ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CE

TÜV SÜD Italia

CERTIFICATO

Nr. 50 100 11497 - Rev. 003

Si attesta che / *This is to certify that*

IL SISTEMA QUALITÀ DI
THE QUALITY SYSTEM OF

LIOFILCHEM S.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

VIA SCOZIA SNC - ZONA INDUSTRIALE
I-64026 ROSETO DEGLI ABRUZZI (TE)

SEDE OPERATIVA:
OPERATIONAL SITE:

CONTRADA PIANE VOMANO – TRAVERSA DI VIA GRECIA
I-64026 ROSETO DEGLI ABRUZZI (TE)

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE

Progettazione e sviluppo, produzione e commercializzazione di dispositivi medico diagnostici in-vitro: terreni di coltura per batteriologia, sistemi di identificazione e antibiogramma, kit per la determinazione di plasmaproteine (IAF 12, 29)

Design and development, production and sale of in-vitro diagnostic medical devices: culture media for bacteriology, identification and susceptibility testing systems, kits for plasma protein determination (IAF 12, 29)

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Andrea Coscia
Direttore Divisione Business Assurance

Validità / *Validity*

Dal / From: **2019-02-11**

Al / To: **2022-02-10**

Data emissione / *Issuing Date*
2019-02-11

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* **2012-09-25**

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"

"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

Liofilchem®

DICHIARAZIONE DI CONFORMITÀ CE / EC DECLARATION OF CONFORMITY

DICHIARAZIONE DI CONFORMITÀ CE

La società Liofilchem® S.r.l., con Sede Legale in Via Scozia, 64026 Roseto degli Abruzzi (TE) Italia, in qualità di fabbricante del dispositivo medico-diagnostico *in vitro* elencato nella tabella allegata Revisione 32.1 del 07.06.2017

dichiara sotto la propria responsabilità

1. che il dispositivo sopra indicato soddisfa tutte le disposizioni applicabili della Direttiva 98/79/CE (Allegato III) recepita nella Legislazione Italiana dal Decreto Legislativo n° 332 del 8 settembre 2000;
2. che il dispositivo in oggetto non è incluso nell'Allegato II, lista A e B della Direttiva 98/79/CE
3. che la documentazione tecnica di cui all'allegato III della direttiva Direttiva 98/79/CE è a disposizione delle autorità nazionali presso la sua sede e sarà conservata per 5 anni dall'ultima data di fabbricazione del prodotto;
4. che il processo di fabbricazione segue adeguati principi di assicurazione della qualità;
5. di aver attivato e di mantenere aggiornato, un sistema di sorveglianza post-produzione per il monitoraggio dei prodotti;
6. che il dispositivo in oggetto è stato messo in commercio munito di marcatura CE.

EC DECLARATION OF CONFORMITY

The company Liofilchem® S.r.l., registered office in Via Scozia, 64026 Roseto degli Abruzzi (TE) Italy, as a manufacturer of the in vitro medical-diagnostic device listed in the attached table, Revision 32.1 of 07.06.2017

hereby certifies under its own responsibility

1. that the above mentioned device complies with all the applicable provisions of Directive 98/79/EC (Annex III) and its relevant transposition into national law;
2. the above mentioned is not included in Annex II , List A and B of Directive 98/79/EC;
3. that the technical documentation referred to at Annex III of the Directive 98/79/EC is available for the national authorities in its facility and that this documentation shall be kept for 5 years after the last product has been manufactured;
4. that the manufacturing process follows suitable principles of quality assurance;
5. that, has implemented and keep up to date, a post-production surveillance system for monitoring the products;
6. that the device in question, was introduced into the market provided with CE mark.

Roseto, 07.06.2017

Direttore Tecnico/ Technical Director
Dott. Silvio Brocco

PRODOTTI CE DI LIBERA VENDITA / FREE SALE CE PRODUCTS

Rev. 32.1 del 07.06.2017

10002	DNA AGAR + BLU DI TOLUIDINA
10004	CLED ANDRADE AGAR
10004*	CLED ANDRADE AGAR
10005	MAC CONKEY SORBITOL AGAR
10005*	MAC CONKEY SORBITOL AGAR
10006	TRYPTIC SOY AGAR + 0,6% YEAST EXTRACT
10007	BACILLUS CEREUS AGAR (PEMBA)
10007*	BACILLUS CEREUS AGAR (PEMBA)
10013	DNase TEST AGAR
10013*	DNase TEST AGAR
10014	Purple Lactose Agar
10014*	Purple Lactose Agar
10017	CZAPEK DOX AGAR
10018	DRIGALSKY LACTOSE AGAR
10020	Baird Parker Agar
10020*	Baird Parker Agar
10021	BIGGY (NICKERSON) AGAR
10021*	BIGGY (NICKERSON) AGAR
10022	BRILLIANT GREEN AGAR
10022*	BRILLIANT GREEN AGAR
10023	Chocolate Agar
10023*	Chocolate Agar
10024	TRYPTOSE AGAR
10024*	TRYPTOSE AGAR
10025	COLUMBIA AGAR (Horse Blood 5%)
10025*	COLUMBIA AGAR (Horse Blood 5%)
10026	CLED AGAR
10026*	CLED AGAR
10027	BACILLUS CEREUS AGAR (Mossel)
10027*	BACILLUS CEREUS AGAR (Mossel)
10028	ISOSENSITEST AGAR
10028*	ISOSENSITEST AGAR
10029	MAC CONKEY AGAR
10029*	MAC CONKEY AGAR
10030	MANNITOL SALT AGAR
10030*	MANNITOL SALT AGAR
10031	MUELLER HINTON II AGAR
10031*	MUELLER HINTON II AGAR
10033	PSEUDOMONAS (CETRIMIDE) AGAR
10033*	PSEUDOMONAS (CETRIMIDE) AGAR
10035	SABOURAUD AGAR
10035*	SABOURAUD AGAR
10035S	SABOURAUD AGAR Irradiated
10036	S.S. AGAR
10036*	S.S. AGAR
10037	Tryptic Soy Agar
10037*	Tryptic Soy Agar
10037S	TRYPTIC SOY AGAR Irradiated
10039	ROGOSA AGAR
10039*	ROGOSA AGAR
10040	NEW YORK CITY AGAR
10040*	NEW YORK CITY AGAR
10041	LISTERIA PALCAM AGAR
10041*	LISTERIA PALCAM AGAR
10042	CRYSTAL VIOLET AGAR (Sheep Blood 5%)
10042*	CRYSTAL VIOLET AGAR (Sheed 5%)
10043	HEKTOEN ENTERIC AGAR
10043*	HEKTOEN ENTERIC AGAR
10044	NUTRIENT AGAR
10044*	NUTRIENT AGAR

10046	SERUM TELLURITE AGAR
10047	BISMUTH SULFITE AGAR
10047*	BISMUTH SULFITE AGAR
10048	E.M.B. LEVINE AGAR
10048*	E.M.B. LEVINE AGAR
10050	CAMPYLOBACTER AGAR (Sheep Blood 5%)
10050*	CAMPYLOBACTER AGAR (Sheep Blood 5%)
10051	Legionella BCYE Agar
10051*	Legionella BCYE Agar
10052	YERSINIA SELECTIVE AGAR
10052*	YERSINIA SELECTIVE AGAR
10053	WILKINS CHALGREEN AGAR
10053*	WILKINS CHALGREEN AGAR
10054	WURTZ LACTOSE AGAR
10054*	WURTZ LACTOSE AGAR
10056	X.L.D. AGAR
10056*	X.L.D. AGAR
10057	BILE AESCULIN AGAR
10057*	BILE AESCULIN AGAR
10058S	TRYPTIC SOY AGAR Irradiated -30 mL-
10060	BRAIN HEART INFUSION AGAR
10060*	BRAIN HEART INFUSION AGAR
10064	CHRISTENSEN UREA AGAR
10065	SCHAEDLER KKV AGAR(Sheep Blood 5%)
10065*	SCHAEDLER KKV AGAR(Sheep Blood 5%)
10067	SCHAEDLER KVN AGAR (Sheep Blood 5%)
10069	XLT 4 Agar
10069*	XLT 4 Agar
10074S	TRYPTIC SOY AGAR+NEUTRALIZING Irradiated
10078	MUELLER HINTON II MOD. AGAR
10078*	MUELLER HINTON II MOD. AGAR
10079	CASITONE AGAR
10079*	CASITONE AGAR
10080	HAEMOPHYLUS TEST AGAR
10080*	HAEMOPHYLUS TEST AGAR
10082	HELICOBACTER PYLORI AGAR
10082*	HELICOBACTER PYLORI AGAR
10090	M.R.S. Agar
10090*	M.R.S. Agar
10095	BRAIN HEART AGAR FOR HAEMOPHILUS
10129	MAC CONKEY AGAR MMG
10129*	MAC CONKEY AGAR MMG
10131	Mueller Hinton II Agar (Sheep Blood 5%)
10131*	Mueller Hinton II Agar (Sheep Blood 5%)
10132	Mueller Hinton Fastidious Agar (Horse blood 5% + 20 mg/L β-NAD)
10132*	Mueller Hinton Fastidious Agar (Horse blood 5% + 20 mg/L β-NAD)
10134	Legionella BMPA Agar
10141	SALMONELLA TEST AGAR
10141*	SALMONELLA TEST AGAR
10142	BLOOD AGAR (Sheep Blood 7%)(ISO 10560)
10142*	BLOOD AGAR (Sheep Blood 7%)(ISO 10560)
10143	Mueller Hinton Agar + 5 % Horse Blood Lysed
10145	CAMPYLOBACTER KARMALI AGAR
10146	CAMPYLOBACTER PRESTON AGAR
10148	CAMPYLOBACTER AGAR (Sheep Blood 10%)
10224	Baird Parker Agar
10225	LISTERIA PALCAM AGAR 140 mm
10231	MUELLER HINTON II AGAR 140 mm
10233	R.P.M.I. AGAR

10235	Sabouraud CAF Agar + Gentamicin
10235*	Sabouraud CAF Agar + Gentamicin
10235S	Sabouraud CAF Agar + Gentamicin Irradiated
10236	CLED AGAR 140 mm
10240	SCHAEDLER K AGAR (Sheep Blood 5%) 140mm
10241	SCHAEDLER KKV AGAR(Sheep blood 5%) 140mm
10242	SABOURAUD CAF AGAR 140 mm
10243	Sabouraud CAF Agar + Gentamicin 140mm
10244	DERMATOPHYTE (D.T.M.) AGAR 140 mm
10245	BRUCELLA BLOOD AGAR w HEMIN AND VITAMIN K1
10246	Chromatic™ MH
10247	Brucella Blood Agar with Hemin and Vitamin K1
10249	Purple Lactose Agar 140 mm
10334	NEOMYCIN BLOOD AGAR (Sheep Blood 5%)
10334*	NEOMYCIN BLOOD AGAR (Sheep Blood 5%)
10335	MUELLER HINTON CHOCOLATE AGAR
10353	BORDET GENGOU AGAR (Sheep Blood 15%)
10353*	BORDET GENGOU AGAR (Sheep Blood 15%)
10405	SCHAEDLER CNA AGAR (Sheep Blood 5%)
10407	VANCOMYCIN SCREEN AGAR
10408	WILKINS CHALGREN AGAR +5% SHEEP BLOOD
10409	CAMPYLOBACTER CCDA AGAR
10410	MUELLER HINTON AGAR w VITALEX
10411	BILE ESCULIN AZIDE AGAR w VANCOMYCIN
10412	Legionella BCYE Agar w/o Cysteine
10413	XLD Agar EP, USP, JP Formulation
10416	MIDDLEBROOK 7H11 AGAR
10424	Legionella BCYE Agar w Vancomycin + Colistin
10425	SCEDOSPORIUM SELECTIVE AGAR
10438	MacConkey Agar No.2
10438*	MacConkey Agar No.2
10439	Group A Selective Strep Agar w/ 5% Sheep Blood
10441	Sabouraud CAF Agar 50 mg
10445	Chocolate Agar w/ Bacitracin, Vancomycin, Clindamycin
10599	CHROMATIC™ MRSA
10600	OXACILLIN RESISTANCE STAPHYLOCOCCUS AGAR
10601	CHOCOLATE AGAR w/o VITOX
10602	CAMPYLOBACTER SKIRROW AGAR
10605	HELICOBACTER PYLORI EGG YOLK EMULSION AGAR
10620	O.A.LISTERIA
11023	CHOCOLATE BACITRACIN AGAR
11023*	CHOCOLATE BACITRACIN AGAR
11024	COLUMBIA CNA AGAR (Sheep Blood 5%)
11024*	COLUMBIA CNA AGAR (Sheep Blood 5%)
11025	COLUMBIA AGAR (Sheep Blood 5%)
11025*	COLUMBIA AGAR (Sheep Blood 5%)
11027	DESOXYCHOLATE AGAR
11027*	DESOXYCHOLATE AGAR
11030	ANAEROBIC AGAR
11033	PSEUDOMONAS ISOLATION AGAR
11033*	PSEUDOMONAS ISOLATION AGAR
11035	SABOURAUD CAF AGAR
11035*	SABOURAUD CAF AGAR
11035S	SABOURAUD CAF AGAR Irradiated
11037	TRYPTIC SOY AGAR (Sheep Blood 5%)
11037*	TRYPTIC SOY AGAR (Sheep Blood 5%)
11038	TRYPTIC SOY AGAR (Horse Blood 5%)
11038*	TRYPTIC SOY AGAR (Horse Blood 5%)
11040	THAYER MARTIN AGAR
11040*	THAYER MARTIN AGAR

11041	AZIDE AGAR (Sheep Blood 5%)
11041*	AZIDE AGAR (Sheep Blood 5%)
11052	DERMATOPHYTE (D.T.M.) AGAR
11052*	DERMATOPHYTE (D.T.M.) AGAR
11054	GARDNERELLA AGAR (Sheep Blood 5%)
11054*	GARDNERELLA AGAR (Sheep Blood 5%)
11057	ENTEROCOCCO AGAR
11057*	ENTEROCOCCO AGAR
11058	SLANETZ BARTLEY AGAR(m-ENTEROCOCCUS)
11058*	SLANETZ BARTLEY AGAR(m-ENTEROCOCCUS)
11060	CLOSTRIDIUM AGAR (Sheep Blood 5%)
11060*	CLOSTRIDIUM AGAR (Sheep Blood 5%)
11065	SCHAEDLER K AGAR (Sheep Blood 5%)
11065*	SCHAEDLER K AGAR (Sheep Blood 5%)
11070	MYCOSEL AGAR
11070*	MYCOSEL AGAR
11124	COLUMBIA CNA MOD. AGAR (Sheep blood 5%)
11124*	COLUMBIA CNA MOD. AGAR (Sheep blood 5%)
11132	Mueller Hinton Fastidious Agar (Horse blood 5% + 20 mg/L β-NAD) (140 mm)
11135	SABOURAUD AGAR MODIFIED
11135*	SABOURAUD AGAR MODIFIED
11143	HERELLEA AGAR
11143*	HERELLEA AGAR
11185	VOGEL JOHNSON AGAR
11185*	VOGEL JOHNSON AGAR
11195	T.C.B.S. AGAR
11195*	T.C.B.S. AGAR
11196	SPS AGAR
11196*	SPS AGAR
11200	PAR TEST AGAR
11200*	PAR TEST AGAR
11205	MYCOPLASMA AGAR
11206	Mueller Hinton II Agar + 2% NaCl
11231	Mueller Hinton II Agar (Sheep Blood 5%) 140 mm
11235	SABOURAUD CAF AGAR + TTC
11235*	SABOURAUD CAF AGAR + TTC
11236	Sabouraud CAF Agar + Actidione
11250	TINSDALE AGAR
11250*	TINSDALE AGAR
11335	SABOURAUD AGAR + GENTAMICIN
11335*	SABOURAUD AGAR + GENTAMICIN
11501	ENTEROCOCCUS AGAR + VANCOMYCIN
11506	BURKHOLDERIA CEPACIA SELECTIVE AGAR
11509	R.P.M.I. AGAR
11510	M.HINTON+GLUCOSE+METHYLEN BLUE
11512	NUTRIENT AGAR acc.to ISO 21528
11513	NUTRIENT AGAR acc.to ISO 6579
11517	COLUMBIA AGAR(Sheep Blood 5%)+VANCOMYCIN
11518	Mueller Hinton Agar + Cloxacillin
11610	Chromatic™ E.coli O157
11611	CHROMATIC™ DETECTION
11612	CHROMATIC™ CANDIDA
11614	CHROMATIC™ SALMONELLA
11616	CHROMATIC™ STAPH AUREUS
11617	CHROMATIC™ STREPTO B
11618	CHROMATIC™ MH
11619	CHROMATIC™ CRE
11621	CHROMATIC™ VRE
11622	CHROMATIC™ ESBL
11627	Chromatic™ Enterococcus

PRODOTTI CE DI LIBERA VENDITA / FREE SALE CE PRODUCTS
Rev. 32.1 del 07.06.2017

11629	CHROMATIC™ ESBL + AmpC
11629*	CHROMATIC™ ESBL + AmpC
11631	Chromatic™ OXA-48
11632	Chromatic™ Clostridium difficile
11633	Chromatic™ Vibrio
11634	Chromatic™ Detection opaque
11635	Chromatic™ Pseudomonas
12031	MUELLER HINTON II AGAR (120X120 mm)
12032	Mueller Hinton II Agar (Sheep Blood 5%) (120 mm x 120 mm)
12033	Mueller Hinton Fastidious Agar (Horse blood 5% + 20 mg/L β-NAD) (120 mm x 120 mm)
13012	CLED/MACCONKEY/TSA BLOOD AGAR
13012*	CLED/MACCONKEY/TSA BLOOD AGAR
13013	BAIRD PARKER/BIGGY/MACCONKEY
13013*	BAIRD PARKER/BIGGY/MACCONKEY
13014	COLUMBIA CNA/CIOCCOLATO/THAYER MARTIN
13014*	COLUMBIA CNA/CIOCCOLATO/THAYER MARTIN
13017	CLED/MACCONKEY MMG/MALTO
13017*	CLED/MACCONKEY MMG/MALTO
13018	BROM CRESOL PURPLE/COLUMBIA CNA/M.CONKEY
13018*	BROM CRESOL PURPLE/COLUMBIA CNA/M.CONKEY
13019	CLED/MACCONKEY/CETRIMIDE
13019*	CLED/MACCONKEY/CETRIMIDE
13020	MAC CONKEY/B.PARKER/TSA BLOOD
13345	GARDNERELLA V./ROGOSA/THAYER MARTIN
13345*	GARDNERELLA V./ROGOSA/THAYER MARTIN
13356	Gard.V. / Chocolate / Thayer Martin
13371	BAIRD PARKER/MACCONKEY/SABOURAUD CAF
13371*	BAIRD PARKER/MACCONKEY/SABOURAUD CAF
13480	MACCONKEY/VOGEL JOHNSON/SABOURAUD
13480*	MACCONKEY/VOGEL JOHNSON/SABOURAUD
13602	SABOURAUD CAF/BAIRD PARKER/BILE ESCULINE
13602*	SABOURAUD CAF/BAIRD PARKER/BILE ESCULINE
13607	CHOC. BAC./COLUMBIA/MAC CONKEY
13607*	CHOC. BAC./COLUMBIA/MAC CONKEY
13614	CLED/MACCONKEY/ENTEROCOCCO
13614*	CLED/MACCONKEY/ENTEROCOCCO
165312	MYCOPLASMA AGAR
18007	CHROMATIC™ STAPH AUREUS/ MRSA
18008	TSA BLOOD/CROMagar ORIENTATION
18008*	TSA BLOOD/CROMagar ORIENTATION
18009	Chromatic™ Salmonella/Hektoen Enteric
18011	CHROMATIC™ DETECTION/ESBL
18012	BRILLIANT GREEN / SS AGAR
18012*	BRILLIANT GREEN / SS AGAR
18015	BIGGY (NICKERSON) / MALT AGAR
18015*	BIGGY (NICKERSON) / MALT AGAR
18017	COLUMBIA CNA BLOOD/CHROMAGAR
18017*	COLUMBIA CNA BLOOD/CHROMAGAR
18018	MAC CONKEY/ SABOURAUD CAF
18020	EMB LEVINE / TSA BLOOD
18020*	EMB LEVINE / TSA BLOOD
18021	Chromatic™ CRE / Chromatic™ ESBL
18021*	Chromatic™ CRE / Chromatic™ ESBL
18022	TSA Blood/Columbia CNA
18023	Chromatic™ CRE / Chromatic™ OXA-48
18024	MSA / Chromatic™ MRSA
18025	Schaedler K / Schaedler KKV
18327	COLUMBIA CNA / MAC CONKEY
18327*	COLUMBIA CNA / MAC CONKEY

18379	GARDNERELLA V. / THAYER MARTIN
18379*	GARDNERELLA V. / THAYER MARTIN
18380	MAC CONKEY / TSA BLOOD
18380*	MAC CONKEY / TSA BLOOD
18390	BAIRD PARKER / SABOURAUD CAF
18390*	BAIRD PARKER / SABOURAUD CAF
18391	HEKTOEN ENTERIC / YERSINIA
18391*	HEKTOEN ENTERIC / YERSINIA
18422	COLUMBIA CNA / GARDNERELLA
18422*	COLUMBIA CNA / GARDNERELLA
18500	BAIRD PARKER / MAC CONKEY
18500*	BAIRD PARKER / MAC CONKEY
18502	CLED / MAC CONKEY
18502*	CLED / MAC CONKEY
18503	HEKTOEN ENTERIC / SS
18503*	HEKTOEN ENTERIC / SS
18505	MAC CONKEY / S.S.AGAR
18505*	MAC CONKEY / S.S.AGAR
18507	COLUMBIA CNA / CHOCOLATE
18507*	COLUMBIA CNA / CHOCOLATE
18595	D.T.M. / SABOURAUD
18595*	D.T.M. / SABOURAUD
18700	Group A Selective/TSA II + Sheep Blood 5%
18703	CHOCOLATE AGAR /THAYER MARTIN
20075	MAC CONKEY BROTH(7516MC2) 20x5ml
20077	PHYSIOLOGICAL SOLUTION 2.5 ml
20079	PHYSIOLOGICAL SOLUTION 4.5 ML
20081	INOCULUM SOLUTION 5 ML
20089	SUSPENSION BROTH
20090	HELICOBACTER PYLORI TEST
20095	PHYSIOLOGICAL SOLUTION
20105	Glucose Broth
20121	INOCULUM BROTH 7 ML
20129	TRYPTIC SOY BROTH 15 ml
20140	PURPLE LACTOSE BROTH
20156	SUSPENSION MEDIUM 7 ML
20158	MYCOPLASMA TRANSPORT BROTH
20159	TRICHOMONAS BROTH w/o CLORAMPHENICOL
20171	Thioglycollate Medium w Vit.K1 & Hemin
20340	VAGITUBE
21241	Fluid Thioglycollate Medium
22130	SCHAEDLER BROTH
23001	F.B. FASTIDIOUS BROTH
23002	MUELLER HINTON BROTH w HORSE BLOOD (11ml)
23003	MUELLER HINTON BROTH
24070	MYCOSEL BROTH 20PV
24071	Cooked Meat Medium
24091	HAEMOPHILUS TEST BROTH 20 PV
24098	PEPTONE WATER 20PV
24100	Alkaline Peptone Water
24103	NUTRIENT BROTH 20PV
24104	BRAIN HEART INFUSION BROTH 20PV
24105	Glucose Broth
24107	MUELLER HINTON II BROTH 20 PV
24108	MULLER KAUFFMANN BROTH 20PV
24109	Sabouraud Dextrose Broth
24110	Selenite Broth
24111	TODD HEWITT BROTH 20PV
24112	TRYPTOSE BROTH 20PV
24115	TRICHOMONAS BROTH 20PV

24117	Pergola Broth
24119	GN HAJNA BROTH 20PV
24120	BILE AESCULIN BROTH 20PV
24124	Fluid Thioglycollate Medium
24125	SERUM BROTH 20PV
24127	Fluid Thioglycollate Medium + 1% Tween 80
24128	TRYPTIC SOY BROTH + TWEEN 80 1% 20PV
24135	SALMONELLA DIFFERENTIAL BROTH 20PV
24136	TRYPTONE WATER 20PV
24137	MALONATE BROTH 20PV
24139	LYSINE DECARBOXYLASE BROTH 20PV
24141	BRAIN HEART INFUSION BROTH 2 ml 20PV
24142	PHYSIOLOGICAL SOLUTION 3ml 20PV
24143	Selenite Broth
24144	TODD HEWITT w Gentam/Nalidixic acid 20PV
24145	TODD HEWITT B. w Colistin/Nalid.a. 20PV
24146	THIOGLYCOLLATE M w/o INDICATOR acc.USP 20PV
24147	Thiogycollate Bile
24149	MR-VP MEDIUM 20PV
24161	Sabouraud Dextrose Broth + CAF
24241	Fluid Thioglycollate Medium
24342	Motility Test Medium
24343	MIU Semisolid Agar
24345	O.F. Medium with Glucose
24400	RAPPAPORT VASSILIADIS SOY (RSV) BROTH 20PV
24403	BIOTONE BROTH 20PV
24404	CAMPYLOBACTER BROTH 20PV
24411	S.F. BROTH 20PV
24412	STREPTOCOCCUS BROTH 20PV
24413	MOSSEL AND MARTIN w MANNITOL 20PV
24416	UREA BROTH 20PV
24417	Wilkins Chalgren Broth
24430	SCHAEDLER BROTH 20PV
24432	YERSINIA BROTH 20PV
24433	EUGON BROTH 20PV
24436	MIDDLEBROOK 7H9 BROTH 20PV
24446	PHENOL RED BROTH 20PV
24450	Rappaport Broth w/o Soy
24451	Tetrathionate Broth
24459	CASO BROTH (Double Concentration) CE 20PV
24461	RPMI Broth
24462	RPMI Broth (double strength)
24471	Listeria Motility Medium
24513	TRYPTIC SOY BROTH (Harm.EP)
24514	TRYPTIC SOY BROTH
24516	UREA BROTH
26105	Glucose Broth
26124	Fluid Thioglycollate Medium 100 x 10 ml
26342	Motility Test Medium
26400	RAPPAPORT VASSILIADIS SOY (RSV) BROTH
26475	Tryptic Soy Agar
26513	Tryptic Soy Broth
27001	GESA MEDIUM
27500	Triptic Soy Broth
27501	Todd Hewitt Broth
27502	Brain Heart Infusion Broth
27503	Nutrient Broth
29000	CHECK-SET BROTH Irradiated 20 Test
30007	CAMPYLOBACTER SELECTIVE THIOGLYCOLLATE MEDIUM
30008	CLOSTRIDIUM AGAR (Sheep Blood 5%)

30009	HELICOBACTER PYLORI AGAR
30010	STREPTOCOCCAL KF + TTC AGAR
30011	SIMMONS CITRATE AGAR
30013	NITRATI AGAR
30014	MOSSEL AGAR
30022	T.C.B.S. AGAR
30023	Sabouraud CAF Agar
30024	SABOURAUD CAF + ACTIDIONE AGAR
30030	M.R.S. AGAR
30080	BORDET GENGOU AGAR (Sheep Blood 15%)
30081	CHRISTENSEN UREA AGAR
30082	Tryptic Soy Agar
30083	NUTRIENT AGAR
30084	BRAIN HEART INFUSION AGAR
30085	PHENYLALANINE AGAR
30087	KLIGLER IRON AGAR
30088	KLIGLER IRON AGAR + NaCl 2%
30090	Mueller Hinton II Agar
30091	BIGGY (NICKERSON) AGAR
30093	SABOURAUD AGAR
30095	SIM MEDIUM
30096	T.S.I. AGAR
30097	Tryptose Agar
30098	LYSINE IRON AGAR
30099	Chocolate Agar
30116	LOEFFLER MEDIUM
30117	PERGOLA MEDIUM
30118	Lowenstein Jensen Medium
30119	LOWENSTEIN JENSEN MEDIUM w/o GLYCEROL
30121	Stonebrink Medium
30125	DORSET EGG MEDIUM
30368	MIDDLEBROOK 7H10 AGAR
31023	Sabouraud CAF Agar
31065	SPS Agar
31075	Mueller Hinton II Agar
31082	Tryptic Soy Agar
31083	Nutrient Agar ISO 16266
31090	Mueller Hinton II Agar
31097	Tryptose Agar
31099	Chocolate Agar
31121	Stonebrink Medium
31204	MIU Agar
33040	THAYER MARTIN AGAR
33055	MYCOSEL AGAR
33060	SERUM TELLURITE AGAR
33066	O.N.P.G. AGAR
33085	BILE AESCULIN AGAR
33086	DERMATOPHYTE (D.T.M.) AGAR
33118	I.U.T.M. MEDIUM
33120	PETRAGNANI MEDIUM
34070	CAMPYLOBACTER AGAR
34071	CYSTINE TRYPTIC AGAR (CTA)
34075	Mueller Hinton II Agar
34121	LOWENSTEIN JENSEN + RIFAMPICIN 15 µg/mL
34121/1	LOWENSTEIN JENSEN + RIFAMPICIN 5 µg/mL
34121/2	LOWENSTEIN JENSEN + RIFAMPICIN 10 µg/mL
34121/3	LOWENSTEIN JENSEN + RIFAMPICIN 25 µg/mL
34121/4	LOWENSTEIN JENSEN + RIFAMPICIN 50 µg/mL
34121/5	LOWENSTEIN JENSEN + RIFAMPICIN 40 µg/mL
34121/6	LOWENSTEIN JENSEN + RIFAMPICIN 20 µg/mL

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34122	LOWENSTEIN JENSEN + RIFAPENTIN 9 µg/mL
34123	LOWENSTEIN JENSEN + ISONIAZID 0.1 µg/mL
34123/1	LOWENSTEIN JENSEN + ISONIAZID 0.2 µg/mL I
34123/2	LOWENSTEIN JENSEN + ISONIAZID 1 µg/mL
34123/3	LOWENSTEIN JENSEN + ISONIAZID 5 µg/mL
34123/4	LOWENSTEIN JENSEN + ISONIAZID 10 µg/mL
34124/1	LOWENSTEIN JENSEN + PYRAZINAMIDE 5 µg/mL
34124/2	LOWENSTEIN JENSEN + PYRAZINAMIDE 15 µg/mL
34124/3	LOWENSTEIN JENSEN + PYRAZINAMIDE 20 µg/mL
34124/4	LOWENSTEIN JENSEN+PYRAZINAMIDE 200 µg/mL
34125/1	LOWENSTEIN JENSEN + STREPTOMYCIN 4 µg/mL
34125/2	LOWENSTEIN JENSEN + STREPTOMYCIN 10 µg/mL
34125/3	LOWENSTEIN JENSEN + STREPTOMYCIN 25 µg/mL
34125/4	LOWENSTEIN JENSEN + STREPTOMYCIN 2 µg/mL
34125/5	LOWENSTEIN JENSEN + STREPTOMYCIN 50 µg/mL
34126/1	LOWENSTEIN JENSEN + ETHAMBUTOL 2 µg/mL
34126/2	LOWENSTEIN JENSEN + ETHAMBUTOL 4 µg/mL
34126/3	LOWENSTEIN JENSEN + ETHAMBUTOL 5 µg/mL
34126/4	LOWENSTEIN JENSEN + ETHAMBUTOL 1 µg/mL
34126/5	LOWENSTEIN JENSEN + ETHAMBUTOL 3 µg/mL
34126/6	LOWENSTEIN JENSEN + ETHAMBUTOL 10 µg/mL
34127	LOWENSTEIN JENSEN + AMIKACIN 5 µg/mL
34127/1	LOWENSTEIN JENSEN + AMIKACIN 40 µg/mL
34128/1	LOWENSTEIN JENSEN + OFLOXACIN 5 µg/mL
34128/2	LOWENSTEIN JENSEN + OFLOXACIN 10 µg/mL
34128/3	LOWENSTEIN JENSEN + OFLOXACIN 25 µg/mL
34128/4	LOWENSTEIN JENSEN + OFLOXACIN 2 µg/mL
34128/5	LOWENSTEIN JENSEN + OFLOXACIN 20 µg/mL
34129/1	LOWENSTEIN JENSEN + PAS 1 µg/mL
34129/2	LOWENSTEIN JENSEN + PAS 10 µg/mL
34129/3	LOWENSTEIN JENSEN + PAS 0.5 µg/mL
34129/4	LOWENSTEIN JENSEN + PAS 0.1 µg/mL
34129/5	LOWENSTEIN JENSEN + PAS 5 µg/mL
34130/1	LOWENSTEIN JENSEN + RIFABUTIN 10 µg/mL
34130/2	LOWENSTEIN JENSEN + RIFABUTIN 30 µg/mL
34130/3	LOWENSTEIN JENSEN + RIFABUTIN 50 µg/mL
34131/1	LOWENSTEIN JENSEN+CLARITHROMICIN 4 µg/mL
34131/2	LOWENSTEIN JENSEN+CLARITHROMYCIN 32 µg/mL
34132/1	LOWENSTEIN JENSEN + ETHIONAMIDE 10 µg/mL
34132/2	LOWENSTEIN JENSEN + ETHIONAMIDE 20 µg/mL
34132/3	LOWENSTEIN JENSEN + ETHIONAMIDE 30 µg/mL
34132/4	LOWENSTEIN JENSEN + ETHIONAMIDE 40 µg/mL
34135/1	LOWENSTEIN JENSEN + NICOTINAMIDE 10 µg/mL
34135/2	LOWENSTEIN JENSEN + NICOTINAMIDE 20 µg/mL
34135/3	LOWENSTEIN JENSEN + NICOTINAMIDE 30 µg/mL
34136	LOWENSTEIN JENSEN + PEFLOXACIN 2 µg/mL
34137/1	LOWENSTEIN JENSEN + CYCLOSERINE 30 µg/mL
34137/2	LOWENSTEIN JENSEN + CYCLOSERINE 10 µg/mL
34137/3	LOWENSTEIN JENSEN + CYCLOSERINE 20 µg/mL
34137/4	LOWENSTEIN JENSEN + CYCLOSERINE 40 µg/mL
34137/5	LOWENSTEIN JENSEN + CYCLOSERINE 50 µg/mL
34138/1	LOWENSTEIN JENSEN + CAPREOMYCIN 10 µg/mL
34138/2	LOWENSTEIN JENSEN + CAPREOMYCIN 40 µg/mL
34138/3	LOWENSTEIN JENSEN + CAPREOMYCIN 20 µg/mL
34138/4	LOWENSTEIN JENSEN + CAPREOMYCIN 30 µg/mL
34139/1	LOWENSTEIN JENSEN + CLOFAZIMINE 5 µg/mL
34139/2	LOWENSTEIN JENSEN + CLOFAZIMINE 10 µg/mL
34143/1	LOWENSTEIN JENSEN + KANAMYCIN 10 µg/mL
34143/2	LOWENSTEIN JENSEN + KANAMYCIN 20 µg/mL
34143/3	LOWENSTEIN JENSEN + KANAMYCIN 30 µg/mL

34144	LOWENSTEIN JENSEN + PYRUVATE 0.2%
34145	LOW.JENSEN + PACT
34146/1	Lowenstein Jensen + Levofloxacin 2 µg/ml
35000	LOWENSTEIN JENSEN MEDIUM
35001	LOWENSTEIN JENSEN + ISONIAZID 0.20 µg/mL
35002	LOWENSTEIN JENSEN + ISONIAZID 1 µg/ml
35010	LOWENSTEIN JENSEN + RIFAMPICIN 40 µg/mL
35011	LOWENSTEIN JENSEN + RIFAMPICIN 20 µg/mL
35020	LOWENSTEIN JENSEN + STREPTOMYCIN 4 µg/mL
35021	LOWENSTEIN JENSEN + STREPTOMYCIN 10µg/ml
35030	LOWENSTEIN JENSEN + ETHAMBUTOL 2 µg/mL
35040	LOWENSTEIN JENSEN + ETHIONAMIDE 20 µg/mL
35041	LOWENSTEIN JENSEN + ETHIONAMIDE 30µg/ml
35050	LOWENSTEIN JENSEN + PYRAZINAMIDE 1 µg/mL
35060	LOWENSTEIN JENSEN + KANAMYCIN 20 µg/mL
35061	LOWENSTEIN JENSEN + KANAMYCIN 30µg/ml
35070	LOWENSTEIN JENSEN + PAS 1 µg/mL
35071	LOWENSTEIN JENSEN + PAS 0.5 µg/mL
35080	LOWENSTEIN JENSEN + OFLOXACIN 2 µg/ml
35081	LOWENSTEIN JENSEN + OFLOXACIN 10 µg/ml
35082	LOWENSTEIN JENSEN + OFLOXACIN 40 µg/ml
35090	LOWENSTEIN JENSEN + CAPREOMYCIN 30 µg/ml
35091	LOWENSTEIN JENSEN + CAPREOMYCIN 20 µg/ml
35147	LOWENSTEIN JENSEN + PNB 500 µg/ml
35148	LOWENSTEIN JENSEN + TCH 2 µg/ml
36001/1	IUTM + STREPTOMYCIN 2 µg/mL
36001/2	IUTM + STREPTOMYCIN 4 µg/mL
36001/3	IUTM + STREPTOMYCIN 10 µg/mL
36001/4	IUTM + STREPTOMYCIN 25 µg/mL
36001/5	IUTM + STREPTOMYCIN 50 µg/mL
36002/1	IUTM + ISONIAZID 0.1 µg/mL
36002/2	IUTM + ISONIAZID 0.2 µg/mL
36002/3	IUTM + ISONIAZID 1 µg/mL
36002/4	IUTM + ISONIAZID 5 µg/mL
36002/5	IUTM + ISONIAZID 10 µg/mL
36003/1	IUTM + ETHAMBUTOL 1 µg/mL
36003/2	IUTM + ETHAMBUTOL 2 µg/mL
36003/3	IUTM + ETHAMBUTOL 3 µg/mL
36003/4	IUTM + ETHAMBUTOL 5 µg/mL
36003/5	IUTM + ETHAMBUTOL 10 µg/mL
36004/1	IUTM + RIFAMPICIN 5 µg/mL
36004/2	IUTM + RIFAMPICIN 10 µg/mL I
36004/3	IUTM + RIFAMPICIN 20 µg/mL
36004/4	IUTM + RIFAMPICIN 40 µg/mL
36004/5	IUTM + RIFAMPICIN 50 µg/mL
36005/1	IUTM + RIFABUTIN 10 µg/mL
36005/2	IUTM + RIFABUTIN 20 µg/mL
36005/3	IUTM + RIFABUTIN 30 µg/mL
36005/4	IUTM + RIFABUTIN 40 µg/mL
36005/5	IUTM + RIFABUTIN 50 µg/mL
36006/1	IUTM + CYCLOSERINE 10 µg/mL
36006/2	IUTM + CYCLOSERINE 20 µg/mL
36006/3	IUTM + CYCLOSERINE 30 µg/mL
36006/4	IUTM + CYCLOSERINE 40 µg/mL
36006/5	IUTM + CYCLOSERINE 50 µg/mL
36007/1	IUTM + OFLOXACIN 1.25 µg/mL
36007/2	IUTM + OFLOXACIN 2.5 µg/mL
36007/3	IUTM + OFLOXACIN 10 µg/mL
36007/4	IUTM + OFLOXACIN 25 µg/mL
36007/5	IUTM + OFLOXACIN 50 µg/mL

36008/1	IUTM + PAS 0.1 µg/mL
36008/2	IUTM + PAS 0.5 µg/mL
36008/3	IUTM + PAS 1 µg/mL
36008/4	IUTM + PAS 5 µg/mL
36008/5	IUTM + PAS 10 µg/mL
36009/1	IUTM + PYRAZINAMIDE 10 µg/mL
36009/2	IUTM + PYRAZINAMIDE 30 µg/mL
36009/3	IUTM + PYRAZINAMIDE 50 µg/mL
36009/4	IUTM + PYRAZINAMIDE 70 µg/mL
36009/5	IUTM + PYRAZINAMIDE 90 µg/mL
37000	MIDDLEBROOK 7H11
37001	MIDDLEBROOK 7H11 + AMIKACIN 2 µg/mL
37002	MIDDLEBROOK 7H11 + AMIKACIN 4 µg/mL
37006	MIDDLEBROOK 7H11 + ETHAMBUTOL 7.5 µg/mL
37011	MIDDLEBROOK 7H11 + ETHIONAMIDE 10 µg/mL
37016	MIDDLEBROOK 7H11 + ISONIAZIDE 0.2 µg/mL
37017	MIDDLEBROOK 7H11 + ISONIAZIDE 1 µg/mL
37021	MIDDLEBROOK 7H11 + KANAMYCIN 6 µg/mL
37026	MIDDLEBROOK 7H11 + PAS 8 µg/mL
37031	MIDDLEBROOK 7H11 + PYRAZINAMIDE 25 µg/mL
37036	MIDDLEBROOK 7H11 + RIFABUTIN 1 µg/mL
37037	MIDDLEBROOK 7H11 + RIFABUTIN 0.5 µg/mL
37041	MIDDLEBROOK 7H11 + RIFAMPICIN 1 µg/mL
37046	MIDDLEBROOK 7H11 + STREPTOMYCIN 2 µg/mL
37051	MIDDLEBROOK 7H11 + OFLOXACIN 2 µg/mL
37056	MIDDLEBROOK 7H11 + CYCLOSERINE 30 µg/mL
400020	Fluid Thioglycollate Medium 6 x 100 ml
400120	Fluid Thioglycollate Medium 6 x 300 ml
400220	Fluid Thioglycollate Medium 6 x 1000 ml
401890	BUFFER SOLUTION pH 7 6X100 ml
401930	SPS Agar 6X150 ml
401980	TRYPTONE WATER 6X100 ml
401990	Alkaline Peptone Water 6 x 100 ml
402000	NUTRIENT BROTH 6X100 ml
402020	MUELLER HINTON II BROTH 6X100 ml
402030	MULLER KAUFFMANN BROTH 6X100 ml
402040	Sabouraud Dextrose Broth 6 x 100 ml
402050	Selenite Broth 6 x 100 ml
402060	SALMONELLA DIFF.BROTH 6X90 ml
402070	TRYPTOSE BROTH 6X100 ml
402120	MRS AGAR 6X100 ml
402130	PEPTONE WATER 6X100 ml
402140	BLOOD AGAR BASE 6X100 ml
402170	AZIDE BLOOD AGAR BASE 6X100 ml
402180	CLED AGAR 6X100 ml
402190	NUTRIENT AGAR 6X100 ml
402200	DERMATHOPHYTE (D.T.M.) AGAR 6X100 ml
402210	COLUMBIA CNA AGAR BASE 6X100 ml
402220	DRIGALSKI LACTOSE AGAR 6X100 ml
402230	HEKTOEN ENTERIC AGAR 6X100 ml
402240	MAC CONKEY AGAR 6X100 ml
402250	MUELLER HINTON II AGAR 6X100 ml
402270	PSEUDOMONAS CETRIMIDE AGAR 6X100 ml
402280	SABOURAUD AGAR 6X100 ml
402290	MANNITOL SALT AGAR 6X100 ml
402300	S.S. AGAR 6X100 ml
402320	TRYPTOSE AGAR 6X100 ml
402330	BRILLIANT GREEN AGAR 6X100 ml
402340	DESOXYCHOLATE AGAR 6X100 ml
402350	E.M.B. LEVINE AGAR 6X100 ml

