upon a multiplicity of factors: the specificity of the method, the population tested and the precision of the method in the hands of the analyst. For these reasons each laboratory should depend upon the range of expected values established by the Manufacturer only until an in-house range can be determined by the analysts using the method with a population indigenous to the area in which the laboratory is located.

14.0 PERFORMANCE CHARACTERISTICS

14.1 Precision

The within and between assay precisions of the hCG AccuBind® ELISA were determined by analyses on three different levels of control sera. The number (N), mean value (X), standard deviation (σ) and coefficient of variation (C.V.) for each of these control sera are presented in Table 3 and Table 4.

TABLE 3
Within Assay Precision (Values in mIU/ml)

Sample	N	X	σ	C.V.
Level 1	20	4.4	0.22	4.9%
Level 2	20	18.7	0.75	4.0%
Level 3	20	214.8	14.59	6.8%

TABLE 4
Between Assay Precision* (Values in mIU/ml)

Sample	N	X	σ	C.V.
Level 1	20	5.4	0.52	9.6%
Level 2	20	22.4	1.97	8.8%
Level 3	20	213.1	15.16	7.1%

*As measured in ten experiments in duplicate.

14.2 Sensitivity

The hCG AccuBind® ELISA test system has a sensitivity of 0.003 mIU/well. This is equivalent to a sample containing 0.102 mIU/ml hCG concentration. The analytical sensitivity (detection limit) was ascertained by deteremining the variability of the '0 mIU/ml' calibrator and using the 2σ (95% certainty) statistic to calculate the minimum dose.

14.3 Accuracy

This hCG AccuBind® ELISA test system was compared with a reference radioimmunoassay. Biological specimens from normal and pregnant populations were assayed. The total number of such specimens was 110. The least square regression equation and the correlation coefficient were computed for the hCG ELISA in comparison with the reference method. The data obtained is displayed below.

TABLE 5

Method	Mean (x)	Least Square Regression Analysis	Correlation Coefficient
Monobind	14.8	y = 0.081 + 0.93(x)	0.989
Reference	15.1		

Only slight amounts of bias between the hCG ELISA method and the reference method are indicated by the closeness of the mean values. The least square regression equation and correlation coefficient indicates excellent method agreement.

14.4 Specificity

The cross-reactivity of the hCG AccuBind® ELISA to selected substances was evaluated by adding the interfering substance to a serum matrix at various concentrations, The cross-reactivity was calculated by deriving a ratio between dose of interfering substance to dose of chorionic gonadotropin needed to produce the same absorbance.

Substance	Cross Reactivity	Concentration
Chorionic Gonadotropin (hCG)	1.0000	----
β-hCG subunit	< 0.0001	1000ng/ml
Follitropin (FSH)	< 0.0001	1000ng/ml
Lutropin Hormone (LH)	< 0.0001	1000ng/ml
hrotropin (TSH)	< 0.0001	1000ng/ml

14.5 Hook Effect

The test shows no hook effect up to concentrations of > 150,000 mIU/ml.

15.0 REFERENCES

1. Kosasa TS, "Measurement of Human Chorionic Gonadotropin", *Journal of Reproductive Medicine,* 26, 201-6 (1981).
2. Danzer H, Braunstein GD, et al, "Maternal Serum Human Chorionic Gonadotropic Concentrations and Fetal Sex Predictions*", Fertility and Sterility,* 34, 336-40 (1980).
3. Braunstein G.D., et al., "Serum Human Chorionic Gonadotropin Levels through Normal Pregnancy", *American Journal of Obstetrics and Gynecology* 126, pg. 678-81 (1976).
4. Goldstein DP, and Kosasa TS, "The Subunit Radioimmunoassay for HCG Clinical Application", *Gynecology, 6*, 145-84 (1975).
5. Batzer F, "Hormonal Evaluation of Early Pregnancy", *Fertility and Sterility*, 34, 1-12 (1980).
6. Braunstein GD, et al, "First-Trimester Chorionic Gonadotropin Measurements as an Aid to the Diagnosis of Early Pregnancy Disorders", *American Journal of Obstetrics and Gynecology,* 131, 25-32 (1978).
7. Lenton E, Neal L and Sulaiman R, "Plasma Concentrations of Human Gonadotropin from the time of Implantation until the Second Week of Pregnancy ", *Fertility and Sterility,* 37, 773-78 (1982).