402360	SALMONELLA RAPID TEST 6X100 ml
402370	SABOURAUD CAF AGAR 6X100 ml
402380	BRAIN HEART INFUSION AGAR 6X100 ml
402430	PEPTONE DILUITIONS 6X100 ml
402450	MAC CONKEY SORBITOL AGAR 6X100 ml
402500	Fluid Thioglycollate Medium + 1% Tween 80
402570	X.L.D. AGAR 6X100 ml
403030	BIOTONE BROTH 6X100 ml
403050	S.I.M. MEDIUM 6X100 ml
403060	UREA INDOLE BROTH 6X100 ml
403130	Monsur Agar 6 x 100 ml
403140	TCBS Agar 6 x 100 ml
412010	BRAIN HEART INFUSION BROTH 6X200 ml
412030	SIMMONS CITRATE AGAR 6X200 ml
412040	LYSINE IRON AGAR 6X200 ml
412050	Selenite Broth 6 x 200 ml
412060	TODD HEWITT BROTH 6X200 ml
412080	TRICHOMONAS BROTH 6X200 ml
412100	CHRISTENSEN UREA AGAR 5X200 ml
412110	TRYPTIC SOY BROTH + TWEEN80 1% 6x200ml
412130	PSEUDOMONAS AGAR BASE 6x200ml
412150	AZIDE BLOOD AGAR BASE 6X200 ml
412170	PHENILALANINE AGAR 6X200 ml
412180	CLED AGAR 6X200 ml
412190	NUTRIENT AGAR 6X200 ml
412210	COLUMBIA CNA AGAR BASE 6X200 ml
412230	HEKTOEN ENTERIC AGAR 6X200 ml
412240	MAC CONKEY AGAR 6X200 ml
412250	MUELLER HINTON II AGAR 6X200 ml
412270	PSEUDOMONAS CETRIMIDE AGAR 6X200 ml
412280	SABOURAUD AGAR 6X200 ml
412290	MANNITOL SALT AGAR 6X200 ml
412300	S.S. AGAR 6X200 ml
412370	SABOURAUD CAF AGAR 6X200 ml
413010	ISOSENSITEST AGAR 6X200 ml
413030	CAMPYLOBACTER AGAR 6X200 ml
413040	CLOSTRIDIUM AGAR BASE 6X200 ml
413080	NUTRIENT AGAR acc. to ISO 6579
413130	Nutrient Agar semisolid 6 x 200 ml
414010	PEPTONE WATER pH 8.4 + NaCl 1% 6X225 ml
432050	Selenite Broth (Double Concentration)
432080	TRYPTIC SOY BROTH 6X225 ml
432250	D-Nase TEST AGAR 6X200 ml
432290	Tryptic Soy Agar 6 x 200 ml
442080	TRYPTIC SOY BROTH 6X200 ml
442220	Chocolate Agar 6x 100 ml
442280	SABOURAUD MODIFIED AGAR 6X100 ml
442290	Tryptic Soy Agar 6 x 100 ml
442300	WURTZ LACTOSE AGAR 6X100 ml
442320	BILE AESCULIN AGAR 6X100 ml
442350	BIGGY (NICKERSON) AGAR 6X100 ml
442490	SPS AGAR 6X100 ml
451404	Alkaline Peptone Water 25 x 225 ml
452040	Sabouraud Dextrose Broth 25 x 100 mL
452060	Fluid Thioglycollate Medium 6 x 100 ml
452080	TRYPTIC SOY BROTH 6X100 ml
452210	COLUMBIA AGAR BASE 6X200 ml
452500	Fluid Thioglycollate Medium + 1% Tween 80 25 x 100 ml
453060	Fluid Thioglycollate Medium 25 x 100 ml
463100	Fluid Thioglycollate Medium 6 x 900 ml

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463130	Selenite Broth 6 x 1000 ml
470010	Tryptic Soy Agar 6 x 500 ml
470020	Selenite Broth 6 x 500 ml
470030	DESOXYCHOLATE AGAR 6X500 ml
470040	SABOURAUD AGAR 6X500 ml
470050	NUTRIENT BROTH 6X500 ml
470060	NUTRIENT AGAR 6X500 ml
470070	Mueller Hinton II Agar 6X500 ml
470080	MANNITOL SALT AGAR 6X500 ml
470090	MAC CONKEY AGAR 6X500 ml
470100	COLUMBIA AGAR BASE 6X500 ml
470110	CLED AGAR 6X500 ml
470120	Chocolate Agar 6 x 500 ml
470130	BLOOD AGAR BASE 6X500 ml
470140	BILE AESCULIN AGAR 6X500 ml
470150	TRICHOMONAS BROTH 6X500 ml
470160	DESOXYCHOLATE CITRATE AGAR 6X500 ml
470210	Alkaline Peptone Water 6 x 500 ml
470220	CZAPEK DOX AGAR 6X500 ml
470280	DRIGALSKI LACTOSE AGAR 6X500 ml
470290	CARY BLAIR TRANSPORT MEDIUM 6X500 ml
470300	Fluid Thioglycollate Medium 6 x 500 ml
470320	PEPTONE WATER 6X500 ml
470370	TRYPTIC SOY BROTH 6 x 500 ml
471070	Sabouraud Dextrose Broth 6 x 500 ml
471120	PHYSIOLOGICAL SOLUTION 6X240 ml
473000	PHYSIOLOGICAL SOLUTION 6X500 ml
481110	CHROMATIC™ CANDIDA 6X100 ml
481130	CHROMATIC™ DETECTION 6X100 ml
481140	CHROMATIC™ SALMONELLA 6X100 ml
481160	CHROMATIC™ STAPH AUREUS 6X100 ml
481180	CHROMATIC™ STREP B 6X100ml
482190	Chromatic™ E.coli O157 6 x 200 ml
490010	HEMO-AEROBIC culturing 6X80 ml
490020	HEMO-ANAEROBIC culturing 6X80 ml
490030	HEMO-AEROBIC culturing-Pediatric 6X40 ml
490040	HEMO-ANAEROBIC culturing-Pediatric 6X40ml
490050	HEMO-AEROBIC culturing NEONATAL 6x9 ml
490060	HEMO-ANAEROBIC culturing NEONATAL 6x9 ml
493000	Fluid Thioglycollate Medium 6 x 100 ml
495010	TRYPTIC SOY BROTH 6x100 ml
495020	Fluid Thioglycollate Medium 6 x 100 ml
500142	URITEST PENTA
500152	URITEST
500182	URITEST M
500702	URITEST EF
50020	VAGITEST
50021	DERMATEST
500232	URITEST N
500302	URITEST 2
500402	URITEST MALTO
500412	URITEST EC
51014	URITEST PENTA
51015	URITEST
51018	URITEST M
51020	VAGITEST 120 slide
51021	DERMATEST
51023	URITEST N
51024	URITEST C
51030	URITEST 2

51040	URITEST MALTO
51041	URITEST EC
51070	URITEST EF
51118	URITEST M
51123	URITEST N 500 slide
51130	URITEST 2 500 slide
51140	URITEST MALTO
51170	CLED/MAC CONKEY/ BILE AESCULIN
52115	CLED/MAC CONKEY/SLANETZ 120 slide
52119	URITEST SF 500 slide
610001	BILE AESCULIN AZIDE AGAR
610002	DEXTROSE AGAR
610005	BLOOD AGAR BASE
610006	BORDET GENGOU AGAR BASE
610007	BRAIN HEART INFUSION AGAR
610008	BRAIN HEART INFUSION BROTH
6100085	BRAIN HEART INFUSION BROTH
610009	BRILLIANT GREEN AGAR
610012	CLED AGAR
6100125	CLED AGAR
610013	COLUMBIA AGAR BASE
6100135	COLUMBIA AGAR BASE
610014	DESOXYCHOLATE AGAR
6100145	DESOXYCHOLATE AGAR
610015	DESOXYCHOLATE CITRATE AGAR
610016	DRIGALSKI LACTOSE AGAR
610019	E.M.B. LEVINE AGAR
610021	HEKTOEN ENTERIC AGAR
6100215	HEKTOEN ENTERIC AGAR
610022	G.C. MEDIUM
610023	KLIGLER IRON AGAR
610024	M.R.S. AGAR (ISO/FDIS 15214)
610025	M.R.S. BROTH (ISO/FDIS 15214)
610026	LOWENSTEIN JENSEN MEDIUM
6100265	LOWENSTEIN JENSEN MEDIUM
610027	LYSINE IRON AGAR
610028	MAC CONKEY AGAR
6100285	MAC CONKEY AGAR
610029	MANNITOL SALT AGAR
6100295	MANNITOL SALT AGAR
610032	MR-VP BROTH
610033	MUELLER HINTON AGAR
6100335	MUELLER HINTON AGAR
610034	MUELLER HINTON BROTH
610035	MULLER KAUFFMANN BROTH
610036	Nutrient Agar ISO 16266
6100365	Nutrient Agar ISO 16266
610037	NUTRIENT BROTH
6100375	NUTRIENT BROTH
610038	PEPTONE WATER
610039	PHENYLALANINE AGAR
610041	PSEUDOMONAS CETRIMIDE AGAR (ISO 8360-1)
6100415	PSEUDOMONAS CETRIMIDE AGAR
610042	SS AGAR (MODIFIED)
6100425	SS AGAR (MODIFIED)
610043	SCHAEDLER AGAR BASE
610044	PURPLE LACTOSE AGAR
610046	SIMMONS CITRATE AGAR
610047	MONSUR AGAR
610048	AEROMONAS AGAR BASE

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610049	LEGIONELLA BCYE AGAR BASE (ISO 11731)
610050	Fluid Thioglycollate Medium
6100505	Fluid Thioglycollate Medium
610051	TODD HEWITT BROTH
6100515	TODD HEWITT BROTH
610052	Tryptic Soy Agar
6100525	Tryptic Soy Agar
610053	TRYPTIC SOY BROTH
6100535	TRYPTIC SOY BROTH
610055	T.S.I. AGAR USP
610056	CLOSTRIDIUM BROTH
6100565	CLOSTRIDIUM BROTH
610057	MAC CONKEY AGAR No.2
6100575	MAC CONKEY AGAR No.2 5 KG
610060	X.L.D. AGAR (ISO 6579)
6100605	X.L.D. AGAR
610061	TRICHOMONAS BROTH
610065	GSB AGAR BASE (ISLAM)
610071	PSEUDOMONAS AGAR BASE
610072	CZAPEK DOX BROTH
610075	PHENYLALANINE MALONATE BROTH
610079	BRUCELLA AGAR BASE
610080	WORT BROTH W/O NaCl
610092	XLT 4 AGAR
610095	CZAPEK DOX AGAR
610096	REINFORCED CLOSTRIDIAL AGAR
610097	STAPHYLOCOCCUS BROTH
610098	Alkaline Peptone Water
610101	MALT AGAR
610103	SABOURAUD AGAR
6101035	SABOURAUD AGAR
610104	Sabouraud Dextrose Broth
610107	UREA AGAR BASE (ISO 6785)
610108	MAC CONKEY SORBITOL AGAR
610109	P.P.L.O. BROTH
610110	MUELLER HINTON AGAR MODIFIED
610111	YERSINIA SELECTIVE AGAR BASE
610112	CLED ANDRADE AGAR
610113	COLUMBIA CNA AGAR BASE
610114	BACILLUS CEREUS AGAR BASE (MOSSEL) ISO 7932
610115	CLOSTRIDIUM DIFFICILE AGAR BASE
610117	TRYPTONE YEAST AGAR
610118	ANDRADE LACTOSE PEPTONE WATER
610123	CORN MEAL AGAR
610125	LEGIONELLA CYE AGAR BASE
610128	MAC CONKEY AGAR w/o BILE SALT
610130	CAMPYLOBACTER BLOOD FREE MEDIUM BASE
610131	CAMPYLOBACTER ENRICHMENT BROTH BASE
610132	MOTILITY TEST AGAR
610134	SLANETZ BARTLEY AGAR BASE ISO 7899-2
610135	BIGGY (NICKERSON) AGAR
610136	BACILLUS CEREUS AGAR BASE (PEMBA)
610137	SCHAEDLER BROTH
610140	E.M.B. AGAR w LACTOSE + SUCROSE
610143	LIVER BROTH
610144	MRS BROTH w/o GLUCOSE
610145	Selenite Broth
6101455	Selenite Broth
610146	SABOURAUD MALTOSE AGAR
610147	SLANETZ AND BARTLEY AGAR + TTC

6101475	SLANETZ AND BARTLEY AGAR + TTC
610148	SPS AGAR
610151	BILE AESCULIN BROTH
610152	AMIES TRANSPORT MEDIUM + CHARC.
6101525	AMIES TRANSPORT MEDIUM + CHARC.
610153	AZIDE BLOOD AGAR BASE
610155	AZIDE VIOLET BLOOD AGAR BASE
610157	BIOTONE AGAR
610158	BIOTONE BROTH
610159	CPLM SELECTIVE WITH CAF
610160	DERMATOPHYTE (D.T.M.) AGAR
610161	DEXTROSE BROTH
610163	G.N. HAJNA BROTH
610164	HERELLEA AGAR
6101645	HERELLEA AGAR
610165	KOSER CITRATE MEDIUM
610168	LISTERIA PALCAM AGAR
610169	I.U.T.M. MEDIUM
610170	MAC CONKEY MMG AGAR
6101705	MAC CONKEY MMG AGAR
610172	MALONATE BROTH
610174	PHENOL RED BROTH BASE
610175	RAPPAPORT VASSILIADIS BROTH (ISO 6785-6579)
610176	ROGOSA AGAR
610177	ROGOSA BROTH
610179	SABOURAUD CAF AGAR + ACTIDIONE
610180	S.F. BROTH
610181	S.I.M. MEDIUM
610182	STUART TRANSPORT MEDIUM
610183	TETRATHIONATE BROTH BASE
610185	TRYPTIC (CTA) MEDIUM
610186	VOGEL JOHNSON AGAR
610188	BLOOD AGAR BASE N. 2
610191	AMIES TRANSPORT MEDIUM (w/o CHARCOAL)
6101915	AMIES TRANSPORT MEDIUM (w/o CHARCOAL)
610193	TRYPTOSE AGAR
610195	MAC CONKEY AGAR w/o CRYSTAL VIOLET
610196	TRYPTIC BILE AGAR
610197	TRYPTOFAN BROTH
610200	CAMPYLOBACTER KARMALI AGAR BASE
610203	SABOURAUD CAF AGAR
6102035	SABOURAUD CAF AGAR 5 KG
610205	DNase TEST AGAR
610206	TRYPTONE WATER (ISO/DIS 3811)
610207	CLOSTRIDIUM PERFRIGENS AGAR BASE
610210	BILE AESCULIN AGAR
610211	KLIGLER IRON AGAR MOD.
610214	MIDDLEBROOK 7H9 BROTH BASE
610217	NUTRIENT BROTH N.2
610218	Mueller Hinton II Broth
610221	ANTIBIOTIC TEST MEDIUM
610222	CLOSTRIDIUM BROTH w/o AGAR
6102225	CLOSTRIDIUM BROTH w/o AGAR
610223	MAC CONKEY AGAR w/o Salt
610227	PHENOL RED AGAR BASE
610229	ANTIBIOTIC MEDIUM E
610230	OXIDATIVE/FERMENTATIVE MEDIUM
610233	TRYPTOSE BROTH
610235	MANNITOL MOTILITY TEST MEDIUM
610236	MOTILITY INDOLE UREA AGAR (M.I.U.)

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610245	LB AGAR
610301	BISMUTH SULPHITE AGAR
610303	Lysine Decarboxylase Broth
610304	OF BASAL MEDIUM
610305	ORNITHINE DECARBOXYLASE BROTH
610306	ARGININE DECARBOXYLASE BROTH
610308	PHENOL RED AGAR BASE
610309	PSEUDOMONAS AGAR F
610310	PSEUDOMONAS AGAR P
610311	UREA BROTH
610315	ANTIBIOTIC AGAR N.11
610319	PFIZER SELECTIVE ENTEROCOCCUS AGAR
610322	NITRATE BROTH
610331	DIAGNOSTIC SENSITIVITY TEST AGAR (D.S.T.)
610339	T.S.I. AGAR acc.EP
610341	EMGON BROTH
610343	MANNITOL SALT BROTH
610363	Yeast Extract Sodium Lactate medium
610364	Tryptose Phosphate Broth
6103645	Tryptose Phosphate Broth
610372	Cooked Meat Medium
610492	POLYPEPTONE
610495	BRAIN HEART INFUSION
6104955	BRAIN HEART INFUSION
610496	ACID HYDROLISATE OF CASEIN
610497	BEEF EXTRACT
6104975	BEEF EXTRACT
610498	LACTOSE
6104985	LACTOSE
610506	CYSTINE HEART AGAR
610611	CHROMATIC™ SALMONELLA
610612	CHROMATIC™ DETECTION
6106125	CHROMATIC™ DETECTION
610613	CHROMATIC™ CANDIDA
610614	Chromatic™ E.coli O157
610615	CHROMATIC™ MRSA
610616	CHROMATIC™ STAPH AUREUS
610617	CHROMATIC™ STREP B
610625	SABOURAUD CAF (50 mg/L) AGAR
610627	MUELLER HINTON II AGAR
6106275	MUELLER HINTON II AGAR
610629	CHROMATIC™ ESBL
610633	Chromatic™ Vibrio
611000	SODIUM CHLORIDE
611001	AGAR
6110015	AGAR
611002	GELATIN BACTERIOLOGICAL
6110025	GELATIN BACTERIOLOGICAL
611003	SODIUM SELENITE
6110035	SODIUM SELENITE
611004	TRYPTONE
6110045	TRYPTONE
611005	YEAST EXTRACT
6110055	YEAST EXTRACT
611006	MALT EXTRACT
6110065	MALT EXTRACT
611007	CAMPYLOBACTER AGAR BASE
611008	TRYPTOSE
6110085	TRYPTOSE
611009	GLUCOSIO

611010	T.C.B.S. AGAR
611015	SIERRA LIPOLYTIC AGAR
611021	HEART INFUSION BROTH
6110215	HEART INFUSION BROTH
611022	MIDDLEBROOK 7H10 AGAR BASE
611203	SABOURAUD CAF (1g/l) AGAR
611210	WURTZ LACTOSE AGAR
611265	ISOSENSITEST AGAR
611366	STAPHYLOCOCCUS 110 AGAR
611367	BILE BACTERIOLOGICAL
611401	IRON SULPHITE AGAR
611402	CARY BLAIR TRANSPORT MEDIUM
611502	CASEIN PEPTONE
611601	GLUCOSE
6116015	GLUCOSE
611602	Maltose
611618	CHROMATIC™ MH
611619	CHROMATIC™ CRE AGAR BASE
611701	PEPTONE BACTERIOLOGICAL
6117015	PEPTONE BACTERIOLOGICAL
611706	Hemoglobin
611801	SUCROSE
6118015	SUCROSE
611901	BILE SALT N.3
6119015	BILE SALT N.3
612001	LIVER EXTRACT
6120015	LIVER EXTRACT
612101	PEPTONE MYCOLOGICAL
6121015	PEPTONE MYCOLOGICAL
612201	PROTEOSE PEPTONE
6122015	PROTEOSE PEPTONE
612202	STREPTOCOCCUS SELECTIVE AGAR
612203	STREPTOCOCCUS BROTH
612501	SOY PEPTONE
6125015	SOY PEPTONE
620001	BILE AESCULIN AZIDE AGAR
620002	DEXTROSE AGAR
620005	BLOOD AGAR BASE
620006	BORDET GENGOU AGAR BASE
620007	BRAIN HEART INFUSION AGAR
620008	BRAIN HEART INFUSION BROTH
620009	BRILLIANT GREEN AGAR
620012	CLED AGAR
620013	COLUMBIA AGAR BASE
620014	DESOXYCHOLATE AGAR
620015	DESOXYCHOLATE CITRATE AGAR
620016	DRIGALSKY LACTOSE AGAR
620019	E.M.B. LEVINE AGAR
620021	HEKTOEN ENTERIC AGAR
620022	G.C. MEDIUM
620023	KLIGLER IRON AGAR
620024	M.R.S. AGAR (ISO/FDIS 15214)
620025	M.R.S. BROTH (ISO/FDIS 15214)
620026	LOWENSTEIN JENSEN MEDIUM
620027	LYSINE IRON AGAR
620028	MAC CONKEY AGAR
620029	MANNITOL SALT AGAR
620032	MR-VP BROTH
620033	MUELLER HINTON AGAR
620034	MUELLER HINTON BROTH

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620035	MULLER KAUFFMANN BROTH
620036	Nutrient Agar ISO 16266
620037	NUTRIENT BROTH
620038	PEPTONE WATER
620039	PHENYLALANINE AGAR
620041	PSEUDOMONAS CETRIMIDE AGAR (ISO 8360-1)
620042	SS AGAR (MODIFIED)
620043	SCHAEDLER AGAR BASE
620044	PURPLE LACTOSE AGAR
620046	SIMMONS CITRATE AGAR
620047	MONSUR AGAR
620048	AEROMONAS AGAR BASE
620049	LEGIONELLA BCYE AGAR BASE (ISO 11731)
620050	Fluid Thioglycollate Medium
620051	TODD HEWITT BROTH
620052	Tryptic Soy Agar
620053	TRYPTIC SOY BROTH
620055	T.S.I. AGAR USP
620056	CLOSTRIDIUM BROTH
620057	MAC CONKEY AGAR No.2
620060	X.L.D. AGAR (ISO 6579)
620061	TRICHOMONAS BROTH
620065	GSB AGAR BASE (ISLAM)
620071	PSEUDOMONAS AGAR BASE
620072	CZAPEK DOX BROTH
620075	PHENYLALANINE MALONATE BROTH
620079	BRUCELLA AGAR BASE
620092	XLT 4 AGAR
620095	CZAPEK DOX AGAR
620096	REINFORCED CLOSTRIDIAL AGAR
620097	STAPHYLOCOCCUS BROTH
620098	Alkaline Peptone Water
620101	MALT AGAR
620103	SABOURAUD AGAR
620104	Sabouraud Dextrose Broth
620107	UREA AGAR BASE (ISO 6785)
620108	MAC CONKEY SORBITOL AGAR
620109	P.P.L.O. BROTH
620110	MUELLER HINTON AGAR MODIFIED
620111	YERSINIA SELECTIVE AGAR BASE
620112	CLED ANDRADE AGAR
620113	COLUMBIA CNA AGAR BASE
620114	BACILLUS CEREUS AGAR BASE (MOSSEL) ISO 7932
620115	CLOSTRIDIUM DIFFICILE AGAR BASE
620117	TRYPTONE YEAST AGAR
620118	ANDRADE LACTOSE PEPTONE WATER
620122	MIDDLEBROOK 7H10 AGAR BASE
620123	CORN MEAL AGAR
620125	LEGIONELLA CYE AGAR BASE
620130	CAMPYLOBACTER BLOOD FREE MEDIUM BASE
620131	CAMPYLOBACTER ENRICHMENT BROTH BASE
620132	MOTILITY TEST AGAR
620134	SLANETZ BARTLEY AGAR BASE ISO 7899-2
620135	BIGGY (NICKERSON) AGAR
620136	BACILLUS CEREUS AGAR BASE (PEMBA)
620137	SCHAEDLER BROTH
620140	E.M.B. AGAR w LACTOSE + SUCROSE
620143	LIVER BROTH
620144	MRS BROTH w/o GLUCOSE
620145	Selenite Broth

620146	SABOURAUD MALTOSE AGAR
620147	SLANETZ AND BARTLEY AGAR + TTC
620148	SPS AGAR
620151	BILE AESCULIN BROTH
620152	AMIES TRANSPORT MEDIUM + CHARC.
620153	AZIDE BLOOD AGAR BASE
620155	AZIDE VIOLET BLOOD AGAR BASE
620157	BIOTONE AGAR
620158	BIOTONE BROTH
620159	CPLM SELECTIVE WITHCAF
620160	DERMATOPHYTE (D.T.M.) AGAR
620161	DEXTROSE BROTH
620163	G.N. HAJNA BROTH
620164	HERELLEA AGAR
620165	KOSER CITRATE BROTH
620168	LISTERIA PALCAM AGAR
620169	I.U.T.M. MEDIUM
620170	MAC CONKEY MMG AGAR
620172	MALONATE BROTH
620174	PHENOL RED BROTH BASE
620175	RAPPAPORT VASSILIADIS BROTH
620176	ROGOSA AGAR
620177	ROGOSA BROTH
620179	SABOURAUD CAF AGAR + ACTIDIONE
620180	S.F. BROTH
620181	S.I.M. MEDIUM
620182	STUART TRANSPORT MEDIUM
620183	TETRATHIONATE BROTH BASE
620185	TRYPTIC (CTA) MEDIUM
620186	VOGEL JOHNSON AGAR
620188	BLOOD AGAR BASE N. 2
620191	AMIES TRANSPORT MEDIUM (w/o CHARCOAL)
620193	TRYPTOSE AGAR
620195	MAC CONKEY AGSAR w/o CRYSTAL VIOLET
620196	TRYPTIC BILE AGAR
620197	TRYPTOFAN BROTH
620200	CAMPYLOBACTER KARMALI AGAR BASE
620203	SABOURAUD CAF AGAR
620205	DNase TEST AGAR
620206	TRYPTONE WATER (ISO/DIS 3811)
620207	CLOSTRIDIUM PERFRIGENS AGAR BASE
620210	BILE AESCULIN AGAR
620211	KLIGLER IRON AGAR MOD.
620214	MIDDLEBROOK 7H9 BROTH BASE
620217	NUTRIENT BROTH N.2
620218	Mueller Hinton II Broth
620227	PHENOL RED AGAR BASE
620229	ANTIBIOTIC MEDIUM E
620233	TRYPTOSE BROTH
620235	MANNITOL MOTILITY TEST MEDIUM
620303	Lysine Decarboxylase Broth
620309	PSEUDOMONAS AGAR F
620311	UREA BROTH
620495	BRAIN HEART INFUSION
620496	ACID HYDROLISATE OF CASEIN
620497	BEEF EXTRACT
620498	LACTOSE
620511	CHROMATIC™ SALMONELLA
620512	CHROMATIC™ DETECTION
620513	CHROMATIC™ CANDIDA

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620614	Chromatic™ E.coli O157
620615	CHROMATIC™ MRSA
620616	CHROMATIC™ STAPH AUREUS
620617	CHROMATIC™ STREP B
620627	MUELLER HINTON II AGAR
620629	CHROMATIC™ ESBL
621000	SODIUM CHLORIDE
621001	AGAR
621003	SODIUM SELENITE
621004	TRYPTONE
621005	YEAST EXTRACT
621006	MALT EXTRACT
621007	CAMPYLOBACTER AGAR BASE
621010	TCBS AGAR
621015	SIERRA LIPOLYTIC AGAR
621021	HEART INFUSION BROTH
621022	MIDDLEBROOK 7H10 AGAR BASE
621210	WURTZ LACTOSE AGAR
621265	ISOSENSITEST AGAR
621367	BILE BACTERIOLOGICAL
621401	IRON SULPHITE AGAR
621402	CARY BLAIR TRANSPORT MEDIUM
621601	GLUCOSE
621618	CHROMATIC™ MH
621619	CHROMATIC™ CRE AGAR BASE
621701	PEPTONE BACTERIOLOGICAL
622202	STREPTOCOCCUS SELECTIVE AGAR
630026	LOWENSTEIN JENSEN MEDIUM w GLYCEROL 1 litre
71618	ENTEROSYSTEM 18R 20 Test
71619	Enterosytem 24R 20 Test
71620	Anaerobe System 20 Test
71630	STAF SYSTEM 18 R 20 Test
71670	COPRO SYSTEM 40 Test
71675	COPRO SYSTEM Plus 20 Test
71678	PATHOGENIC SYSTEM DOUBLE 40 Test
71679	PATHOGENIC SYSTEM 20 Test
71681	PATHOGENIC SYSTEM AST
71714	INTEGRAL SYSTEM ENTEROBATTERI 20 Test
71718	INTEGRAL SYSTEM STAFILOCOCCHI 20 Test
71720	INTEGRAL SYSTEM STREPTOCOCCHI 20 Test
71724	INTEGRAL SYSTEM GARDNERELLA 20 TEST
71822	INTEGRAL SYSTEM YEASTS Plus 20 Test
72560	STREPTO SYSTEM 12 R 40 Test
72592	MYCOPLASMA SYSTEM Plus 20 Test
74156	A.F. GENITAL SYSTEM 20 Test
74160	URIN SYSTEM Plus 20 Test
74161	URIN SYSTEM Chrom 20 Test
75001	SensiTest Colistin 0.25 - 16 mg/L
76010	Sensi Test gram-negative 20 Test
76020	Sensi Test gram-positive 20 Test
76031	SensiQuattro Gram-negative 20 Test
76032	SensiQuattro Gram-positive 20 Test
76033	SensiQuattro Candida EU 20 Test
78618	ENTERO PLURI TEST 10 Test
78619	ENTERO PLURI TEST 25 Test
78620	OXI/FERM PLURI TEST 10 Test
78621	OXI/FERM PLURI TEST 25 Test
79010	Sensi Test gram-negative 4 Test
79020	Sensi Test gram-positive 4 Test
79031	SensiQuattro Gram-negative 4 Test

79032	SensiQuattro Gram-positive 4 Test
79033	SensiQuattro Candida EU 4 Test
79156	A.F. GENITAL SYSTEM 4 Test
79160	URIN SYSTEM Plus 4 Test
79161	URIN SYSTEM Chrom 4 Test
79560	STREPTO SYSTEM 12 R 8 Test
79592	MYCOPLASMA SYSTEM Plus 4 Test
79618	ENTEROSYSTEM 18R 4 Test
79619	Enterosytem 24R 4 Test
79620	Anaerobe System 4 Test
79630	STAF SYSTEM 18 R 4 Test
79670	COPRO SYSTEM 8 Test
79675	COPRO SYSTEM Plus 4 Test
79678	PATHOGENIC SYSTEM DOUBLE 8 Test
79679	PATHOGENIC SYSTEM 4 Test
79681	PATHOGENIC SYSTEM AST
79714	INTEGRAL SYSTEM ENTEROBATTERI 4 Test
79718	INTEGRAL SYSTEM STAFILOCOCCHI 4 Test
79720	INTEGRAL SYSTEM STREPTOCOCCHI 4 Test
79724	INTEGRAL SYSTEM GARDNERELLA 4 Test
79822	INTEGRAL SYSTEM YEASTS Plus 4 Test
80009	IODINE MKTT SOLUTION 10 x 10 ml
80010	XLT 4 supplement 2 x 50 ml
80021	GLYCEROL supplement 4 x 50 ml
80022	POTASSIUM TELLURITE 1% suppl. 5 x 10 ml
80031	TWEEN 80 supplement 2 x 50 ml
80040	CHROMATIC™ SALMONELLA Supplement 2x50 ml
80047	MULLER KAUFFMANN 3X50 ml (Iodio/B.G.0,1%)
80053	VITAMIN K 1% supplement 5 x 5 ml
80056	LEGIONELLA growth supplement 10 vials
80057	H2O2 REAGENT 1 x 10 ml
80060	DECONTAM-KIT
80110	UREA 40% 6X100 ml
80219	EGG YOLK emulsion 4 x 50 ml
80252	ENTEROSYSTEM 18R REAGENT 100/200 Test
80253	COPRO SYSTEM REAGENTS (antisera)
80257	LISTERIA SYSTEM 18R -REAG 100/200 Test
80258	AF GENITAL SYSTEM REAGENT
80260	IDENTIF. SYSTEM-REAGENT 100/200 Test
80271	KOVAC'S REAGENT 4x25 ml
80272	FERRIC CHLORIDE 10% 2x 25 ml
80273	NINHYDRIN 7% 10 ml
80275	MIF COLOR KIT 50 Test
80276	ZIEHL-NEELSEN 3 x 250 ml
80277	METHYLENE BLUE Solution 250 ml
80279	VASELINE OIL 4 x 50 ml
80280	V.P. TEST-Reagent 10x10ml
80281	V.P. TEST EP 10 x 10 mL
80282	Kit May-Grünwald Giemsa
80290	SAFRANIN SOLUTION 1000 ml
80291	POTASSIUM TELLURITE 3.5% suppl.5x10 ml
80292	UREA 40 % supplement 10 x 5 ml
80293	GRAM COLOR KIT 4 x 250 ml
80294	KIT COLOR ALBERT 2 x 250 ml
80295	DECOLOURIZING SOLUTION 1000 ml
80296	LUGOL PVP SOLUTION 1000 ML
80298	LUGOL PVP SOLUTION 250 ml
80299	CRYSTAL VIOLET SOLUTION 1000 ml
80300	TTC 1% supplement 5 x 10 ml
80350	ANTIBIOTIC TEST

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80351	RAPID ANTIBIOTIC TEST 50 Test
80380	KINYOUN COLOR KIT 2 x 250 ml
80390	FIXUR 1
80409	IODINE SOLUTION 10 x 10 ml
80410	XLT 4 SUPPLEMENT 4 x 50 ml
80422	POTASSIUM TELLURITE 1% Supplement 10 x 10 ml
80430	TTC 1% supplement 10 x 10 ml
80431	TWEEN 80 Supplement 4 x 50 ml
80453	VITAMIN K 1% SUPPLEMENT 10 x 5 ml
81001	AMPICILLIN supplement 10 vials
81002	LEGIONELLA (BMPA) supplement 10 vials
81003	BRUCELLA supplement 10 vials
81004	CAMPYLOBACTER Preston supplem 10 vials
81006	CN (Pseudomonas) supplement 10 vials
81007	CLOSTRIDIUM difficile suppleme 10 vials
81008	LEGIONELLA (GVPC) supplement 10 vials
81009	IODINE solution 5 x 10 ml
81011	CLOSTRIDIUM perfrigens (T,S.C.) sup.10 v.
81012	LCAT supplement 10 vials
81013	BORDETELLA supplement 10 vials
81014	HAEMOPHILUS supplement 10 vials
81015	CAMPYLOBACTER Butzler supplement 10 vials
81016	BACILLUS Cereus Supplement 10 Vials
81017	CHLORAMPHENICOL supplement 10 vials
81019	LEGIONELLA (MWY) supplement 10 vials
81020	MMG Supplement 10 vials
81022	V.C.N. supplement 10 vials
81023	VITALEX growth supplement 10 vials
81024	V.C.N.T. supplement 10 vials
81025	DERMATOPHYTE supplement 10 vials
81026	LISTERIA PALCAM supplement 10 vials
81032	ONPG 1,5% Supplement 10 vials
81033	GENTAMYCIN supplement 10 vials
81035	MIDDLEBROOK 7H 10 supplement 4 x 50 ml
81036	CAMPYLOBACTER KARMALI Supplement 10 vials
81037	CAMPYLOBACTER CCDA supplement 10 vials
81038	CAMPYLOBACTER C.T.V.N. Supplement 10 vials
81039	YERSINIA supplement 10 vials
81040	GARDNERELLA vaginalis Supplement 10vials
81041	V.C.A.T. supplement 10 vials
81042	LISTERIA FRASER supplement (1125mg)10 vials
81048	CNA (Staf/Strep) supplemet 10 vials
81050	CAMPYLOBACTER growth supplement 10 vials
81051	CAMPYLOBACTER Blaser Wang supp 10 vials
81054	SCHAEDLER supplement 10 vials
81055	CAMPYLOBACTER Skirrow supple 10 vials
81056	LEGIONELLA (BCYE) growth suppl.10 vials
81062	VANCOMYCIN Supplement for VRE 10 vials
81077	CAMPYLOBACTER C.T.V.A. Supplement 10 vials
81078	CHROMATIC™ MRSA Supplement
81079	UREA-ARGININE SCREEN
81082	CEFIXIME TELLURITE Supplement
81083	MEROPENEM Supplement
81084	NEOMYCIN Solution
81085	CHROMATIC™ STAPH AUREUS Supplement
81086	VCC MOD SELECTIVE Supplement
81088	CHROMATIC™ CRE Supplement
81089	Chromatic™ ESBL Supplement
81090	CHROMATIC™ ESBL+AmpC Supplement
81091	Legionella BCYE Growth Supplement w/o L-Cysteine

81098	D-Cycloserine 4-MUP Supplement
85501	COPRO KIT (SELENITE BROTH)
85502	COPRO KIT 2 (SALMONELLA BROTH)
87001	KOVAC'S Reagent
87002	VP (NaOH) Reagent
87003	CATALASE Reagent
87004	PHENYLALANINE Reagent
87005	OXIDASE Reagent
87006	Vaseline Oil
87007	VP (KOH) Reagent
87008	Lactophenol Cotton Blue Droppers
87009	Methyl Red Droppers
87101	GRAM COLOR KIT
88003	OXIDASE TEST SWABS 30 Test
88004	OXIDASE TEST DISCS 30 Discs
88005	O.N.P.G. TEST 30 Test
88006	E.COLI TEST 30 Test
88007	HIPPURATE TEST 30 Test
88008	AESCULIN BILE TEST 30 Test
88009	NITRATI TEST 30 Test 30 Test
88010	LISTERIA MONO TEST 20 Test
88011	UREA RAPID TEST 30 Test
88013	H2S RAPID TEST 30 Test
88014	LYSINE DECARBOXYLASE TEST 30 Test
88015	ORNITHINE DECARBOXYLASE TEST 30 Test
88016	ARGININE DECARBOXYLASE TEST 30 Test
88017	INDOLE TEST 30 Test
88020	S.F. RAPID TEST 30 Test
88021	CAMP TEST-S 30 Test
88023	CATALASI/OXY TEST 30 Test
88024	UREA / INDOLO TEST 30 Test
88027	CAMP TEST-R 30 Test
88028	PEPTIDASE A TEST 30 Test
88029	OXIDASE TEST STICKS 50 Test
88029N	Oxidase Test Stick
88030	COAGULASE TEST 40 Test
88031	GRAM TEST STICK 30 Test
88032	INDOLO TEST STICK 30 Test
88033	BETA LACTAMASE STICKS 30 Test
88034	PEPTIDASE A STICKS 30 Test
88035	VP TEST KIT
88040	C 390 50 Discs
88041	Brilliant Green 100 µg
88042	CITRATE TEST
88043	O129 Disc 150 µg
88044	O129 Disc 10 µg
88105	O.N.P.G. TEST
88201	GALACTOSE TEST 30 Test
88202	GLUCOSE TEST 30 Test
88203	LACTOSE TEST 30 Test
88204	MALTOSE TEST 30 Test
88205	RAFFINOSE TEST 30 Test
88206	SUCROSE TEST 30 Test
88207	ARABITOL TEST 30 Test
88208	ADONITOL TEST 30 Test
88209	ARABINOSE TEST 30 Test
88210	DULCITOL TEST 30 Test
88211	INOSITOL TEST 30 Test
88212	INULIN TEST 30 Test
88213	LEVULOSE TEST 30 Test

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88214	MANNITOL TEST 30 Test
88215	MANNOSE TEST 30 Test
88216	RHAMNOSE TEST 30 Test
88217	SALICIN TEST 30 Test
88218	SORBITOL TEST 30 Test
88219	TREHALOSE TEST 30 Test
88220	XYLOSE TEST 30 Test
89021	CultiControl™ Aspergillus brasiliensis ATCC® 16404™
89022	CultiControl™ Bacillus Cereus ATCC® 11778™
89023	CultiControl™ Bacillus subtilis ATCC® 6633™
89024	CultiControl™ Candida albicans ATCC® 10231™
89025	CultiControl™ Enterococcus faecalis ATCC® 19433™
89026	CultiControl™ Enterococcus faecalis ATCC® 29212™
89027	CultiControl™ Escherichia coli ATCC® 25922™
89028	CultiControl™ Escherichia coli ATCC® 8739™
89029	CultiControl™ Listeria innocua ATCC® 33090™
89030	CultiControl™ Listeria ivanovii ATCC® 19119™
89031	CultiControl™ Listeria monocytogenes ATCC® 19111™
89032	CultiControl™ Proteus mirabilis ATCC® 25933™
89033	CultiControl™ Pseudomonas aeruginosa ATCC® 27853™
89034	CultiControl™ Pseudomonas aeruginosa ATCC® 9027™
89035	CultiControl™ Rhodococcus equi ATCC® 6939™
89036	CultiControl™ Saccharomyces cerevisiae ATCC® 9763™
89037	CultiControl™ Salmonella typhimurium ATCC® 14028™
89038	CultiControl™ Shigella flexneri ATCC® 12022™
89039	CultiControl™ Staphylococcus aureus NCTC 12493
89040	CultiControl™ Staphylococcus aureus ATCC® 25923™
89041	CultiControl™ Staphylococcus aureus ATCC® 29213™
89042	CultiControl™ Staphylococcus aureus ATCC® 33862™
89043	CultiControl™ Staphylococcus aureus ATCC® 43300™
89044	CultiControl™ Staphylococcus aureus ATCC® 6538™
89045	CultiControl™ Staphylococcus epidermidis ATCC® 12228™
89046	CultiControl™ Streptococcus agalactiae ATCC® 13813™
89047	CultiControl™ Streptococcus pneumoniae ATCC® 49619™
89048	CultiControl™ Streptococcus pyogenes ATCC® 19615™
89049	CultiControl™ Proteus mirabilis ATCC® 12453™
89050	CultiControl™ Yersinia enterocolitica ATCC® 9610™
89051	CultiControl™ Listeria monocytogenes ATCC® 19115™
89052	CultiControl™ Legionella pneumophila subsp. pneumophila ATCC® 33152™
89053	CultiControl™ Clostridium pertringens ATCC® 13124™
89054	CultiControl™ Salmonella enterica subsp. enterica serovar Typhimurium ATCC® 13311™
89055	CultiControl™ Lactobacillus paracasei subsp. paracasei ATCC® BAA-52™
89056	CultiControl™ Vibrio parahaemolyticus ATCC® 17802™
89057	CultiControl™ Aspergillus fumigatus ATCC® 204305™
89058	CultiControl™ Shigella sonnei ATCC® 25931™
89059	CultiControl™ Clostridium sordellii ATCC® 9714™
89060	CultiControl™ Listeria monocytogenes ATCC® 7644™
89061	CultiControl™ Streptococcus bovis ATCC® 33317™
89062	CultiControl™ Streptococcus mutans ATCC® 25175™
89063	CultiControl™ Streptococcus pneumoniae ATCC® 27336™
89064	CultiControl™ Streptococcus sanguinis ATCC® 10556™
89065	CultiControl™ Enterobacter cloacae subsp. cloacae ATCC® BAA-1143™
89066	CultiControl™ Enterococcus faecalis ATCC® 49532™
89067	CultiControl™ Enterococcus faecalis ATCC® 49533™
89068	CultiControl™ Escherichia coli NCTC 11954™
89069	CultiControl™ Klebsiella pneumoniae ATCC® BAA-2146™

89070	CultiControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 700603™
89071	CultiControl™ Candida parapsilosis ATCC® 22019™
89072	CultiControl™ Candida albicans ATCC® 90028™
89073	CultiControl™ Issatchenkia orientalis ATCC® 6258™
89074	CultiControl™ Neisseria gonorrhoeae ATCC® 19424™
89075	CultiControl™ Neisseria gonorrhoeae ATCC® 31426™
89076	CultiControl™ Haemophilus influenzae ATCC® 49766™
89077	CultiControl™ Haemophilus influenzae ATCC® 49247™
89078	CultiControl™ Bacteroides fragilis ATCC® 25285™
89079	CultiControl™ Bacteroides thetaiotaomicron ATCC® 29741™
89080	CultiControl™ Lactobacillus acidophilus ATCC® 4356™
89081	CultiControl™ Lactobacillus leichmannii ATCC® 4797™
89082	CultiControl™ Lactococcus lactis ATCC® 19435™
89083	CultiControl™ Proteus mirabilis ATCC® 29906™
89084	CultiControl™ Salmonella enterica subsp. enterica serovar Enteritidis ATCC® 13076™
89085	CultiControl™ Listeria monocytogenes ATCC® 13932™
89086	CultiControl™ Campylobacter jejuni ATCC® 33291™
89087	CultiControl™ Klebsiella pneumoniae ATCC® BAA-1706™
89088	CultiControl™ Klebsiella pneumoniae ATCC® BAA-1705™
89089	CultiControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC® 13883™
89090	CultiControl™ Clostridium difficile ATCC® 9689™
89091	CultiControl™ Aggregatibacter aphrophilus ATCC® 7901™
89092	CultiControl™ Staphylococcus aureus subsp. aureus ATCC® 700698™
89093	CultiControl™ Staphylococcus aureus subsp. aureus ATCC® 700699™
89094	CultiControl™ Plesiomonas shigelloides ATCC® 14029™
89095	CultiControl™ Clostridium sporogenes ATCC® 19404™
89096	CultiControl™ Micrococcus luteus ATCC® 10240™
89097	CultiControl™ Candida tropicalis ATCC® 750™
89098	CultiControl™ Candida krusei ATCC® 14243™
89099	CultiControl™ Gardnerella vaginalis ATCC® 14018™
89100	CultiControl™ Lactobacillus fermentum ATCC® 9338™
89101	CultiControl™ Listeria grayi ATCC® 25401™
89102	CultiControl™ Micrococcus luteus ATCC® 4698™
89103	CultiControl™ Moraxella (Branhamella) catarrhalis ATCC® 25238™
89104	CultiControl™ Neisseria gonorrhoeae ATCC® 49226™
89105	CultiControl™ Proteus mirabilis ATCC® 35659™
89106	CultiControl™ Proteus mirabilis ATCC® 43071™
89107	CultiControl™ Proteus vulgaris ATCC® 6380™
89108	CultiControl™ Pseudomonas aeruginosa ATCC® 10145™
89109	CultiControl™ Pseudomonas aeruginosa ATCC® 15442™
89110	CultiControl™ Pseudomonas fluorescens ATCC® 13525™
89111	CultiControl™ Bacteroides ovatus ATCC® 8483™
89112	CultiControl™ Clostridium histolyticum ATCC® 19401™
89113	CultiControl™ Bacteroides fragilis ATCC® 23745™
89114	CultiControl™ Actinomyces odontolyticus ATCC® 17929™
89115	CultiControl™ Enterococcus faecalis ATCC® 33186™
89116	CultiControl™ Staphylococcus aureus subsp. aureus ATCC® 33591™
89117	CultiControl™ Enterococcus faecium ATCC® 51559™
89118	CultiControl™ Fusobacterium nucleatum ATCC® 25586™
89119	CultiControl™ Aeromonas hydrophila ATCC® 7966™
89120	CultiControl™ Haemophilus influenzae ATCC® 10211™
89121	CultiControl™ Serratia marcescens ATCC® 8100™
89122	CultiControl™ Neisseria gonorrhoeae ATCC® 49981™

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89123	CultiControl™ Haemophilus haemolyticus ATCC ® 33390™
89124	CultiControl™ Haemophilus influenzae ATCC ® 33533™
89125	CultiControl™ Providencia stuartii ATCC ® 33672™
89126	CultiControl™ Staphylococcus haemolyticus ATCC ® 29970™
89127	CultiControl™ Streptococcus anginosus ATCC ® 33397™
89128	CultiControl™ Streptococcus dysgalactiae subsp.equisimilis ATCC ® 12388™
89129	CultiControl™ Streptococcus mitis ATCC ® 6249™
89130	CultiControl™ Streptococcus pyogenes ATCC ® 49399™
89131	CultiControl™ Streptococcus salivarius ATCC® 13419™
89132	CultiControl™ Salmonella enterica subsp. enterica serovar Abony NCTC 6017
89133	CultiControl™ Staphylococcus xylosus ATCC ® 29971™
89134	CultiControl™ Prevotella melaninogenica ATCC ® 25845™
89135	CultiControl™ Propionibacterium acnes ATCC® 11827™
89136	CultiControl™ Haemophilus influenzae NCTC 8468
89137	CultiControl™ Staphylococcus aureus subsp. aureus ATCC ® 19095™
89138	CultiControl™ Cronobacter sakazakii ATCC ® 29544™
89139	CultiControl™ Bordetella bronchiseptica ATCC ® 4617™
89140	CultiControl™ Trichophyton mentagrophytes ATCC ® 9533™
89141	CultiControl™ Acinetobacter baumannii ATCC ® BAA-747™
89144	CultiControl™ Vibrio alginolyticus ATCC ® 17749™
89145	CultiControl™ Campylobacter jejuni subsp. jejuni ATCC ® 33560™
89146	CultiControl™ Citrobacter freundii ATCC ® 43864™
89147	CultiControl™ Burkholderia cepacia ATCC ® 25416™
89148	CultiControl™ Listeria monocytogenes ATCC ® 35152™
89149	CultiControl™ Stenotrophomonas maltophilia ATCC® 13637™
89151	CultiControl™ Legionella pneumophila subsp. fraseri ATCC ® 33156™
89152	CultiControl™ Enterococcus faecium ATCC ® 6057™
89153	CultiControl™ Staphylococcus saprophyticus ATCC ® 15305™
89154	CultiControl™ Salmonella enterica subsp. arizonae ATCC ® 13314™
89155	CultiControl™ Bacillus cereus ATCC ® 10876™
89156	CultiControl™ Enterobacter aerogenes ATCC ® 13048™
89158	CultiControl™ Cronobacter muytjensii ATCC ® 51329™
89159	CultiControl™ Citrobacter freundii ATCC ® 8090™
89160	CultiControl™ Haemophilus influenzae ATCC ® 19418™
89162	CultiControl™ Porphyromonas gingivalis ATCC ® 33277™
89163	CultiControl™ Escherichia coli ATCC ® 35218™
89164	CultiControl™ Neisseria meningitidis ATCC ® 13090™
89165	CultiControl™ Peptostreptococcus anaerobius ATCC ® 27337™
89166	CultiControl™ Burkholderia cepacia ATCC ® 25608™
89167	CultiControl™ Campylobacter jejuni subsp. jejuni ATCC ® 29428™
89168	CultiControl™ Yersinia enterocolitica subsp. enterocolitica ATCC ® 23715™
89170	CultiControl™ Staphylococcus aureus subsp. aureus ATCC ® BAA-44™
89171	CultiControl™ Enterococcus faecium ATCC ® 19434™
89172	CultiControl™ Enterococcus faecium ATCC ® BAA-2319™
89173	CultiControl™ Enterococcus faecalis ATCC ® 51299™
89174	CultiControl™ Acinetobacter baumannii ATCC ® 19606™
89175	CultiControl™ Streptococcus pneumoniae ATCC ® 700671™
89176	CultiControl™ Haemophilus influenzae ATCC ® 33391™
89177	CultiControl™ Candida albicans ATCC ® 18804™
89178	CultiControl™ Candida albicans ATCC ® 64124™
89179	CultiControl™ Shigella boydii ATCC ® 9207™
89180	CultiControl™ Shigella sonnei ATCC ® 9290™
89181	CultiControl™ Staphylococcus aureus subsp. aureus ATCC ® 49476™
89182	CultiControl™ Staphylococcus aureus subsp. aureus ATCC ® 9144™
89183	CultiControl™ Candida albicans ATCC ® 14053™
89184	CultiControl™ Escherichia coli ATCC ® 11303™
89186	CultiControl™ Streptococcus salivarius subsp. thermophilus ATCC ® 19258™
89189	CultiControl™ Nocardia brasiliensis ATCC ® 19296™
89191	CultiControl™ Serratia marcescens ATCC ® 14756™
89192	CultiControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC ® 4352™
89193	CultiControl™ Bacteroides ovatus ATCC ® BAA-1296™
89194	CultiControl™ Stenotrophomonas maltophilia ATCC ® 17666™
89195	CultiControl™ Enterococcus casseliflavus ATCC ® 700327™
89196	CultiControl™ Eikenella corrodens ATCC ® BAA-1152™
89197	CultiControl™ Salmonella enterica subsp. enterica serovar Typhimurium ATCC ® 49416™
89198	CultiControl™ Shigella flexneri ATCC ® 9199™
89199	CultiControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC ® 31488™
89200	CultiControl™ Enterobacter cloacae ATCC ® 49141™
9001	NALIDIXIC ACID NA 30 µg 250 Discs
9001/1	NALIDIXIC ACID NA 30 µg 50 Discs
9002	Oxolinic acid OA 2 µg 250 Discs
9002/1	Oxolinic acid OA 2 µg 50 Discs
9003	PIPEMIDIC ACID PI 20 µg 250 Discs
9003/1	PIPEMIDIC ACID PI 20 µg 50 Discs
9004	AMIKACIN AK 30 µg 250 Discs
9004/1	AMIKACIN AK 30 µg 50 Discs
9005	AMOXICILLIN AML 30 µg 250 Discs
9005/1	AMOXICILLIN AML 30 µg 50 Discs
9006	AMPICILLIN AMP 10 µg 250 Discs
9006/1	AMPICILLIN AMP 10 µg 50 Discs
9007	AZLOCILLIN AZL 75 µg 250 Discs
9007/1	AZLOCILLIN AZL 75 µg 50 Discs
9008	AZTREONAM ATM 30 µg 250 Discs
9008/1	AZTREONAM ATM 30 µg 50 Discs
9009	CARBENICILLIN CAR 100 µg 250 Discs
9009/1	CARBENICILLIN CAR 100 µg 50 Discs
9010	CEFACLOR CEC 30 µg 250 Discs
9010/1	CEFACLOR CEC 30 µg 50 Discs
9011	CEPHALEXIN CL 30 µg 250 Discs
9011/1	CEPHALEXIN CL 30 µg 50 Discs
9013	CEPHALOTHIN KF 30 µg 250 Discs
9013/1	CEPHALOTHIN KF 30 µg 50 Discs
9014	CEFAMANDOLE MA 30 µg 250 Discs
9014/1	CEFAMANDOLE MA 30 µg 50 Discs
9015	CEFAZOLIN KZ 30 µg 250 Discs
9015/1	CEFAZOLIN KZ 30 µg 50 Discs
9016	CEFOPERAZONE CFP 30 µg 250 Discs
9016/1	CEFOPERAZONE CFP 30 µg 50 Discs
9017	CEFOTAXIME CTX 30 µg 250 Discs
9017/1	CEFOTAXIME CTX 30 µg 50 Discs
9018	CEFOXITIN FOX 30 µg 250 Discs
9018/1	CEFOXITIN FOX 30 µg 50 Discs
9019	CEFTAZIDIME CAZ 30 µg 250 Discs
9019/1	CEFTAZIDIME CAZ 30 µg 50 Discs
9020	CEFTRIAXONE CRO 30 µg 250 Discs
9020/1	CEFTRIAXONE CRO 30 µg 50 Discs
9021	CEFUROXIME CXM 30 µg 250 Discs
9021/1	CEFUROXIME CXM 30 µg 50 Discs

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9022	CHLORAMPHENICOL C 30 µg 250 Discs
9022/1	CHLORAMPHENICOL C 30 µg 50 Discs
9023	COLISTIN SULFATE CS 10 µg 250 Discs
9023/1	COLISTIN SULFATE CS 10 µg 50 Discs
9024	ERYTHROMYCIN E 15 µg 250 Discs
9024/1	ERYTHROMYCIN E 15 µg 50 Discs
9025	FOSFOMYCIN FOS 50 µg 250 Discs
9025/1	FOSFOMYCIN FOS 50 µg 50 Discs
9026	GENTAMICIN CN 10 µg 250 Discs
9026/1	GENTAMICIN CN 10 µg 50 Discs
9027	KANAMYCIN K 30 µg 250 Discs
9027/1	KANAMYCIN K 30 µg 50 Discs
9028	LINCOMYCIN MY 2 µg 250 Discs
9028/1	LINCOMYCIN MY 2 µg 50 Discs
9029	METHICILLIN MET 5 µg 250 Discs
9029/1	METHICILLIN MET 5 µg 50 Discs
9030	MINOCYCLINE MN 30 µg 250 Discs
9030/1	MINOCYCLINE MN 30 µg 50 Discs
9031	AMPICILLIN-SULBACTAM AMS 20 µg 250 Discs
9031/1	AMPICILLIN-SULBACTAM AMS 20µg 50 DISCS
9032	NEOMYCIN N 30 µg 250 Discs
9032/1	NEOMYCIN N 30 µg 50 Discs
9033	NETILMICIN NET 30 µg 250 Discs
9033/1	NETILMICIN NET 30 µg 50 Discs
9034	NITROFURANTOIN F 300 µg 250 Discs
9034/1	NITROFURANTOIN F 300 µg 50 Discs
9035	NORFLOXACIN NOR 10µg 250 Discs
9035/1	NORFLOXACIN NOR 10 µg 50 Discs
9036	OXACILLIN OX 1µg 250 Discs
9036/1	OXACILLIN OX 1 µg 50 Discs
9037	PENICILLIN G P 10 IU 250 Discs
9037/1	PENICILLIN G P 10 IU 50 Discs
9038	PIPERACILLIN PRL 100 µg 250 Discs
9038/1	PIPERACILLIN PRL 100 µg 50 Discs
9039	RIFAMPICIN RD 30 µg 250 Discs
9039/1	RIFAMPICIN RD 30 µg 50 Discs
9040	STREPTOMYCIN S 10 µg 250 Discs
9040/1	STREPTOMYCIN S 10 µg 50 Discs
9041	SULFAFURAZOLE SF 300 µg 250 Discs
9041/1	SULFAFURAZOLE SF 300 µg 50 Discs
9042	TRIMETHOPRIM-SULFAMETHOXAZOLE SXT 25 µg 250 Discs
9042/1	TRIMETHOPRIM-SULFAMETHOXAZOLE SXT 25 µg 50 Discs
9043	TETRACYCLINE TE 30 µg 250 Discs
9043/1	TETRACYCLINE TE 30 µg 50 Discs
9044	TOBRAMYCIN TOB 10 µg 250 Discs
9044/1	TOBRAMYCIN TOB 10 µg 50 Discs
9045	VANCOMYCIN VA 30 µg 250 Discs
9045/1	VANCOMYCIN VA 30 µg 50 Discs
9046	SISOMYCIN SIS 30µg 250 Discs
9046/1	SISOMYCIN SIS 30 µg 50 Discs
9047	CLINDAMYCIN CD 2 µg 250 Discs
9047/1	CLINDAMYCIN CD 2 µg 50 Discs
9048	AMOXICILLIN-CLAVULANIC ACID AUG 30 µg 250 Discs
9048/1	AMOXICILLIN-CLAVULANIC ACID AUG 30 µg 50 Discs
9049	FUSIDIC ACID FC 10 µg 250 Discs
9049/1	FUSIDIC ACID FC 10 µg 50 Discs
9050	TEICOPLANIN TEC 30 µg 250 Discs
9050/1	TEICOPLANIN TEC 30 µg 50 Discs
9051	BACITRACIN BA 10 IU 250 Discs
9051/1	BACITRACIN BA 10 IU 50 Discs
9052	CEFADROXIL CDX 30 µg 250 Discs
9052/1	CEFADROXIL CDX 30 µg 50 Discs
9053	CEFSULODIN CSD 30 µg 250 Discs
9053/1	CEFSULODIN CSD 30 µg 50 Discs
9054	CEFTIZOXIME CZX 30 µg 250 Discs
9054/1	CEFTIZOXIME CZX 30 µg 50 Discs
9055	CEPHRADINE CE 30 µg 250 Discs
9055/1	CEPHRADINE CE 30 µg 50 Discs
9056	CIPROFLOXACIN CIP 5 µg 250 Discs
9056/1	CIPROFLOXACIN CIP 5 µg 50 Discs
9057	CINOXACIN CIN 100 µg 250 Discs
9057/1	CINOXACIN CIN 100 µg 50 Discs
9058	CLOXACILLIN CX 5 µg 250 Discs
9058/1	CLOXACILLIN CX 5 µg 50 Discs
9059	DOXYCYCLINE DXT 30 µg 250 Discs
9059/1	DOXYCYCLINE DXT 30 µg 50 Discs
9060	ROXITROMYCIN RXT 15 µg 250 Discs
9060/1	ROXITROMYCIN RXT 15 µg 50 Discs
9061	ERTAPENEM ETP 10 µg 250 Discs
9061/1	ERTAPENEM ETP 10 µg 50 Discs
9062	MEZLOCILLIN MEZ 75 µg 250 Discs
9062/1	MEZLOCILLIN MEZ 75 µg 50 Discs
9063	NOVOBIOCIN NO 30 µg 250 Discs
9063/1	NOVOBIOCIN NO 30 µg 50 Discs
9064	CEFPODOXIME PX 10 ug 250 Discs
9064/1	CEFPODOXIME PX 10 ug 50 Discs
9065	OXYTETRACYCLINE OT 30 µg 250 Discs
9065/1	OXYTETRACYCLINE OT 30 µg 50 Discs
9066	POLYMYXIN B PB 100 IU 250 Discs
9066/1	POLYMYXIN B PB 100 IU 50 Discs
9067	SPECTINOMYCIN SPC 100 µg 250 Discs
9067/1	SPECTINOMYCIN SPC 100 µg 50 Discs
9068	MEROPENEM MRP 10 µg 250 Discs
9068/1	MEROPENEM MRP 10 µg 50 Discs
9069	FLUCONAZOLE FLU 100 µg 250 Discs
9069/1	FLUCONAZOLE FLU 100 µg 50 Discs
9070	TICARCILLIN TC 75 µg 250 Discs
9070/1	TICARCILLIN TC 75 µg 50 Discs
9071	AMPHOTERICIN B AMB 20 µg 250 Discs
9071/1	AMPHOTERICIN B AMB 20 µg 50 Discs
9072	ECONAZOLE ECN 10 µg 250 Discs
9072/1	ECONAZOLE ECN 10 µg 50 Discs
9073	FLUCYTOSINE AFY 1 µg 250 Discs
9073/1	FLUCYTOSINE AFY 1 µg 50 Discs
9074	GRISEOFULVIN AGF 10 µg 250 Discs
9074/1	GRISEOFULVIN AGF 10 µg 50 Discs
9075	KETOCONAZOLE KCA 10 µg 250 Discs
9075/1	KETOCONAZOLE KCA 10 µg 50 Discs
9076	METRONIDAZOLE MTZ 5 µg 250 Discs
9076/1	METRONIDAZOLE MTZ 5 µg 50 Discs
9077	MICONAZOLE MCL 10 µg 250 Discs
9077/1	MICONAZOLE MCL 10 µg 50 Discs
9078	NYSTATIN NY 100 IU 250 Discs
9078/1	NYSTATIN NY 100 IU 50 Discs
9079	IMIPENEM IMI 10 µg 250 Discs
9079/1	IMIPENEM IMI 10 µg 50 Discs
9080	OFLOXACIN OFX 5 µg 250 Discs
9080/1	OFLOXACIN OFX 5 µg 50 Discs
9081	CEFOTETAN CTT 30 µg 250 Discs

9081/1	CEFOTETAN CTT 30 µg 50 Discs
9082	TYLOSIN TY 30 µg 250 Discs
9082/1	TYLOSIN TY 30 µg 50 Discs
9083	TRIMETHOPRIM TM 2,5 µg 250 Discs
9083/1	TRIMETHOPRIM TM 2,5 µg 50 Discs
9084	SULFAMETHOXAZOLE SMX 50 µg 250 Discs
9084/1	SULFAMETHOXAZOLE SMX 50µg 50 Discs
9085	Imipenem + Phenylboronic acid IMI + BO 250 Discs
9085/1	Imipenem + Phenylboronic acid IMI + BO 50 Discs
9086	Imipenem + Cloxacillin IMI + CL 250 Discs
9086/1	Imipenem + Cloxacillin IMI + CL 50 Discs
9087	EDTA ED 250 Discs
9087/1	EDTA ED 50 Discs
9088	SPIRAMYCIN SP 100 µg 250 Discs
9088/1	SPIRAMYCIN SP 100 µg 50 Discs
9089	CEFIXIME CFM 5 µg 250 Discs
9089/1	CEFIXIME CFM 5 µg 50 Discs
9090	Daptomycin DAP 30 µg 250 Discs
9090/1	Daptomycin DAP 30 µg 50 Discs
9091	PEFLOXACIN PEF 5 µg 250 Discs
9091/1	PEFLOXACIN PEF 5 µg 50 Discs
9093	DICLOXACILLIN DCX 1 µg 250 Discs
9093/1	DICLOXACILLIN DCX 1 µg 50 Discs
9094	TIAMULIN T 30 µg 250 Discs
9094/1	TIAMULIN T 30 µg 50 Discs
9095	IMIPENEM/CILASTATIN IMC 20 µg 250 Discs
9095/1	IMIPENEM/CILASTATIN IMC 20 µg 50 Discs
9096	TICARCILLIN-CLAVULINC ACID TTC 85 µg 250 Discs
9096/1	TICARCILLIN-CLAVULINC ACID TTC 85 µg 50 Discs
9097	CLOTRIMAZOLE CLO 50 µg 250 Discs
9097/1	CLOTRIMAZOLE CLO 50 µg 50 Discs
9098	CLARITHROMYCIN CLR 15 µg 250 Discs
9098/1	CLARITHROMYCIN CLR 15 µg 50 Discs
9099	FURAZOLIDON FR 50 µg 250 Discs
9099/1	FURAZOLIDON FR 50 µg 50 Discs
9100	PIPERACILLIN-TAZOBACTAM TZP 110 µg 250 Discs
9100/1	PIPERACILLIN-TAZOBACTAM TZP 110 µg 50 Disc
9101	CEFTIBUTEN CTB 30 µg 250 Discs
9101/1	CEFTIBUTEN CTB 30 µg 50 Discs
9102	LEVOFLOXACIN LEV 5 µg 250 Discs
9102/1	LEVOFLOXACIN LEV 5 µg 50 Discs
9103	MOXIFLOXACIN MOX 5 µg 250 Discs
9103/1	MOXIFLOXACIN MOX 5 µg 50 Discs
9104	CEFEPIME FEP 30 µg 250 Discs
9104/1	CEFEPIME FEP 30 µg 50 Discs
9105	AZITHROMYCIN AZM 15 µg 250 Discs
9105/1	AZITHROMYCIN AZM 15 µg 50 Discs
9106	MYOKAMYCIN MK 15 µg 250 Discs
9106/1	MYOKAMYCIN MK 15 µg 50 Discs
9107	ITRACONAZOLE ITC 50 µg 250 Discs
9107/1	ITRACONAZOLE ITC 50 µg 50 Discs
9108	CEFOPERAZONE CFP 75 µg 250 Discs
9108/1	CEFOPERAZONE CFP 75 µg 50 Discs
9109	FOSFOMYCIN (includes G-6-p) FOS 200 µg 250 Discs
9109/1	FOSFOMYCIN (includes G-6-p) FOS 200 µg 50 Discs
9110	TRIMETHOPRIM TM 5 µg 250 Discs
9110/1	TRIMETHOPRIM TM 5 µg 50 Discs
9111	FUSIDIC ACID FC 30 µg 250 Discs
9111/1	FUSIDIC ACID FC 30 µg 50 Discs
9112	CEFPROZIL CPR 30 µg 250 Discs

9112/1	CEFPROZIL CPR 30 µg 50 Discs
9113	LOMEFLOXACIN LOM 10 µg 250 Discs
9113/1	LOMEFLOXACIN LOM 10 µg 50 Discs
9115	AMPICILLIN AMP 2 µg 250 Discs
9115/1	AMPICILLIN AMP 2 µg 50 Discs
9116	LINCOMYCIN MY 15 µg 250 Discs
9116/1	LINCOMYCIN MY 15 µg 50 Discs
9117	NOVOBIOCIN NO 5 µg 250 Discs
9117/1	NOVOBIOCIN NO 5 µg 50 Discs
9118	RIFAMPICIN RD 5 µg 250 Discs
9118/1	RIFAMPICIN RD 5µg 50 Discs
9119	METRONIDAZOLE MTZ 50 µg 250 Discs
9119/1	METRONIDAZOLE MTZ 50 µg 50 Discs
9120	POLYMYXIN B PB 300 UI 250 Discs
9120/1	POLYMYXIN B PB 300 UI 50 Discs
9121	FOSFOMYCIN (includes G-6-p) FOS 100 µg 250 Discs
9121/1	FOSFOMYCIN (includes G-6-p) FOS 100 µg 50 Discs
9122	AMPLICLOX (Ampicillin-Cloxacillin) ACL 30 µg 250 Discs
9122/1	AMPLICLOX (Ampicillin-Cloxacillin) ACL 30 µg 50 Discs
9124	GENTAMICIN CN 120 µg 250 Discs
9124/1	GENTAMICIN CN 120 µg 50 Discs
9125	GENTAMICIN CN 30 µg 250 Discs
9125/1	GENTAMICIN CN 30 µg 50 Discs
9126	SULFONAMIDE S3 300 µg 250 Discs
9126/1	SULFONAMIDE S3 300 µg 50 Discs
9127	PENICILLIN G P 2 IU 250 Discs
9127/1	PENICILLIN G P 2 IU 50 Discs
9128	CHLORAMPHENICOL C 10 µg 250 Discs
9128/1	CHLORAMPHENICOL C 10 µg 50 Discs
9129	SULBACTAM SU 20µg 250 Discs
9129/1	SULBACTAM SU 20µg 50 Discs
9130	PENICILLIN G P 1 IU 250 Discs
9130/1	PENICILLIN G P 1 IU 50 Discs
9131	SODIUM FUSIDATE FC 30 250 Discs
9132	SULFAPRIM SXT 50 µg 250 Discs
9132/1	SULFAPRIM SXT 50 µg 50 Discs
9133	AMOXICILLIN AML 10 µg 250 Discs
9133/1	AMOXICILLIN AML 10 µg 50 Discs
9134	CEFOTAXIME CTX 75 µg 250 Discs
9134/1	CEFOTAXIME CTX 75 µg 50 Discs
9135	OXACILLIN OX 5µg 250 Discs
9135/1	OXACILLIN OX 5µg 50 Discs
9136	LINEZOLID LNZ 30µg 250 Discs
9136/1	LINEZOLID LNZ 30µg 50 Discs
9137	AMPHOTERICIN B AMB 10 µg 250 Discs
9137/1	AMPHOTERICIN B AMB 10 µg 50 Discs
9139	ITRACONAZOLE ITC 8 µg 250 Discs
9139/1	ITRACONAZOLE ITC 8 µg 50 Discs
9140	KETOCONAZOLE KCA 15 µg 250 Discs
9140/1	KETOCONAZOLE KCA 15 µg 50 Discs
9141	COLISTIN SULFATE CS 30 UI 250 Discs
9141/1	COLISTIN SULFATE CS 30 UI 50 Discs
9143	CEFEPIME+CLAVULANIC ACID FEL 40 µg 250 Discs
9144	Cefoxitin+Cloxacillin FOC 230 µg 250 Discs
9144/1	Cefoxitin+Cloxacillin FOC 230 µg 50 Discs
9145	CEFTAZIDIME+CLAVULANIC ACID CAL 40 µg 250 Discs
9145/1	CEFTAZIDIME+CLAVULANIC ACID CAL 40 µg 50 Discs
9146	CLINDAMYCIN CD 10 µg 250 Discs
9146/1	CLINDAMYCIN CD 10 µg 50 Discs
9147	TIGECYCLIN TGC 15 µg 250 Discs

9147/1	TIGECYCLIN TGC 15 µg 50 Discs
9148	FLUCYTOSINE AFY 10 µg 250 Discs
9148/1	FLUCYTOSINE AFY 10 µg 50 Discs
9150	SULFADIAZINE SUZ 300 ug 250 Discs
9150/1	SULFADIAZINE SUZ 300 ug 50 Discs
9151	AMOXICILLIN AML 2 µg 250 Discs
9151/1	AMOXICILLIN AML 2 µg 50 Discs
9152	CEFOTAXIME CTX 5 µg 250 Discs
9152/1	CEFOTAXIME CTX 5 µg 50 Discs
9153	CEFTAZIDIME CAZ 10 µg 250 Discs
9153/1	CEFTAZIDIME CAZ 10 µg 50 Discs
9154	DORIPENEM DOR 10 µg 250 Discs
9154/1	DORIPENEM DOR 10 µg 50 Discs
9155	LINEZOLID LNZ 10 µg 250 Discs
9155/1	LINEZOLID LNZ 10 µg 50 Discs
9156	MECILLINAM MEC 10 µg 250 Discs
9156/1	MECILLINAM MEC 10 µg 50 Discs
9157	MUPIROCIN MUP 200 µg 250 Discs
9157/1	MUPIROCIN MUP 200 µg 50 Discs
9158	NITROFURANTOIN F 100 µg 250 Discs
9158/1	NITROFURANTOIN F 100 µg 50 Discs
9159	PIPERACILLIN PRL 30 µg 250 Discs
9159/1	PIPERACILLIN PRL 30 µg 50 Discs
9160	PIPERACILLIN-TAZOBACTAM TZP 36 µg 250 Discs
9160/1	PIPERACILLIN-TAZOBACTAM TZP 36 µg 50 Discs
9161	QUINUPRISTIN-DALFOPRISTIN QDA 15 µg 250 Discs
9161/1	QUINUPRISTIN-DALFOPRISTIN QDA 15 µg 50 Discs
9162	STREPTOMYCIN S 300 µg 250 Discs
9162/1	STREPTOMYCIN S 300 µg 50 Discs
9163	TOBRAMYCIN TOB 30 µg 250 Discs
9163/1	TOBRAMYCIN TOB 30 µg 50 Discs
9164	VANCOMYCIN VA 5 µg 250 Discs
9164/1	VANCOMYCIN VA 5 µg 50 Discs
9165	CASPOFUNGIN CAS 5 µg 250 Discs
9165/1	CASPOFUNGIN CAS 5 µg 50 Discs
9166	FLUCONAZOLE FLU 25 µg 250 Discs
9166/1	FLUCONAZOLE FLU 25 µg 50 Discs
9167	POSACONAZOLE POS 5 µg 250 Discs
9167/1	POSACONAZOLE POS 5 µg 50 Discs
9168	VORICONAZOLE VO 1 µg 250 Discs
9168/1	VORICONAZOLE VO 1 µg 50 Discs
9169	GATIFLOXACIN GAT 5 µg 250 Discs
9169/1	GATIFLOXACIN GAT 5 µg 50 Discs
9170	NETILMICIN NET 10 µg 250 Discs
9170/1	NETILMICIN NET 10 µg 50 Discs
9171	PHENOXYMETHYLPENICILLIN PV 10 µg 250 Discs
9171/1	PHENOXYMETHYLPENICILLIN PV 10 µg 50 Discs
9172	TELITHROMYCIN TEL 15 µg 250 Discs
9172/1	TELITHROMYCIN TEL 15 µg 50 Discs
9173	LORACARBEF LOR 30 µg 250 Discs
9173/1	LORACARBEF LOR 30 µg 50 Discs
9174	NAFCILLIN NAF 1 µg 250 Discs
9174/1	NAFCILLIN NAF 1 µg 50 Discs
9175	MEROPENEM+CLOXACILLIN MR+CL 250 Discs
9175/1	MEROPENEM+CLOXACILLIN MR+CL 50 Discs
9176	Meropenem + Phenylboronic acid MR + BO 250 Discs
9176/1	Meropenem + Phenylboronic acid MR + BO 50 Discs
9177	MEROPENEM+DIPICOLINIC ACID MR+DP 250 Discs
9177/1	MEROPENEM+DIPICOLINIC ACID MR+DP 50 Discs
9178	Meropenem + EDTA MR + ED 250 Discs

9178/1	Meropenem + EDTA MR + ED 50 Discs
9179	AMOXICILLIN AML 25 µg 250 Discs
9179/1	AMOXICILLIN AML 25 µg 50 Discs
9180	ERYTHROMYCIN E 2 µg 250 Discs
9180/1	ERYTHROMYCIN E 2 µg 50 Discs
9181	NITROFURANTOIN F 50 µg 250 Discs
9181/1	NITROFURANTOIN F 50 µg 50 Discs
9182	CEFOTAXIME+CLAVULANIC ACID CTL 40 µg 250 Discs
9182/1	CEFOTAXIME+CLAVULANIC ACID CTL 40 µg 50 Discs
9183	Imipenem + EDTA IMI + ED 250 Discs
9183/1	Imipenem + EDTA IMI + ED 50 Discs
9184	COLISTIN SULFATE CS 25 µg 250 Discs
9184/1	COLISTIN SULFATE CS 25 µg 50 Discs
9185	CEFPIROME CR 30 µg 250 Discs
9185/1	CEFPIROME CR 30 µg 50 Discs
9186	TEMOCILLIN TMO 30 µg 250 Discs
9186/1	TEMOCILLIN TMO 30 µg 50 Discs
9187	Sulfamethoxazole SMX 100 µg 250 Discs
9187/1	Sulfamethoxazole SMX 100 µg 50 Discs
9188	Metronidazole MTZ 10 µg 250 Discs
9188/1	Metronidazole MTZ 10 µg 50 Discs
9189	MUPIROCIN MUP 5 µg 250 Discs
9190	CEFPODOXIME+CLAVULANIC ACID PXL 11 µg 250 Discs
9190/1	CEFPODOXIME+CLAVULANIC ACID PXL 11 µg 50 Discs
9191	AMOXICILLIN-CLAVULANIC ACID AUG 3 µg 250 Discs
9191/1	AMOXICILLIN-CLAVULANIC ACID AUG 3 µg 50 Discs
9192	ROKITAMYCIN ROK 30 µg 250 Discs
9192/1	ROKITAMYCIN ROK 30 µg 50 Discs
9193	Phenylboronic acid BO 250 Discs
9193/1	Phenylboronic acid BO 50 Discs
9194	DIPICOLINIC ACID DP 250 Discs
9194/1	DIPICOLINIC ACID DP 50 Discs
9195	CEFTAROLINE CPT 5 µg 250 Discs
9195/1	CEFTAROLINE CPT 5 µg 50 Discs
9198	CEFTAROLINE CPT 30 µg 250 Discs
9198/1	CEFTAROLINE CPT 30 µg 50 Discs
9199	ERTAPENEM+CLOXACILLIN ET+CL 250 Discs
9199/1	ERTAPENEM+CLOXACILLIN ET+CL 50 Discs
9202	Ertapenem+Phenylboronic acid ET+BO 250 Discs
9202/1	Ertapenem+Phenylboronic acid ET+BO 50 Discs
9203	Cefotaxime+Clavulanic acid+Cloxacillin CTLC 250 Discs
9203/1	Cefotaxime+Clavulanic acid+Cloxacillin CTLC 50 Discs
9204	Ceftazidime+Clavulanic acid+Cloxacillin CALC 250 Discs
9204/1	Ceftazidime+Clavulanic acid+Cloxacillin CALC 50 Discs
9205	Ceftazidime-avibactam CZA 50 µg 250 Discs
9205/1	Ceftazidime -avibactam CZA 50 µg 50 Discs
9206	Ceftazidime -avibactam CZA 14 µg 250 Discs
9206/1	Ceftazidime-avibactam CZA 14 µg 50 Discs
9209	Nitroxolin NI 30 µg
9209/1	Nitroxolin NI 30 µg
9219	Cefepime FEP 5 µg
9219/1	Cefepime FEP 5 µg
9220	Cefepime FEP 10 µg
9220/1	Cefepime FEP 10 µg
9224	Cefotaxime + Cloxacillin CTC
9224/1	Cefotaxime + Cloxacillin CTC
9225	Ceftazidime + Cloxacillin CAC
9225/1	Ceftazidime + Cloxacillin CAC
9246	Ceftolozane-tazobactam CT 40 µg

9246/1	Ceftolozane-tazobactam C/T 40 µg
9247	Solithromycin SOL 15 µg 250 Discs
9247/1	Solithromycin SOL 15 µg 50 Discs
9248	Rifampicin 2 µg
9248/1	Rifampicin 2 µg
91200	DISC DISPENSER 8 CARTRIDGES
91203	DISC DISPENSER 6 CARTRIDGES
92000	AMOX*/SULB 2/1 AXS 0.016-256* 30 MIC Test
920000	AMOX*/SULB 2/1 AXS 0.016-256* 100 MIC Test
92001	Rifampicin RD 0.002-32 mg/L 30 MIC Test
920010	Rifampicin RD 0.002-32 mg/L 100 MIC Test
920011	Rifampicin RD 0.002-32 mg/L 10 MIC Test
92002	Fusidic Acid FU 0.016-256 mg/L 30 MIC Test
920020	Fusidic Acid FU 0.016-256 mg/L 100 MIC Test
920021	Fusidic Acid FU 0.016-256 mg/L 10 MIC Test
92003	Ampicillin AMP 0.016-256 mg/L 30 MIC Test
920030	Ampicillin AMP 0.016-256 mg/L 100 MIC Test
920031	Ampicillin AMP 0.016-256 mg/L 10 MIC Test
92004	Polymyxin B PB 0.064-1024 mg/L 30 MIC Test
920040	Polymyxin B PB 0.064-1024 mg/L 100 MIC Test
920041	Polymyxin B PB 0.064-1024 mg/L 10 MIC Test
92005	Cefpodoxime PX 0.016-256 mg/L 30 MIC Test
920050	Cefpodoxime PX 0.016-256 mg/L 100 MIC Test
920051	Cefpodoxime PX 0.016-256 mg/L 10 MIC Test
92006	Cefotaxime CTX 0.016-256 mg/L 30 MIC Test
920060	Cefotaxime CTX 0.016-256 mg/L 100 MIC Test
920061	Cefotaxime CTX 0.016-256 mg/L 10 MIC Test
92007	Cefotaxime CTX 0.002-32 mg/L 30 MIC Test
920070	Cefotaxime CTX 0.002-32 mg/L 100 MIC Test
920071	Cefotaxime CTX 0.002-32 mg/L 10 MIC Test
92008	Cefpirome CR 0.016-256 mg/L 30 MIC Test
920080	Cefpirome CR 0.016-256 mg/L 100 MIC Test
920081	Cefpirome CR 0.016-256 mg/L 10 MIC Test
92009	Gentamicin CN 0.016-256 mg/L 30 MIC Test
920090	Gentamicin CN 0.016-256 mg/L 100 MIC Test
920091	Gentamicin CN 0.016-256 mg/L 10 MIC Test
92010	Gentamicin CN 0.064-1024 mg/L 30 MIC Test
920100	Gentamicin CN 0.064-1024 mg/L 100 MIC Test
920101	Gentamicin CN 0.064-1024 mg/L 10 MIC Test
92011	Gatifloxacin GAT 0.002-32 mg/L 30 MIC Test
920110	Gatifloxacin GAT 0.002-32 mg/L 100 MIC Test
920111	Gatifloxacin GAT 0.002-32 mg/L 10 MIC Test
92012	Teicoplanin TEC 0.016-256 mg/L 30 MIC Test
920120	Teicoplanin TEC 0.016-256 mg/L 100 MIC Test
920121	Teicoplanin TEC 0.016-256 mg/L 10 MIC Test
92013	Enrofloxacin ENR 0.002-32 mg/L 30 MIC Test
920130	Enrofloxacin ENR 0.002-32 mg/L 100 MIC Test
920131	Enrofloxacin ENR 0.002-32 mg/L 10 MIC Test
92014	Spectinomycin SPC 0.064-1024 mg/L MIC Test
920140	Spectinomycin SPC 0.064-1024 mg/L 100 MICTest
920141	Spectinomycin SPC 0.064-1024 mg/L 10 MIC Test
92015	Oxacillin OX 0.016-256 mg/L 30 MIC Test
920150	Oxacillin OX 0.016-256 mg/L 100 MIC Test
920151	Oxacillin OX 0.016-256 mg/L 10 MIC Test
92016	Ceftizoxime CZX 0.016-256 mg/L 30 MIC Test
920160	Ceftizoxime CZX 0.016-256 mg/L 100 MIC Test
920161	Ceftizoxime CZX 0.016-256 mg/L 10 MIC Test
92017	Mecillinam MEC 0.016-256 mg/L 30 MIC Test
920170	Mecillinam MEC 0.016-256 mg/L 100 MIC Test
920171	Mecillinam MEC 0.016-256 mg/L 10 MIC Test

92018	Amikacin AK 0.016-256 mg/L 30 MIC Test
920180	Amikacin AK 0.016-256 mg/L 100 MIC Test
920181	Amikacin AK 0.016-256 mg/L 10 MIC Test
92019	Bacitracin BA 0.016-256 mg/L 30 MIC Test
920190	Bacitracin BA 0.016-256 mg/L 100 MIC Test
920191	Bacitracin BA 0.016-256 mg/L 10 MIC Test
92020	Cefoxetan CTT 0.016-256 mg/L 30 MIC Test
920200	Cefoxetan CTT 0.016-256 mg/L 100 MIC Test
920201	Cefoxetan CTT 0.016-256 mg/L 10 MIC Test
92021	Amoxicillin AML 0.016-256 mg/L 30 MIC Test
920210	Amoxicillin AML 0.016-256 mg/L 100 MIC Test
920211	Amoxicillin AML 0.016-256 mg/L 10 MIC Test
92022	Nitrofurantoin F 0.032-512 mg/L 30 MIC Test
920220	Nitrofurantoin F 0.032-512 mg/L 100 MIC Test
920221	Nitrofurantoin F 0.032-512 mg/L 10 MIC Test
92023	Cefoperazone* - sulbactam (2/1) CPS 0.016-256* mg/L 30 MIC Test
920230	Cefoperazone* - sulbactam (2/1) CPS 0.016-256* mg/L 100 MIC Test
920231	Cefoperazone* - sulbactam (2/1) CPS 0.016-256* mg/L 10 MIC Test
92024	Amoxicillin* - clavulanic acid (2/1) AUG 0.016-256* mg/L 30 MIC Test
920240	Amoxicillin* - clavulanic acid (2/1) AUG 0.016-256* mg/L 100 MIC Test
920241	Amoxicillin* - clavulanic acid (2/1) AUG 0.016-256* mg/L 10 MIC Test
92025	Rifampicin RD 0.016-256 mg/L 30 MIC Test
920250	Rifampicin RD 0.016-256 mg/L 100 MIC Test
920251	Rifampicin RD 0.016-256 mg/L 10 MIC Test
92026	Quinupristin-dalfopristin QDA 0.002-32 mg/L 30 MIC Test
920260	Quinupristin-dalfopristin QDA 0.002-32 mg/L 100 MIC Test
920261	Quinupristin-dalfopristin QDA 0.002-32 mg/L 10 MIC Test
92027	Ampicillin* - sulbactam (2/1) AMS 0.016-256* mg/L 30 MIC Test
920270	Ampicillin* - sulbactam (2/1) AMS 0.016-256* mg/L 100 MIC Test
920271	Ampicillin* - sulbactam (2/1) AMS 0.016-256* mg/L 10 MIC Test
92028	Sulbactam SUL 0.016-256 mg/L 30 MIC Test
920280	Sulbactam SUL 0.016-256 mg/L 100 MIC Test
920281	Sulbactam SUL 0.016-256 mg/L 10 MIC Test
92029	Temocillin TMO 0.064-1024 mg/L 30 MIC Test
920290	Temocillin TMO 0.064-1024 mg/L 100 MIC Test
920291	Temocillin TMO 0.064-1024 mg/L 10 MIC Test
92030	Azithromycin AZM 0.016-256 mg/L 30 MIC Test
920300	Azithromycin AZM 0.016-256 mg/L 100 MIC Test
920301	Azithromycin AZM 0.016-256 mg/L 10 MIC Test
92031	Sulfamethoxazole SMX 0.064-1024 mg/L 30 MIC Test
920310	Sulfamethoxazole SMX 0.064-1024 mg/L 100 MIC Test
920311	Sulfamethoxazole SMX 0.064-1024 mg/L 10 MIC Test
92032	Minocycline MN 0.016-256 mg/L 30 MIC Test
920320	Minocycline MN 0.016-256 mg/L 100 MIC Test
920321	Minocycline MN 0.016-256 mg/L 10 MIC Test
92033	Aztreonam ATM 0.016-256 mg/L 30 MIC Test
920330	Aztreonam ATM 0.016-256 mg/L 100 MIC Test
920331	Aztreonam ATM 0.016-256 mg/L 10 MIC Test
92034	Kanamycin K 0.016-256 mg/L 30 MIC Test
920340	Kanamycin K 0.016-256 mg/L 100 MIC Test
920341	Kanamycin K 0.016-256 mg/L 10 MIC Test
92035	Gemifloxacin GEM 0.002-32 mg/L 30 MIC Test
920350	Gemifloxacin GEM 0.002-32 mg/L 100 MIC Test
920351	Gemifloxacin GEM 0.002-32 mg/L 10 MIC Test
92036	Cefaclor CEC 0.016-256 mg/L 30 MIC Test