Revision: 4 Date: 2019-Jul-16 DCO: 1353
MP825 Product Code: *825-300*

Size		96(A)	192(B)
Reagent (fill)	A)	1ml set	1ml set
	B)	1 (13ml)	2 (13ml)
	C)	1 plate	2 plates
	D)	1 (20ml)	1 (20ml)
	E)	1 (7ml)	2 (7ml)
	F)	1 (7ml)	2 (7ml)
	G)	1 (8ml)	2 (8ml)

For Orders and Inquires, please contact
Monobind Inc.
100 North Pointe Drive
Lake Forest, CA 92630 USA
Tel: +1 949.951.2665 Mail: info@monobind.com
Fax: +1 949.951.3539 Fax: www.monobind.com

IVD 2°-8° CE
EC REP CEpartner4U, Esdoornlaan 13 3951 DBMaarn, The Neatherlands www.cepartner4u.eu

Please visit our website to learn more about our products and services.

Glossary of Symbols
(EN 980/ISO 15223)

IVD — In Vitro - Diagnostic Medical Device
2°-8° — Temperature Limitation Storage Condition (2-8°C)
Consult Instructions for Use
REF — Catalogue Number
Σ — Contains Sufficient Test for Σ
LOT — Batch Code
Used By (Expiration Day)
Date of Manufacturer
Manufacturer
EC REP — Authorized Rep in European Country
CE — European Conformity

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 16 марта 2015 года № ФСР 2007/01095

На медицинское изделие
Дозаторы пипеточные, одно- и многоканальные, «Лайт» по ТУ 9443-007-33189998-2007

Настоящее регистрационное удостоверение выдано
Закрытое акционерное общество "Термо Фишер Сайентифик" (ЗАО "Термо Фишер Сайентифик"), Россия, 196240, Санкт-Петербург, ул. Кубинская, д. 73, корп. 1, литер А

Производитель
Закрытое акционерное общество "Термо Фишер Сайентифик" (ЗАО "Термо Фишер Сайентифик"), Россия, 196240, Санкт-Петербург, ул. Кубинская, д. 73, корп. 1, литер А

Место производства медицинского изделия
196240, Санкт-Петербург, ул. Кубинская, д.73, корп. 1, литер А

Номер регистрационного досье **№ РД-6506/50043 от 04.03.2015**

Вид медицинского изделия -

Класс потенциального риска применения медицинского изделия **2а**

Код Общероссийского классификатора продукции для медицинского изделия **94 4330**

Настоящее регистрационное удостоверение имеет приложение на 1 листе

приказом Росздравнадзора от 16 марта 2015 года № 1678
допущено к обращению на территории Российской Федерации.

Врио руководителя Федеральной службы по надзору в сфере здравоохранения **М.А. Мурашко**

0011726

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 16 марта 2015 года № ФСР 2007/01095

Лист 1

На медицинское изделие
Дозаторы пипеточные, одно- и многоканальные, «Лайт» по ТУ 9443-007-33189998-2007:

1. Дозатор пипеточный ДПОФ-1 -1.
2. Дозатор пипеточный ДПОФ-1-5.
3. Дозатор пипеточный ДПОФ-1-10.
4. Дозатор пипеточный ДПОФ-1-20.
5. Дозатор пипеточный ДПОФ-1 -25.
6. Дозатор пипеточный ДПОФ-1-50.
7. Дозатор пипеточный ДПОФ-1-100.
8. Дозатор пипеточный ДПОФ-1-200.
9. Дозатор пипеточный ДПОФ-1-250.
10. Дозатор пипеточный ДПОФ-1-500.
11. Дозатор пипеточный ДПОФ-1-1000.
12. Дозатор пипеточный ДПОП-1-1-10.
13. Дозатор пипеточный ДПОП-1-2-20.
14. Дозатор пипеточный ДПОП-1-5-50.
15. Дозатор пипеточный ДПОП-1-10-100.
16. Дозатор пипеточный ДПОП-1-20-200.
17. Дозатор пипеточный ДПОП-1-100-1000.
18. Дозатор пипеточный ДПОП-1-1000-10 000.
19. Дозатор пипеточный ДПМП-8-1-10.
20. Дозатор пипеточный ДПМП-8-5-50.
21. Дозатор пипеточный ДПМП-8-30-300.
22. Дозатор пипеточный ДПМП-8-50-300.
23. Дозатор пипеточный ДПМП-12-1-10.
24. Дозатор пипеточный ДПМП-12-5-50.
25. Дозатор пипеточный ДПМП-12-30-300.
26. Дозатор пипеточный ДПМП-12-50-300.
27. Дозатор пипеточный ДПМП-16-5-50.

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения **М.А. Мурашко**

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