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920360	Cefaclor CEC 0.016-256 mg/L 100 MIC Test
920361	Cefaclor CEC 0.016-256 mg/L 10 MIC Test
92037	Trimethoprim TM 0.002-32 mg/L 30 MIC Test
920370	Trimethoprim TM 0.002-32 mg/L 100 MIC Test
920371	Trimethoprim TM 0.002-32 mg/L 10 MIC Test
92038	Mupirocin MUP 0.064-1024 mg/L 30 MIC Test
920380	Mupirocin MUP 0.064-1024 mg/L 100 MIC Test
920381	Mupirocin MUP 0.064-1024 mg/L 10 MIC Test
92039	Cephalotin KF 0.016-256 mg/L 30 MIC Test
920390	Cephalotin KF 0.016-256 mg/L 0.016-256 100 MIC Test
920391	Cephalotin KF 0.016-256 mg/L 10 MIC Test
92040	Doripenem DOR 0.002-32 mg/L 30 MIC Test
920400	Doripenem DOR 0.002-32 mg/L 100 MIC Test
920401	Doripenem DOR 0.002-32 mg/L 10 MIC Test
92041	Pefloxacin PEF 0.016-256 mg/L 30 MIC Test
920410	Pefloxacin PEF 0.016-256 mg/L 100 MIC Test
920411	Pefloxacin PEF 0.016-256 mg/L 10 MIC Test
92042	Ceftriaxone CRO 0.016-256 mg/L 30 MIC Test
920420	Ceftriaxone CRO 0.016-256 mg/L 100 MIC Test
920421	Ceftriaxone CRO 0.016-256 mg/L 10 MIC Test
92043	Ceftriaxone CRO 0.002-32 mg/L 30 MIC Test
920430	Ceftriaxone CRO 0.002-32 mg/L 100 MIC Test
920431	Ceftriaxone CRO 0.002-32 mg/L 10 MIC Test
92044	Cloxacillin CX 0.016-256 mg/L 30 MIC Test
920440	Cloxacillin CX 0.016-256 mg/L 100 MIC Test
920441	Cloxacillin CX 0.016-256 mg/L 10 MIC Test
92045	Ciprofloxacin CIP 0.002-32 mg/L 30 MIC Test
920450	Ciprofloxacin CIP 0.002-32 mg/L 100 MIC Test
920451	Ciprofloxacin CIP 0.002-32 mg/L 10 MIC Test
92046	Spiramycin SP 0.002-32 mg/L 30 MIC Test
920460	Spiramycin SP 0.002-32 mg/L 100 MIC Test
920461	Spiramycin SP 0.002-32 mg/L 10 MIC Test
92048	Clarithromycin CLR 0.016-256 mg/L 30 MIC Test
920480	Clarithromycin CLR 0.016-256 mg/L 100 MIC Test
920481	Clarithromycin CLR 0.016-256 mg/L 10 MIC Test
92049	Ceftaroline CPT 0.016-256 mg/L 30 MIC Test
920490	Ceftaroline CPT 0.016-256 mg/L 100 MIC Test
920491	Ceftaroline CPT 0.016-256 mg/L 10 MIC Test
92050	Fosmidomycin FOM 0.016-256 mg/L 30 MIC Test
920500	Fosmidomycin FOM 0.016-256 mg/L 100 MIC Test
920501	Fosmidomycin FOM 0.016-256 mg/L 10 MIC Test
92051	Erythromycin E 0.016-256 mg/L 30 MIC Test
920510	Erythromycin E 0.016-256 mg/L 100 MIC Test
920511	Erythromycin E 0.016-256 mg/L 10 MIC Test
92052	Telavancin TLV 0.002-32 mg/L 30 MIC Test
920520	Telavancin TLV 0.002-32 mg/L 100 MIC Test
920521	Telavancin TLV 0.002-32 mg/L 10 MIC Test
92053	Telavancin TLV 0.016-256 mg/L 30 MIC Test
920530	Telavancin TLV 0.016-256 mg/L 100 MIC Test
920531	Telavancin TLV 0.016-256 mg/L 10 MIC Test
92054	Imipenem IMI 0.002-32 mg/L 30 MIC Test
920540	Imipenem IMI 0.002-32 mg/L 100 MIC Test
920541	Imipenem IMI 0.002-32 mg/L 10 MIC Test
92056	Ceftaroline CPT 0.002-32 mg/L 30 MIC Test
920560	Ceftaroline CPT 0.002-32 mg/L 100 MIC Test
920561	Ceftaroline CPT 0.002-32 mg/L 10 MIC Test
92057	Vancomycin VA 0.016-256 mg/L 30 MIC Test
920570	Vancomycin VA 0.016-256 mg/L 100 MIC Test
920571	Vancomycin VA 0.016-256 mg/L 10 MIC Test
92058	Ceftibuten CTB 0.002-32 mg/L 30 MIC Test

920580	Ceftibuten CTB 0.002-32 mg/L 100 MIC Test
920581	Ceftibuten CTB 0.002-32 mg/L 10 MIC Test
92060	Cefixime CFM 0.016-256 mg/L 30 MIC Test
920600	Cefixime CFM 0.016-256 mg/L 100 MIC Test
920601	Cefixime CFM 0.016-256 mg/L 10 MIC Test
92066	Celoxitin FOX 0.016-256 mg/L 30 MIC Test
920660	Celoxitin FOX 0.016-256 mg/L 100 MIC Test
920661	Celoxitin FOX 0.016-256 mg/L 10 MIC Test
92070	Plazomicin PLZ 0.016-256 mg/L 30 MIC Test
920700	Plazomicin PLZ 0.016-256 mg/L 100 MIC Test
920701	Plazomicin PLZ 0.016-256 mg/L 10 MIC Test
92072	Clindamycin CD 0.016-256 mg/L 30 MIC Test
920720	Clindamycin CD 0.016-256 mg/L 100 MIC Test
920721	Clindamycin CD 0.016-256 mg/L 10 MIC Test
92074	Meropenem-vaborbactam (8 mg/L) M/V 0.016-256mg/L 30 MIC Test
920740	Meropenem-vaborbactam (8 mg/L) M/V 0.016-256mg/L 100 MIC Test
920741	Meropenem-vaborbactam (8 mg/L) M/V 0.016-256mg/L 10 MIC Test
92075	Chloramphenicol C 0.016-256 mg/L 30 MIC Test
920750	Chloramphenicol C 0.016-256 mg/L 100 MIC Test
920751	Chloramphenicol C 0.016-256 mg/L 10 MIC Test
92078	Fosfomycin FOS 0.016-256 mg/L 30 MIC Test
920780	Fosfomycin FOS 0.016-256 mg/L 100 MIC Test
920781	Fosfomycin FOS 0.016-256 mg/L 10 MIC Test
92079	Fosfomycin FOS 0.064-1024 mg/L 30 MIC Test
920790	Fosfomycin FOS 0.064-1024 mg/L 100 MIC Test
920791	Fosfomycin FOS 0.064-1024 mg/L 10 MIC Test
92080	Delafloxacin DLX 0.002-32 mg/L 30 MIC Test
920800	Delafloxacin DLX 0.002-32 mg/L 100 MIC Test
920801	Delafloxacin DLX 0.002-32 mg/L 10 MIC Test
92081	Levofloxacin LEV 0.002-32 mg/L 30 MIC Test
920810	Levofloxacin LEV 0.002-32 mg/L 100 MIC Test
920811	Levofloxacin LEV 0.002-32 mg/L 10 MIC Test
92084	Meropenem MRP 0.002-32 mg/L 30 MIC Test
920840	Meropenem MRP 0.002-32 mg/L 100 MIC Test
920841	Meropenem MRP 0.002-32 mg/L 10 MIC Test
92085	Meropenem MRP 0.016-256 mg/L 30 MIC Test
920850	Meropenem MRP 0.016-256 mg/L 100 MIC Test
920851	Meropenem MRP 0.016-256 mg/L 10 MIC Test
92087	Metronidazole MTZ 0.016-256 mg/L 30 MIC Test
920870	Metronidazole MTZ 0.016-256 mg/L 100 MIC Test
920871	Metronidazole MTZ 0.016-256 mg/L 10 MIC Test
92090	Moxifloxacin MXF 0.002-32 mg/L 30 MIC Test
920900	Moxifloxacin MXF 0.002-32 mg/L 100 MIC Test
920901	Moxifloxacin MXF 0.002-32 mg/L 10 MIC Test
92093	Netilmicin NET 0.016-256 mg/L 30 MIC Test
920930	Netilmicin NET 0.016-256 mg/L 100 MIC Test
920931	Netilmicin NET 0.016-256 mg/L 10 MIC Test
92096	Norfloxacin NOR 0.016-256 mg/L 30 MIC Test
920960	Norfloxacin NOR 0.016-256 mg/L 100 MIC Test
920961	Norfloxacin NOR 0.016-256 mg/L 10 MIC Test
92099	Ofloxacin OFX 0.002-32 mg/L 30 MIC Test
920990	Ofloxacin OFX 0.002-32 mg/L 100 MIC Test
920991	Ofloxacin OFX 0.002-32 mg/L 10 MIC Test
92102	Penicillin G P 0.016-256 mg/L 30 MIC Test
921020	Penicillin G P 0.016-256 mg/L 100 MIC Test
921021	Penicillin G P 0.016-256 mg/L 10 MIC Test
92103	Penicillin G P 0.002-32 mg/L 30 MIC Test
921030	Penicillin G P 0.002-32 mg/L 100 MIC Test
921031	Penicillin G P 0.002-32 mg/L 10 MIC Test

92105	Piperacillin PIP 0,016-256 mg/L 30 MIC Test
921050	Piperacillin PIP 0,016-256 mg/L 100 MIC Test
921051	Piperacillin PIP 0,016-256 mg/L 10 MIC Test
92108	Piperacillin* - tazobactam TZP 0,016-256* mg/L 30 MICTest
921080	Piperacillin* - tazobactam TZP 0,016-256* mg/L 100 MIC Test
921081	Piperacillin* - tazobactam TZP 0,016-256* mg/L 10 MIC Test
92111	Streptomycin S 0,064-1024 mg/L 30 MIC Test
921110	Streptomycin S 0,064-1024 mg/L 100 MIC Test
921111	Streptomycin S 0,064-1024 mg/L 10 MIC Test
92112	Streptomycin S 0,016-256 mg/L 30 MIC Test
921120	Streptomycin S 0,016-256 mg/L 100 MIC Test
921121	Streptomycin S 0,016-256 mg/L 10 MIC Test
92114	Tetracycline TE 0,016-256 mg/L 30 MIC Test
921140	Tetracycline TE 0,016-256 mg/L100 MIC Test
921141	Tetracycline TE 0,016-256 mg/L 10 MIC Test
92117	Ticarcillin* - clavulanic acid TTC 0,016-256* mg/L 30 MIC Test
921170	Ticarcillin* - clavulanic acid TTC 0,016-256* mg/L 100 MIC Test
921171	Ticarcillin* - clavulanic acid TTC 0,016-256* mg/L 10 MIC Test
92120	Tobramycin TOB 0,064-1024 mg/L 30 MIC Test
921200	Tobramycin TOB 0,064-1024 mg/L 100 MIC Test
921201	Tobramycin TOB 0,064-1024 mg/L 10 MIC Test
92121	Tobramycin TOB 0,016-256 mg/L 30 MIC Test
921210	Tobramycin TOB 0,016-256 mg/L 100 MIC Test
921211	Tobramycin TOB 0,016-256 mg/L 10 MIC Test
92123	Trimethoprim* - sulfamethoxazole (1/19) SXT 0,002-32* mg/L 30 MIC Test
921230	Trimethoprim*-sulfamethoxazole (1/19) SXT 0,002-32* mg/L 100 MIC Test
921231	Trimethoprim*-sulfamethoxazole (1/19) SXT 0,002-32* mg/L 10 MIC Test
92126	Cefepime FEP 0,016-256 mg/L 30 MIC Test
921260	Cefepime FEP 0,016-256 mg/L 100 MIC Test
921261	Cefepime FEP 0,016-256 mg/L 10 MIC Test
92127	Cefepime FEP 0,002-32 mg/L 30 MIC Test
921270	Cefepime FEP 0,002-32 mg/L 100 MIC Test
921271	Cefepime FEP 0,002-32 mg/L 10 MIC Test
92129	Cefuroxime CXM 0,016-256 mg/L 30 MIC Test
921290	Cefuroxime CXM 0,016-256 mg/L 100 MIC Test
921291	Cefuroxime CXM 0,016-256 mg/L 10 MIC Test
92132	Nalidixic Acid NA 0,016-256 mg/L 30 MIC Test
921320	Nalidixic Acid NA 0,016-256 mg/L 100 MIC Test
921321	Nalidixic Acid NA 0,016-256 mg/L 10 MIC Test
92135	Linezolid LNZ 0,016-256 mg/L 30 MIC Test
921350	Linezolid LNZ 0,016-256 mg/L 100 MIC Test
921351	Linezolid LNZ 0,016-256 mg/L 10 MIC Test
92136	Tedizolid TZD 0,002-32 mg/L 30 MIC Test
921360	Tedizolid TZD 0,002-32 mg/L 100 MIC Test
921361	Tedizolid TZD 0,002-32 mg/L 10 MIC Test
92137	Dalbavancin DAL 0,002-32 mg/L 30 MIC Test
921370	Dalbavancin DAL 0,002-32 mg/L 100 MIC Test
921371	Dalbavancin DAL 0,002-32 mg/L 10 MIC Test
92138	Ceftazidime CAZ 0,016-256 mg/L 30 MIC Test
921380	Ceftazidime CAZ 0,016-256 mg/L 100 MIC Test
921381	Ceftazidime CAZ 0,016-256 mg/L 10 MIC Test
92139	Ceftazidime*- avibactam CZA 0,016-256* mg/L 30 MIC Test
921390	Ceftazidime*- avibactam CZA 0,016-256* mg/L 100 MIC Test
921391	Ceftazidime*- avibactam CZA 0,016-256* mg/L 10 MIC Test
92140	Ceftobiprole BPR 0,002-32 mg/L 30 MIC Test

921400	Ceftobiprole BPR 0,002-32 mg/L 100 MIC Test
921401	Ceftobiprole BPR 0,002-32 mg/L 10 MIC Test
92141	Colistin CS 0,016-256 mg/L 30 MIC Test
921410	Colistin CS 0,016-256 mg/L 100 MIC Test
921411	Colistin CS 0,016-256 mg/L 10 MIC Test
92142	Colistin CS 0,064-1024 mg/L 30 MIC Test
921420	Colistin CS 0,064-1024 mg/L 100 MIC Test
921421	Colistin CS 0,064-1024 mg/L 10 MIC Test
92144	Tigecycline TGC 0,016-256 mg/L 30 MIC Test
921440	Tigecycline TGC 0,016-256 mg/L 100 MIC Test
921441	Tigecycline TGC 0,016-256 mg/L 10 MIC Test
92145	Daptomycin DAP 0,016-256 mg/L 30 MIC Test
921450	Daptomycin DAP 0,016-256 mg/L 100 MIC Test
921451	Daptomycin DAP 0,016-256 mg/L 10 MIC Test
92146	Ceftolozane*-tazobactam C/T 0,016-256* mg/L 30 MIC Test
921460	Ceftolozane*-tazobactam C/T 0,016-256* mg/L 100 MIC Test
921461	Ceftolozane*-tazobactam C/T 0,016-256* mg/L 10 MIC Test
92147	Fluconazole FLU 0,016-256 mg/L 30 MIC Test
921470	Fluconazole FLU 0,016-256 mg/L 100 MIC Test
921471	Fluconazole FLU 0,016-256 mg/L 10 MIC Test
92148	Itraconazole ITC 0,002-32 mg/L 30 MIC Test
921480	Itraconazole ITC 0,002-32 mg/L 100 MIC Test
921481	Itraconazole ITC 0,002-32 mg/L 10 MIC Test
92149	Flucytosine FC 0,002-32 mg/L 30 MIC Test
921490	Flucytosine FC 0,002-32 mg/L 100 MIC Test
921491	Flucytosine FC 0,002-32 mg/L 10 MIC Test
92150	Voriconazole VO 0,002-32 mg/L 30 MIC Test
921500	Voriconazole VO 0,002-32 mg/L 100 MIC Test
921501	Voriconazole VO 0,002-32 mg/L 10 MIC Test
92151	Ketoconazole KE 0,002-32 mg/L 30 MIC Test
921510	Ketoconazole KE 0,002-32 mg/L 100 MIC Test
921511	Ketoconazole KE 0,002-32 mg/L 10 MIC Test
92152	Posaconazole POS 0,002-32 mg/L 30 MIC Test
921520	Posaconazole POS 0,002-32 mg/L 100 MICTest
921521	Posaconazole POS 0,002-32 mg/L 10 MIC Test
92153	Amphotericin B AMB 0,002-32 mg/L 30 MIC Test
921530	Amphotericin B AMB 0,002-32 mg/L 100 MICTest
921531	Amphotericin B AMB 0,002-32 mg/L 10 MIC Test
92154	Caspofungin CAS 0,002-32 mg/L 30 MIC Test
921540	Caspofungin CAS 0,002-32 mg/L 100 MIC Test
921541	Caspofungin CAS 0,002-32 mg/L 10 MIC Test
92155	Anidulafungin AND 0,002-32 mg/L 30 MIC Test
921550	Anidulafungin AND 0,002-32 mg/L 100 Test
921551	Anidulafungin AND 0,002-32 mg/L 10 MIC Test
92156	Doxycycline DXT 0,016-256 mg/L 30 MIC Test
921560	Doxycycline DXT 0,016-256 mg/L 100 MIC Test
921561	Doxycycline DXT 0,016-256 mg/L 10 MIC Test
92157	Ertapenem ETP 0,002-32 mg/L 30 MIC Test
921570	Ertapenem ETP 0,002-32 mg/L 100 MIC Test
921571	Ertapenem ETP 0,002-32 mg/L 10 MIC Test
92159	Ceftazidime/Ceftazidime + Clavulanic acid (4 mg/L) CAZ/CAL 0,5-32/0,064-4 mg/L 30 MIC Test
921590	Ceftazidime/Ceftazidime + Clavulanic acid (4 mg/L) CAZ/CAL 0,5-32/0,064-4 mg/L 100 MIC Test
921591	Ceftazidime/Ceftazidime + Clavulanic acid (4 mg/L) CAZ/CAL 0,5-32/0,064-4 mg/L 10 MIC Test
92160	Cefotaxime/Cefotaxime + Clavulanic acid (4 mg/L) CTX/CTL 0,25-16/0,016-1 mg/L 30 MIC Test
921600	Cefotaxime/Cefotaxime + Clavulanic acid (4 mg/L) CTX/CTL 0,25-16/0,016-1 mg/L 100 MIC Test
921601	Cefotaxime/Cefotaxime + Clavulanic acid (4 mg/L) CTX/CTL 0,25-16/0,016-1 mg/L 10 MIC Test

92161	Cefepime/Cefepime + Clavulanic acid (4 mg/L) FEP/FEL 0,25-16 / 0,064-4 mg/L 30 MIC Test
921610	Cefepime/Cefepime + Clavulanic acid (4 mg/L) FEP/FEL 0,25-16 / 0,064-4 mg/L100 MIC Test
921611	Cefepime/Cefepime + Clavulanic acid (4 mg/L) FEP/FEL 0,25-16 / 0,064-4 mg/L 10 MIC Test
92162	Imipenem/Imipenem + EDTA IMI/IMD 4-256/1-64 mg/L 30 MIC Test
921620	Imipenem/Imipenem + EDTA IMI/IMD 4-256/1-64 mg/L 100 MIC Test
921621	Imipenem/Imipenem + EDTA IMI/IMD 4-256/1-64 mg/L 10 MIC Test
92163	Vancomycin/Teicoplanin VA/TEC 0,5-32/0,5-32 mg/L 30 MIC Test
921630	Vancomycin/Teicoplanin VA/TEC 0,5-32/0,5-32 mg/L 100 MIC Test
921631	Vancomycin/Teicoplanin VA/TEC 0,5-32/0,5-32 mg/L 10 MIC Test
92164	Cefotetan/Cefotetan + Cloxacillin CTT/CXT 0,5-32/0,5-32 mg/L 30 MIC Test
921640	Cefotetan/Cefotetan + Cloxacillin CTT/CXT 0,5-32/0,5-32 mg/L 100 MIC Test
921641	Cefotetan/Cefotetan + Cloxacillin CTT/CXT 0,5-32/0,5-32 mg/L 10 MIC Test
92165	Meropenem/Meropenem + EDTA MRP/MRD 0,125-8/0,032-2 mg/L 30 MIC Test
921650	Meropenem/Meropenem + EDTA MRP/MRD 0,125-8/0,032-2 mg/L 100 MIC Test
921651	Meropenem/Meropenem + EDTA MRP/MRD 0,125-8/0,032-2 mg/L 10 MIC Test
92166	Imipenem/Imipenem + EDTA IMI/IMD 0,125-8/0,032-2 mg/L 30 MIC Test
921660	Imipenem/Imipenem + EDTA IMI/IMD 0,125-8/0,032-2 mg/L 100 MIC Test
921661	Imipenem/Imipenem + EDTA IMI/IMD 0,125-8/0,032-2 mg/L 10 MIC Test
92167	Meropenem/Meropenem + Phenylboronic acid MRP/MBO 0,125-8/0,032-2 mg/L 30 MIC Test
921670	Meropenem/Meropenem + Phenylboronic acid MRP/MBO 0,125-8/0,032-2 mg/L 100 MIC Test
921671	Meropenem/Meropenem + Phenylboronic acid MRP/MBO 0,125-8/0,032-2 mg/L 10 MIC Test
92168	Ertapenem/Ertapenem + Phenylboronic acid ETP/EBO 0,125-8/0,032-2 mg/L 30 MIC Test
921680	Ertapenem/Ertapenem + Phenylboronic acid ETP/EBO 0,125-8/0,032-2 mg/L 100 MIC Test
921681	Ertapenem/Ertapenem + Phenylboronic acid ETP/EBO 0,125-8/0,032-2 mg/L 10 MIC Test
92169	Ertapenem/Ertapenem + Cloxacillin ETP/ECX 0,125-8/0,032-2 mg/L 30 MIC Test
921690	Ertapenem/Ertapenem + Cloxacillin ETP/ECX 0,125-8/0,032-2 mg/L 100 MIC Test
921691	Ertapenem/Ertapenem + Cloxacillin ETP/ECX 0,125-8/0,032-2 mg/L 10 MIC Test
92170	Ethambutol EB 0,016-256 mg/L 30 MIC Test
921700	Ethambutol EB 0,016-256 mg/L 100 MIC Test
921701	Ethambutol EB 0,016-256 mg/L 10 MIC Test
92171	Isoniazide IZ 0,016-256 mg/L 30 MIC Test
921710	Isoniazide IZ 0,016-256 mg/L 100 MIC Test
921711	Isoniazide IZ 0,016-256 mg/L 10 MIC Test
92172	Ethionamide ET 0,016-256 mg/L 30 MIC Test
921720	Ethionamide ET 0,016-256 mg/L 100 MIC Test
921721	Ethionamide ET 0,016-256 mg/L 10 MIC Test
92173	Aztreonam ATM 0,064-1024 mg/L 30 MIC Test
921730	Aztreonam ATM 0,064-1024 mg/L 100 MIC Test
921731	Aztreonam ATM 0,064-1024 mg/L 10 MIC Test
92174	Cefazolin KZ 0,016-256 mg/L 30 MIC Test
921740	Cefazolin KZ 0,016-256 mg/L 100 MIC Test
921741	Cefazolin KZ 0,016-256 mg/L 10 MIC Test
92180	Amoxicillin* - clavulanic acid (2 mg/L) AMC 0,016-256* mg/L 30 MICTest
921800	Amoxicillin* - clavulanic acid (2 mg/L) AMC 0,016-256* mg/L 100 MIC Test
921801	Amoxicillin* - clavulanic acid (2 mg/L) AMC 0,016-256* mg/L 10 MIC Test
92181	Ampicillin* - sulbactam (4 mg/L) SAM 0,016-256* mg/L 30 MIC Test
921810	Ampicillin* - sulbactam (4 mg/L) SAM 0,016-256* mg/L 100 MIC Test

921811	Ampicillin* - sulbactam (4 mg/L) SAM 0,016-256* mg/L 10 MIC Test
92182	Micafungin MYC 0,002-32 mg/L 30 MIC Test
921820	Micafungin MYC 0,002-32 mg/L 100 MIC Test
921821	Micafungin MYC 0,002-32 mg/L 10 MIC Test
92183	Ticarcillin TC 0,016-256 mg/L 30 MIC Test
921830	Ticarcillin TC 0,016-256 mg/L 100 MIC Test
921831	Ticarcillin TC 0,016-256 mg/L 10 MIC Test
92184	Isavuconazole IVU 0,002-32 mg/L 30 MIC Test
921840	Isavuconazole IVU 0,002-32 mg/L 100 MIC Test
921841	Isavuconazole IVU 0,002-32 mg/L 10 MIC Test
92200	Tiamulin TIA 0,002-32 mg/L 30 MIC Test
922000	Tiamulin TIA 0,002-32 mg/L 100 MIC Test
922001	Tiamulin TIA 0,002-32 mg/L 10 MIC Test
92201	Tilmicosin TIL 0,002-32 mg/L 30 MIC Test
922010	Tilmicosin TIL 0,002-32 mg/L 100 MIC Test
922011	Tilmicosin TIL 0,002-32 mg/L 10 MIC Test
93001	EASY RID h-IgG
93002	EASY RID h-IgA
93003	EASY RID h-IgM
93004	EASY RID h-C3c
93005	EASY RID h-C4
93006	EASY RID h-Transferrin
93007	EASY RID h-Albumin
93008	EASY RID h-Apolipoprotein A1
93009	EASY RID h-Apolipoprotein B
93010	EASY RID h-Alfa 1 Acid Glicoprotein
93011	EASY RID h-Fibrinogen
93012	EASY RID h-Antitrombin III
93013	EASY RID h-Ig Light Chain K
93014	EASY RID h-Ig Light Chain Lambda
93015	Anti h-alfa 1 Antitrypsin
93016	Anti h-Ceruloplasmin
93018	Anti h-Haptoglobin
93104	Multiplate h-IgG/IgA/IgM
93106	MULTIPLATE h-C3c/C4
93110	MULTIPLATE h-Apo A1/Apo B
93115	MULTIPLATE h-Kappa Chain/Lambda Chain
93201	BENCE JONES TEST
940010	RID CONTROL SERUM
9501	Optochine Test 100 Discs
9502	Bacitracin Test 100 Discs
9503	X FACTOR TEST 100 Discs
9504	V FACTOR TEST 100 Discs
9505	V+X FACTOR TEST 100 Discs
9508	METRONIDAZOLE TEST 100 Discs
9511	SULPHONAMIDE TEST 100 Discs
95200	ANAEROBES
95210	ENTEROCOCCI
95220	ENTEROBACTERIA 1
95230	ENTEROBACTERIA URINE
95240	ENTEROBACTERIA 2
95250	PSEUDOMONAS
95260	STAPH
95270	ACINETOBACTER
95280	YEASTS
95290	Strepto
95380	ENTEROBACTERIA
9555	MT-HAEMOPHILUS
9562	URIN-2
9563	MICE

9564	KGL I (Gram + ve) 1 x 100 Test
9565	KGL II (Gram - ve) 1 x 100 Test
9566	KGL III 100 Test
9567	MULTODISC A
9568	MULTODISC B
9569	MULTODISC C
9570	MULTODISC D
9571	MULTODISC A (100 Pz) (Tender106/2003)
9573	MULTODISC C (100 Pz) (Tender106/2003)
9574	MULTODISC D (100 Pz) (Tender106/2003)
9575	URINE RING (Tender238/2006)
9576	PSEUDOMONAS RING (Tender238/2006)
9577	GRAM NEGATIVE RING (Tender238/2006)
9578	GRAM POSITIVE RING (Tender238/2006)
96001	SALMONELLA TYPHI H 20 ml
96002	SALMONELLA TYPHI O 20 ml
96003	SALMONELLA PARATYPHI AH 20 ml
96004	SALMONELLA PARATYPHI AO 20 ml
96005	SALMONELLA PARATYPHI BH 20 ml
96006	SALMONELLA PARATYPHI BO 20 ml
96007	BRUCELLA TOTALE 20 ml
96008	BRUCELLA ABORTUS 20 ml
96009	SALMONELLA TYPHI TOTALE 20 ml CE
96010	SALMONELLA PARATYPHI A TOTALE 20 ml
96011	PROTEUS OX2 20 ml
96012	PROTEUS OXK 20 ml
96013	PROTEUS OX19 20 ml
96015	FEBRILE MULTITEST KIT
96016	STREP-CHECK KIT
96017	STAPH LATEX KIT
96018	SALMONELLA PARATYPHI B TOTALE 20 ml
96019	SALMONELLA PARATYPHI CH 20 ml
96020	SALMONELLA PARATYPHI CO 20 ml
96021	SALMONELLA PARATYPHI C TOTALE 20 ml
96022	BRUCELLA MELITENSIS 20 ml
96023	BRUCELLA SUIS 20 ml
96031	SALMONELLA TYPHI H SLIDE 5 ml
96032	SALMONELLA TYPHI O SLIDE 5 ml
96033	SALMONELLA TYPHI TOTALE 5 ml SLIDE
96034	SALMONELLA PARATYPHI AH SLIDE 5 ml
96035	SALMONELLA PARATYPHI AO 5 ml SLIDE
96036	SALMONELLA PARATYPHI A TOTALE 5ml SLIDE
96037	SALMONELLA PARATYPHI BH 5 ml SLIDE
96038	SALMONELLA PARATYPHI BO 5 ml SLIDE
96039	SALMONELLA PARATYPHI B TOTALE 5ml SLIDE
96040	SALMONELLA PARATYPHI CH 5 ml SLIDE
96041	SALMONELLA PARATYPHI CO 5 ml SLIDE
96042	SALMONELLA PARATYPHI C TOTALE 5 ml SLIDE
96043	BRUCELLA TOTALE SLIDE 5 ml SLIDE
96044	BRUCELLA ABORTUS 5 ml SLIDE
96045	BRUCELLA MELITENSIS SLIDE 5 ml
96047	PROTEUS OX2 5 ml SLIDE
96048	PROTEUS OX19 5 ml SLIDE
96049	PROTEUS OXK 5 ml SLIDE
96093	CONTROLLO NEGATIVO/NEGATIVE CONTROL 0.5ml
96096	POSITIVE CONTROL FOR SALMONELLA 0.5ml
96097	POSITIVE CONTROL FOR PROTEUS 0.5ml
96098	POSITIVE CONTROL FOR BRUCELLA 0.5ml
96142	Legionella Latex Kit
96143	CAMPYLOBACTER LATEX KIT

96144	CLOSTRIDIUM DIFFICILE LATEX KIT
96148	SHIGELLA ANTISERUM
96150	E. COLI O157 LATEX KIT
96151	SALMONELLA LATEX KIT
96153	STREPTO B LATEX KIT
96154	STREPTO A LATEX KIT
96155	BENCE JONES LATEX TEST
96316	Clostridium difficile GDH Card
96317	Clostridium Difficile Toxin A+B Card
96318	Giardia Card
96319	Listeria Monocytogenes Card
96320	Salmonella Ag Card
96321	O157 E.coli Card
96401	ONE STEP AMP DRMG SCREEN 20 CARDS
96404	ONE STEP COC DRMG SCREEN
96405	ONE STEP THC DRMG SCREEN
96406	ONE STEP M-AMP DRMG SCREEN 20 CARDS
96415/20	FECAL OCCULT BLOOD CARD
96418	STREPTO A CARD 30 CARDS
96441	Gonorrea Ag Card
96442	Gardnerella Vaginalis Card
96443	Trichomonas Vaginalis Card
96444	B.J. Free Kappa/Lambda Dipstick
96455	H.PYLORI CARD 20 CARD
96460	HCG URINE/SERUM CARD 50 CARD
96461	HCG URINE/SERUM CARD 100 CARD
96462	MICROALBUMIN CARD URINE 20 Cards
96465	AFP -ALFA FETO CARD 20 CARDS
96468	TUBERCOLOSI CARD 20 CARDS
96480	IgE TOTAL CARD
96485	CEA CARD 20 Cards
96487	MYOGLOBIN
96488	TROPONIN 20 CARDS
96490	FERRITIN CARD
96495	SIFILIDE CARD 20 CARDS
96498	IM MONONUCLEOSIS INFECTION 20 CARDS
96590	URINE STRIP
96899	Giotto 2
96900	GIOTTO READER
96909	BIOMIC V3
96914	BIOMIC V3 AST
96915	BIOMIC V3 ID
96916	BIOMIC V3 CC
96919	AST Software
96931	ID Software
96932	CC Software
96933	Micropiastre 96 pozzetti Software
97800	ROTASTICK ONE STEP KIT 20 Test
97801	RSV STICK ONE STEP 20 Test
97802	ROTA/ADENO COMBI STICK ONE STEP 20 Test
97803	H.PYLORI FECAL Ag ONE STEP 20 Test
97807	ADENOSTICK ONE STEP ASSAY 20 Test
97809	Strepto B Card
9999	Blank Discs
99003	KPC&MBL disc kit (acc. to EUCAST)
99004	ESBL disc kit (acc. to EUCAST)
99005	ESBL disc kit (acc. to CLSI)
99006	ESBL (Chromos. Ind. AmpC) disc kit (acc. to EUCAST)
99007	KPC&MBL&OXA-48 disc kit (acc. to EUCAST)
99008	ESBL+AmpC screen disc kit

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99009	AmpC disc kit

Direttore Tecnico/ Technical Director
Dr.Silvio Brocco

©Liofilchem® s.r.l. Via Scozia - Zona Industriale 64026, Roseto degli Abruzzi (TE) Italy - Tel +39 0858930745 - Fax +39 0858930330

ENGLISH

KPC&MBL&OXA-48 disc kit (acc. to EUCAST)

Disc tests for confirmation of carbapenemase-producing Enterobacteriaceae.

DESCRIPTION

Carbapenemases are β-lactamases that hydrolyze penicillins, in most cases cephalosporins and to various degree carbapenems. The most important carbapenemases are categorized as three types of enzymes:

1. *Klebsiella pneumoniae* carbapenemases (KPC) belonging to the Ambler class A of β-lactamases;
2. VIM, IMP and NDM belonging to the class B metallo β-lactamases (MBL);
3. Class D β-lactamases of OXA-48-like enzymes.

Since the 1990s, the increased consumption of carbapenems to treat infections caused by extended-spectrum β-lactamases (ESBL) producing bacteria has in turn contributed to the dramatic increase in carbapenem-resistant Enterobacteriaceae (CRE). Bacterial acquisition of carbapenemases is crucial to the emergence of CRE. Indeed, the corresponding genes are mostly plasmid-located and associated with various mobile genetic structures and may confer resistance to virtually all β-lactams. Infections with carbapenemase-producing Enterobacteriaceae are associated with high mortality posing a serious threat especially to hospitalized patients. Carbapenemases are considered to be of high epidemiological importance and one of the most important concerns is the spread in the community, particularly in *E. coli*. Adequate treatment and control of CRE infections is predicted upon their accurate and prompt diagnosis from patient samples in the clinical laboratory. Carbapenem resistance can also arise in both ESBL and AmpC-producing organisms (Ambler class A and C, respectively) by mutation that regulate the synthesis of porins contained in the outer membrane.

Carbapenem MICs for carbapenemase-producing enterobacteriaceae may be below the clinical breakpoints, however, the epidemiological cut-off (ECOFF) defined by EUCAST can be used to detect carbapenemase-producers. Meropenem, offering the best compromise between sensitivity and specificity, is recommended for screening.
Following detection of reduced susceptibility to carbapenems, a phenotypic method for confirmation of carbapenemase-production should be applied. Meropenem discs supplemented with different inhibitors of carbapenemase are used to evaluate carbapenem-resistant strains.

CONTENTS OF THE PACKAGES

5 x 50 discs cartridges, each packaged in a "blister" with a dryer.

METHOD PRINCIPLE

Enterobacteriaceae suspected to be producers of carbapenemases may be confirmed by using meropenem and evaluating the synergistic effects when combined with the following inhibitors:

- **Phenylboronic acid** inhibits class A carbapenemase;
- **EDTA** inhibits class B carbapenemase;
- **Cloxacillin**, which inhibits AmpC β-lactamases, permits to differentiate between AmpC hyperproduction plus porin loss and carbapenemase-production.

There is no currently available inhibitor for class D carbapenemases. However, when there is no synergy of meropenem with any of the above mentioned inhibitors, 30 µg **Temocillin** disc (TMO) can be used in order to differentiate between ESBL plus porin loss and OXA-48 like enzymes.

For each combined disc test (CDT), discs containing meropenem alone and in combination with a carbapenemases inhibitor are applied. The inhibition zone around the meropenem disc combined with inhibitor is compared with the zone around the 10 µg meropenem disc (MRP).

GATHERING AND KEEPING SAMPLES

The colonies that are to be subjected to the susceptibility test are taken up by culture media that have been previously swabbed with the sample under examination.

TEST PROCEDURE

1. Using a fresh, pure culture prepare a suspension of the test organism equal to 0.5 McFarland Standard.
2. Using a sterile cotton swab, spread the adjusted suspension over the entire area of a Mueller Hinton agar plate.
3. Apply Meropenem, Meropenem + EDTA, Meropenem + Phenylboronic acid, Meropenem + Cloxacillin, on the inoculated plate, ensuring sufficient space between individual discs to allow for proper measurement of inhibition zones.
4. Incubate at 36±1°C for 18-24 hours.

EVALUATING THE RESULTS

At the end of the incubation period, measure the inhibition halos and interpret as indicated in the table below.

Interpretative Table. Synergy of meropenem with carbapenem inhibitors for confirmation of CRE.

Increase in inhibition zone of meropenem with the following inhibitor			Temocillin (TMO)*	β-lactamases
Phenylboronic acid (MR+BO)	EDTA (MR+ED)	Cloxacillin (MR+CL)		
≥ 4 mm	< 5 mm	< 5 mm	---	KPC
< 4 mm	≥ 5 mm	< 5 mm	---	MBL
≥ 4 mm AND	< 5 mm	≥ 5 mm	---	AmpC + porin loss or efflux
< 4 mm	< 5 mm	< 5 mm	< 11 mm	OXA-48-like

*Temocillin susceptibility test is recommended only in cases where no synergy is detected.

QUALITY CONTROL

Each production batch of discs is subjected to the quality control with the following bacterial strains:

Microorganism		
Klebsiella pneumoniae	ATCC® 700603	Negative control
Klebsiella pneumoniae	ATCC® BAA-2146	MBL positive
Klebsiella pneumoniae	ATCC® BAA-1705	KPC positive
Klebsiella pneumoniae	NCTC 13442	OXA-48 positive

LIMITS

Diffusion susceptibility tests use an *in vitro* technique and cannot therefore reproduce the extremely complex *in vivo* conditions. Nevertheless, it is a useful and important tool that helps the clinician choose the correct therapy. Many variable factors influence the final result of the diffusion susceptibility test. The main ones are: the culture medium used, impregnation of the discs, inoculation of the medium, temperature, time and incubation atmosphere of the plates, pre-incubation and pre-diffusion conditions, depth of the medium, etc.

PRECAUTIONS

The discs cannot be classified as being hazardous according to current legislation but fall within the specific field of application where a safety data sheet must be supplied because they can cause phenomena of sensitization in sensitive subjects if they come into contact with the skin.
The discs are disposable products. They are only for diagnostic *in vitro use* and are intended for professional use. They must be used in the laboratory by properly trained operators using approved aseptic and safety methods for pathogenic agents.

STORAGE

Store the unopened blister at -20°C to +8°C till the expiry date. Allow unopened cartridge to come to room temperature before removing it from the blister for minimising condensation on the discs. Leftover discs from an opened cartridge should be stored at 2-8°C for no more than 7 days. Return unused discs to the refrigerator as soon as the application of the discs has been completed. Dispose of expire discs.

ELIMINATING USED MATERIAL

After use, the discs and the material that comes into contact with the sample must be decontaminated and disposed of in accordance with current laboratory techniques for the decontamination and disposal of potentially infected material.

REFERENCES

- EUCAST guidelines for detection of resistance mechanisms and specific resistances of clinical and/or epidemiological importance. Version 1.0, 2013.

PRESENTATION

DESCRIPTION		PACKAGING	REF
Meropenem 10 µg	MRP	50 Discs	99007
Meropenem + EDTA	MR+ED	50 Discs	
Meropenem + Phenylboronic acid	MR+BO	50 Discs	
Meropenem + Cloxacillin	MR+CL	50 Discs	
Temocillin 30 µg	TMO	50 Discs	

TABLE OF SYMBOLS

LOT Batch code	IVD *In Vitro* Diagnostic Medical Device	Manufacturer	Use by	Fragile, handle with care
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Caution, consult accompanying documents	Do not reuse

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Via Scozia zona ind.le, 64026 Roseto degli Abruzzi (Te) Italy
Tel. +39 0858930745 Fax +39 0858930330 www.liofilchem.net liofilchem@liofilchem.net

CE IVD

Chromatic™ CRE

Chromogenic medium for the detection of carbapenem-resistant Enterobacteriaceae directly from clinical specimens.

TYPICAL FORMULA

	(g/l)
Peptone Mix	30.0
Selective Mix	11.0
Chromogenic Mix	1.0
Agar	15.0
Final pH 7.0 ± 0.2	

DESCRIPTION

Chromatic™ CRE is a medium used for the detection of carbapenem-resistant Enterobacteriaceae directly from clinical specimens. Carbapenems are the last shelter from multi-resistant Gram-negative bacterial infections. Carbapenemase is an enzyme class which can be produced by *Klebsiella pneumoniae* and by other organisms including *Serratia* spp., *Enterobacter* spp., *Escherichia coli* and *Citrobacter freundii*. Early detection of carbapenems resistance is essential in order to limit the spread of these pathogens.

PRINCIPLE

Peptone mix is a source of amino acids, nitrogen, minerals, vitamins, and other factors which increases the growth of bacteria. The chromogenic and selective mix facilitates the identification of bacteria on the basis of the color and colony morphology, inhibiting most of the non-Enterobacteriaceae. Agar is the solidifying agent.

TECHNIQUE

Inoculate the plates by streaking the specimen or its initial suspension onto the agar surface. Incubate for 24-48 h at 35 ± 2°C.

INTERPRETATION OF RESULTS

At the end of incubation, observe the appearance of the colonies and interpret the results as indicated in table 1.

Table 1.

Microorganism	Typical appearance of the colonies
Carbapenem-resistant *Klebsiella pneumoniae*	Blue-violet
Carbapenem-resistant *Escherichia coli*	Red
Carbapenem-resistant *Enterobacter* spp.	Blue-green
Carbapenem-resistant *Citrobacter* spp.	Blue with red halo
Carbapenem-resistant Non Enterobacteriaceae	White to natural pigmented
Other microorganisms	Inhibited

STORAGE AND TRANSPORT CONDITIONS

2-8°C away from light, until the expiry date on the label. However, our stability studies have shown that the transport at 18-25°C for 4 days, or at 35-39°C for 48 hours, does not alter in any way the performance of the product. Eliminate if signs of deterioration or contamination are evident.

WARNING AND PRECAUTIONS

The product CHROMATIC CRE does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is designed for *In vitro* diagnostic use and must be used only by properly trained operators.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to the national and local regulations in force.

REFERENCES

- Kochar S, Sheard T, Sharma R, Hui A, Tolentino E, Allen G, Landman D, Bratu S, Augenbraun M, Quale J. (2009) Success of an infection control program to reduce the spread of carbapenem-resistant *Klebsiella pneumoniae*. Infect. Control Hosp. Epidemiol. 30(5):447-52.
- Podschun R, Ullman U (1998). *Klebsiella spp* as Nosocomial Pathogens: Epidiemology, Taxonomy, Typing Methods, and Pathogenicity Factors. Clinical Microbiology Reviews 11 (4): 589–603.

LIOFILCHEM® S.r.l.
Via Scozia, Zona Ind.le - 64026, Roseto degli Abruzzi (TE) - ITALY
Tel +39 0858930745 Fax +39 0858930330 Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

CE IVD

PRODUCT SPECIFICATIONS

NAME
Chromatic™ CRE

PRESENTATION
Ready-to-use plates (90 mm) containing 22 ± 1 ml of medium

STORAGE
2-8°C

PACKAGING

Ref.	Content	Packaging
11619	20 plates	• 10 plates in thermally soldered film • 2 x 10 plates in cardboard box

pH OF THE MEDIUM
7.0 ± 0.2

USE
Chromatic™ CRE is a medium for the detection of carbapenem-resistant Enterobacteriaceae directly from clinical specimens

TECHNIQUE
Refer to product technical sheet

APPEARANCE OF THE MEDIUM
Light amber, slightly opalescent

SHELFLIFE
90 days

QUALITY CONTROL

1. Control of general characteristics, label and print
2. **Sterility control**
   7 days at 22 ± 2°C
   7 days at 35 ± 2°C
3. **Microbiological control**
   Inoculum for productivity: 50-100 CFU
   Inoculum for selectivity: 10^4-10^5 CFU
   Incubation Conditions: 24-48 h at 35 ± 2°C, in aerobiosis

Microorganism		Growth	Colony color
Klebsiella pneumoniae	ATCC® 1705	Good	Blue-violet
Klebsiella pneumoniae	ATCC® 1706	Good	Violet
Klebsiella pneumoniae	ATCC® 700603	Inhibited	—
Escherichia coli	ATCC® 25922	Inhibited	—

TABLE OF SYMBOLS

LOT Batch code	IVD *In vitro* Diagnostic Medical Device	Manufacturer	Use by	Fragile, handle with care
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Caution, consult instructions for use	Do not reuse

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Via Scozia, Zona Ind.le - 64026, Roseto degli Abruzzi (TE) - ITALY
Tel +39 0858930745 Fax +39 0858930330 Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

CE IVD

Chromatic™ ESBL

Chromogenic medium for detection of ESBLs in Enterobacteriaceae directly from clinical specimens.

Instructions For Use

ENGLISH

DESCRIPTION

Chromatic™ ESBL is a chromogenic medium used for detection of Extended-spectrum β-lactamase (ESBL)-producing Enterobacteriaceae. ESBLs are enzymes that hydrolyze most penicillins and cephalosporins, inhibited by β-lactamase inhibitors such as clavulanic acid, sulbactam and tazobactam.

ESBL-producing Enterobacteriaceae have become one of the most important causes of nosocomial community-acquired infections caused by *Escherichia coli* and *Klebsiella pneumoniae*, but also other Gram-negative bacteria. Patients infected by ESBL producers often received inadequate empirical therapy until the pathogen's resistance is recognized. Early detection is, therefore, essential in order to limit the spread of these pathogens.

TYPICAL FORMULA

	(g/l)
Peptone Mix	43.2
Chromogenic Mix	1.0
Selective Mix	0.5
Agar	15.0
Final pH 7.2 ± 0.2 at 25°C	

METHOD PRINCIPLE

Peptones supply amino acids, nitrogen, carbon, minerals, vitamins and other nutrients which support the growth of microorganisms. Chromogenic mix allows the identification of microorganisms on the basis of the colony color and morphology. Selective mix inhibits the ESBL-non-producing organisms. Agar is the solidifying agent.

TEST PROCEDURE

Inoculate the plates by streaking directly the specimen onto the agar surface. Incubate aerobically at 37°C for 18-24 hours.

INTERPRETING RESULTS

After incubation, observe the color of the colonies and interpret the results as indicated in the ID table.

ID Table.

Microorganism*	Typical colony color
E. coli	Pink-reddish-mauve
Klebsiella spp, Enterobacter spp, Serratia spp	Green-blue
Proteus spp	Brown

*Notice that only ESBL-producing organisms grow on this medium, while other organisms as well as AmpC producers are inhibited.

See pictures in Appendix I.

APPEARANCE

Slightly opalescent, amber.

STORAGE

Store at 2-8°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

4 months.

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QUALITY CONTROL

Plates are inoculated with the microbial strains indicated in the QC table.
Inoculum for productivity: 10-100 CFU/ml.
Inoculum for selectivity: 10^4-10^5 CFU/ml.
Incubation conditions: aerobically at 35±2°C for 18-24 h.

QC Table.

Microorganism		ESBL phenotype	AmpC phenotype	Growth	Specification
Escherichia coli	DSM 22311	Positive	Negative	Good	Reddish colonies
Klebsiella pneumoniae	ATCC® 700603	Positive	Negative	Good	Green-blue colonies
Klebsiella pneumoniae	ATCC® BAA-1144	Negative	Positive	Inhibited	---
Escherichia coli	ATCC® 25922	Negative	Negative	Inhibited	---

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is intended for *In vitro* diagnostic use and must be used only by properly trained operators.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAPHY

1. EUCAST guidelines for detection of resistance mechanisms and specific resistances of clinical and/or epidemiological importance. Version 1.0, 2013.
2. Podschun R, Ullman U. *Klebsiella* spp as Nosocomial Pathogens: Epidemiology, Taxonomy, Typing Methods, and Pathogenicity Factors. Clinical Microbiology Reviews. 1998; 11 (4): 589–603.
3. Geiss H.K. Comparison of two test kits for rapid identification of *Escherichia coli* by a beta-glucuronidase assay. European Journal of Clinical Microbiology & Infections Diseases. 1990; 9 (2):151-152.

PRESENTATION

		Contents	Ref.
Chromatic™ ESBL	90 mm ready-to-use plates	20 plates	11622

TABLE OF SYMBOLS

LOT Batch code	IVD *In vitro* Diagnostic Medical Device	Manufacturer	Use by	Fragile, handle with care	Keep away from sunlight
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Caution, consult Instruction For Use	Do not reuse	

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Via Scozia zona ind.le, 64026 Roseto degli Abruzzi (Te) Italy
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CE IVD

G.C. MEDIUM

Basal medium for *Haemophilus spp* and *Neisseria spp* isolation and cultivation.

TYPICAL FORMULAS

G.C. MEDIUM	(g/l)
Proteose Peptone No.3	15.0
Corn Starch	1.0
Potassium Phosphate, Dibasic	4.0
Potassium Phosphate, Monobasic	1.0
Sodium Chloride	5.0
Agar	17.0

V.C.N. supplement	(mg / vial *)
Vancomycin	1.5 mg
Colistin Sulfate	3.75 mg
Nystatin	6250 UI

*1 vial for 500 ml of medium

V.C.N.T. supplement	(mg / vial *)
Vancomycin	1.5 mg
Colistin Sulfate	3.75 mg
Nystatin	6250 UI
Trimethoprim	2.5 mg

*1 vial for 500 ml of medium

VITALEX growth supplement	(mg / vial *)
Vitamin B12	0.1 mg
L-Glutamine	100.0 mg
Adenine SO4	10.0 mg
Guanine HCl	0.3 mg
p-Aminobenzoic Acid	0.13 mg
NAD (Coenzime 1)	2.5 mg
Cocarboxylase	1.0 mg
Ferric Nitrate	0.2 mg
Thiamine hydrochloride	0.03 mg
Cysteine hydrochloride	259.0 mg

VITALEX RESTORING solution	
Glucose	0.5 mg
Distilled water	5.0 ml

*1 vial for 500 ml of medium

HAEMOPHILUS supplement	(mg / vial *)
Bacitracin	150.0 mg
Vancomycin	5.0 mg
Clyndamicin	0.5 mg

*1 vial for 500 ml of medium

L.C.A.T. supplement	(mg / vial *)
Lincomycin	0.5 mg
Colistin Sulfate	3.0 mg
Amphotericin B	0.5 mg
Trimethoprim	3.25 mg

*1 vial for 500 ml of medium

V.C.A.T. supplement	(mg / vial *)
Vancomycin	1.0 mg
Colistin Sulfate	3.75 mg
Amphotericin B	0.5 mg
Trimethoprim	1.5 mg

*1 vial for 500 ml of medium

Final pH = 7.2 ± 0.2 at 25 °C.

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Via Scozia, Zona Ind.le - 64026, Roseto D.A. (TE) - ITALY
Phone +390858930745 Fax +390858930330
Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

CE IVD

DIRECTIONS

Suspend 43.0 g of powder in 1 liter of distilled or deionized water. Heat until completely dissolved.
Sterilize in autoclave at 121 °C for 15 minutes. Cool to 45-50 °C.
Add 5-10% of defibrinated horse blood (code 83396) to the sterilized medium aseptically and heat in a water bath heat-controlled to 80 °C for 15 minutes.
Cool to 45-50 °C and add 2 vial of Vitalex growth supplement reconstituted with 5 ml of Vitalex restoring solution (code 81023).
Additionally add 2 vial of V.C.N. supplement (code 81022), reconstituted with 5 ml of distilled water, in order to obtain a *Neisseria* selective medium.
For the examination of specimens of rectal origins, V.C.N.T. supplement (code 81024), instead of V.C.N. supplement, may be added in order to inhibit the overgrowth and swarming of *Proteus spp.*
Add 2 vial of Haemophilus supplement (code 81014), reconstituted with 5 ml of distilled water, in order to obtain a *Haemophilus* selective medium. Prepare the medium as directed and pour into Petri dishes.

DESCRIPTION

G.C. MEDIUM, supplemented with enrichment and selective supplements, is used to isolate and cultivate gonococci, meningococci and *Haemophilus spp.* Haemophilus supplement, containing bacitracin, vancomycin and clindamycin, can be added for the selective isolation of *H. influenzae* from specimens contaminated with upper respiratory tract microbial flora.

TECHNIQUE

Inoculate by rolling a culture swab across a segment of the plate or in a large "Z" pattern so that an adequate area of the plate is inoculated. Streaking of the plate is carried out with a sterile loop to ensure an adequate dispersion of the organisms. Plates are incubated at 36 ± 1 °C, in a sealed jar with at least 70% humidity and 5-10% carbon dioxide. Examine the plates after 24 hours incubation and, if negative, incubate for further 24 hours. Presumptive gonococcus colonies are identified by the Gram stain, oxidase and sugar fermentation reactions.

QUALITY CONTROL

Dehydrated medium
Appearance: free-flowing granules.
Color: beige.
Prepared medium
Appearance: opaque.
Color: chocolate brown.

Incubation conditions: 36 ± 1 °C for 24-48 hours, 5-10% CO_2, basal medium.

Microorganism	ATCC	Growth
Neisseria gonorrhoeae	43069	good
Haemophilus influenzae	10211	good

Incubation conditions:
36 ± 1 °C for 24-48 hours, 5-10% CO_2, basal medium + V.C.N., V.C.N.T., V.C.A.T. or L.C.A.T. supplement.

Microorganism	ATCC	Growth
Neisseria gonorrhoeae	43069	good
Neisseria meningitidis	13090	good
Staphylococcus aureus	25923	partially inhibited

Incubation conditions:
36 ± 1 °C for 24-48 hours, 5-10% CO_2, basal medium + Haemophilus supplement.

Microorganism	ATCC	Growth
Enterococcus faecalis	19433	good
Haemophilus influenzae	10211	good

PERFORMANCE AND LIMITATIONS

G.C. Medium is intended for use with supplementation. Although certain diagnostic tests may be directly on this medium, biochemical and, if indicated, immunological testing using pure cultures are recommended for complete identification. Improper specimen collection, environment, temperature, CO_2 level, moisture and pH can adversely affect the growth and the viability of the organisms.

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Via Scozia, Zona Ind.le - 64026, Roseto D.A. (TE) - ITALY
Phone +390858930745 Fax +390858930330
Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

CE IVD

STORAGE

The powder is very hygroscopic: store the powder at 10-30 °C, in a dry environment, in its original container tightly closed and use it before the expiry date on the label or until signs of deterioration or contamination are evident.
Store prepared plates at 2-8 °C.

REFERENCES

1. Chapin, C.K., G.V. Doern (1983). J. Clin. Microbiol. **17**: 1163-1165.
2. Martin, J.E., Armstrong J.H., Smith P.B. (1974). Appl. Microbiol. **27**: 802-805.
3. NCCLS document M22-A2, 1996. Quality Assurance for Commercially prepared Microbiological Culture Media-Second ed. Approved Standard.
4. Seth, A. (1970). Brit. J. Vener. Dis. **46**: 201-202.

PRESENTATION

Product	REF	Σ
G.C. MEDIUM (11.6 l)	610022	500 g
G.C. MEDIUM (2.3 l)	620022	100 g
HORSE BLOOD DEFIBRINATED	83396	100 ml
VITALEX growth supplement	81023	10 vials
L.C.A.T. supplement	81012	10 vials
V.C.A.T. supplement	81041	10 vials
V.C.N. supplement	81022	10 vials
V.C.N. T. supplement	81024	10 vials
HAEMOPHILUS supplement	81014	10 vials

TABLE OF SYMBOLS

LOT	Batch code		Caution, consult accompanying documents		Manufacturer	Σ	Contains sufficient for <n> tests
REF	Catalogue number		Fragile, handle with care		Use by		Temperature limitation

IVD	*In Vitro* Diagnostic Medical Device
	Keep away from heat source

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Via Scozia, Zona Ind.le - 64026, Roseto D.A. (TE) - ITALY
Phone +390858930745 Fax +390858930330
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SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

GRUPPO VACUTEST KIMA

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Via dell'Industria, 12 – 35020 Arzergrande (PD) - Italia

Unità Operative / *Operative Units*

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MEUS S.r.l. - Via dell'Industria, 2 - 16 – 35020 Arzergrande (PD) - Italia
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È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 14 - 29

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Progettazione e produzione di Holders (camicie) per prelievo sottovuoto. Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia. Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico. Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili. Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi. Stampaggio di materie termoplastiche ad iniezione per articoli medicali.

Design and production of test tubes with predetermined vacuum for collection of haematological samples, biological liquids and urine samples. Production of test tubes for micro-collection of haematological samples. Design and production of Holders for vacuum sampling. Design and production of diagnostic kits for blood and biological liquids analysis. Design and production of culture media for microbiology. Design and production of sterile needles and devices for collection of haematological samples. Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles. Design and production of moulds for plastic labware. Injection moulding of thermoplastic materials for medical devices.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

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ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)
www.icim.it

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Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

FEDERAZIONE CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

0860CM_02_IT

ITALCERT

CERTIFICATO N° 505DM06

CERTIFICATE N° 505DM06

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 CEI EN ISO 13485-2016 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e 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.

Management of 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 analysis laboratories. Marketing of medical and diagnostic devices in vitro.

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*
2007-10-30	2011-10-30	2019-11-06	2020-10-29

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

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.
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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

MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

ENAC CERTIFICACIÓN Nº 39/C-SG055

LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS
THE AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

otorga el certificado número
grants the certificate no.

2013 11 0039 EN

según la norma
in accordance with the standard

UNE-EN ISO 13485:2018

(EN ISO 13485: 2016 & ISO 13485: 2016)

Productos Sanitarios: Sistemas de Gestión de Calidad – Requisitos para fines reglamentarios
Medical devices – Quality management systems - Requirements for regulatory purposes

a la empresa
to the company

Dia.Pro Diagnostic Bioprobes S.r.l.

Sede social y de fabricación/ *Headquarters and manufacturing facility*
Via G. Carducci, 27-20099-Sesto San Giovanni-Milano-Italy

Para las siguientes actividades / *For the following activities:*

Diseño, desarrollo y producción de productos sanitarios para diagnóstico *in vitro*:

Reactivos y productos reactivos, calibradores y materiales de control para Inmunología Infecciosa y Técnicas de Biología Molecular

Design, development and manufacturing of "in vitro" medical devices:
Reagents, reagent products, calibrators and control materials for infectious immunology and molecular biology techniques.

Modificaciones de alcance: N/A
Fecha de validez/ *Date of validity:* **Desde/** *From:* **18-12-2018** **Hasta/***To:* **17-12-2021**
Certificación inicial/ *Initial certification date:* **27-11-2013**
Renovación / *Renewal of certification date:* **18-12-2018**

Madrid, 18 de diciembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

ENAC CERTIFICACIÓN Nº 39/C-SG055

ANEXO I / *ANNEX I*

CERTIFICADO UNE-EN ISO 13485:2018/ *UNE-EN ISO 13485:2018 CERTIFICATE*

Modificaciones del alcance / *Scope modifications:*

Fecha/*Date*	**Descripción de la modificación**/ *Modification description*
18-12-2018	Cambio en la descripción del tipo de técnica en el ámbito tecnológico (inmunología infecciosa y técnicas de biología molecular). Cambio del nivel de detalle en la descripción del ámbito tecnológico
	Change in the description of the method of analysis in the technological scope (infectious immunology and molecular biology techniques). *Change in the level of detail of the technological scope description.*

MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

agencia española de medicamentos y productos sanitarios

CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
in accordance with Annex IV, Section 4, Directive 98/79/EC

PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date*: **04/12/2008**
Fecha de última prórroga/ *Last extension date*: **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2008 12 0588 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**0318**

A favor de /*In favour of:*

Fabricante/*Manufacturer:*
Nombre/*Name:* DIA. Pro Diagnostic Bioprobes S.r.l.
Dirección/*Address:* Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).
Representante autorizado ante la UE/*Authorized EU representative:*
Nombre/*Name:* Idem Dirección/*Address:* Idem

Para el producto/*For the product:*

Categoría/*Category:* Productos Sanitarios para Diagnóstico "In Vitro" / *In Vitro Diagnostic Medical Devices*
Grupo genérico/*Generic group*: Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*
Tipo/*Type*: Especificados en Anexos de este Certificado/*Specified in Annexes to this Certificate.*

Elaborado en/*In the facilities:*

Dia. Pro Diagnostic Bioprobes S.r.l.
Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total Nº 2003 12 0388 CT/ *This certificate must be accompanied by the EC Full Quality Assurance System Certificate Nº 2003 12 0388 CT.*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ *This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.*

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 19/11/2018
Localizador: P6LLDBAA94

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO
on0318@aemps.es

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902 101 322 /(+34) 91 822 59 97
Fax: (+34) 91 822 52 89

ORGANISMO NOTIFICADO 0318

CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
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Fecha de última prórroga/ *Last extension date*: **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2008 12 0588 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**0318**

A favor de/*In favour of:*

Fabricante/*Manufacturer:*
Nombre/*Name:* Dia. Pro Diagnostic Bioprobes S.r.l.
Dirección/*Address:* Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).
Representante autorizado ante la UE/*Authorized EU representative:*
Nombre/*Name:* Idem Dirección/*Address:* Idem

Tipo de producto / *Device type*: **Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas** / *Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.*

Clasificación/*Classification:* **Lista A, Anexo II** / *List A, Annex II*

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis B, mediante técnicas de Inmunoabsorción enzimática (ELISA)/ *Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis B infection, by Enzyme-linked immunosorbent assay (ELISA)* **[NANDO: IVD 0203]**

HBs Ag one Version ULTRA ELISA cualitativo / *ELISA qualitative*

- SAG1ULTRA.CE (192 tests)
- SAG1ULTRA.CE.96 (96 tests)
- SAG1ULTRA.CE.480 (480 tests)
- SAG1ULTRA.CE.960 (960 tests)
- SAG1ULTRA.CE.DB (192 tests - for Dia.Blood application)

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / *This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.*

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 19/11/2018
Localizador: P6LLDBAA94

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C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902 101 322 /(+34) 91 822 59 97
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ORGANISMO NOTIFICADO 0318

MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

agencia española de medicamentos y productos sanitarios

CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
in accordance with Annex IV, Section 4, Directive 98/79/EC

PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date*: **11/12/2003**
Fecha de última prórroga/ *Last extension date*: **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0391 ED	**Desde/*From* 26/11/2018 Hasta/*To* 18/11/2023**	**0318**

A favor de /*In favour of*:

Fabricante/*Manufacturer*:
Nombre/*Name:* DIA. Pro Diagnostic Bioprobes S.r.l.
Dirección/*Address:* Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).
Representante autorizado ante la UE/*Authorized EU representative*:
Nombre/*Name:* Idem Dirección/*Address:* Idem

Para el producto/*For the product:*

Categoría/*Category:* Productos Sanitarios para Diagnóstico "In Vitro" / *In Vitro Diagnostic Medical Devices*
Grupo genérico/*Generic group*: Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*
Tipo/*Type*: Especificados en Anexos de este Certificado/*Specified in Annexes to this Certificate.*

Elaborado en/*In the facilities:*

Dia. Pro Diagnostic Bioprobes S.r.l.
Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total Nº 2003 12 0388 CT/ *This certificate must be accompanied by the EC Full Quality Assurance System Certificate Nº 2003 12 0388 CT.*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ *This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.*

Madrid, 23 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

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Fecha de la firma: 23/11/2018
Localizador: RP3FCJG870

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Fax: (+34) 91.822.52.89

ORGANISMO NOTIFICADO 0318

CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
in accordance with Annex IV, Section 4, Directive 98/79/EC

PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date*: **11/12/2003**
Fecha de última prórroga/ *Last extension date*: **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0391 ED	**Desde/*From* 26/11/2018 Hasta/*To* 18/11/2023**	**0318**

A favor de/*In favour of*:

Fabricante/*Manufacturer*:
Nombre/*Name:* Dia. Pro Diagnostic Bioprobes S.r.l.
Dirección/*Address:* Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).
Representante autorizado ante la UE/*Authorized EU representative*:
Nombre/*Name:* Idem Dirección/*Address:* Idem

Tipo de producto / *Device type*: **Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas** / *Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.*

Clasificación/*Classification:* **Lista A, Anexo II** / *List A, Annex II*

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis B, mediante técnicas de Inmunoabsorción enzimática (ELISA)/ *Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis B infection, by Enzyme-linked immunosorbent assay (ELISA)* **[NANDO: IVD 0203]**

HBc Ab ELISA cualitativo / *ELISA qualitative*

- BCAB.CE (96 tests)

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / *This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.*

Madrid, 23 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

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Fecha de la firma: 23/11/2018
Localizador: RP3FCJG870

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ORGANISMO NOTIFICADO 0318

MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

agencia española de medicamentos y productos sanitarios

CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
in accordance with Annex IV, Section 4, Directive 98/79/EC

PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date*: 15/03/2004
Fecha de última prórroga/ *Last extension date*: 27/11/2013

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*		ON nº/*NB no*
2004 03 0424 ED	Desde/*From* 26/11/2018	Hasta/*To* 18/11/2023	0318

A favor de /*In favour of:*

Fabricante/*Manufacturer:*
Nombre/*Name:* DIA. Pro Diagnostic Bioprobes S.r.l.
Dirección/*Address:* Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).
Representante autorizado ante la UE/*Authorized EU representative:*
Nombre/*Name:* Idem Dirección/*Address:* Idem

Para el producto/*For the product:*

Categoría/*Category:* Productos Sanitarios para Diagnóstico "In Vitro" / *In Vitro Diagnostic Medical Devices*
Grupo genérico/*Generic group*: Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*
Tipo/*Type*: Especificados en Anexos de este Certificado/*Specified in Annexes to this Certificate.*

Elaborado en/*In the facilities:*

Dia. Pro Diagnostic Bioprobes S.r.l.
Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

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Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ *This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.*

Madrid, 23 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 23/11/2018
Localizador: LVZBL763FF

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in accordance with Annex IV, Section 4, Directive 98/79/EC

PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date*: 15/03/2004
Fecha de última prórroga/ *Last extension date*: 27/11/2013

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*		ON nº/*NB no*
2004 03 0424 ED	Desde/*From* 26/11/2018	Hasta/*To* 18/11/2023	0318

A favor de/*In favour of:*

Fabricante/*Manufacturer:*
Nombre/*Name:* Dia. Pro Diagnostic Bioprobes S.r.l.
Dirección/*Address:* Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).
Representante autorizado ante la UE/*Authorized EU representative:*
Nombre/*Name:* Idem Dirección/*Address:* Idem

Tipo de producto / *Device type*: **Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas** / *Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.*

Clasificación/*Classification:* Lista A, Anexo II / *List A, Annex II*

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis B, mediante técnicas de Inmunoabsorción enzimática (ELISA)/ *Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis B infection, by Enzyme-linked immunosorbent assay (ELISA)* **[NANDO: IVD 0203]**

HBc IgM ELISA cualitativo-cuantitativo / *ELISA qualitative-quantitative*

- BCM.CE (96 tests)

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / *This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.*

Madrid, 23 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 23/11/2018
Localizador: LVZBL763FF

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902 101 322 /(+34) 91 822 59 97
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MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

agencia española de medicamentos y productos sanitarios

CERTIFICADO DE EXAMEN CE DE DISEÑO
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Fecha de última prórroga/ *Last extension date*: **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0390 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**0318**

A favor de /*In favour of:*

Fabricante/*Manufacturer:*
Nombre/*Name:* DIA. Pro Diagnostic Bioprobes S.r.l.
Dirección/*Address:* Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).
Representante autorizado ante la UE/*Authorized EU representative:*
Nombre/*Name:* Idem Dirección/*Address:* Idem

Para el producto/*For the product:*

Categoría/*Category:* Productos Sanitarios para Diagnóstico "In Vitro" / *In Vitro Diagnostic Medical Devices*
Grupo genérico/*Generic group*: Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*
Tipo/*Type*: Especificados en Anexos de este Certificado/*Specified in Annexes to this Certificate.*

Elaborado en/*In the facilities:*

Dia. Pro Diagnostic Bioprobes S.r.l.
Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total Nº 2003 12 0388 CT/ *This certificate must be accompanied by the EC Full Quality Assurance System Certificate Nº 2003 12 0388 CT.*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ *This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.*

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 19/11/2018
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CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
in accordance with Annex IV, Section 4, Directive 98/79/EC

PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date*: **11/12/2003**
Fecha de última prórroga/ *Last extension date*: **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0390 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**0318**

A favor de/*In favour of:*

Fabricante/*Manufacturer:*
Nombre/*Name:* Dia. Pro Diagnostic Bioprobes S.r.l.
Dirección/*Address:* Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).
Representante autorizado ante la UE/*Authorized EU representative:*
Nombre/*Name:* Idem Dirección/*Address:* Idem

Tipo de producto / *Device type*: **Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas /** *Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.*

Clasificación/*Classification:* Lista A, Anexo II / *List A, Annex II*

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis B, mediante técnicas de Inmunoabsorción enzimática (ELISA)/ *Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis B infection, by Enzyme-linked immunosorbent assay (ELISA)* **[NANDO: IVD 0203]**

HBs Ab ELISA cualitativo-cuantitativo / *ELISA qualitative-quantitative*

- SAB.CE (96 tests)

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / *This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.*

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

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MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

Agencia española de medicamentos y productos sanitarios

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PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date*: 12/09/2007
Fecha de última prórroga/ *Last extension date*: 27/11/2013

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2007 09 0532 ED	Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023	0318

A favor de /*In favour of:*

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Representante autorizado ante la UE/*Authorized EU representative:*
Nombre/*Name:* Idem Dirección/*Address:* Idem

Para el producto/*For the product:*

Categoría/*Category:* Productos Sanitarios para Diagnóstico "In Vitro" / *In Vitro Diagnostic Medical Devices*
Grupo genérico/*Generic group*: Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*
Tipo/*Type*: Especificados en Anexos de este Certificado/*Specified in Annexes to this Certificate.*

Elaborado en/*In the facilities:*

Dia. Pro Diagnostic Bioprobes S.r.l.
Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total Nº 2003 12 0388 CT/ *This certificate must be accompanied by the EC Full Quality Assurance System Certificate Nº 2003 12 0388 CT.*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ *This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.*

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

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Fecha de la firma: 19/11/2018
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C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel. (+34) 902 101 322 /(+34) 91 822 59 97
Fax: (+34) 91 822 52 89

ORGANISMO NOTIFICADO 0318

CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
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Clasificación/*Classification:* ~~Lista A, Anexo II~~ */ List A, Annex II*

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis C, mediante técnicas de Inmunoabsorción enzimática (ELISA)/ *Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis C infection, by Enzyme-linked immunosorbent assay (ELISA)* **[NANDO: IVD 0203]**

HCV IgM ELISA cualitativo-cuantitativo / *ELISA qualitative-quantitative*

- CVM.CE (96 tests)

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / *This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.*

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

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Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0392 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**0318**

A favor de /*In favour of*:

Fabricante/*Manufacturer*:
Nombre/*Name:* DIA. Pro Diagnostic Bioprobes S.r.l.
Dirección/*Address:* Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).
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Nombre/*Name:* Idem Dirección/*Address:* Idem

Para el producto/*For the product*:

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Grupo genérico/*Generic group*: Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*
Tipo/*Type*: Especificados en Anexos de este Certificado/*Specified in Annexes to this Certificate.*

Elaborado en/*In the facilities*:

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Madrid, 19 de noviembre de 2018
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agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

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C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902.101.322 /(+34) 91 822 59 97
Fax: (+34) 91 822 52 89

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HCV Ab ELISA cualitativo / *ELISA qualitative*

- CVAB.CE (192 tests)
- CVAB.CE.96 (96 tests)
- CVAB.CE.480 (480 tests)
- CVAB.CE.960 (960 tests)
- CVAB.CE.DB (192 tests - for Dia.Blood application)

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / *This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.*

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Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HEV IgM CODE: EVM.CE (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC DEVICES.

ISO CERTIFICATE(S)	UNI CEI EN ISO 13485–Nr 50 100 5931/B RELEASED BY CERTIFICATION BODY TÜV Italia S.r.l.

PLACE & DATE OF FIRST ISSUE	MILANO – MARCH 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	DIA.PRO DIAGNOSTIC BIOPROBES S.r.l.

Rev: 05/2018

Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HEV IgG CODE: EVG.CE (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC DEVICES.

ISO CERTIFICATE(S)	UNI CEI EN ISO 13485–Nr 50 100 5931/B RELEASED BY CERTIFICATION BODY TÜV Italia S.r.l.

PLACE & DATE OF FIRST ISSUE	MILANO – JULY 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.

Rev: 05/2018

Dia.Pro
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BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HAV IgM CODE: AVM.CE (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC DEVICES.

ISO CERTIFICATE(S)	UNI CEI EN ISO 13485–Nr 50 100 5931/B RELEASED BY CERTIFICATION BODY TÜV Italia S.r.l.

PLACE & DATE OF FIRST ISSUE	MILANO – SEPTEMBER 2003
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	DIA.PRO DIAGNOSTIC BIOPROBES S.r.l.

Rev: 05/2018

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BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HAV Ab CODE: AVAB.CE (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC DEVICES.

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SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	DIA.PRO DIAGNOSTIC BIOPROBES s.r.l.

Rev: 05/2018

HBsAg one

Version ULTRA

Fourth generation Enzyme Immunoassay (ELISA) for the determination of Hepatitis B surface Antigen or HBsAg in human serum and plasma

- for "in vitro" diagnostic use only -

DIA.PRO
Diagnostic Bioprobes Srl
Via G. Carducci n° 27
20099 Sesto San Giovanni
(Milano) - Italy
Phone +39 02 27007161
Fax +39 02 26007726
e-mail: info@diapro.it

REF SAG1ULTRA.CE
96-192-480-960 Tests

HBsAg One version ULTRA

A. INTENDED USE

Fourth generation Enzyme Immunoassay (ELISA) for the one-step determination of Hepatitis B surface Antigen or HBsAg in human plasma and sera.
The kit is intended for the screening of blood units, is able to detect HBsAg mutants and finds application in the follow-up of HBV-infected patients.
For "in vitro" diagnostic use only.

B. INTRODUCTION

The World Health Organization (WHO) defines Hepatitis B Virus infection as follows:

"Hepatitis B is one of the major diseases of mankind and is a serious global public health problem. Hepatitis means inflammation of the liver, and the most common cause is infection with one of 5 viruses, called hepatitis A,B,C,D, and E. All of these viruses can cause an acute disease with symptoms lasting several weeks including yellowing of the skin and eyes (jaundice); dark urine; extreme fatigue; nausea; vomiting and abdominal pain. It can take several months to a year to feel fit again. Hepatitis B virus can cause chronic infection in which the patient never gets rid of the virus and many years later develops cirrhosis of the liver or liver cancer.

HBV is the most serious type of viral hepatitis and the only type causing chronic hepatitis for which a vaccine is available. Hepatitis B virus is transmitted by contact with blood or body fluids of an infected person in the same way as human immunodeficiency virus (HIV), the virus that causes AIDS. However, HBV is 50 to 100 times more infectious than HIV. The main ways of getting infected with HBV are: (a) perinatal (from mother to baby at the birth); (b) child- to-child transmission; (c) unsafe injections and transfusions; (d) sexual contact.

Worldwide, most infections occur from infected mother to child, from child to child contact in household settings, and from reuse of un-sterilized needles and syringes. In many developing countries, almost all children become infected with the virus. In many industrialized countries (e.g. Western Europe and North America), the pattern of transmission is different. In these countries, mother-to-infant and child-to-child transmission accounted for up to one third of chronic infections before childhood hepatitis B vaccination programmes were implemented. However, the majority of infections in these countries are acquired during young adulthood by sexual activity, and injecting drug use. In addition, hepatitis B virus is the major infectious occupational hazard of health workers, and most health care workers have received hepatitis B vaccine.

Hepatitis B virus is not spread by contaminated food or water, and cannot be spread casually in the workplace. High rates of chronic HBV infection are also found in the southern parts of Eastern and Central Europe. In the Middle East and Indian sub-continent, about 5% are chronically infected. Infection is less common in Western Europe and North America, where less than 1% are chronically infected.

Young children who become infected with HBV are the most likely to develop chronic infection. About 90% of infants infected during the first year of life and 30% to 50% of children infected between 1 to 4 years of age develop chronic infection. The risk of death from HBV-related liver cancer or cirrhosis is approximately 25% for persons who become chronically infected during childhood. Chronic hepatitis B in some patients is treated with drugs called *interferon or lamivudine*, which can help some patients. Patients with cirrhosis are sometimes given liver transplants, with varying success. It is preferable to prevent this disease with vaccine than to try and cure it.

Hepatitis B vaccine has an outstanding record of safety and effectiveness. Since 1982, over one billion doses of hepatitis B vaccine have been used worldwide. The vaccine is given as a series of three intramuscular doses. Studies have shown that the vaccine is 95% effective in preventing children and adults from developing chronic infection if they have not yet been infected. In many countries where 8% to 15% of children used to become chronically infected with HBV, the rate of chronic infection has been reduced to less than 1% in immunized groups of children. Since 1991, WHO has called for all countries to add hepatitis B vaccine into their national immunization programs."

Hepatitis B surface Antigen or HBsAg is the most important protein of the envelope of Hepatitis B Virus, responsible for acute and chronic viral hepatitis.
The surface antigen contains the determinant "a", common to all the known viral subtypes, immunologically distinguished by two distinct subgroups (ay and ad).
The ability to detect HBsAg with high sensitive immunoassays in the last years has led to an understanding of its distribution and epidemiology worldwide and to radically decrease the risk of infection in transfusion.

C. PRINCIPLE OF THE TEST

A mix of mouse monoclonal antibodies specific to the determinants "a", "d" and "y" of HBsAg is fixed to the surface of microwells. Patient's serum/plasma is added to the microwell together with a second mix of mouse monoclonal antibodies, conjugated with Horseradish Peroxidase (HRP) and directed against a different epitope of the determinant "a" and against "preS".
The specific immunocomplex, formed in the presence of HBsAg in the sample, is captured by the solid phase.
At the end of the one-step incubation, microwells are washed to remove unbound serum proteins and HRP conjugate.
The chromogen/substrate is then added and, in the presence of captured HBsAg immunocomplex, the colorless substrate is hydrolyzed by the bound HRP conjugate to a colored end-product. After blocking the enzymatic reaction, its optical density is measured by an ELISA reader.
The color intensity is proportional to the amount of HBsAg present in the sample.
The version ULTRA is particularly suitable for automated screenings and is able to detect "s" mutants.

D. COMPONENTS

The standard configuration contains reagents to perform 192 tests and is made of the following components:

1. Microplate MICROPLATE
n° 2. 12 strips of 8 breakable wells coated with anti HBsAg, affinity purified mouse monoclonal antibodies, specific to "a", "y" and "d" determinants, and sealed into a bag with desiccant.

2. Negative Control CONTROL -
1x4.0ml/vial. Ready to use control. It contains goat serum, 10 mM phosphate buffer pH 7.4+/-0.1, 0.09% Na-azide and 0.1% Kathon GC as preservatives. The negative control is pale yellow color coded.

3. Positive Control CONTROL +
1x4.0ml/vial. Ready to use control. It contains goat serum, non infectious recombinant HBsAg, 10 mM phosphate buffer pH 7.4+/-0.1, 0.02% gentamicine sulphate and 0.1% Kathon GC as preservatives. The positive control is color coded green.

4. Calibrator CAL ...
n° 2 vials. Lyophilized calibrator. To be dissolved with EIA grade water as reported in the label. Contains fetal bovine serum, non infectious recombinant HBsAg at 0.5 IU/ml (2nd WHO international standard for HBsAg, NIBSC code 00/588), 10 mM phosphate buffer pH 7.4+/-0.1, 0.02% gentamicine sulphate and 0.1% Kathon GC as preservatives.
Note: The volume necessary to dissolve the content of the vial may vary from lot to lot. Please use the right volume reported on the label.

5. Wash buffer concentrate WASHBUF 20X
2x60ml/bottle. 20X concentrated solution. Once diluted, the wash solution contains 10 mM phosphate buffer pH 7.0+/-0.2, 0.05% Tween 20 and 0.1% Kathon GC.

6. Enzyme Conjugate Diluent CONJ DIL
2x15ml/vial. Ready to use and pink/red color coded regent. It contains 10 mM Tris buffer pH 6.8+/-0.1, 1% normal mouse serum, 5% BSA, 0.1% Kathon GC and 0.02% gentamicine sulphate as preservatives. The solution is normally opalescent.

7. Enzyme Conjugate CONJ 20X
2x1ml/vial. 20X concentrated reagent. It contains Horseradish Peroxidase (HRP) labeled mouse monoclonal antibodies to HBsAg, determinant "a" and "preS", 10 mM Tris buffer pH 6.8+/-0.1, 5% BSA, 0.1% Kathon GC and 0.02% gentamicine sulphate as preservatives.

8. Chromogen/Substrate SUBS TMB
2x25ml/bottle. It contains a 50 mM citrate-phosphate buffered solution at pH 3.5-3.8, 4% dimethylsulphoxide, 0.03% tetra-methyl-benzidine (TMB) and 0.02% hydrogen peroxide (H_2O_2).
Note: To be stored protected from light as sensitive to strong illumination.

9. Sulphuric Acid H_2SO_4 0.3 M
1x25ml/bottle. It contains 0.3 M H_2SO_4 solution.
Note: Attention: Irritant (H315; H319; P280; P302+P352; P332+P313; P305+P351+P338; P337+P313; P362+P363)

10. Plate sealing foils n° 4

11. Package insert

Important note:
Only upon specific request , Dia.Pro can supply reagents for 96, 480, 960 tests , as reported below:

Microplates	N°0	N°5	N°10
Negative Control	1x2ml/vial	1x10ml/vial	1x20ml/vial
Positive Control	1x2ml/vial	1x10ml/vial	1x20ml/vial
Calibrator	N° 1 vial	N° 5 vials	N° 10 vials
Wash buffer concentrate	1x60ml/vial	5x60ml/vial	4x150ml/vial
Enzyme conjugate	1x0.8ml/vial	1x4ml/vial	2x4ml/vial
Conjugate Diluent	1x16ml/vial	2x40ml/vial	2x80ml/vial
Chromogen/Substrate	1x25ml/vial	3x42ml/vial	2x125ml/vial
Sulphuric Acid	1x15ml/vial	2x40ml/vial	2x80ml/vial
Plate sealing foils	N° 2	N° 10	N° 20
Package insert	N° 1	N° 1	N° 1
Number of tests	96	480	960
Code SAG1ULTRA.CE	96	480	960

E. MATERIALS REQUIRED BUT NOT PROVIDED
1. Calibrated Micropipettes (150ul, 100ul and 50ul) and disposable plastic tips.
2. EIA grade water (double distilled or deionised, charcoal treated to remove oxidizing chemicals used as disinfectants).
3. Timer with 60 minute range or higher.
4. Absorbent paper tissues.
5. Calibrated ELISA microplate thermostatic incubator (dry or wet), capable to provide shaking at 1300 rpm+/-150, set at +37°C.
6. Calibrated ELISA microwell reader with 450nm (reading) and with 620-630nm (blanking) filters.
7. Calibrated ELISA microplate washer.
8. Vortex or similar mixing tools.

F. WARNINGS AND PRECAUTIONS
1. The kit has to be used by skilled and properly trained technical personnel only, under the supervision of a medical doctor responsible of the laboratory.
2. When the kit is used for the screening of blood units and blood components, it has to be used in a laboratory certified and qualified by the national authority in that field (Ministry of Health or similar entity) to carry out this type of analysis.
3. All the personnel involved in performing the assay have to wear protective laboratory clothes, talc-free gloves and glasses. The use of any sharp (needles) or cutting (blades) devices should be avoided. All the personnel involved should be trained in biosafety procedures, as recommended by the Center for Disease Control, Atlanta, U.S. and reported in the National Institute of Health's publication: "Biosafety in Microbiological and Biomedical Laboratories", ed. 1984.
4. All the personnel involved in sample handling should be vaccinated for HBV and HAV, for which vaccines are available, safe and effective.
5. The laboratory environment should be controlled so as to avoid contaminants such as dust or air-born microbial agents, when opening kit vials and microplates and when performing the test. Protect the Chromogen (TMB) from strong light and avoid vibration of the bench surface where the test is undertaken.
6. Upon receipt, store the kit at 2..8°C into a temperature controlled refrigerator or cold room.
7. Do not interchange components between different lots of the kits. It is recommended that components between two kits of the same lot should not be interchanged.
8. Check that the reagents are clear and do not contain visible heavy particles or aggregates. If not, advise the laboratory supervisor to initiate the necessary procedures for kit replacement.
9. Avoid cross-contamination between serum/plasma samples by using disposable tips and changing them after each sample.
10. Avoid cross-contamination between kit reagents by using disposable tips and changing them between the use of each one.
11. Do not use the kit after the expiration date stated on the external container and internal (vials) labels. A study conducted on an opened kit has not pointed out any relevant loss of activity up to 6 re-use of the device and up to 6 months.
12. Treat all specimens as potentially infective. All human serum specimens should be handled at Biosafety Level 2, as recommended by the Center for Disease Control, Atlanta, U.S. in compliance with what reported in the Institutes of Health's publication: "Biosafety in Microbiological and Biomedical Laboratories", ed. 1984.
13. The use of disposable plastic-ware is recommended in the preparation of the liquid components or in transferring components into automated workstations, in order to avoid cross contamination.
14. Waste produced during the use of the kit has to be discarded in compliance with national directives and laws concerning laboratory waste of chemical and biological substances. In particular, liquid waste generated from the washing procedure, from residuals of controls and from samples has to be treated as potentially infective material and inactivated before waste. Suggested procedures of inactivation are treatment with a 10% final concentration of household bleach for 16-18 hrs or heat inactivation by autoclave at 121°C for 20 min..
15. Accidental spills from samples and operations have to be adsorbed with paper tissues soaked with household bleach and then with water. Tissues should then be discarded in proper containers designated for laboratory/hospital waste.
16. The Stop Solution is an irritant. In case of spills, wash the surface with plenty of water
17. Other waste materials generated from the use of the kit (example: tips used for samples and controls, used microplates) should be handled as potentially infective and disposed according to national directives and laws concerning laboratory wastes.

G. SPECIMEN: PREPARATION AND WARNINGS
1. Blood is drawn aseptically by venepuncture and plasma or serum is prepared using standard techniques of preparation of samples for clinical laboratory analysis. No influence has been observed in the preparation of the sample with citrate, EDTA and heparin.
2. Avoid any addition of preservatives to samples; especially sodium azide as this chemical would affect the enzymatic activity of the conjugate, generating false negative results.
3. Samples have to be clearly identified with codes or names in order to avoid misinterpretation of results. When the kit is used for the screening of blood units, bar code labeling and electronic reading is strongly recommended.
4. Haemolysed (red) and lipemic ("milky") samples have to be discarded as they could generate false results. Samples containing residues of fibrin or heavy particles or microbial filaments and bodies should be discarded as well as they could give rise to false positive results. Specimens with an altered pathway of coagulation, presenting particles after blood collection and preparation of serum/plasma as those coming from hemodialized patients, could give origin to false positive results.
5. Sera and plasma can be stored at +2°..8°C for up to seven days after collection. For longer storage periods, samples can be stored frozen at –20°C for several months. Any frozen sample should not be frozen/thawed more than once as this may generate particles that could affect the test result. If some turbidity is present or presence of microparticles is suspected after thawing, filter the sample on a disposable 0,2-0,8u filter to clean it up for testing or use the two-steps alternative method.

H. PREPARATION OF COMPONENTS AND WARNINGS
A study conducted on an opened kit has not pointed out any relevant loss of activity up to 6 re-uses of the device and up to 6 months.

1. Microplates:
Allow the microplate to reach room temperature (about 1 hr) before opening the container. Check that the desiccant has not turned green, indicating a defect in conservation.
In this case, call Dia.Pro's customer service.
Unused strips have to be placed back inside the aluminum pouch, with the desiccant supplied, firmly zipped and stored at +2°..8°C. After first opening, remaining strips are stable until the humidity indicator inside the desiccant bag turns from yellow to green.

2. Negative Control:
Ready to use. Mix well on vortex before use.

3. Positive Control:
Ready to use. Mix well on vortex before use. The positive control does not contain any infective HBV as it is composed of recombinant synthetic HBsAg.

4. Calibrator:
Add the volume of ELISA grade water, reported on the label, to the lyophilized powder; let fully dissolve and then gently mix on vortex. The solution is not stable. Store the Calibrator frozen in aliquots at –20°C.

5. Wash buffer concentrate:
The 20x concentrated solution has to be diluted with EIA grade water up to 1200 ml and mixed gently end-over-end before use. As some salt crystals may be present into the vial, take care to dissolve all the content when preparing the solution.
In the preparation avoid foaming as the presence of bubbles could give origin to a bad washing efficiency.
Note: *Once diluted, the wash solution is stable for 1 week at +2..8° C.*

6. Enzyme conjugate:
The working solution is prepared by diluting the 20X concentrated reagent into the Conjugate
Mix well on vortex before use.
Avoid any contamination of the liquid with oxidizing chemicals, dust or microbes. If this component has to be transferred, use only plastic sterile disposable containers.
Important note: *The working solution is not stable. Prepare only the volume necessary for the work of the day. As an example when the kit is used in combination with other instruments or manually, dilute 0,1 ml 20X Conjugate with 1,9 ml Conjugate Diluent into a disposable plastic vial and mix carefully before use.*

7. Chromogen/Substrate:
Ready to use. Mix well by end-over-end mixing.
Avoid contamination of the liquid with oxidizing chemicals, air-driven dust or microbes. Do not expose to strong light, oxidizing agents and metallic surfaces.
If this component has to be transfered use only plastic, and if possible, sterile disposable container.

8. Sulphuric Acid:
Ready to use. Mix well by end-over-end mixing.
Attention: *Irritant* (H315; H319; P280; P302+P352; P332+P313; P305+P351+P338; P337+P313; P362+P363).

Legenda:

Warning ***H statements:***
H315 *– Causes skin irritation.*
H319 *– Causes serious eye irritation.*

Precautionary ***P statements:***
P280 *– Wear protective gloves/protective clothing/eye protection/face protection.*
P302 + P352 *– IF ON SKIN: Wash with plenty of soap and water.*
P332 + P313 *– If skin irritation occurs: Get medical advice/attention.*
P305 + P351 + P338 *– IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*
P337 + P313 *– If eye irritation persists: Get medical advice/attention.*
P362 + P363 *- Take off contaminated clothing and wash it before reuse.*

I. INSTRUMENTS AND TOOLS USED IN COMBINATION WITH THE KIT
1. **Micropipettes** have to be calibrated to deliver the correct volume required by the assay and must be submitted to regular decontamination (70% ethanol, 10% solution of bleach, hospital grade disinfectants) of those parts that could accidentally come in contact with the sample or the components of the kit. They should also be regularly maintained in order to show a precision of 1% and a trueness of ±2%.
2. The **ELISA incubator** has to be set at +37°C (tolerance of ±1°C) and regularly checked to ensure the correct temperature is maintained. Both dry incubators and water baths are suitable for the incubations, provided that the instrument is validated for the incubation of ELISA tests.
3. In case of **shaking** during incubations, the instrument has to ensure 350 rpm ±150. Amplitude of shaking is very important as a wrong one could give origin to splashes and therefore to some false positive result.
4. The **ELISA washer** is extremely important to the overall performances of the assay. The washer must be carefully validated and correctly optimized using the kit controls/calibrator and reference panels, before using the kit for routine laboratory tests. Usually 4-5 washing cycles (aspiration + dispensation of 350ul/well of washing solution = 1 cycle) are sufficient to ensure that the assay performs as expected. A soaking time of 20-30 seconds between cycles is suggested. In order to set correctly their number, it

is recommended to run an assay with the kit controls/calibrator and well-characterized negative and positive reference samples, and check to match the values reported below in the section "Internal Quality Control". Regular calibration of the volumes delivered and maintenance (decontamination and cleaning of needles) of the washer has to be carried out according to the instructions of the manufacturer.

5. **Incubation times** have a tolerance of ±5%.
6. The **microplate reader** has to be equipped with a reading filter of 450nm and with a second filter (620-630nm, strongly recommended) for blanking purposes. Its standard performances should be (a) bandwidth ≤ 10 nm; (b) absorbance range from 0 to ≥ 2.0; (c) linearity to ≥ 2.0; (d) repeatability ≥ 1%. Blanking is carried out on the well identified in the section "Assay Procedure". The optical system of the reader has to be calibrated regularly to ensure that the correct optical density is measured. It should be regularly maintained according to the manufacturer 's instructions.
7. When using **ELISA automated workstations**, all critical steps (dispensation, incubation, washing, reading, shaking, data handling, etc.) have to be carefully set, calibrated, controlled and regularly serviced in order to match the values reported in the sections "Internal Quality Control". The assay protocol has to be installed in the operating system of the unit and validated by checking full matching the declared performances of the kit. In addition, the liquid handling part of the station (dispensation and washing) has to be validated and correctly set paying particular attention to avoid carry over by the needles used for dispensing samples and for washing. The carry over effect must be studied and controlled to minimize the possibility of contamination of adjacent wells due to strongly reactive samples, leading to false positive results. The use of ELISA automated work stations is recommended for blood screening and when the number of samples to be tested exceed 20-30 units per run.
8. When using automatic devices, in case the vial holder of the instrument does not fit with the vials supplied in the kit, transfer the solution into appropriate containers and label them with the same label peeled out from the original vial. This operation is important in order to avoid mismatching contents of vials, when transferring them. When the test is over, return the secondary labeled containers to 2..8°C, firmly capped.
9. **Dia.Pro's customer service** offers support to the user in the setting and checking of instruments used in combination with the kit, in order to assure full compliance with the essential requirements of the assay. Support is also provided for the installation of new instruments to be used in combination with the kit.

L. PRE ASSAY CONTROLS AND OPERATIONS

1. Check the expiration date of the kit printed on the external label of the kit box. Do not use if expired.
2. Check that the liquid components are not contaminated by naked-eye visible particles or aggregates. Check that the Chromogen/Substrate is colorless or pale blue. Check that no breakage occurred in transportation and no spillage of liquid is present inside the box. Check that the aluminum pouch, containing the microplate, is not punctured or damaged.
3. Dilute all the content of the 20x concentrated Wash Solution as described above.
4. Dilute the 20X concentrated Enzyme Conjugate with its Diluent as reported.
5. Dissolve the Calibrator as described above.
6. Allow all the other components to reach room temperature (about 1 hr) and then mix as described.
7. Set the ELISA incubator at +37°C and prepare the ELISA washer by priming with the diluted washing solution, according to the manufacturers instructions. Set the right number of washing cycles as found in the validation of the instrument for its use with the kit.
8. Check that the ELISA reader has been turned on at least 20 minutes before reading.
9. If using an automated workstation, turn it on, check settings and be sure to use the right assay protocol.
10. Check that the micropipettes are set to the required volume.
11. Check that all the other equipment is available and ready to use.
12. In case of problems, do not proceed further with the test and advise the supervisor.

M. ASSAY PROCEDURE

The assay has to be carried out according to what reported below, taking care to maintain the same incubation time for all the samples in testing.

Automated assay:

In case the test is carried out automatically with an ELISA system, we suggest to make the instrument dispense first 150 ul controls & calibrator, then all the samples and finally 100 ul diluted Enzyme Conjugate.
For the pre-washing step (point 1 of the assay procedure) and all the next operations follow the operative instructions reported below for the Manual Assay.
It is strongly recommended to check that the time lap between the dispensation of the first and the last sample will be calculated by the instrument and taken into consideration by delaying the first washing operation accordingly.

Manual Assay:

1. Place the required number of strips in the plastic holder and wash them once to hydrate wells. Carefully identify the wells for controls, calibrator and samples.

Important note: *Pre washing (1 cycle: dispensation of 350ul/well of washing solution+ aspiration) is fundamental to obtain reliable and specific results both in the manual and in the automatic procedures. Do not omit it !*

2. Leave the A1 well empty for blanking purposes.
3. Pipette 150µl of the Negative Control in triplicate, 150ul of the Calibrator in duplicate and then 150ul of the Positive Control in single followed by 150ul of each of the samples.
4. Check for the presence of samples in wells by naked eye (there is a marked color difference between empty and full wells) or by reading at 450/620nm. (samples show OD values higher than 0.100).
5. Dispense 100ul diluted Enzymatic Conjugate in all wells, except for A1, used for blanking operations.

Important note: *Be careful not to touch the inner surface of the well with the pipette tip when the conjugate is dispensed. Contamination might occur.*

6. Following addition of the conjugate, check that the color of the samples have changed from yellowish to pink/red and then incubate the microplate for **120 min at +37°C.**

Important notes:

a. Strips have to be sealed with the adhesive sealing foil, only when the test is performed manually. Do not cover strips when using ELISA automatic instruments.
b. If the procedure is carried out on shaking, be sure to deliver the rpm reported for in Section I.3 as otherwise intra-well contamination could occur.

7. When the first incubation is over, wash the microwells as previously described (section I.4).

8. Pipette 200 µl Chromogen/Substrate into all the wells, A1 included.

Important note: *Do not expose to strong direct light as a high background might be generated.*

9. Incubate the microplate protected from light at **18-24°C for 30 min.** Wells dispensed with the positive control, the calibrator and positive samples will turn from clear to blue.
10. Pipette 100 µl Sulphuric Acid into all the wells to stop the enzymatic reaction, using the same pipetting sequence as in step 8. Addition of the acid solution will turn the positive control, the calibrator and positive samples from blue to yellow/brown.
11. Measure the color intensity of the solution in each well, as described in section I.6 using a 450nm filter (reading) and a 620-630nm filter (background subtraction, strongly recommended), blanking the instrument on A1.

Important general notes:

1. *If the second filter is not available, ensure that no fingerprints or dust are present on the external bottom of the microwell before reading at 450nm. They could generate false positive results on reading.*
2. *Reading should ideally be performed immediately after the addition of the acid solution but definitely no longer than 20 minutes afterwards. Some self-oxidation of the chromogen can occur leading to a higher background.*
3. *When samples to be tested are not surely clean or have been stored frozen, the assay procedure reported below is recommended as long as it is far less sensitive to interferences due to hemolysis, hyperlipaemia, bacterial contamination and fibrin microparticles. The assay is carried out in two-steps at +37°C on shaking at 350 rpm ±150 as follows:*
   - *dispense 100 ul of controls, calibrator and samples*
   - *incubate 60 min at +37°C on shaking*
   - *wash according to instructions (section I.4)*
   - *dispense 100 ul diluted enzyme tracer*
   - *incubate 30 min at +37°C on shaking*
   - *wash*
   - *dispense 100 ul TMB&H2O2 mix*
   - *incubate 30 min at r.t. on shaking*
   - *stop and read*

   In this procedure the pre-wash can be omitted.
   This method shows performances similar to the standard one and therefore can be used in alternative.
4. *The Calibrator (CAL) does not affect the cut-off calculation and therefore the test results calculation. The Calibrator may be used only when a laboratory internal quality control is required by the management.*

N. ASSAY SCHEME

Operations	Procedure
Pre-Washing step	n° 1 cycle
Controls&Calibrator&samples	150 ul
Diluted Enzyme Conjugate	100 ul
1st incubation	120 min
Temperature	+37°C
Washing steps	n° 4-5
Chromogen/Substrate	200ul
2nd incubation	30 min
Temperature	room
Sulphuric Acid	100 ul
Reading OD	450nm

An example of dispensation scheme is reported in the following section:

Microplate

	1	2	3	4	5	6	7	8	9	10	11	12
A	BLK	S2										
B	NC	S3										
C	NC	S4										
D	NC	S5										
E	CAL	S6										
F	CAL	S7										
G	PC	S8										
H	S1	S9										

Legenda: BLK = Blank NC = Negative Control
CAL = Calibrator PC = Positive Control S = Sample

O. INTERNAL QUALITY CONTROL

A check is performed on the controls/calibrator any time the kit is used in order to verify whether the expected OD450nm or S/Co values have been matched in the analysis.

Ensure that the following results are met:

Parameter	Requirements
Blank well	< 0.100 OD450nm value
Negative Control (NC)	< 0.050 mean OD450nm value after blanking
Calibrator 0.5 IU/ml	S/Co ≥ 2
Positive Control	> 1.000 OD450nm value

If the results of the test match the requirements stated above, proceed to the next section.
If they do not, do not proceed any further and perform the following checks:

Problem	Check
Blank well > 0.100 OD450nm	1. that the Chromogen/Substrate solution has not become contaminated during the assay
Negative Control (NC) > 0.050 OD450nm after blanking	1. that the washing procedure and the washer settings are as validated in the pre qualification study; 2. that the proper washing solution has been used and the washer has been primed with it before use; 3. that no mistake has been done in the assay procedure (dispensation of positive control instead of the negative one); 4. that no contamination of the negative control or of the wells where the control was dispensed has occurred due to spills of positive samples or of the enzyme conjugate; 5. that micropipettes have not become contaminated with positive samples or with the enzyme conjugate 6. that the washer needles are not blocked or partially obstructed.

Calibrator S/Co < 2	1. that the procedure has been correctly performed; 2. that no mistake has occurred during its distribution (ex.: dispensation of negative control instead of calibrator) 3. that the washing procedure and the washer settings are as validated in the pre qualification study; 4. that no external contamination of the calibrator has occurred.
Positive Control < 1.000 OD450nm	1. that the procedure has been correctly performed; 2. that no mistake has occurred during the distribution of the control (dispensation of negative control instead of positive control. In this case, the negative control will have an OD450nm value > 0.050). 3. that the washing procedure and the washer settings are as validated in the pre qualification study; 4. that no external contamination of the positive control has occurred.

If any of the above problems have occurred, report the problem to the supervisor for further actions.

P. CALCULATION OF THE CUT-OFF

The test results are calculated by means of a cut-off value determined on the mean OD450nm value of the negative control (NC) with the following formula:

NC + 0.050 = Cut-Off (Co)

The value found for the test is used for the interpretation of results as described in the next paragraph.

***Important note**: When the calculation of results is performed by the operating system of an ELISA automated work station, ensure that the proper formulation is used to calculate the cut-off value and generate the correct interpretation of results.*

Q. INTERPRETATION OF RESULTS

Test results are interpreted as a ratio of the sample OD450nm (S) and the Cut-Off value (Co), mathematically S/Co, according to the following table:

S/Co	Interpretation
< 0.9	Negative
0.9 – 1.1	Equivocal
> 1.1	Positive

A negative result indicates that the patient is not infected by HBV and that the blood unit may be transfused.
Any patient showing an equivocal result should be retested on a second sample taken 1-2 weeks after the initial sample; the blood unit should not be transfused.
A positive result is indicative of HBV infection and therefore the patient should be treated accordingly or the blood unit should be discarded.

Important notes:

1. *Interpretation of results should be done under the supervision of the laboratory supervisor to reduce the risk of judgment errors and misinterpretations.*
2. *Any positive result must be confirmed first by repeating the test on the sample, after having filtered it on 0.2-0.8 u filter to remove any microparticles interference. Then, if still positive, the sample has to be submitted to a confirmation test before a diagnosis of viral hepatitis is released.*
3. *When test results are transmitted from the laboratory to another department, attention must be paid to avoid erroneous data transfer.*
4. *Diagnosis of viral hepatitis infection has to be taken and released to the patient by a suitably qualified medical doctor.*

An example of calculation is reported below.

The following data must not be used instead or real figures obtained by the user.

Negative Control: 0.012 – 0.008 – 0.010 OD450nm
Mean Value: 0.010 OD450nm
Lower than 0.050 – Accepted
Positive Control: 2.489 OD450nm
Higher than 1.000 – Accepted
Cut-Off = 0.010+0.050 = 0.060
Calibrator: 0.350 - 0.370 OD450nm
Mean value: 0.360 OD450nm S/Co = 6.0
S/Co higher than 2.0 – Accepted
Sample 1: 0.028 OD450nm
Sample 2: 1.690 OD450nm
Sample 1 S/Co < 0.9 = negative
Sample 2 S/Co > 1.1 = positive

R. PERFORMANCE CHARACTERISTICS

Evaluation of Performances has been conducted in accordance to what reported in the Common Technical Specifications or CTS (art. 5, Chapter 3 of IVD Directive 98/79/EC). Version ULTRA proved to be at least equivalent to the original design in a study conducted for the validation of the new version.

1. Analytical Sensitivity

The limit of detection of the assay has been calculated on the 2ND WHO international standard, NIBSC code 00/588.
In the following table, results are given for three lots (P1, P2 and P3) of the version ULTRA in comparison with the reference device (Ref.):

WHO IU/ml	Lot # P1 S/Co	Lot # P2 S/Co	Lot # P3 S/Co	Ref. S/Co
0.4	4.6	4.8	4.6	4.6
0.2	2.3	2.4	2.4	2.4
0.1	1.4	1.4	**1.5**	1.2
0.05	0.8	0.8	***1.0***	0.7
0.025	0.6	0.6	0.6	0.4
FCS (NC)	0.3	0.2	0.3	0.1

The assay shows an Analytical Sensitivity better than 0.1 WHO IU/ml of HBsAg.

In addition two panels of sensitivity supplied by EFS, France, and by SFTS, France, were tested and gave in the best conditions the following results:

Panel EFS Ag HBs HB1-HB6 lot n° 04

Sample ID	Characteristics	ng/ml	S/Co
HB1	diluent	/	0.2
HB2	adw2+ayw3	0.05	0.6
HB3	adw2+ayw3	0.1	1.0
HB4	adw2+ayw3	0.2	1.8
HB5	adw2+ayw3	0.3	2.4
HB6	adw2+ayw3	0.5	4.2

Sensitivity panel SFTS, France, Ag HBs 2005

Sample ID	Characteristics	ng/ml	S/Co
171	Adw2 + ayw3	2.21 ± 0.15	15,4
172	Adw2 + ayw3	1.18 ± 0.10	8,7
173	Adw2 + ayw3	1.02 ± 0.05	6,1
174	Adw2 + ayw3	0.64 ± 0.04	4,6
175	Adw2 + ayw3	0.49 ± 0.03	3,4
176	Adw2 + ayw3	0.39 ± 0.02	2,6
177	Adw2 + ayw3	0.25 ± 0.02	2,0
178	Adw2 + ayw3	0.11 ± 0.02	1,3
179	Adw2 + ayw3	0.06 ± 0.01	**0,9**
180	Adw2 + ayw3	0.03 ± 0.01	0,8
181	Adw2	0.5 – 1.0	4,7
182	Adw4	0.5 – 1.0	3,6
183	Adr	0.5 – 1.0	4,5
184	Ayw1	0.5 – 1.0	5,1
185	Ayw2	0.5 – 1.0	6,4
186	Ayw3	0.5 – 1.0	7,3
187	Ayw3	0.5 – 1.0	5,8
188	Ayw4	0.5 – 1.0	6,9
189	Ayr	0.5 – 1.0	6,1
190	diluent	/	0.6

The panel # 808, supplied by Boston Biomedical Inc., USA, was also tested to define the limit of sensitivity.
Results in the best conditions are as follows :

BBI panel PHA 808

Sample ID	Characteristics	ng/ml	S/Co
01	ad	2,49	10,2
02	ad	1,17	4,8
03	ad	1,02	4,3
04	ad	0,96	3,8
05	ad	0,69	2,9
06	ad	0,50	2,2
07	ad	0,41	1,5
08	ad	0,37	1,3
09	ad	0,30	1,2
10	ad	0,23	***1,0***
11	ay	2,51	11,2
12	ay	1,26	5,9
13	ay	0,97	4,1
14	ay	0,77	3,7
15	ay	0,63	2,6
16	ay	0,48	2,4
17	ay	0,42	2,0
18	ay	0,33	1,8
19	ay	0,23	1,6
20	ay	0,13	1,1
21	negative	/	0.6

2. Diagnostic Sensitivity:

The diagnostic sensitivity was tested according to what required by Common Technical Specifications (CTS) of the directive 98/79/EC on IVD for HBsAg testing.
Positive samples, including HBsAg subtypes and a panel of "s" mutants from most frequent mutations, were collected from different HBV pathologies (acute, a-symptomatic and chronic hepatitis B) or produced synthetically, and were detected positive in the assay.
All the HBsAg known subtypes, "ay" and "ad", and isoforms "w" and "r", supplied by CNTS, France, were tested in the assay and determined positive by the kit as expected.
An overall value of 100% has been found in a study conducted on a total number of more than 400 samples positive with the original reference IVD code SAG1.CE, CE marked.
A total of 30 sero-conversions were studied, most of them produced by Boston Biomedica Inc., USA.

Results obtained by examining eight panels supplied by Boston Biomedica Inc., USA, are reported below for the version ULTRA in comparison with the reference device code SAG1.CE.

Panel ID	1st sample positive	HBsAg subtype	HBsAg ng/ml	Version ULTRA S/Co	Ref. device S/Co
PHM 906	02	ad	0.5	3.7	1.4
PHM 907 (M)	06	ay	1.0	4.4	2.9
PHM 909	04	ad	0.3	1.2	0.8
PHM 914	04	ad	0.5	1.1	1.1
PHM 918	02	ad	0.1	1.8	0.5
PHM 923	03	ay	< 0.2	2.2	1.3
PHM 925	03	Ind.	n.d.	1.4	0.9
PHM 934	01	ad	n.d.	1.0	0.8

3. Diagnostic Specificity:

It is defined as the probability of the assay of scoring negative in the absence of specific analyte. In addition to the first study, where more than 5000 negative samples from blood donors (two blood centers), classified negative with a CE marked device in use at the laboratory of collection were examined, the diagnostic specificity was recently assessed by testing a total of 2288 negative blood donors on seven different lots. A value of specificity of 100% was found.
Both plasma, derived with different standard techniques of preparation (citrate, EDTA and heparin), and sera have been used to determine the specificity.
No false reactivity due to the method of specimen preparation has been observed.
Frozen specimens have also been tested to check whether samples freezing interferes with the performance of the test. No interference was observed on clean and particle free samples.
Samples derived from patients with different viral (HCV, HAV) and non viral pathologies of the liver that may interfere with the test were examined. No cross reaction were observed.

4. Precision:

It has been calculated for the version ULTRA on two samples examined in 16 replicates in 3 different runs for three lots.
Results are reported in the following tables:

Average values Total n = 144	Negative Sample	Calibrator 0.5 IU/ml
OD450nm	0.026	0.332
Std.Deviation	0.004	0.027
CV %	16%	8%

The variability shown in the tables did not result in sample misclassification.

5. LIMITATIONS

Repeatable false positive results were assessed on freshly collected specimens in less than 0.1% of the normal population, mostly due to high titers Heterophilic Anti Mouse Antibodies (HAMA).
Interferences in fresh samples were also observed when they were not particles-free or were badly collected (see chapter G).
Old or frozen samples, presenting fibrin clots, crioglobulins, lipid-containing micelles or microparticles after storage or thawing, can generate false positive results.

REFERENCES

1. Aach R.D., Grisham J.W., Parker S.W.. Detection of Australia antigen by radioimmunoassay. Proc.Natl.Acad.Scl..USA, 68:1956, 1971.
2. Blumerg B.S., Suinick A.I., London W.T.. Hepatitis and leukemia: their relation to Australia antigen. Bull.N.Y.Acad.Med.. 44:1566, 1968.
3. Boniolo A., Dovis M., Matteja R.. The use of enzyme-linked immunosorbent assay for screening hybridoma antibodies against hepatitis B surface antigen. J.Immunol.Meth.. 49:1, 1982.
4. Caldwell C.W., Barpet J.T.. Enzyme immunoassay for hepatitis B and its comparison to other methods. Cli.Chim.Acta 81; 305, 1977
5. Fazekas S., De St.Groth, Scheidegger D.. production of monoclonal antibodies: strategy and tactics. J.Immunol.Meth.. 35: 1, 1980
6. Reesink H.W.. et al.. Comparison of six 3rd generation tests for the detection of HBsAg. Vox.Sang.. 39:61, 1980
7. Rook G.A.W.. Chromogens for the enzyme-linked immunosorbent assay (ELISA) using horseradish peroxidase. Lepr.Rev. 52: 281, 1981
8. Schroder J.. Monoclonal antibodies: a new tool for reasearch and immunodiagnostic. Med.Biol.. 58: 281, 1981
9. Coleman PF, Chen YC, Mushahwar IK. Immunoassay detection of hepatitis B surface antigen mutants. J.Med.Virol. 1999;59(1):19-24

All the IVD Products manufactured by the company are under the control of a certified Quality Management System approved by an EC Notified Body. Each lot is submitted to a quality control and released into the market only if conforming with the EC technical specifications and acceptance criteria.

Manufacturer:
Dia.Pro Diagnostic Bioprobes S.r.l.
Via G. Carducci n° 27 – Sesto San Giovanni (MI) – Italy

CE
0318

HEV IgM

Enzyme Immunoassay (ELISA) for the determination of IgM antibodies to Hepatitis E Virus in human serum and plasma

- for "in vitro" diagnostic use only -

DIA.PRO
Diagnostic Bioprobes Srl
Via G. Carducci n° 27
20099 Sesto San Giovanni
(Milano) - Italy
Phone +39 02 27007161
Fax +39 02 26007726
e-mail: info@diapro.it

REF EVM.CE
96 Tests

HEV IgM

A. INTENDED USE

Enzyme ImmunoAssay (ELISA) for the determination of IgM antibodies to Hepatitis E Virus in human plasma and sera.
The kit may be used for the determination of the acute phase of infection where IgM antibodies are generated before the other immunoglobulins and for the follow-up of HEV-infected patients.
For "in vitro" diagnostic use only.

B. INTRODUCTION

Hepatitis E Virus or HEV is a recently discovered agent of enterically transmitted viral hepatitis. HEV is an un-enveloped single-strand RNA virus, after being provisionally assigned to the Caliciviridae family, HEV was re-classified as the sole member of the genus Hepevirus, family Hepeviridae, in 2004.
HEV is found in the stool of infected patients and present in 4 strains (1, 2, 3 and 4) differently spread geographically and virulent.
HEV is a serious problem in many developing countries since its first outbreak was reported in 1955 in New Delhi, India.
A high case-fatality rate has been found among pregnant women and chronic hepatitis carriers.
The cloning and sequencing of HEV genome have led to the development of serological tests for the detection of anti HEV antibodies based on recombinant immunodominant antigens derived from conservative regions of the four virus strains.

C. PRINCIPLE OF THE TEST

Microplates are coated with HEV-specific recombinant antigens encoding for conservative and immunodominant determinants of all the 4 subtypes.
The solid phase is first treated with the diluted sample and anti HEV IgM are captured, if present, by the antigens.
After washing out all the other components of the sample, in the 2nd incubation bound anti-HEV IgM are detected by the addition of polyclonal specific anti hIgM antibodies, labelled with peroxidase (HRP).
The enzyme captured on the solid phase, acting on the substrate/chromogen mixture, generates an optical signal that is proportional to the amount of anti HEV IgM present in the sample. A cut-off value let optical densities be interpreted into anti-HEV IgM negative and positive results.
Neutralization of IgG anti-HEV and Rheumatoid Factor, carried out directly in the well, is performed in the assay in order to block such kind of interferences.

D. COMPONENTS

Code EVM.CE contains reagents for 96 tests.

1. Microplate MICROPLATE
n° 1 microplate. 12 strips of 8 microwells coated with HEV specific recombinant antigens. Plates are sealed into a bag with desiccant.

2. Negative Control CONTROL -
1x4.0ml/vial. Ready to use control. It contains 1% goat serum proteins, 10 mM Na-citrate buffer pH 6.0 +/-0.1, 0.5% Tween 20, 0.09% Na-azide and 0.1% Kathon GC as preservatives. The negative control is yellow colour coded.

3. Positive Control CONTROL +
1x4.0ml/vial. Ready to use control. It contains 1% goat serum proteins, human anti HEV IgM, 10 mM Na-citrate buffer pH 6.0 +/-0.1, 0.5% Tween 20, 0.09% Na-azide and 0.1% Kathon GC as preservatives.
The Positive Control is dark green colour coded.

4. Wash buffer concentrate WASHBUF 20X
1x60ml/bottle, 20x concentrated solution. Once diluted, the wash solution contains 10 mM phosphate buffer pH 7.0+/-0.2, 0.05% Tween 20 and 0.1% Kathon GC.

5. Enzyme Conjugate CONJ
1x16ml/vial. Ready to use and red colour coded reagent. It contains Horseradish Peroxidase conjugated goat polyclonal antibodies to human IgM, 5% BSA, 10 mM Tris buffer pH 6.8+/-0.1, 0.1% Kathon GC and 0.02% gentamicine sulphate as preservatives.

6. Chromogen/Substrate SUBS TMB
1x16ml/vial. Ready-to-use component. It contains 50 mM citrate-phosphate buffer pH 3.5-3.8, 4% dimethylsulphoxide, 0.03% tetra-methyl-benzidine or TMB and 0.02% hydrogen peroxide or H2O2.
Note: To be stored protected from light as sensitive to strong illumination.

7. Sulphuric Acid H_2SO_4 0.3 M
1x15ml/vial. It contains 0.3 M H_2SO_4 solution.
Attention: Irritant (H315, H319; P280, P302+P352, P332+P313, P305+P351+P338, P337+P313, P362+P363).

8. Specimen Diluent: DILSPE
2x60ml/vial. It contains 2% casein, 10 mM Na-citrate buffer pH 6.0 +/-0.1, 0.1% Tween 20, 0.09% Na-azide and 0.1% Kathon GC as preservatives. To be used to dilute the sample.

9. Neutralizing Reagent: SOLN NTR
1x8ml/vial. Ready-to-use Reagent. It contains goat anti hIgG, 2% casein, 10 mM Na-citrate buffer pH 6.0 +/-0.1, 0.1% Tween 20, 0.09% Na-azide and 0.1% Kathon GC as preservatives.

10. Plate sealing foils n° 2

11. Package insert n° 1

E. MATERIALS REQUIRED BUT NOT PROVIDED

1. Calibrated Micropipettes (100ul and 10ul) and disposable plastic tips.
2. EIA grade water (bidistilled or deionised, charcoal treated to remove oxidizing chemicals used as disinfectants).
3. Timer with 60 minute range or higher.
4. Absorbent paper tissues.
5. Calibrated ELISA microplate thermostatic incubator capable to provide a temperature of +37°C.
6. Calibrated ELISA microwell reader with 450nm (reading) and with 620-630nm (blanking) filters.
7. Calibrated ELISA microplate washer.
8. Vortex or similar mixing tools.

F. WARNINGS AND PRECAUTIONS

1. The kit has to be used by skilled and properly trained technical personnel only, under the supervision of a medical doctor responsible of the laboratory.
2. All the personnel involved in performing the assay have to wear protective laboratory clothes, talc-free gloves and glasses. The use of any sharp (needles) or cutting (blades) devices should be avoided. All the personnel involved should be trained in biosafety procedures, as recommended by the Center for Disease Control, Atlanta, U.S. and reported in the National Institute of Health's publication: "Biosafety in Microbiological and Biomedical Laboratories", ed. 1984.
3. All the personnel involved in sample handling should be vaccinated for HBV and HAV, for which vaccines are available, safe and effective.
4. The laboratory environment should be controlled so as to avoid contaminants such as dust or air-born microbial agents when opening kit vials and microplates and when performing the

test. Protect the Chromogen/Substrate from strong light and avoid vibration of the bench surface where the test is undertaken.
5. Upon receipt, store the kit at 2..8°C into a temperature controlled refrigerator or cold room.
6. Do not interchange components between different lots of the kits. It is recommended that components between two kits of the same lot should not be interchanged.
7. Check that the reagents are clear and do not contain visible heavy particles or aggregates. If not, advise the laboratory supervisor to initiate the necessary procedures for kit replacement.
8. Avoid cross-contamination between serum/plasma samples by using disposable tips and changing them after each sample.
9. Avoid cross-contamination between kit reagents by using disposable tips and changing them between the use of each one.
10. Do not use the kit after the expiration date stated on the external container and internal (vials) labels.
11. Treat all specimens as potentially infective. All human serum specimens should be handled at Biosafety Level 2, as recommended by the Center for Disease Control, Atlanta, U.S. in compliance with what reported in the Institutes of Health's publication: "Biosafety in Microbiological and Biomedical Laboratories", ed. 1984.
12. The use of disposable plastic-ware is recommended in the preparation of the liquid components or in transferring components into automated workstations, in order to avoid cross contamination.
13. Waste produced during the use of the kit has to be discarded in compliance with national directives and laws concerning laboratory waste of chemical and biological substances. In particular, liquid waste generated from the washing procedure, from residuals of controls and from samples has to be treated as potentially infective material and inactivated before waste. Suggested procedures of inactivation are treatment with a 10% final concentration of household bleach for 16-18 hrs or heat inactivation by autoclave at 121°C for 20 min..
14. Accidental spills from samples and operations have to be adsorbed with paper tissues soaked with household bleach and then with water. Tissues should then be discarded in proper containers designated for laboratory/hospital waste.
15. The Sulphuric Acid is an irritant. In case of spills, wash the surface with plenty of water
16. Other waste materials generated from the use of the kit (example: tips used for samples and controls, used microplates) should be handled as potentially infective and disposed according to national directives and laws concerning laboratory wastes.

G. SPECIMEN: PREPARATION AND RECOMMANDATIONS

1. Blood is drawn aseptically by venepuncture and plasma or serum is prepared using standard techniques of preparation of samples for clinical laboratory analysis. No influence has been observed in the preparation of the sample with citrate, EDTA and heparin.
2. Samples have to be clearly identified with codes or names in order to avoid misinterpretation of results. When the kit is used for the screening of blood units, bar code labeling and electronic reading is strongly recommended.
3. Haemolysed (red) and visibly hyperlipemic ("milky") samples have to be discarded as they could generate false results. Samples containing residues of fibrin or heavy particles or microbial filaments and bodies should be discarded as they could give rise to false results.
4. Sera and plasma can be stored at +2°..8°C for up to five days after collection. For longer storage periods, samples can be stored frozen at –20°C for several months. Any frozen samples should not be frozen/thawed more than once as this may generate particles that could affect the test result.
5. If particles are present, centrifuge at 2.000 rpm for 20 min or filter using 0.2-0.8u filters to clean up the sample for testing.

H. PREPARATION OF COMPONENTS AND WARNINGS

A study conducted on an opened kit has not pointed out any relevant loss of activity up to 6 re-use of the device and up to 6 months.

Microplates:
Allow the microplate to reach room temperature (about 1 hr) before opening the container. Check that the desiccant is not turned to dark green, indicating a defect of conservation.
In this case call Dia.Pro's customer service.
Unused strips have to be placed back into the aluminium pouch, in presence of desiccant supplied, firmly zipped and stored at +2°..8°C.
When opened the first time, residual strips are stable till the indicator of humidity inside the desiccant bag turns from yellow to green.

Negative Control:
Ready to use. Mix well on vortex before use.

Positive Control:
Ready to use. Mix well on vortex before use. Handle this component as potentially infective, even if HCV, eventually present in the control, has been chemically inactivated.

Wash buffer concentrate:
The whole content of the 20x concentrated solution has to be diluted with bidistilled water up to 1200 ml and mixed gently end-over-end before use.
Once diluted, the wash solution is stable for 1 week at +2..8° C.
In the preparation avoid foaming as the presence of bubbles could give origin to a bad washing efficiency.
Note: *Once diluted, the wash solution is stable for 1 week at +2..8° C.*

Enzyme conjugate:
Ready to use. Mix well on vortex before use.
Be careful not to contaminate the liquid with oxidizing chemicals, air-driven dust or microbes.
If this component has to be transferred use only plastic, possibly sterile disposable containers.

Chromogen/Substrate:
Ready to use. Mix well on vortex before use.
Be careful not to contaminate the liquid with oxidizing chemicals, air-driven dust or microbes.
Do not expose to strong illumination, oxidizing agents and metallic surfaces.
If this component has to be transferred use only plastic, possible sterile disposable container.

Neutralizing Reagent
Ready to use component. Mix carefully on vortex before use.

Sample Diluent:
Ready to use. Mix well on vortex before use.

Sulphuric Acid:
Ready to use. Mix well on vortex before use.
Attention: Irritant (H315, H319; P280, P302+P352, P332+P313, P305+P351+P338, P337+P313, P362+P363).

Legenda:

Warning **H** statements:
H315 – Causes skin irritation.
H319 – Causes serious eye irritation.

Precautionary **P** statements:
P280 – Wear protective gloves/protective clothing/eye protection/face protection.

P302 + P352 – IF ON SKIN: Wash with plenty of soap and water.
P332 + P313 – If skin irritation occurs: Get medical advice/attention.
P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 – If eye irritation persists: Get medical advice/attention.
P362 + P363 – Take off contaminated clothing and wash it before reuse.

I. INSTRUMENTS AND TOOLS USED IN COMBINATION WITH THE KIT

1. **Micropipettes** have to be calibrated to deliver the correct volume required by the assay and must be submitted to regular decontamination (household alcohol, 10% solution of bleach, hospital grade disinfectants) of those parts that could accidentally come in contact with the sample. They should also be regularly maintained in order to show a precision of 1% and a trueness of +/-2%. Decontamination of spills or residues of kit components should also be carried out regularly.
2. The **ELISA incubator** has to be set at +37°C (tolerance of +/-0.5°C) and regularly checked to ensure the correct temperature is maintained. Both dry incubators and water baths are suitable for the incubations, provided that the instrument is validated for the incubation of ELISA tests.
3. The **ELISA washer** is extremely important to the overall performances of the assay. The washer must be carefully validated and correctly optimised using the kit controls and reference panels, before using the kit for routine laboratory tests. Usually 4-5 washing cycles (aspiration + dispensation of 350ul/well of washing solution = 1 cycle) are sufficient to ensure that the assay performs as expected. A soaking time of 20-30 seconds between cycles is suggested. In order to set correctly their number, it is recommended to run an assay with the kit controls and well characterized negative and positive reference samples, and check to match the values reported below in the sections "Validation of Test" and "Assay Performances". Regular calibration of the volumes delivered by, and maintenance (decontamination and cleaning of needles) of the washer has to be carried out according to the instructions of the manufacturer.
4. Incubation times have a tolerance of ±5%.
5. The **ELISA reader** has to be equipped with a reading filter of 450nm and with a second filter (620-630nm, strongly recommended) for blanking purposes. Its standard performances should be (a) bandwidth ≤ 10 nm; (b) absorbance range from 0 to ≥ 2.0; (c) linearity to ≥ 2.0; repeatability ≥ 1%. Blanking is carried out on the well identified in the section "Assay Procedure". The optical system of the reader has to be calibrated regularly to ensure that the correct optical density is measured. It should be regularly maintained according to the manufacturer 's instructions.
6. When using an **ELISA automated work station**, all critical steps (dispensation, incubation, washing, reading, data handling) have to be carefully set, calibrated, controlled and regularly serviced in order to match the values reported in the sections "Validation of Test" and "Assay Performances". The assay protocol has to be installed in the operating system of the unit and validated as for the washer and the reader. In addition, the liquid handling part of the station (dispensation and washing) has to be validated and correctly set. Particular attention must be paid to avoid carry over by the needles used for dispensing and for washing. This must be studied and controlled to minimize the possibility of contamination of adjacent wells. The use of ELISA automated work stations is recommended when the number of samples to be tested exceed 20-30 units per run.
7. Dia.Pro's customer service offers support to the user in the setting and checking of instruments used in combination with the kit, in order to assure compliance with the requirements described. Support is also provided for the installation of new instruments to be used with the kit.

L. PRE ASSAY CONTROLS AND OPERATIONS

1. Check the expiration date of the kit printed on the external label (primary container). Do not use if expired.
2. Check that the liquid components are not contaminated by visible particles or aggregates.
3. Check that the Chromogen (TMB) is colourless or pale blue by aspirating a small volume of it with a sterile plastic pipette.
4. Check that no breakage occurred in transportation and no spillage of liquid is present inside the box (primary container). Check that the aluminium pouch, containing the microplate, is not punctured or damaged.
5. Dissolve the content of the Control Serum as reported.
6. Dilute all the content of the 20x concentrated Wash Solution as described above.
7. Allow all the other components to reach room temperature (about 1 hr) and then mix gently on vortex all liquid reagents.
8. Set the ELISA incubator at +37°C and prepare the ELISA washer by priming with the diluted washing solution, according to the manufacturers instructions. Set the right number of washing cycles as found in the validation of the instrument for its use with the kit.
9. Check that the ELISA reader is turned on or ensure it will be turned on at least 20 minutes before reading.
10. If using an automated work station, turn on, check settings and be sure to use the right assay protocol.
11. Check that the micropipettes are set to the required volume.
12. Check that all the other equipment is available and ready to use.
13. In case of problems, do not proceed further with the test and advise the supervisor.

M. ASSAY PROCEDURE

The assay has to be carried out according to what reported below, taking care to maintain the same incubation time for all the samples in testing.

1. Dilute samples 1:101 into a properly defined dilution tube (example: 1000 µl Sample Diluent + 10 µl sample). Do not dilute the negative Control and the Positive Control as they are ready to use. Mix carefully all the liquid components on vortex and then proceed as described below.
2. Place the required number of Microwells in the microwell holder. Leave A1 well empty for the operation of blanking.
3. Dispense 50 µl of the Neutralizing Reagent (SOLN NTR) in all the wells of the samples. Do not add it in the wells used for Controls and in A1 !
4. Dispense 100 µl of Negative Control in duplicate and 100 µl of Positive control in single. Then dispense 100 µl of diluted samples in each properly identified well.
5. Incubate the microplate for **60 min at +37°C.**

Important note: *Strips have to be sealed with the adhesive sealing foil, supplied, only when the test is carried out manually. Do not cover strips when using ELISA automatic instruments.*

6. Wash the microplate with an automatic washer by delivering and aspirating 300 µl/well of diluted washing solution as reported previously (section I.3).
7. Pipette 100 µl Enzyme Conjugate into each well, except the A1 well, and cover with the sealer. Check that this red coloured component has been dispensed in all the wells, except A1.

Important note: *Be careful not to touch the plastic inner surface of the well with the tip filled with the Enzyme Conjugate. Contamination might occur.*

8. Incubate the microplate for **60 min at +37°C**.
9. Wash microwells as in step 6.
10. Pipette 100 µl Chromogen/Substrate mixture into each well, the blank well included. Then incubate the microplate at **room temperature (18-24°C) for 20 minutes**.

Important note: *Do not expose to strong direct illumination. High background might be generated.*

11. Pipette 100 µl Sulphuric Acid into all the wells using the same pipetting sequence as in step 10. Addition of acid will turn the positive calibrators, the control serum and the positive samples from blue to yellow.
12. Measure the colour intensity of the solution in each well, as described in section I.5, at 450nm filter (reading) and at 620-630nm (background subtraction, strongly recommended), blanking the instrument on A1.

General Important notes:

1. *If the second filter is not available ensure that no finger prints are present on the bottom of the microwell before reading at 450nm. Finger prints could generate false positive results on reading.*
2. *Reading has to be carried out just after the addition of the Stop Solution and anyway not any longer than 20 minutes after its addition. Some self oxidation of the chromogen can occur leading to high background.*

N. ASSAY SCHEME

Method	Operations
Neutralizing Reagent (in sample wells only !)	50 µl
Negative and Positive Controls	100 µl
Samples diluted 1:101	100 µl
1st incubation	**60 min**
Temperature	+37°C
Wash step	4-5 cycles
Enzyme conjugate	100 µl
2nd incubation	**60 min**
Temperature	+37°C
Wash step	4-5 cycles
TMB/H2O2	100 µl
3rd incubation	**20 min**
Temperature	r.t.
Sulphuric Acid	100 ul
Reading OD	450nm

An example of dispensation scheme is reported below:

Microplate

	1	2	3	4	5	6	7	8	9	10	11	12
A	BLK	S5										
B	NC	S6										
C	NC	S7										
D	PC	S8										
E	S1	S9										
F	S2	S10										
G	S3	S11										
H	S4	S12										

Legenda: BLK = Blank NC = Negative Control
PC = Positive Control S = Sample

O. INTERNAL QUALITY CONTROL

A check is carried out on the controls any time the kit is used in order to verify whether their OD450nm values are as expected and reported in the table below.

Check	Requirements
Blank well	< 0.100 OD450nm value
Negative Control (NC)	< 0.100 mean OD450nm value after blanking
Positive Control	> 0.500 OD450nm value

If the results of the test match the requirements stated above, proceed to the next section.
If they do not, do not proceed any further and operate as follows:

Problem	Check
Blank well > 0.100 OD450nm	1. that the Chromogen/Sustrate solution has not got contaminated during the assay
Negative Control (NC) > 0.100 OD450nm after blanking	1. that the washing procedure and the washer settings are as validated in the pre qualification study; 2. that the proper washing solution has been used and the washer has been primed with it before use; 3. that no mistake has been done in the assay procedure (dispensation of positive control instead of negative control; 4. that no contamination of the negative control or of their wells has occurred due to positive samples, to spills or to the enzyme conjugate; 5. that micropipettes haven't got contaminated with positive samples or with the enzyme conjugate 6. that the washer needles are not blocked or partially obstructed.
Positive Control < 0.500 OD450nm	1. that the procedure has been correctly executed; 2. that no mistake has been done in the distribution of controls (dispensation of negative control instead of positive control. In this case, the negative control will have an OD450nm value > 0.150, too. 3. that the washing procedure and the washer settings are as validated in the pre qualification study; 4. that no external contamination of the positive control has occurred.

Should these problems happen, after checking, report any residual problem to the supervisor for further actions.

P. CALCULATION OF THE CUT-OFF

The tests results are calculated by means of a cut-off value determined with the following formula:

Cut-Off = NC mean OD450nm + 0.250

The value found for the test is used for the interpretation of results as described in the next paragraph.

Important note*: When the calculation of results is done by the operative system of an ELISA automated work station be sure that the proper formulation is used to calculate the cut-off value and generate the right interpretations of results.*

Q. INTERPRETATION OF RESULTS

Test results are interpreted as ratio of the sample OD450nm and the Cut-Off value (or S/Co) according to the following table:

S/Co	Interpretation
< 1.0	Negative
1.0 – 1.2	Equivocal
> 1.2	Positive

A negative result indicates that the patient has no detectable anti HEV IgM reactivity.
Any patient showing an equivocal result should be tested again on a second sample taken 1-2 weeks later from the patient and examined.
A positive result is indicative of HEV infection and therefore the patient should be treated accordingly.

Important notes:

1. *Interpretation of results should be done under the supervision of the responsible of the laboratory to reduce the risk of judgment errors and misinterpretations.*
2. *Any positive result should be confirmed by an alternative method before a diagnosis of viral hepatitis is formulated.*
3. *When test results are transmitted from the laboratory to an informatics center, attention has to be done to avoid erroneous data transfer.*
4. *Diagnosis of viral hepatitis E infection has to be done and released to the patient only by a qualified medical doctor.*

An example of calculation is reported below:

The following data must not be used instead or real figures obtained by the user.

Negative Control: 0.060 – 0.080 OD450nm
Mean Value: 0.070 OD450nm
Lower than 0.100 – Accepted
Positive Control: 1.589 OD450nm
Higher than 0.500 – Accepted
Cut-Off = 0.070+0.250 = 0.320

Sample 1: 0.070 OD450nm
Sample 2: 1.690 OD450nm
Sample 1 S/Co < 1.0 = negative
Sample 2 S/Co > 1.2 = positive

R. PERFORMANCES

Evaluation of Performances has been conducted on negative and positive samples in an external clinical center with reference to a FDA approved kit.

1. LIMIT OF DETECTION

The limit of detection of the product has been checked on the international reference reagent for HEV antibody supplied by NIBSC/WHO with code n° 95/584. This material was assessed to be positive also for anti HEV IgM, low titer. The observed value is about 1 IU/ml.

2. DIAGNOSTIC SPECIFICITY AND SENSITIVITY

They were checked on about 700 sample derived from acute infections, HEV Ab positive patients, random individuals under diagnostic examination and healthy individuals with a sensitivity set at about 5 IU/ml in order to assure the highest sensitivity and be able to detect primary infection at the earliest phase.

2.1 Diagnostic specificity:

It is defined as the probability of the assay of scoring negative in the absence of specific analyte.
A total of more 500 unselected donors and HEV negative hospitalized patients, including 1st time donors, were examined.
The diagnostic specificity was assessed against a kit US FDA approved. A diagnostic specificity of ≥ 95% was observed.
Moreover, diagnostic specificity was assessed by testing more than 100 potentially interfering specimens (other infectious diseases, patients affected by non viral hepatic diseases, dialysis patients, pregnant women, haemolized, lipemic, etc.).
A value of specificity of 100% was assessed.
No false reactivity due to the method of specimen preparation has been observed. Both plasma, derived with different standard techniques of preparation (citrate, EDTA and heparin), and sera have been used to determine the value of specificity.
Frozen specimens have been tested, as well, to check for interferences due to collection and storage.
No interference was observed.
High reactive RF positive samples were observed to give origin to false positive results in not more than 5% of HEV Ab negative individuals.

2.2 Diagnostic Sensitivity

It defined as the probability of the assay of scoring positive in the presence of specific analyte.
The diagnostic sensitivity has been assessed externally and internally on a total number of 100 positive specimens coming from Germany, Mexico and from Burma.
A diagnostic sensitivity of 100% was found.

3. PRECISION:

It has been calculated on two samples, one negative and one positive, examined in 16 replicates in three separate runs.
CV values ranging between 5-15%, depending on OD450nm values, were found. The variability seen did not result in sample misclassification.

S. LIMITATIONS

Repeatable false positive results were assessed for high titer RF positive samples, escaping the effect of the Neutralizing Reagent.
Frozen samples containing fibrin particles or aggregates after thawing have been observed to generate some false results.

REFERENCES

1. Ellner PD,Neu HC. Viral agents of gastroenteritis. In "Understanding infectious disease. St.Louis: Mosby-Year Book, 1992, pp183-186.
2. Hollinger FB, Dreesman GR. Hepatitis virus. In "Rose NR, de Macario EC, Fahey JL, et al. (eds), Manual of clinical laboratory immunology, 4th ed. Washington, DC: ASM, 1992, pp634-650.
3. Fody EP, Johnson DF. J Med Technol 1987, 4:54-59.
4. Bradley D.W, et al., Br.Med.Bull. 45: 442-461, 1990
5. Dawson G.J, et al., J.Virol.Methods 38: 175-186, 1992
6. Favorov M.O. et al., J.Med.Virol., 38: 246-250, 1992
7. Purdy M. et al., J.Arch.Virol. 123: 335-349, 1992
8. Tam A.W, et al., Virology 185: 120-131, 1991

All the IVD Products manufactured by the company are under the control of a certified Quality Management System in compliance with ISO 13485 rule. Each lot is submitted to a quality control and released into the market only if conforming with the EC technical specifications and acceptance criteria.

Manufacturer:
Dia.Pro. Diagnostic Bioprobes Srl.
Via G. Carducci n° 27 – Sesto San Giovanni (MI) – Italy

CE

HEV IgG

Third generation Enzyme Immunoassay for the determination of IgG antibodies to Hepatitis E Virus in human serum and plasma

- for "in vitro" diagnostic use only -

DIA.PRO
Diagnostic Bioprobes Srl
Via G. Carducci n° 27
20099 Sesto San Giovanni
(Milano) - Italy
Phone +39 02 27007161
Fax +39 02 26007726
e-mail: info@diapro.it

REF EVG.CE
96 Tests

HEV IgG

A. INTENDED USE

Third generation Enzyme ImmunoAssay (ELISA) for the qualitative determination of IgG antibodies to Hepatitis E Virus in human plasma and sera.
The kit is intended for the follow-up of HEV-infected patients.
For "in vitro" diagnostic use only.

B. INTRODUCTION

Hepatitis E Virus or HEV is a recently discovered agent of enterically transmitted viral hepatitis. HEV is an un-enveloped single-strand RNA virus, after being provisionally assigned to the Caliciviridae family, HEV was re-classified as the sole member of the genus Hepevirus, family Hepeviridae, in 2004.
HEV is found in the stool of infected patients and present in 4 strains (1, 2, 3 and 4) differently spread geographically and virulent.
HEV is a serious problem in many developing countries since its first outbreak was reported in 1955 in New Delhi, India.
A high case-fatality rate has been found among pregnant women and chronic hepatitis carriers.
The cloning and sequencing of HEV genome have led to the development of serological tests for the detection of anti HEV antibodies based on recombinant immunodominant antigens derived from conservative regions of the four virus strains.

C. PRINCIPLE OF THE TEST

Microplates are coated with HEV-specific recombinant antigens encoding for conservative and immunodominant determinants of all the 4 subtypes.
The solid phase is first treated with the diluted sample and anti HEV IgG are captured, if present, by the antigens.
After washing out all the other components of the sample, in the 2nd incubation bound anti-HEV IgG are detected by the addition of polyclonal specific anti hIgG antibodies, labelled with peroxidase (HRP).
The enzyme captured on the solid phase, acting on the substrate/chromogen mixture, generates an optical signal that is proportional to the amount of anti HEV IgG present in the sample. A cut-off value let optical densities be interpreted into anti-HEV IgG negative and positive results.

D. COMPONENTS

Code EVG.CE contains reagents for 96 tests.

1. Microplate MICROPLATE
n° 1 microplate, 12 strips of 8 microwells coated with HEV specific recombinant antigens. Plates are sealed into a bag with desiccant.

2. Negative Control CONTROL -
1x4.0ml/vial. Ready to use control. It contains 1% goat serum proteins, 10 mM Na-citrate buffer pH 6.0 +/-0.1, 0.5% Tween 20, 0.09% Na-azide and 0.1% Kathon GC as preservatives. The negative control is olive green colour coded.

3. Positive Control CONTROL +
1x4.0ml/vial. Ready-to-use control. It contains 1% goat serum proteins, human antibodies positive to HEV, 10 mM Na-citrate buffer pH 6.0 +/-0.1, 0.5% Tween 20, 0.09% Na-azide and 0.1% Kathon GC as preservatives.
The Positive Control is blue colour coded.

4. Calibrator CAL ...
n° 1 vial. Lyophilized calibrator. To be dissolved with the volume of EIA grade water reported on the label. It contains foetal bovine serum proteins, human antibodies to HEV whose content is calibrated on 1st WHO reference reagent for HEV antibody, NIBSC code 95/584 at 1 IU/ml +/-20%, 10 mM Na-citrate buffer pH 6.0 +/-0.1, 0.3 mg/ml gentamicine sulphate and 0.1% Kathon GC as preservatives.
Note: The volume necessary to dissolve the content of the vial may vary from lot to lot. Please use the right volume reported on the label.

5. Wash buffer concentrate WASHBUF 20X
1x60ml/bottle. 20x concentrated solution. Once diluted, the wash solution contains 10 mM phosphate buffer pH 7.0+/-0.2, 0.05% Tween 20 and 0.1% Kathon GC.

6. Enzyme Conjugate CONJ
1x16ml/vial. Ready to use and red colour coded reagent. It contains Horseradish Peroxidase conjugated goat polyclonal antibodies to human IgG, 5% BSA, 10 mM Tris buffer pH 6.8+/-0.1, 0.1% Kathon GC and 0.02% gentamicine sulphate as preservatives.

7. Chromogen/Substrate SUBS TMB
1x16ml/vial. Ready-to-use component. It contains 50 mM citrate-phosphate buffer pH 3.5-3.8, 4% dimethylsulphoxide, 0.03% tetra-methyl-benzidine or TMB and 0.02% hydrogen peroxide or H_2O_2.
Note: To be stored protected from light as sensitive to strong illumination.

8. Assay Diluent DILAS
1x8ml/vial. 10 mM tris buffered solution pH 8.0 +/-0.1 containing 0.1% Kathon GC for the pre-treatment of samples and controls in the plate, blocking interference.

9. Sulphuric Acid H_2SO_4 0.3 M
1x15ml/vial. It contains 0.3 M H_2SO_4 solution.
Attention: Irritant (H315, H319; P280, P302+P352, P332+P313, P305+P351+P338, P337+P313, P362+P363).

10. Sample Diluent: DILSPE
1x50ml/vial. It contains 10 mM Na-citrate buffer pH 6.0 +/-0.1, 0.5% Tween 20, 0.09% Na-azide and 0.1% Kathon GC as preservatives. To be used to dilute the sample.
Note: The diluent changes colour from olive green to dark bluish green in the presence of sample.

11. Plate sealing foils n° 2

12. Package insert n° 1

E. MATERIALS REQUIRED BUT NOT PROVIDED

1. Calibrated Micropipettes (200ul and 10ul) and disposable plastic tips.
2. EIA grade water (bidistilled or deionised, charcoal treated to remove oxidizing chemicals used as disinfectants).
3. Timer with 60 minute range or higher.
4. Absorbent paper tissues.
5. Calibrated ELISA microplate thermostatic incubator capable to provide a temperature of +37°C.
6. Calibrated ELISA microwell reader with 450nm (reading) and with 620-630nm (blanking) filters.
7. Calibrated ELISA microplate washer.
8. Vortex or similar mixing tools.

F. WARNINGS AND PRECAUTIONS

1. The kit has to be used by skilled and properly trained technical personnel only, under the supervision of a medical doctor responsible of the laboratory.
2. When the kit is used for the screening of blood units and blood components, it has to be used in a laboratory certified and

qualified by the national authority in that field (Ministry of Health or similar entity) to carry out this type of analysis.
3. All the personnel involved in performing the assay have to wear protective laboratory clothes, talc-free gloves and glasses. The use of any sharp (needles) or cutting (blades) devices should be avoided. All the personnel involved should be trained in biosafety procedures, as recommended by the Center for Disease Control, Atlanta, U.S. and reported in the National Institute of Health's publication: "Biosafety in Microbiological and Biomedical Laboratories", ed. 1984.
4. All the personnel involved in sample handling should be vaccinated for HBV and HAV, for which vaccines are available, safe and effective.
5. The laboratory environment should be controlled so as to avoid contaminants such as dust or air-born microbial agents, when opening kit vials and microplates and when performing the test. Protect the Chromogen/Substrate from strong light and avoid vibration of the bench surface where the test is undertaken.
6. Upon receipt, store the kit at +2..8°C into a temperature controlled refrigerator or cold room.
7. Do not interchange components between different lots of the kits. It is recommended that components between two kits of the same lot should not be interchanged.
8. Check that the reagents are clear and do not contain visible heavy particles or aggregates. If not, advise the laboratory supervisor to initiate the necessary procedures for kit replacement.
9. Avoid cross-contamination between serum/plasma samples by using disposable tips and changing them after each sample.
10. Avoid cross-contamination between kit reagents by using disposable tips and changing them between the use of each one.
11. Do not use the kit after the expiration date stated on the external container and internal (vials) labels.
12. Treat all specimens as potentially infective. All human serum specimens should be handled at Biosafety Level 2, as recommended by the Center for Disease Control, Atlanta, U.S. in compliance with what reported in the Institutes of Health's publication: "Biosafety in Microbiological and Biomedical Laboratories", ed. 1984.
13. The use of disposable plastic-ware is recommended in the preparation of the liquid components or in transferring components into automated workstations, in order to avoid cross contamination.
14. Waste produced during the use of the kit has to be discarded in compliance with national directives and laws concerning laboratory waste of chemical and biological substances. In particular, liquid waste generated from the washing procedure, from residuals of controls and from samples has to be treated as potentially infective material and inactivated before waste. Suggested procedures of inactivation are treatment with a 10% final concentration of household bleach for 16-18 hrs or heat inactivation by autoclave at 121°C for 20 min..
15. Accidental spills from samples and operations have to be adsorbed with paper tissues soaked with household bleach and then with water. Tissues should then be discarded in proper containers designated for laboratory/hospital waste.
16. The Sulphuric Acid is an irritant. In case of spills, wash the surface with plenty of water
17. Other waste materials generated from the use of the kit (example: tips used for samples and controls, used microplates) should be handled as potentially infective and disposed according to national directives and laws concerning laboratory wastes.

G. SPECIMEN: PREPARATION AND RECOMMANDATIONS

1. Blood is drawn aseptically by venepuncture and plasma or serum is prepared using standard techniques of preparation of samples for clinical laboratory analysis. No influence has been observed in the preparation of the sample with citrate, EDTA and heparin.
2. Avoid any addition of preservatives to samples; especially sodium azide as this chemical would affect the enzymatic activity of the conjugate, generating false negative results.
3. Samples have to be clearly identified with codes or names in order to avoid misinterpretation of results. When the kit is used for the screening of blood units, bar code labeling and electronic reading is strongly recommended.
4. Haemolysed (red) and visibly hyperlipemic ("milky") samples have to be discarded as they could generate false results. Samples containing residues of fibrin or heavy particles or microbial filaments and bodies should be discarded as they could give rise to false results.
5. Sera and plasma can be stored at +2°..8°C for up to seven days after collection. For longer storage periods, samples can be stored frozen at –20°C for several months. Any frozen samples should not be frozen/thawed more than once as this may generate particles that could affect the test result.
6. If particles are present, centrifuge at 2,000 rpm for 20 min or filter using 0,2-0,8u filters to clean up the sample for testing.

H. PREPARATION OF COMPONENTS AND WARNINGS

A study conducted on an opened kit has not pointed out any relevant loss of activity up to 6 re-use of the device and up to 6 months.

1. Microplates:
Allow the microplate to reach room temperature (about 1 hr) before opening the container. Check that the desiccant is not turned to dark green, indicating a defect of storing.
In this case call Dia.Pro's customer service.
Unused strips have to be placed back-into the aluminium pouch; in presence of desiccant supplied, firmly zipped and stored at +2°..8°C.
When opened the first time, residual strips are stable till the indicator of humidity inside the desiccant bag turns from yellow to green.

2. Negative Control:
Ready to use. Mix well on vortex before use.

3. Positive Control:
Ready to use. Mix well on vortex before use. Handle this component as potentially infective, even if HCV, eventually present in the control, has been chemically inactivated.

4. Calibrator:
Dissolve carefully the content of the lyophilized vial with the volume of EIA grade water reported on its label.
Mix well on vortex before use.
Handle this component as potentially infective, even if HEV, eventually present in the control, has been chemically inactivated.
***Note**: When dissolved the Calibrator is not stable. Store in aliquots at –20°C.*

5. Wash buffer concentrate:
The whole content of the 20x concentrated solution has to be diluted with bidistilled water up to 1200 ml and mixed gently end-over-end before use.
Once diluted, the wash solution is stable for 1 week at +2..8° C.
In the preparation avoid foaming as the presence of bubbles could give origin to a bad washing efficiency.
***Note:** Once diluted, the wash solution is stable for 1 week at +2..8° C.*

6. Enzyme conjugate:
Ready to use. Mix well on vortex before use.
Be careful not to contaminate the liquid with oxidizing chemicals, air-driven dust or microbes.

If this component has to be transferred use only plastic, possibly sterile disposable containers.

7. Chromogen/Substrate:
Ready to use. Mix well on vortex before use.
Be careful not to contaminate the liquid with oxidizing chemicals, air-driven dust or microbes.
Do not expose to strong illumination, oxidizing agents and metallic surfaces.
If this component has to be transferred use only plastic, possible sterile disposable container.

8. Assay Diluent:
Ready to use. Mix well on vortex before use.

9. Sulphuric Acid:
Ready to use. Mix well on vortex before use.
Attention: Irritant (H315, H319; P280, P302+P352, P332+P313, P305+P351+P338, P337+P313, P362+P363).

Legenda:

Warning **H statements:**
H315 – Causes skin irritation.
H319 – Causes serious eye irritation.

Precautionary **P statements:**
P280 – Wear protective gloves/protective clothing/eye protection/face protection.
P302 + P352 – IF ON SKIN: Wash with plenty of soap and water.
P332 + P313 – If skin irritation occurs: Get medical advice/attention.
P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 – If eye irritation persists: Get medical advice/attention.
P362 + P363 – Take off contaminated clothing and wash it before reuse.

10. Sample Diluent:
Ready to use. Mix well on vortex before use.

I. INSTRUMENTS AND TOOLS USED IN COMBINATION WITH THE KIT

1. **Micropipettes** have to be calibrated to deliver the correct volume required by the assay and must be submitted to regular decontamination (household alcohol, 10% solution of bleach, hospital grade disinfectants) of those parts that could accidentally come in contact with the sample. They should also be regularly maintained in order to show a precision of 1% and a trueness of +/-2%. Decontamination of spills or residues of kit components should also be carried out regularly.
2. The **ELISA incubator** has to be set at +37°C (tolerance of +/-0.5°C) and regularly checked to ensure the correct temperature is maintained. Both dry incubators and water baths are suitable for the incubations, provided that the instrument is validated for the incubation of ELISA tests.
3. The **ELISA washer** is extremely important to the overall performances of the assay. The washer must be carefully validated and correctly optimized using the kit controls and reference panels before using the kit for routine laboratory tests. Usually 4-5 washing cycles (aspiration + dispensation of 350ul/well of washing solution = 1 cycle) are sufficient to ensure that the assay performs as expected. A soaking time of 20-30 seconds between cycles is suggested. In order to set correctly their number, it is recommended to run an assay with the kit controls and well characterized negative and positive reference samples, and check to match the values reported below in the sections "Validation of Test" and "Assay Performances". Regular calibration of the volumes delivered by, and maintenance (decontamination and cleaning of needles) of the washer has to be carried out according to the instructions of the manufacturer.
4. **Incubation times** have a tolerance of ±5%.
5. The **ELISA reader** has to be equipped with a reading filter of 450nm and with a second filter (620-630nm, strongly recommended) for blanking purposes. Its standard performances should be (a) bandwidth ≤ 10 nm; (b) absorbance range from 0 to ≥ 2.0; (c) linearity to ≥ 2.0; repeatability ≥ 1%. Blanking is carried out on the well identified in the section "Assay Procedure". The optical system of the reader has to be calibrated regularly to ensure that the correct optical density is measured. It should be regularly maintained according to the manufacturer 's instructions.
6. When using an **ELISA automated work station**, all critical steps (dispensation, incubation, washing, reading, data handling) have to be carefully set, calibrated, controlled and regularly serviced in order to match the values reported in the sections "Validation of Test" and "Assay Performances". The assay protocol has to be installed in the operating system of the unit and validated as for the washer and the reader. In addition, the liquid handling part of the station (dispensation and washing) has to be validated and correctly set. Particular attention must be paid to avoid carry over by the needles used for dispensing and for washing. This must be studied and controlled to minimize the possibility of contamination of adjacent wells. The use of ELISA automated work stations is recommended for blood screening when the number of samples to be tested exceed 20-30 units per run.
7. Dia.Pro's customer service offers support to the user in the setting and checking of instruments used in combination with the kit, in order to assure compliance with the requirements described. Support is also provided for the installation of new instruments to be used with the kit.

L. PRE ASSAY CONTROLS AND OPERATIONS

1. Check the expiration date of the kit printed on the external label of the kit box. Do not use if expired.
2. Check that the liquid components are not contaminated by naked-eye visible particles or aggregates. Check that the Chromogen/Substrate is colorless or pale blue by aspirating a small volume of it with a sterile transparent plastic pipette. Check that no breakage occurred in transportation and no spillage of liquid is present inside the box. Check that the aluminum pouch, containing the microplate, is not punctured or damaged.
3. Dilute all the content of the 20x concentrated Wash Solution as described above.
4. Dissolve the Calibrator as described above.
5. Allow all the other components to reach room temperature (about 1 hr) and then mix as described.
6. Set the ELISA incubator at +37°C and prepare the ELISA washer by priming with the diluted washing solution, according to the manufacturers instructions. Set the right number of washing cycles as found in the validation of the instrument for its use with the kit.
7. Check that the ELISA reader has been turned on at least 20 minutes before reading.
8. If using an automated workstation, turn it on, check settings and be sure to use the right assay protocol.
9. Check that the micropipettes are set to the required volume.
10. Check that all the other equipment is available and ready to use.
11. In case of problems, do not proceed further with the test and advise the supervisor.

M. ASSAY PROCEDURE

The assay has to be carried out according to what reported below, taking care to maintain the same incubation time for all the samples in testing.

Automated assay:

In case the test is carried out automatically with an ELISA workstation, we suggest to make the instrument aspirate 200 ul Sample Diluent and then 10 ul sample.
All the mixture is then carefully dispensed directly into the appropriate sample well of the microplate. Before the next sample is aspirated, needles have to be duly washed to avoid any cross-contamination among samples.
Do not dilute controls/calibrator as they are ready to use.
Dispense 200 ul controls/calibrator in the appropriate control/calibration wells.

Important Note: *Visually monitor that samples have been diluted and dispensed into appropriate wells. This is simply achieved by checking that the color of dispensed samples has turned to dark bluish-green while the color of the negative control has remained olive green.*

For the next operations follow the operative instructions reported below for the Manual Assay.
It is strongly recommended to check that the time lap between the dispensation of the first and the last sample will be calculated by the instrument and taken into consideration by defaying the first washing operation accordingly.

Manual assay:

1. Place the required number of Microwells in the microwell holder. Leave the 1st well empty for the operation of blanking.
2. Dispense 200 ul of Negative Control in triplicate, 200 ul Calibrator in duplicate and 200 ul Positive Control in single in proper wells. Do not dilute Controls and Calibrator as they are pre-diluted, ready to use !
3. Add 200 ul of Sample Diluent (DILSPE) to all the sample wells; then dispense 10 ul sample in each properly identified well. Mix gently the plate, avoiding overflowing and contaminating adjacent wells, in order to fully disperse the sample into its diluent.

Important note: *Check that the color of the Sample Diluent, upon addition of the sample, changes from light green to dark bluish green, monitoring that the sample has been really added.*

4. Dispense 50 ul Assay Diluent (DILAS) into all the controls/calibrator and sample wells. Check that the color of samples has turned to dark blue.
5. Incubate the microplate for **45 min at +37°C.**

Important note: *Strips have to be sealed with the adhesive sealing foil, supplied, only when the test is carried out manually. Do not cover strips when using ELISA automatic instruments.*

6. Wash the microplate with an automatic washer by delivering and aspirating 300ul/well of diluted washing solution as reported previously (section I.3).
7. Pipette 100µl Enzyme Conjugate into each well, except the 1st blanking well, and cover with the sealer. Check that this red colored component has been dispensed in all the wells, except A1.

Important note: *Be careful not to touch the plastic inner surface of the well with the tip filled with the Enzyme Conjugate. Contamination might occur.*

8. Incubate the microplate for **45 min at +37°C.**
9. Wash microwells as in step 6.
10. Pipette 100µl Chromogen/Substrate mixture into each well, the blank well included. Then incubate the microplate at **room temperature (18-24°C) for 15 minutes.**

important note: *Do not expose to strong direct illumination. High background might be generated.*

11. Pipette 100µl Sulphuric Acid into all the wells using the same pipetting sequence as in step 10 to stop the enzymatic reaction. Addition of acid will turn the positive control and positive samples from blue to yellow.
12. Measure the color intensity of the solution in each well, as described in section I.5, at 450nm filter (reading) and at 620-630nm (background subtraction, strongly recommended), blanking the instrument on A1.

Important notes:

1. *If the second filter is not available ensure that no finger prints are present on the bottom of the microwell before reading at 450nm. Finger prints could generate false positive results on reading.*
2. *Reading has to be carried out just after the addition of the Stop Solution and anyway not any longer than 20 minutes after its addition. Some self oxidation of the chromogen can occur leading to high background.*

N. ASSAY SCHEME

Method	Operations
Controls & Calibrator(*)	200 ul
Samples	200ul dil.+10ul
Assay Diluent (DILAS)	50 ul
1st incubation	**45 min**
Temperature	+37°C
Wash step	4-5 cycles
Enzyme conjugate	100 ul
2nd incubation	**45 min**
Temperature	+37°C
Wash step	4-5 cycles
TMB/H2O2	100 ul
3rd incubation	**15 min**
Temperature	r.t.
Sulphuric Acid	100 ul
Reading OD	450nm

(*) Important Notes:

- *The Calibrator (CAL) does not affect the Cut Off calculation, therefore it does not affect the test's results calculation.*
- *The Calibrator (CAL) used only if a laboratory internal quality control is required by the Management.*

An example of dispensation scheme is reported below:

Microplate

	1	2	3	4	5	6	7	8	9	10	11	12
A	BLK	S2										
B	NC	S3										
C	NC	S4										
D	NC	S5										
E	CAL(*)	S6										
F	CAL(*)	S7										
G	PC	S8										
H	S1	S9										

Legenda: BLK = Blank NC = Negative Control
CAL(*) = Calibrator - Not mandatory PC = Positive Control
S = Sample

O. INTERNAL QUALITY CONTROL

A check is carried out on the controls any time the kit is used in order to verify whether their OD450nm values are as expected and reported in the table below.

Check	Requirements
Blank well	< 0.100 OD450nm value
Negative Control (NC)	< 0.050 mean OD450nm value after blanking
Positive Control	> 1.000 OD450nm value

If the results of the test match the requirements stated above, proceed to the next section.
If they do not, do not proceed any further and operate as follows:

Problem	Check
Blank well > 0.100 OD450nm	1. that the Chromogen/Sustrate solution has not got contaminated during the assay
Negative Control (NC) > 0.050 OD450nm after blanking	1. that the washing procedure and the washer settings are as validated in the pre qualification study; 2. that the proper washing solution has been used and the washer has been primed with it before use; 3. that no mistake has been done in the assay procedure (dispensation of positive control instead of negative control; 4. that no contamination of the negative control or of their wells has occurred due to positive samples, to spills or to the enzyme conjugate; 5. that micropipettes haven't got contaminated with positive samples or with the enzyme conjugate. 6. that the washer needles are not blocked or partially obstructed.
Positive Control < 1.000 OD450nm	1. that the procedure has been correctly executed; 2. that no mistake has been done in the distribution of controls (dispensation of negative control instead of positive control. In this case, the negative control will have an OD450nm value > 0.150, too. 3. that the washing procedure and the washer settings are as validated in the pre qualification study; 4. that no external contamination of the positive control has occurred.

Should these problems happen, after checking, report any residual problem to the supervisor for further actions.

**** Note:**
If Calibrator has used, verify the following data:

Check	Requirements
Calibrator	S/Co > 1.1

If the results of the test doesn't match the requirements stated above, operate as follows:

Problem	Check
Calibrator S/Co < 1.1	1. that the procedure has been correctly executed; 2. that no mistake has been done in its distribution (e.g.,: dispensation of negative control instead of Calibrator) 3. that the washing procedure and the washer settings are as validated in the pre qualification study; 4. that no external contamination of the calibrator has occurred.

Anyway, if all other parameters (Blank, Negative Control, Positive Control), match the established requirements, the test may be considered valid.

P. CALCULATION OF THE CUT-OFF

The tests results are calculated by means of a cut-off value determined with the following formula:

Cut-Off = NC mean OD450nm + 0.350

The value found for the test is used for the interpretation of results as described in the next paragraph.
Important note: *When the calculation of results is done by the operative system of an ELISA automated work station be sure that the proper formulation is used to calculate the cut-off value and generate the right interpretations of results.*

Q. INTERPRETATION OF RESULTS

Test results are interpreted as ratio of the sample OD450nm and the Cut-Off value (or S/Co) according to the following table:

S/Co	Interpretation
< 0.9	Negative
0.9 - 1.1	Equivocal
> 1.1	Positive

A negative result indicates that the patient has not been infected by HEV or that the blood unit may be transfused.
Any patient showing an equivocal result should be tested again on a second sample taken 1-2 weeks later from the patient and examined. The blood unit should not be transfused.
A positive result is indicative of HEV infection and therefore the patient should be treated accordingly or the blood unit should be discarded.

Important notes:

1. *Interpretation of results should be done under the supervision of the responsible of the laboratory to reduce the risk of judgment errors and misinterpretations.*
2. *By definition, any positive result should be confirmed by an alternative method before a diagnosis of viral hepatitis is formulated.*
3. *When test results are transmitted from the laboratory to an informatics center, attention has to be done to avoid erroneous data transfer.*
4. *Diagnosis of viral hepatitis infection has to be done and released to the patient only by a qualified medical doctor.*

An example of calculation is reported below:

The following data must not be used instead of real figures obtained by the user.

Negative Control: 0.019 – 0.020 – 0.021 OD450nm
Mean Value: 0.020 OD450nm
Lower than 0.050 – Accepted
Positive Control: 2.189 OD450nm
Higher than 1.000 – Accepted
Cut-Off = 0.020+0.350 = 0.370
Calibrator: 0.600 - 0.640 OD450nm
Mean value: 0.620 OD450nm S/Co = 1.7
S/Co higher than 1.1 – Accepted

Sample 1: 0.070 OD450nm
Sample 2: 1.690 OD450nm
Sample 1 S/Co < 0.9 = negative
Sample 2 S/Co > 1.1 = positive

R. PERFORMANCES

Evaluation of Performances has been conducted on negative and positive samples in an external clinical center with reference to a FDA approved kit.

1. LIMIT OF DETECTION

The limit of detection of the assay has been calculated by means of 1st WHO reference reagent for HEV antibody, NIBSC code 95/584. The assay shows an analytical sensitivity of about 0.1 WHO IU/ml.

2. DIAGNOSTIC SPECIFICITY AND SENSITIVITY

They were checked with a sensitivity set at 0.25 WHO IU/ml on more than total 700 samples.

2.1 Diagnostic Specificity:

It is defined as the probability of the assay of scoring negative in the absence of specific analyte.
A total number of more than one hundred 1-5 years old children, by definition negative for HEV antibodies as they never chanced to eat uncooked swine meat and get therefore infected, were tested; a value of 100% specificity (negativity) was assured at a sensitivity set at a cut-off of 0.25 WHO IU/ml.

In addition, a total of more 500 unselected donors, including 1st time donors, and HEV negative hospitalized patients, coming from Italy, were examined maintaining the sensitivity of 0.25 WHO IU/ml. About 5% of such population turned out to be repeatedly positive; confirmation was not carried out in absence of a commercial Confirmation kit. However, these samples were detected positive with a commercial CE-marked ELISA. From this study a diagnostic specificity of 100% was observed.
Moreover, the Diagnostic Specificity was also assessed by testing more than 100 potentially interfering specimens (other infectious diseases, patients affected by non viral hepatic diseases, dialysis patients, pregnant women, haemolized, lipemic, etc.). A value of specificity of 100% was assessed.
No false reactivity due to the method of specimen preparation has been observed. Both plasma, derived with different standard techniques of preparation (citrate, EDTA and heparin), and sera have been used to determine the value of specificity.
Frozen specimens have been tested, as well, to check for interferences due to collection and storage.
No interference was observed.

2.2 Diagnostic Sensitivity

It is defined as the probability of the assay of scoring positive in the presence of specific analyte.
The diagnostic sensitivity has been assessed externally (Institute of Virology, University of Milan) and internally on a total number of 200 positive specimens (maintaining a sensitivity set at a cut-off of 0.25 WHO IU/ml); a diagnostic sensitivity (or correlation with a commercial reference kit manufactured in Europe and CE marked) of 100% was found.

3. PRECISION:

It has been calculated on two samples, one negative and one low positive, examined in 16 replicates in three separate runs.
CV values ranging between 5-10%, depending on OD450nm values, were found. The variability seen did not result in sample misclassification.

S. LIMITATIONS

Frozen samples containing fibrin particles or aggregates after thawing have been observed to generate some false results.

REFERENCES

1. Ellner PD,Neu HC. Viral agents of gastroenteritis. In "Understanding infectious disease. St.Louis: Mosby-Year Book, 1992, pp183-186.
2. Hollinger FB, Dreesman GR. Hepatitis virus. In "Rose NR, de Macario EC, Fahey JL, et al. (eds), Manual of clinical laboratory immunology, 4th ed. Washington, DC: ASM, 1992, pp634-650.
3. Fody EP, Johnson DF. J Med Technol 1987, 4:54-59.
4. Bradley D.W. et al., Br.Med.Bull. 46: 442-461, 1990
5. Dawson G.J. et al., J.Virol.Methods 38: 175-186, 1992
6. Favorov M.O. et al., J.Med.Virol., 36: 246-250, 1992
7. Purdy M. et al., J.Arch.Virol. 123: 335-349, 1992
8. Tam A.W. et al., Virology 185: 120-131, 1991

All the IVD Products manufactured by the company are under the control of a certified Quality Management System in compliance with ISO 13485 rule. Each lot is submitted to a quality control and released into the market only if conforming with the EC technical specifications and acceptance criteria.

Manufacturer:
Dia.Pro Diagnostic Bioprobes Srl
Via G. Carducci n° 27 – Sesto San Giovanni (MI) – Italy

CE

HBcAb

Competitive Enzyme Immunoassay for the determination of antibodies to Hepatitis B core Antigen in human serum and plasma

- for "in vitro" diagnostic use only -

DIA.PRO
Diagnostic Bioprobes Srl
Via G. Carducci n° 27
20099 Sesto San Giovanni
(Milano) - Italy
Phone +39 02 27007161
Fax +39 02 26007726
e-mail: info@diapro.it

REF BCAB.CE
96 Tests

HBcAb

A. INTENDED USE

Competitive Enzyme ImmunoAssay (ELISA) for the determination of antibodies to Hepatitis B core Antigen in human plasma and sera.
The kit is intended for the screening of blood units and the follow-up of HBV-infected patients.
For "in vitro" diagnostic use only.

B. INTRODUCTION

The World Health Organization (WHO) defines Hepatitis B as follows:

"Hepatitis B is one of the major diseases of mankind and is a serious global public health problem. Hepatitis means inflammation of the liver, and the most common cause is infection with one of 5 viruses, called hepatitis A,B,C,D, and E. All of these viruses can cause an acute disease with symptoms lasting several weeks including yellowing of the skin and eyes (jaundice); dark urine; extreme fatigue; nausea; vomiting and abdominal pain. It can take several months to a year to feel fit again. Hepatitis B virus can cause chronic infection in which the patient never gets rid of the virus and many years later develops cirrhosis of the liver or liver cancer.

HBV is the most serious type of viral hepatitis and the only type causing chronic hepatitis for which a vaccine is available. Hepatitis B virus is transmitted by contact with blood or body fluids of an infected person in the same way as human immunodeficiency virus (HIV), the virus that causes AIDS. However, HBV is 50 to 100 times more infectious than HIV. The main ways of getting infected with HBV are: (a) perinatal (from mother to baby at the birth); (b) child- to-child transmission; (c) unsafe injections and transfusions; (d) sexual contact.

Worldwide, most infections occur from infected mother to child, from child to child contact in household settings, and from reuse of unsterilized needles and syringes. In many developing countries, almost all children become infected with the virus. In many industrialized countries (e.g. Western Europe and North America), the pattern of transmission is different. In these countries, mother-to-infant and child-to-child transmission accounted for up to one third of chronic infections before childhood hepatitis B vaccination programmes were implemented. However, the majority of infections in these countries are acquired during young adulthood by sexual activity, and injecting drug use. In addition, hepatitis B virus is the major infectious occupational hazard of health workers, and most health care workers have received hepatitis B vaccine.

Hepatitis B virus is not spread by contaminated food or water, and cannot be spread casually in the workplace. High rates of chronic HBV infection are also found in the southern parts of Eastern and Central Europe. In the Middle East and Indian sub-continent, about 5% are chronically infected. Infection is less common in Western Europe and North America, where less than 1% are chronically infected.

Young children who become infected with HBV are the most likely to develop chronic infection. About 90% of infants infected during the first year of life and 30% to 50% of children infected between 1 to 4 years of age develop chronic infection. The risk of death from HBV-related liver cancer or cirrhosis is approximately 25% for persons who become chronically infected during childhood.

Chronic hepatitis B in some patients is treated with drugs called *interferon or lamivudine*, which can help some patients. Patients with cirrhosis are sometimes given liver transplants, with varying success. It is preferable to prevent this disease with vaccine than to try and cure it.

Hepatitis B vaccine has an outstanding record of safety and effectiveness. Since 1982, over one billion doses of hepatitis B vaccine have been used worldwide. The vaccine is given as a series of three intramuscular doses. Studies have shown that the vaccine is 95% effective in preventing children and adults from developing chronic infection if they have not yet been infected. In many countries where 8% to 15% of children used to become chronically infected with HBV, the rate of chronic infection has been reduced to less than 1% in immunized groups of children. Since 1991, WHO has called for all countries to add hepatitis B vaccine into their national immunization programmes."

Hepatitis B core Antigen (or HBcAg) is the major component of the core particles of HBV.
HBcAg is composed of a single polypeptide of about 17 kD that is released upon disaggregating the core particles; the antigen contains at least one immunological determinant.
Upon primary infection, anti HBcAg antibodies are one of the first markers of HBV hepatitis appearing in the serum of the patient, slightly later than HBsAg, the viral surface antigen.
Anti HBcAg antibodies are produced usually at high titers and their presence is detectable even years after infection. Isolated HBcAb, in absence of other HBV markers, have been observed in infected blood units, suggesting the use of this test for screening HBV, in addition of HBsAg.
The determination of HBcAb has become important for the classification of the viral agent, together with the detection of the other markers of HBV infection, in sera and plasma.

C. PRINCIPLE OF THE TEST

The assay is based on the principle of competition where the antibodies in the sample compete with a monoclonal antibody for a fixed amount of antigen on the solid phase.
A purified recombinant HBcAg is coated to the microwells.
The patient's serum/plasma is added to the microwell together with an additive able to block interferences present in the sample.
In the second incubation after washing, a monoclonal antibody, conjugated with Horseradish Peroxidase (HRP) and specific for HBcAg is added and binds to the free rec-HBcAg coated on the plastic.
After incubation, microwells are washed to remove any unbound conjugate and then the chromogen/substrate is added. In the presence of peroxidase enzyme the colorless substrate is hydrolyzed to a colored end-product.
The color intensity is inversely proportional to the amount of antibodies to HBcAg present in the sample.

D. COMPONENTS

Each kit contains sufficient reagents to perform 96 tests.

1. Microplate MICROPLATE
8x12 microwell strips coated with recombinant HBcAg and sealed into a bag with desiccant. Allow the microplate to reach room temperature before opening; reseal unused strips in the bag with desiccant and store at 2..8°C.

2. Negative Control CONTROL -
1x1.0ml/vial. Ready to use. Contains 5% bovine serum albumin, 10 mM phosphate buffer pH 7.4 +/-0.1, 0.09% sodium azide and 0.1% Kathon GC as preservatives. The negative control is pale yellow color coded.

3. Positive Control CONTROL +
1x1.0ml/vial. Ready to use. Contains 5% bovine serum albumin, anti HBcAg antibodies at a concentration of about 10 PEI U/ml, (calibrated on PEI HBc Reference Material 82), 10 mM phosphate buffer pH 7.4 +/-0.1, 0.09% sodium azide and 0.1% Kathon GC as preservatives. The positive control is green color coded.

4. Calibrator CAL ...
n°1 vial. Lyophilised. To be dissolved with EIA grade water as reported in the label. Contains fetal bovine serum, human antibodies to HBcAg at a concentration of 2 PEI U/ml +/-10% (calibrated on PEI HBc Reference Material 82) and 0.1% Kathon GC as preservative.
Note: The volume necessary to dissolve the content of the vial may vary from lot to lot. Please use the right volume reported on the label .

5. Wash buffer concentrate WASHBUF 20X
1x60ml/bottle. 20x concentrated solution.
Once diluted, the wash solution contains 10 mM phosphate buffer pH 7.0+/-0.2, 0.05% Tween 20 and 0.1% Kathon GC.

6. Enzyme Conjugate CONJ
1x16ml/vial. Ready-to-use solution. Contains 5% bovine serum albumine, 10 mM tris buffer pH 6.8 +/-0.1, Horseradish peroxidase conjugated mouse monoclonal antibody to HBcAg in presence of 0.3 mg/ml gentamicine sulphate and 0.1% Kathon GC as preservatives. The component is red colour coded .

7. Chromogen/Substrate SUBS TMB
1x16ml/vial. Contains a 50 mM citrate-phosphate buffered solution at pH 3.6 +/-0.1, 0.03% tetra-methyl-benzidine (TMB), 0.02% hydrogen peroxide (H_2O_2) and 4% dimethylsulphoxide.
Note: To be stored protected from light as sensitive to strong illumination.

8. Specimen Diluent DILSPE
4x3ml/vial. 10 mM tris buffered solution pH 8.0 +/-0.1 containing 0.1% Kathon GC for the pre-treatment of samples and controls in the plate, blocking interference.
Note: Use all the content of one vial before opening a second one. The reagent is sensitive to oxidation.

9. Sulphuric Acid H_2SO_4 0.3 M
1x15ml/vial. Contains 0.3 M H_2SO_4 solution.
Attention: Irritant (Xi R36/38; S2/26/30)

10. Plate sealing foil n°2

11. Instruction manual n°1

E. MATERIALS REQUIRED BUT NOT PROVIDED

1. Calibrated Micropipettes (100ul and 50ul) and disposable plastic tips.
2. EIA grade water (double distilled or deionised, charcoal treated to remove oxidizing chemicals used as disinfectants).
3. Timer with 60 minute range or higher.
4. Absorbent paper tissues.
5. Calibrated ELISA microplate thermostatic incubator (dry or wet) set at +37°C.
6. Calibrated ELISA microwell reader with 450nm (reading) and with 620-630nm (blanking) filters.
7. Calibrated ELISA microplate washer.
8. Vortex or similar mixing tools.

F. WARNINGS AND PRECAUTIONS

1. The kit has to be used by skilled and properly trained technical personnel only, under the supervision of a medical doctor responsible of the laboratory.
2. When the kit is used for the screening of blood units and blood components, it has to be used in a laboratory certified and qualified by the national authority in that field (Ministry of Health or similar entity) to carry out this type of analysis.
3. All the personnel involved in performing the assay have to wear protective laboratory clothes, talc-free gloves and glasses. The use of any sharp (needles) or cutting (blades) devices should be avoided. All the personnel involved should be trained in biosafety procedures, as recommended by the Center for Disease Control, Atlanta, U.S. and reported in the National Institute of Health's publication: "Biosafety in Microbiological and Biomedical Laboratories", ed. 1984.
4. All the personnel involved in sample handling should be vaccinated for HBV and HAV, for which vaccines are available, safe and effective.
5. The laboratory environment should be controlled so as to avoid contaminants such as dust or air-born microbial agents, when opening kit vials and microplates and when performing the test. Protect the Chromogen (TMB) from strong light and avoid vibration of the bench surface where the test is undertaken.
6. Upon receipt, store the kit at 2-8°C into a temperature controlled refrigerator or cold room.
7. Do not interchange components between different lots of the kits. It is recommended that components between two kits of the same lot should not be interchanged.
8. Check that the reagents are clear and do not contain visible heavy particles or aggregates. If not, advise the laboratory supervisor to initiate the necessary procedures.
9. Avoid cross-contamination between serum/plasma samples by using disposable tips and changing them after each sample.
10. Avoid cross-contamination between kit reagents by using disposable tips and changing them between the use of each one.
11. Do not use the kit after the expiration date stated on external (primary container) and internal (vials) labels.
12. Treat all specimens as potentially infective. All human serum specimens should be handled at Biosafety Level 2, as recommended by the Center for Disease Control, Atlanta, U.S. in compliance with what reported in the Institutes of Health's publication: "Biosafety in Microbiological and Biomedical Laboratories", ed. 1984.
13. The use of disposable plastic-ware is recommended in the preparation of the washing solution or in transferring components into other containers of automated workstations, in order to avoid contamination.
14. Waste produced during the use of the kit has to be discarded in compliance with national directives and laws concerning laboratory waste of chemical and biological substances. In particular, liquid waste generated from the washing procedure, from residuals of controls and from samples has to be treated as potentially infective material and inactivated. Suggested procedures of inactivation are treatment with a 10% final concentration of household bleach for 16-18 hrs or heat inaclivation by autoclave at 121°C for 20 min..
15. Accidental spills have to be adsorbed with paper tissues soaked with household bleach and then with water. Tissues should then be discarded in proper containers designated for laboratory/hospital waste.
16. The Sulphuric Acid is an irritant. In case of spills, wash the surface with plenty of water.
17. Other waste materials generated from the use of the kit (example: tips used for samples and controls, used microplates) should be handled as potentially infective and disposed according to national directives and laws concerning laboratory wastes.

G. SPECIMEN: PREPARATION AND RECOMMANDATIONS

1. Blood is drawn aseptically by venepuncture and plasma or serum is prepared using standard techniques of preparation of samples for clinical laboratory analysis. No influence has been observed in the preparation of the sample with citrate, EDTA and heperin.
2. Avoid any addition of preservatives to samples; especially sodium azide as this chemical would affect the enzymatic activity of the conjugate.
3. Samples have to be clearly identified with codes or names in order to avoid misinterpretation of results. When the kit is used for the screening of blood units, bar code labeling and electronic reading is strongly recommended.
4. Haemolysed (red) and visibly hyperlipemic ("milky") samples have to be discarded as they could generate false results. Samples containing residues of fibrin or heavy particles or microbial filaments and bodies should be discarded as they could give rise to false results.
5. Sera and plasma can be stored at +2°,8°C for up to five days after collection. For longer storage periods, samples can be stored frozen at –20°C for several months. Any frozen samples should not be frozen/thawed more than once as this may generate particles that could affect the test result.
6. If particles are present, centrifuge at 2,000 rpm for 20 min or filter using 0.2-0.8u filters to clean up the sample for testing.

H. PREPARATION OF COMPONENTS AND WARNINGS

A study conducted on an opened kit has not pointed out any relevant loss of activity up to 6 re-uses of the device and up to 6 months.

1. Microplates:
Allow the microplate to reach room temperature (about 1 hr) before opening the container. Check that the desiccant has not turned dark green, indicating a defect in storage.
In this case, call Dia.Pro's customer service.
Unused strips have to be placed back inside the aluminum pouch, with the desiccant supplied, firmly zipped and stored at +2°,8°C. After first opening, remaining strips are stable until the humidity indicator inside the desiccant bag turns from yellow to green.

2. Negative Control:
Ready to use. Mix well on vortex before use.

3. Positive Control:
Ready to use. Mix well on vortex before use.

4. Calibrator:
Add the volume of ELISA grade water, reported on the label, to the lyophilised powder; let fully dissolve and then gently mix on vortex.
Note: *The dissolved calibrator is not stable. Store it frozen in aliquots at –20°C.*

5. Wash buffer concentrate:
The whole content of the concentrated solution has to be diluted 20x with bidistilled water and mixed gently end-over-end before use. During preparation avoid foaming as the presence of bubbles could impact on the efficiency of the washing cycles.
Note: *Once diluted, the wash solution is stable for 1 week at +2..8°C.*

6. Enzyme conjugate:
Ready to use. Mix well on vortex before use.
Avoid contamination of the liquid with oxidizing chemicals, dust or microbes. If this component has to be transferred, use only plastic, and if possible, sterile disposable containers.

7. Chromogen/Substrate:
Ready to use. Mix well on vortex before use.
Avoid contamination of the liquid with oxidizing chemicals, air-driven dust or microbes. Do not expose to strong light, oxidizing agents and metallic surfaces.
If this component has to be transferred use only plastic, and if possibie, sterile disposable container.

8. Specimen Diluent
Ready to use solution. Mix gently on vortex before use. Use all the content of one vial before opening a second one. The reagent is sensitive to oxidation.

9. Sulphuric Acid:
Ready to use. Mix well on vortex before use.
Attention: Irritant (Xi R36/38; S2/26/30)
Legenda: R 36/38 = Irritating to eyes and skin.
S 2/26/30 = In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

I. INSTRUMENTS AND TOOLS USED IN COMBINATION WITH THE KIT

1. Micropipettes have to be calibrated to deliver the correct volume required by the assay and must be submitted to regular decontamination (70% ethanol, 10% solution of bleach, hospital grade disinfectants) of those parts that could accidentally come in contact with the sample or the components of the kit. They should also be regularly maintained in order to show a precision of 1% and a trueness of ±2%.
2. The ELISA incubator has to be set at +37°C (tolerance of ±0.5°C) and regularly checked to ensure the correct temperature is maintained. Both dry incubators and water baths are suitable for the incubations, provided that the instrument is validated for the incubation of ELISA tests.
3. The ELISA washer is extremely important to the overall performances of the assay. The washer must be carefully validated and correctly optimized using the kit controls/calibrator and reference panels, before using the kit for routine laboratory tests. Usually 4-5 washing cycles (aspiration + dispensation of 350 ul/well of washing solution = 1 cycle) are sufficient to ensure that the assay performs as expected. A soaking time of 20-30 seconds between cycles is suggested. In order to set correctly their number, it is recommended to run an assay with the kit controls/calibrator and well characterized negative and positive reference samples, and check to match the values reported below in the sections "Validation of Test" and "Assay Performances". Regular calibration of the volumes delivered and maintenance (decontamination and cleaning of needles) of the washer has to be carried out according to the instructions of the manufacturer.
4. Incubation times have a tolerance of ±5%.
5. The ELISA microplate reader has to be equipped with a reading filter of 450nm and with a second filter (620-630nm, strongly recommended) for blanking purposes. Its standard performances should be (a) bandwidth ≤ 10 nm; (b) absorbance range from 0 to ≥ 2.0; (c) linearity to ≥ 2.0; repeatability ≥ 1%. Blanking is carried out on the well identified in the section "Assay Procedure". The optical system of the reader has to be calibrated regularly to ensure that the correct optical density is measured. It should be regularly maintained according to the manufacturer 's instructions.

6. When using an ELISA automated work station, all critical steps (dispensation, incubation, washing, reading, shaking, data handling) have to be carefully set, calibrated, controlled and regularly serviced in order to match the values reported in the sections "Validation of Test" and "Assay Performances". The assay protocol has to be installed in the operating system of the unit and validated as for the washer and the reader. In addition, the liquid handling part of the station (dispensation and washing) has to be validated and correctly set. Particular attention must be paid to avoid carry over by the needles used for dispensing samples and for washing. This must be studied and controlled to minimize the possibility of contamination of adjacent wells due to strongly reactive samples, leading to false positive results. The use of ELISA automated work stations is recommended for blood screening and when the number of samples to be tested exceed 20-30 units per run.
7. Dia.Pro's customer service offers support to the user in the setting and checking of instruments used in combination with the kit, in order to assure full compliance with the requirements described. Support is also provided for the installation of new instruments to be used with the kit.

L. PRE ASSAY CONTROLS AND OPERATIONS

1. Check the expiration date of the kit printed on the external label (primary container). Do not use if expired.
2. Check that the liquid components are not contaminated by visible particles or aggregates. Check that the Chromogen (TMB) is colourless or pale blue by aspirating a small volume of it with a sterile plastic pipette. Check that no breakage occurred in transportation and no spillage of liquid is present inside the box (primary container). Check that the aluminium pouch, containing the microplate, is not punctured or damaged.
3. Dilute all the content of the 20x concentrated Wash Solution as described above.
4. Dissolve the Calibrator as described above and gently mix.
5. Allow all the other components to reach room temperature (about 1 hr) and then mix gently on vortex all liquid reagents.
6. Set the ELISA incubator at +37°C and prepare the ELISA washer by priming with the diluted washing solution, according to the manufacturers instructions. Set the right number of washing cycles as found in the validation of the instrument for its use with the kit.
7. Check that the ELISA reader is turned on or ensure it will be turned on at least 20 minutes before reading.
8. If using an automated work station, turn on, check settings and be sure to use the right assay protocol.
9. Check that the micropipettes are set to the required volume.
10. Check that all the other equipment is available and ready to use.
11. In case of problems, do not proceed further with the test and advise the supervisor.

M. ASSAY PROCEDURE

The assay has to be performed according to the procedure given below, taking care to maintain the same incubation time for all the samples being tested.

1. Place the required number of strips in the plastic holder and carefully identify the wells for controls, calibrator and samples.
2. Leave the A1 well empty for blanking purposes.
3. Dispense 50 ul Specimen Diluent into all the control and sample wells.
4. Pipette 50 µl of the Negative Control in triplicate, 50 ul of the Calibrator in duplicate and then 50 ul of the Positive Control in single. Then dispense 50 ul of each of the samples.
5. Incubate the microplate for **60 min at +37°C**.

Important note: Strips have to be sealed with the adhesive sealing foil, only when the test is performed manually. Do not cover strips when using ELISA automatic instruments.

6. When the first incubation is finished, wash the microwells as previously described (section I.3)
7. Pipette 100 µl Enzyme Conjugate in all the wells, except A1; incubate the microplate for **60 min at +37°C**.

Important note: Be careful not to touch the plastic inner surface of the well with the tip filled with the Enzyme Conjugate. Contamination might occur.

8. When the second incubation is finished, wash the microwells as previously described (section I.3)
9. Pipette 100 µl Chromogen/Substrate into all the wells, A1 included.

Important note: Do not expose to strong direct light, as a high background might be generated.

10. Incubate the microplate protected from light at **room temperature (18-24°C) for 20 minutes**. Wells dispensed with negative control and negative samples will turn from clear to blue (competitive method).
11. Pipette 100 µl Sulphuric Acid into all the wells using the same pipetting sequence as in step 9 to stop the enzymatic reaction. Addition of the stop solution will turn the negative control and negative samples from blue to yellow.
12. Measure the colour intensity of the solution in each well, as described in section I.5 using a 450nm filter (reading) and a 620-630nm filter (background subtraction, strongly recommended), blanking the instrument on A1.

Important notes:

1. *If the second filter is not available, ensure that no finger prints are present on the bottom of the microwell before reading at 450nm. Finger prints could generate false positive results on reading.*
2. *Reading has should ideally be performed immediately after the addition of the Stop Solution but definitely no longer than 20 minutes afterwards. Some self oxidation of the chromogen can occur leading to a higher background.*

N. ASSAY SCHEME

Specimen Diluent	50 ul
Controls&calibrator and samples	50 ul
1st incubation	**60 min**
Temperature	+37°C
Wash	n°4-5
Enzyme Conjugate	100 ul
2nd incubation	**60 min**
Temperature	+37°C
Wash	n°4-5
TMB/H2O2 mix	100 ul
3rd incubation	**20 min**
Temperature	r.t.
Sulphuric Acid	100 ul
Reading OD	450nm

An example of dispensation scheme is reported below:

Microplate

	1	2	3	4	5	6	7	8	9	10	11	12
A	BLK	S2										
B	NC	S3										
C	NC	S4										
D	NC	S5										
E	CAL	S6										
F	CAL	S7										
G	PC	S8										
H	S1	S9										

Legenda: BLK = Blank NC = Negative Control
CAL = Calibrator PC = Positive Control S = Sample

O. INTERNAL QUALITY CONTROL

A check is performed on the controls/calibrator any time the kit is used in order to verify whether the expected OD450nm or Co/S values have been matched in the analysis.
Ensure that the following parameters are met:

Parameter	Requirements
Blank well	< 0.050 OD450nm value
Negative Control (NC)	> 1.000 OD450nm after blanking coefficient of variation < 20%
Calibrator (about 2 PEI U/ml)	Co/S > 1
Positive Control	< 0.200 OD450nm

If the results of the test match the requirements stated above, proceed to the next section.

If they do not, do not proceed any further and perform the following checks:

Problem	Check
Blank well > 0,050 OD450nm	that the Chromogen/Substrate solution has not become contaminated during the assay
Negative Control (NC) < 1,000 OD450nm after blanking coefficient of variation > 20%	1. that the washing procedure and the washer settings are as validated in the pre qualification study; 2. that the proper washing solution has been used and the washer has been primed with it before use; 3. that no mistake has been done in the assay procedure (dispensation of positive control instead of negative control; 4. that no contamination of the negative control or of the wells where the control was dispensed has occurred due to positive samples, to spills or to the enzyme conjugate; 5. that micropipettes have not become contaminated with positive samples or with the enzyme conjugate 6. that the washer needles are not blocked or partially obstructed.
Calibrator Co/S < 1	1. that the procedure has been correctly performed; 2. that no mistake has occurred during its distribution (ex.: dispensation of negative control instead 3. that the washing procedure and the washer settings are as validated in the pre qualification study; 4. that no external contamination of the calibrator has occurred.
Positive Control > 0,200 OD450nm	1. that the procedure has been correctly performed; 2. that no mistake has occurred during the distribution of the control (dispensation of negative control instead of positive control); 3. that the washing procedure and the washer settings are as validated in the pre qualification study; 4. that no external contamination of the positive control has occurred.

If any of the above problems have occurred, report the problem to the supervisor for further actions.

P. RESULTS

The results are calculated by means of a cut-off value determined with the following formula:

Cut-Off = (NC + PC) / 5

Important note: *When the calculation of results is performed by the operating system of an ELISA automated work station, ensure that the proper formulation is used to calculate the cut-off value and generate the correct interpretation of results.*

Q. INTERPRETATION OF RESULTS

Results are interpreted as ratio between the cut-off value and the sample OD450nm or Co/S.

Results are interpreted according to the following table:

Co/S	Interpretation
< 0.9	Negative
0.9 - 1.1	Equivocal
> 1.1	Positive

A negative result indicates that the patient has not been infected by HBV.
Any patient showing an equivocal result should be re-tested on a second sample taken 1-2 weeks after the initial sample.
The blood unit should not be transfused.
A positive result is indicative of HBV infection and therefore the patient should be treated accordingly or the blood unit should be discarded.

Important notes:

1. *Interpretation of results should be done under the supervision of the laboratory supervisor to reduce the risk of judgement errors and misinterpretations.*
2. *When test results are transmitted from the laboratory to another facility, attention must be paid to avoid erroneous data transfer.*
3. *Diagnosis of viral hepatitis infection has to be taken by and released to the patient by a suitably qualified medical doctor.*

An example of calculation is reported below.

The following data must not be used instead or real figures obtained by the user.

Negative Control: 2.000 – 2.200 – 2.000 OD450nm
Mean Value: 2.100 OD450nm
Higher than 1.000 – Accepted

Positive Control: 0.100 OD450nm
Lower than 0.200 – Accepted

Cut-Off = (2.100 + 0.100) / 5 = 0.440

Calibrator: 0.400-0.360 OD450nm
Mean value: 0.380 OD450nm
Co/S>1 – Accepted

Sample 1: 0.028 OD450nm
Sample 2: 1.890 OD450nm
Sample 1 Co/S > 1.1 positive
Sample 2 Co/S < 0.9 negative

R. PERFORMANCES

Evaluation of Performances has been conducted in accordance to what reported in the Common Technical Specifications or CTS (art. 5, Chapter 3 of IVD Directive 98/79/EC).

1. LIMIT OF DETECTION:

The sensitivity of the assay has been calculated by means of the reference preparation for HBcAb supplied by Paul Erlich Institute (PEI HBc Reference Material 82). The assay shows a sensitivity of about 1.25 PEI U/ml.
The table below reports the Co/S values shown by the PEI standard diluted as suggested by the manufacturer to prepare a limiting dilution curve in Fetal Calf Serum (FCS).

PEI U/ml	Lot 1001	Lot 0702	Lot 0702/2	Lot 1202
5	22.6	18.0	19.0	17.7
2.5	8.0	5.5	5.4	5.0
1.25	1.1	1.3	1.0	1.0
0.625	0.4	0.4	0.4	0.4

In addition Accurun 1 – series 3000 – supplied by Boston Biomedica Inc., USA, was tested to determine its Co/S value. Results are reported in the table below:

Accurun 1 – series 3000

Value	Lot 1001	Lot 0702	Lot 1202
Co/S	2.9	2.3	2.2

2. DIAGNOSTIC SPECIFICITY AND SENSITIVITY

The Performance Evaluation of the device was carried out in a trial conducted on more than total 6000 samples.

2.1 Diagnostic Specificity

It is defined as the probability of the assay of scoring negative in the absence of specific analyte. A total of more 5000 unselected donors, including 1st time donors, were examined.
In a first study 2023 samples were tested against a US company as reference. A specificity of 99.5% was found. In a second study 1588 samples were examined against a European company. A specificity of 99.7% was found. In the last study 1565 samples were assayed against the same US company; a value of 99.8% was found.
In addition to the above population, 206 samples from hospitalized patients were tested against the European company. A value of 99.3% specificity was found.
Moreover, diagnostic specificity was assessed by testing 164 potentially interfering specimens (other infectious diseases, patients affected by non viral hepatic diseases, dialysis patients, pregnant women, hemolized, lipemic, etc.) against the European company. A value of specificity of 100% was assessed.
Finally, both human plasma, derived with different standard techniques of preparation (citrate, EDTA and heparin), and human sera have been used to determine the specificity.
No false reactivity due to the method of specimen preparation has been observed.

2.2 Diagnostic Sensitivity

It defined as the probability of the assay of scoring positive in the presence of specific analyte.
373 positive specimens were tested against the European company; a diagnostic sensitivity of 99.7 was found.

3. PRECISION

The mean values obtained from a study conducted on three lots and on two samples of different anti-HBcAg reactivity, examined in 16 replicates in three separate runs is reported below:

BCAB.CE: lot # 1202

Negative Control (N = 16)

Mean values	1st run	2nd run	3rd run	Average value
OD 450nm	1.943	1.939	1.924	1.935
Std.Deviation	0.081	0.076	0.103	0.087
CV %	4.2	4.0	5.3	4.5

Calibrator (N = 16)

Mean values	1st run	2nd run	3rd run	Average value
OD 450nm	0.143	0.147	0.148	0.146
Std.Deviation	0.014	0.017	0.018	0.016
CV %	9.8	11.4	12.1	11.1
Co/S	2.8	2.7	2.6	2.7

BCAB.CE: lot # 0702

Negative Control (N = 16)

Mean values	1st run	2nd run	3rd run	Average value
OD 450nm	2.163	2.110	2.106	2.126
Std.Deviation	0.105	0.088	0.139	0.111
CV %	4.9	4.2	6.6	5.2

Calibrator (N = 16)

Mean values	1st run	2nd run	3rd run	Average value
OD 450nm	0.182	0.193	0.195	0.190
Std.Deviation	0.018	0.023	0.019	0.020
CV %	10.0	12.0	9.9	10.6
Co/S	2.5	2.2	2.3	2.3

BCAB.CE: lot # 0702/2

Negative Control (N = 16)

Mean values	1st run	2nd run	3rd run	Average value
OD 450nm	2.278	2.098	2.130	2.169
Std.Deviation	0.135	0.126	0.159	0.140
CV %	5.9	6.0	7.5	6.5

Calibrator (N = 16)

Mean values	1st run	2nd run	3rd run	Average value
OD 450nm	0.193	0.190	0.199	0.194
Std.Deviation	0.023	0.023	0.027	0.025
CV %	12.1	12.3	13.5	12.6
Co/S	2.4	2.2	2.2	2.3

The variability shown in the tables did not result in sample misclassification.

5. LIMITATIONS OF THE PROCEDURE

Bacterial contamination or heat inactivation of the specimen may affect the absorbance values of the samples with consequent alteration of the level of the analyte. This test is suitable only for testing single samples and not pooled ones.
Diagnosis of an infectious disease should not be established on the basis of a single test result. The patient's clinical history, symptomatology, as well as other diagnostic data should be considered.

REFERENCES

1. Aach R.D., Grisham J.W., Parker S.W., Proc.Natl.Acad.Sci.,USA, 68:1956, 1971.
2. Blumerg B.S., Suinick A.I., London W.T., Hepatitis and leukemia: their relation to Australia antigen, Bull.N.Y.Acad.Med., 44:1566, 1968.
3. Boniolo A., Dovis M., Matteja R., J.Immunol.Meth., 49:1, 1982.
4. Caldwell C.W., Barpet J.T., Clin.Chim.Acta 81: 305, 1977
5. Fazekas S., De St.Groth, Scheidegger D., J.Immunol.Meth., 35: 1, 1980
6. Reesink H.W., et al., Vox.Sang., 39:61, 1980
7. Rook G.A.W., Lepr.Rev. 52: 281, 1981
8. Schroder J., Med.Biol., 58: 281, 1981
9. Almeida J.D. et al., Lancet, ii : 1225, 1971
10. Hoofnagle J.H. et al., Lancet, ii: 869, 1973
11. Hoofnagle J.H. et al., N.E.J.Med., 290: 1336, 1974
12. Katchaki J.N. et al., J.Clin.Path., 31: 837, 1978
13. Szmuness W. et al., Am.J.Epidem., 104 : 256, 1976
14. Grebenchtchikiov N. et al., J.Immunol. Methods, 15(2) :219-231, 2002
15. Schrijver RS and Kramps JA, Rev.Sci.Tech. 17(2):550-561, 1998

All the IVD Products manufactured by the company are under the control of a certified Quality Management System approved by an EC Notified Body. Each lot is submitted to a quality control and released into the market only if conforming with the EC technical specifications and acceptance criteria.

Produced by
Dia.Pro Diagnostic Bioprobes Srl
Via G. Carducci n° 27 – Sesto San Giovanni (MI) – Italy

CE
0318

HBc IgM

"Capture" Enzyme ImmunoAssay (ELISA) for the quantitative/qualitative determination of IgM class antibody to Hepatitis B Virus core Antigen in human plasma and sera

- for "in vitro" diagnostic use only -

DIA.PRO
Diagnostic Bioprobes Srl
Via G. Carducci n° 27
20099 Sesto San Giovanni
(Milano) - Italy
Phone +39 02 27007161
Fax +39 02 26007726
e-mail: info@diapro.it

REF BCM.CE
96 Tests

HBc IgM

A. INTENDED USE

Enzyme ImmunoAssay (ELISA) for the quantitative/qualitative determination of IgM class antibodies to Hepatitis B Virus core Antigen in human plasma and sera with the "capture" system.
The kit is intended for the classification of the viral agent and for the follow-up of chronic patients under therapy.
For "in vitro" diagnostic use only.

B. INTRODUCTION

Hepatitis B core Antigen (or HBcAg) is the major component of the core particles of Hepatitis B virus (or HBV).
Particles have a size of 27nm and contain a circular double-stranded DNA molecule, a specific DNA-polymerase and HBcAg. HBcAg is composed of a single polypeptide of aboul 17 kD that is released upon disaggregation of the core particles ; the antigen contains at least one immunological determinant.
Upon primary infection, anti HBcAg IgM antibodies are one of the first markers of HBV hepatitis appearing in the serum of the patient, together or slightly later than HBsAg, the viral surface antigen.
Anti HBcAg IgM titers, very high during the acute phase, decrease along the illness, as IgG antibodies appear, down to undetectable levels in convalescent patients.
In chronic hepatitis, however, spikes of anti HBcAg IgM synthesis are present, confirming reactivation of HBV in hepatocites and giving origin to permanent IgM low titers.
The determination of anti HBcAg IgM antibodies has become very important for the fast classification of the virus, of the phase of the illness and for the monitoring of patients under treatment with interferon.

C. PRINCIPLE OF THE TEST

The assay is based on the principle of "IgM capture" where IgM class antibodies in the sample are first captured by the solid phase coated with anti hIgM antibody.
After washing out all the other components of the sample and in particular IgG antibodies, the specific IgM captured on the solid phase are detected by the addition of a purified preparation of recombinant HBcAg, labelled with a monoclonal antibody conjugated with peroxidase (HRP).
After incubation, microwells are washed to remove unbound conjugate and then the chromogen/substrate is added.
In the presence of peroxidase the colourless substrate is hydrolysed lo a coloured end-product, whose optical density may be detected and is proportional to the amount of IgM antibodies to HBcAg present in the sample.

D. COMPONENTS

Each kit contains sufficient reagents to perform 96 tests.

1. Microplate: MICROPLATE
8x12 microwell strips coated with purified anti human IgM specific mouse monoclonal antibody, post-coated with bovine serum proteins and sealed into a bag with desiccant. Allow the microplate to reach room temperature before opening; reseal unused strips in the bag with desiccant and store at 4°C.

2. Calibration Curve: CAL N° ...
6x2.0 ml/vial. Ready to use and color coded standard curve calibrated on the HBcIgM reference preparation supplied by Paul Erlich Institute (HBc-Referenzserum-IgM 84), ranging: CAL1 = 0 U/ml // CAL2 = 5 U/ml // CAL3 = 10 U/ml // CAL4 = 20 U/ml // CAL 5 = 50 U/ml // CAL 6 = 100 U/ml;
It contains chemical inactivated HBcIgM positive human plasma, 100 mM Tris buffer pH 7.4+/-0.1, 0.5% Tween 20, 0.09% sodium azide and 0.1% Kathon GC as preservatives.
The Calibration Curve is coded with blue alimentary dye.
Important Note: Even if plasma has been chemically inactivated, handle this component as potentially infectious.

3. Wash buffer concentrate: WASHBUF 20X
1x60ml/bottle, 20x concentrated solution.
Once diluted, the wash solution contains 10 mM phosphate buffer pH 7.0+/-0.2, 0.05% Tween 20 and 0.1% Kathon GC.

4. Enzyme Conjugate (Immunocomplex) : CONJ
1x16.0 ml/vial. Ready-to-use solution. Contains an immunocomplex formed by a specific mouse monoclonal antibody, labelled with HRP, and a purified recombinant HBcAg.
The reagent is dissolved into a buffer solution 10 mM Tris buffer pH 6.8+/-0.1, 2% BSA, 0.1% Kathon GC and 0.02% gentamicine sulphate as preservatives. The component is red colour coded.

5. Specimen Diluent : DILSPE
2x60.0 ml/vial. Buffered solution for the dilution of samples; it contains 100 mM Tris buffer pH 7.4+/-0.1, 0.5% Tween 20, 2% Casein, 0.1% Kathon GC and 0.09% sodium azide as preservatives. The component is blue color coded.

6. Control Serum : CONTROL ...ml
1 vial, Lyophilized. Contains fetal bovine serum, human HBcIgM positive human plasma calibrated at 20 ± 10% PEI U/ml, 0.2 mg/ml gentamicine sulphate and 0.1% Kathon GC as preservatives.
Important Notes
1. The volume necessary to dissolve the content of the vial may vary from lot to lot. Please use the right volume reported on the label .
2. Important Note: Even if plasma has been chemically inactivated, handle this component as potentially infectious.

7. Chromogen/Substrate : SUBS TMB
1x16ml/vial. Contains a 50 mM citrate-phosphate buffered solution at pH 3.5-3.8, 4% dimethylsulphoxide, 0.03% tetra-methyl-benzidine or TMB and 0.02% hydrogen peroxide or H_2O_2.
Note: To be stored protected from light as sensitive to strong illumination.

8. Sulphuric Acid: H2SO4 0.3 M
1x15ml/vial. Contains 0.3 M H_2SO_4 solution.
Attention: Irritant (H315, H319; P280, P302+P352, P332+P313, P305+P351+P338, P337+P313, P362+P363).

9. Plate sealing foils: n° 2

10. Package insert: n° 1

E. MATERIALS REQUIRED BUT NOT PROVIDED

1. Calibrated Micropipettes (150ul, 100ul and 50ul) and disposable plastic tips.
2. EIA grade water (double distilled or deionised, charcoal treated to remove oxidizing chemicals used as disinfectants).
3. Timer with 60 minute range or higher.
4. Absorbent paper tissues.
5. Calibrated ELISA microplate thermostatic incubator (dry or wet) set at +37°C.
6. Calibrated ELISA microwell reader with 450nm (reading) and with 620-630nm (blanking) filters.
7. Calibrated ELISA microplate washer.
8. Vortex or similar mixing tools.

F. WARNINGS AND PRECAUTIONS

1. The kit has to be used by skilled and properly trained technical personnel only, under the supervision of a medical doctor responsible of the laboratory.
2. All the personnel involved in performing the assay have to wear protective laboratory clothes, talc-free gloves and glasses. The use of any sharp (needles) or cutting (blades) devices should be avoided. All the personnel involved should be trained in biosafety procedures, as recommended by the Center for Disease Control, Atlanta, U.S. and reported in the National Institute of Health's publication: "Biosafety in Microbiological and Biomedical Laboratories", ed. 1984.
3. All the personnel involved in sample handling should be vaccinated for HBV and HAV, for which vaccines are available, safe and effective.
4. The laboratory environment should be controlled so as to avoid contaminants such as dust or air-born microbial agents, when opening kit vials and microplates and when performing the test. Protect the Chromogen/Substrate (TMB) from strong light and avoid vibration of the bench surface where the test is undertaken.
5. Upon receipt, store the kit at 2-8°C into a temperature controlled refrigerator or cold room.
6. Do not interchange components between different lots of the kits. It is recommended that components between two kits of the same lot should not be interchanged.
7. Check that the reagents are clear and do not contain visible heavy particles or aggregates. If not, advise the laboratory supervisor to initiate the necessary procedures.
8. Avoid cross-contamination between serum/plasma samples by using disposable tips and changing them after each sample.
9. Avoid cross-contamination between kit reagents by using disposable tips and changing them between the use of each one.
10. Do not use the kit after the expiration date stated on external (primary container) and internal (vials) labels.
11. Treat all specimens as potentially infective. All human serum specimens should be handled at Biosafety Level 2, as recommended by the Center for Disease Control, Atlanta, U.S. in compliance with what reported in the Institutes of Health's publication: "Biosafety in Microbiological and Biomedical Laboratories", ed. 1984.
12. The use of disposable plastic-ware is recommended in the preparation of the washing solution or in transferring components into other containers of automated workstations, in order to avoid contamination.
13. Waste produced during the use of the kit has to be discarded in compliance with national directives and laws concerning laboratory waste of chemical and biological substances. In particular, liquid waste generated from the washing procedure, from residuals of controls and from samples has to be treated as potentially infective material and inactivated. Suggested procedures of inactivation are treatment with a 10% final concentration of household bleach for 16-18 hrs or heat inactivation by autoclave at 121°C for 20 min..
14. Accidental spills have to be adsorbed with paper tissues soaked with household bleach and then with water. Tissues should then be discarded in proper containers designated for laboratory/hospital waste.
15. The Stop Solution is an irritant. In case of spills, wash the surface with plenty of water
16. Other waste materials generated from the use of the kit (example: tips used for samples and controls, used microplates) should be handled as potentially infective and disposed according to national directives and laws concerning laboratory wastes.

G. SPECIMEN: PREPARATION AND RECOMMANDATIONS

1. Blood is drawn aseptically by venepuncture and plasma or serum is prepared using standard techniques of preparation of samples for clinical laboratory analysis. No influence has been observed in the preparation of the sample with citrate, EDTA and heparin.
2. Avoid any addition of preservatives; especially sodium azide as this chemical would affect the enzymatic activity of the conjugate, generating false negative results.
3. Samples have to be clearly identified with codes or names in order to avoid misinterpretation of results.
4. Haemolysed and visibly hyperlipemic ("milky") samples have to be discarded as they could generate false results. Samples containing residues of fibrin or heavy particles or microbial filaments and bodies should be discarded as they could give rise to false results.
5. Sera and plasma can be stored at +2°...8°C for up to five days after collection. For longer storage periods, samples can be stored frozen at –20°C for several months. Any frozen samples should not be freeze/thawed more than once as this may generate particles that could affect the test result.
6. If particles are present, centrifuge at 2.000 rpm for 20 min or filter using 0.2-0.8u filters to clean up the sample for testing.

H. PREPARATION OF COMPONENTS AND WARNINGS

A study conducted on an opened kit has not pointed out any relevant loss of activity up to 6 re-uses of the device and up to 3 months.

Microplate:
Allow the microplate to reach room temperature (about 1 hr) before opening the container. Check that the desiccant has not turned dark green, indicating a defect in manufacturing. In this case, call Dia.Pro's customer service.
Unused strips have to be placed back into the aluminium pouch, with the desiccant supplied, firmly zipped and stored at +2°-8°C. When opened the first time, unused strips are stable until the humidity indicator inside the desiccant bag turns from yellow to green.

Calibration Curve:
Ready to use. Mix well on vortex before use.

Wash buffer concentrate:
The whole content of the 20x concentrated solution has to be diluted with bidistilled water up to 1200ml and mixed gently end-over-end before use.
During preparation avoid foaming as the presence of bubbles could impact on the efficiency of the washing cycles.
Note: Once diluted, the wash solution is stable for 1 week at +2...8° C.

Enzyme conjugate:
Ready to use. Mix well on vortex before use.
Avoid contamination of the liquid with oxidizing chemicals, dust or microbes. If this component has to be transferred, use only plastic, and if possible, sterile disposable containers.

Specimen Diluent
Ready to use. Mix on vortex before use.

Control Serum
Dissolve the content of the vial with EIA grade water as reported in the label. Mix well on vortex before use. The dissolved control serum is ready to use.
Note: The control after dissolution is not stable. Store frozen in aliquots at –20°C.

Chromogen/Substrate:
Ready to use. Mix well on vortex before use.
Avoid contamination of the liquid with oxidizing chemicals, air-driven dust or microbes. Do not expose to strong light, oxidizing agents and metallic surfaces.
If this component has to be transferred use only plastic, and if possible, sterile disposable container

Sulphuric Acid:
Ready to use. Mix well on vortex before use.
Attention: Irritant (H315, H319; P280, P302+P352, P332+P313, P305+P351+P338, P337+P313, P362+P363).

Legenda:

Warning **H statements:**
H315 – Causes skin irritation.
H319 – Causes serious eye irritation.

Precautionary **P statements:**
P280 – Wear protective gloves/protective clothing/eye protection/face protection.
P302 + P352 – IF ON SKIN: Wash with plenty of soap and water.
P332 + P313 – If skin irritation occurs: Get medical advice/attention.
P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 – If eye irritation persists: Get medical advice/attention.
P362 + P363 – Take off contaminated clothing and wash it before reuse.

I. INSTRUMENTS AND TOOLS USED IN COMBINATION WITH THE KIT

1. Micropipettes have to be calibrated to deliver the correct volume required by the assay and must be submitted to regular decontamination (household alcohol, 10% solution of bleach, hospital-grade disinfectants) of those parts that could accidentally come in contact with the sample. They should also be regularly maintained. Decontamination of spills or residues of kit components should also be carried out regularly. They should also be regularly maintained in order to show a precision of 1% and a trueness of ±2%.
2. The ELISA incubator has to be set at +37°C (tolerance of +/- 0,5°C) and regularly checked to ensure the correct temperature is maintained. Both dry incubators and water baths are suitable for the incubations, provided that the instrument is validated for the incubation of ELISA tests.
3. The ELISA washer is extremely important to the overall performances of the assay. The washer must be carefully validated and correctly optimized using the kit controls and reference panels, before using the kit for routine laboratory tests. 4-5 washing cycles (aspiration + dispensation of 350ul/well of washing solution = 1 cycle) are sufficient to ensure that the assay performs as expected. A soaking time of 20-30 seconds between cycles is suggested. In order to set correctly their number, it is recommended to run an assay with the kit controls and well characterized negative and positive reference samples, and check to match the values reported below in the sections "Validation of Test" and "Assay Performances". Regular calibration of the volumes delivered by, and maintenance (decontamination and cleaning of needles) of the washer has to be carried out according to the instructions of the manufacturer.
4. Incubation times have a tolerance of ±5%.
5. The ELISA reader has to be equipped with a reading filter of 450nm and with a second filter (620-630nm, strongly recommended) for blanking purposes Blanking is carried out on the well identified in the section "Assay Procedure". The optical system of the reader has to be calibrated regularly to ensure the correct optical density is measured. It should be regularly maintained according to the manufacturer 's instructions.
6. When using an ELISA automated work station, all critical steps (dispensation, incubation, washing, reading, data handling) have to be carefully set, calibrated, controlled and regularly serviced in order to match the values reported in the sections "Validation of Test" and "Assay Performances". The assay protocol has to be installed in the operating system of the unit and validated as for the washer and the reader. In addition, the liquid handling part of the station (dispensation and washing) has to be validated and correctly set. Particular attention must be paid to avoid carry over by the needles used for dispensing and for washing. This must be studied and controlled to minimize the possibility of contamination of adjacent wells. The use of ELISA automated work stations is recommended when the number of samples to be tested exceed 20-30 units per run.
7. Dia.Pro's customer service offers support to the user in the setting and checking of instruments used in combination with the kit, in order to assure compliance with the requirements described. Support is also provided for the installation of new instruments to be used with the kit.

L. PRE ASSAY CONTROLS AND OPERATIONS

1. Check the expiration date of the kit printed on the external label (primary container). Do not use if expired.
2. Check that the liquid components are not contaminated by visible particles or aggregates. Check that the Chromogen/Substrate (TMB+H_2O_2) is colourless or pale blue by aspirating a small volume of it with a sterile plastic pipette. Check that no breakage occurred in transportation and no spillage of liquid is present inside the box (primary container). Check that the aluminium pouch, containing the microplate, is not punctured or damaged.
3. Dilute all the content of the 20x concentrated Wash Solution as described above.
4. Dissolve the Control Serum as described above and gently mix.
5. Allow all the other components to reach room temperature (about 1 hr) and then mix gently on vortex all liquid reagents.
6. Set the ELISA incubator at +37°C and prepare the ELISA washer by priming with the diluted washing solution, according to the manufacturers instructions. Set the right number of washing cycles as found in the validation of the instrument for its use with the kit.
7. Check that the ELISA reader is turned on or ensure it will be turned on at least 20 minutes before reading.
8. If using an automated work station, turn on, check settings and be sure to use the right assay protocol.
9. Check that the micropipettes are set to the required volume.
10. Check that all the other equipment is available and ready to use.

In case of problems, do not proceed further with the test and advise the supervisor.

M. ASSAY PROCEDURE

The assay has to be carried out according to what reported below, taking care to maintain the same incubation time for all the samples in testing.

Two procedures can be carried out with the device according to the request of the clinician.

M.1 Quantitative analysis

1. Place the required number of strips in the plastic holder and carefully identify the wells for standards and samples.
2. Dilute samples **1:101** dispensing 1 ml Sample Diluent into a disposable tube and then 10 ul sample; mix on vortex before use. Do not dilute the Calibrators and the dissolved Control Serum as they are ready-to-use.
3. Leave the A1+B1 wells empty for blanking purposes.
4. Pipette 100 µl of the Calibrators in duplicate, 100 µl dissolved Control Serum in duplicate followed by 100 µl of diluted samples. The Control Serum is used to verify that