STATEMENT

We, Zhejiang Orient Gene Biotech Co., Ltd , having a registered office at 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as non-exclusive authorized representative for Orient Gene Brand product in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This Statement letter will be valid from Mar.22th,2024 to Mar.21th, 2025.

Zhejiang Orient Gene Biotech Co., Ltd

General Manager：

Date:2024/3/22

Digitally signed by Dolgopol Iulian
Date: 2025.02.14 11:51:00 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 092305 0001 Rev. 01

Holder of Certificate: **Zhejiang Orient Gene Biotech Co., Ltd.**
3787#, East Yangguang Avenue, Dipu Street Anji
313300 Huzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagent and Instrument for the Detection of Drugs of Abuse, Fertility, Infectious Diseases, Oncology, Biochemistry, Cardiac Diseases, Allergic Disease based on Rapid Test, PCR and Liquid Biochip Method.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 01

Report No.: SH2198802

Valid from: 2022-04-11
Valid until: 2024-03-16

Date, 2022-04-11

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 092305 0001 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street Anji, 313300
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

.

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TÜV®

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Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 092378 0009 Rev. 00

Manufacturer:

Healgen Scientific Limited Liability Company
3818 Fuqua Street
Houston TX 77047
USA

Product: **Screening test for Hepatitis C marker**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V7 092378 0009 Rev. 00

Report No.: 713234651

Valid from: 2022-04-22
Valid until: 2025-05-26

Date, 2022-04-22

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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ZLG-BS-245.10.07

TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 092378 0009 Rev. 00

Model(s): **HCV Hepatitis C Virus Rapid Test**

Facility(ies):

Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street Anji,
313300 Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Parameters:

Model Name:	Model No.:
--	
HCV Hepatitis C Virus Rapid Test (Serum / Plasma) (Cassette)	GCHCV-302a
HCV Hepatitis C Virus Rapid Test (Whole Blood /Serum / Plasma) (Cassette)	GCHCV-402a

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV®

3818 Fuqua street
Houston, TX 77047, USA
Tel: +1 713 733 8088
Fax: +1 713 733 8848
Web: www.Healgen.com
E-mail: sales@healgen.com

CE-DOC-H003
Ver.1.7

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: Healgen Scientific Limited Liability Company

Legal Manufacturer Address: *3818 Fuqua Street, Houston, TX 77047, USA.*

Declares, that the products
Product Name and Model(s)

Orient Gene HCV Hepatitis C Virus Rapid Test (Serum/Plasma) (Cassette)	GCHCV-302a
Orient Gene HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette)	GCHCV-402a

EDMA Code: 15 70 02 02

Classification: *Annex II List A*
Conformity assessment route: *Annex IV (Full Quality Assurance)*

Compliance of the designated product with the Directive 98/79/EC has been assessed and certified by the Notified Body
Notified Body: TÜV SÜD Product Service GmbH
Notified Body Address: Munich Branch Ridlerstraße 65 80339 München Germany
EC Certificate No.: V1 092378 0004 Rev. 02 Valid until: 2025-05-26
EC Design-Examination Certificate No.: V7 092378 0009 Rev. 00 Valid until: 2025-05-26

It bears the mark

CE 0123

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.
We hereby explicitly appoint
EC Representative Name: QARAD b.v.b.a.
EC Representative Address: Cipalstraat 3, B-2440 Geel, Belgium

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Signature:
Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President
Date: 2022.4.22

浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co., LTD

CE-DOC-OG040
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products
Product Name and Model(s)

H. pylori Ab Rapid Test Strip (Whole blood/Serum/Plasma)	GCHP-401a
H. pylori Ab Rapid Test Cassette (Whole blood/Serum/Plasma)	GCHP-402a

Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: Shanghai International Holding Corp. GmbH (Europe)

EC Representative's Address: Eiffestrasse 80, 20537 Hamburg, Germany

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: November 28, 2017

Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President

Zhejiang Orient Gene Biotech Co., LTD

CERTIFICATE OF ANALYSIS

Product Name：HBsAg Rapid Test (Whole blood/Serum/Plasma) (Cassette)

Catalog NO.: GCHBsg-402a

Purchase NO.: 2025-IEU010#

Lot NO.: 2501182

Quantity: 3000pcs

Expiration Date: 2026.12

CONTROLS		SPECIFICATION	TEST RESULT	CONCLUSION
Negative Specimens		Negative	Negative	☑Pass □Fail
Positive Specimens	1ng/ml	Positive	Positive	☑Pass □Fail
	2ng/ml	Positive	Positive	☑Pass □Fail
	3ng/ml	Positive	Positive	☑Pass □Fail
	5ng/ml	Positive	Positive	☑Pass □Fail

Conclusion: ☑Pass:All results meet QC standard.
□Fail

ZHEJIANG ORIENT GENE BIOTECH CO.,LTD 浙江东方基因生物制品股份有限公司 检验专用章

Test by: 查妍 Date: 2025.01.22

QC Supervisor: 黄仪愚 Date: 2025.01.22

Zhejiang Orient Gene Biotech Co., LTD

CERTIFICATE OF ANALYSIS

Product Name: HBcAb Rapid Test (Whole blood Serum Plasma) (Cassette)

Catalog NO.: GCHBcB-402a

Purchase NO.: 2025-SI045#

Lot NO.: S2501119

Quantity: 100 pcs

Expiration Date: 2026 12

CONTROLS	SPECIFICATION	TEST RESULT	CONCLUSION
Negative Specimens	Negative	Negative	☑Pass □Fail
Positive Specimens	Positive	Positive	☑Pass □Fail

Conclusion: ☑Pass: All results meet QC standard.

□Fail

Test by:

QC Supervisor:

Date: 2025.01.21

Toxicology Urine Test

Product Description	Format	Cut-off Value	Registration
Acetaminophen (ACE) Test	Strip/Cassette/Dip Card/Cup	5000 ng/mL	CE
Alprazolam (ALP) Test	Strip/Cassette/Dip Card/Cup	150 ng/mL	/
Amphetamine (AMP) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500/300/250 ng/mL	CE 510(k)
Barbiturates (BAR) Test	Strip/Cassette/Dip Card/Cup	2000/600/300/200 ng/mL	CE 510(k)
Benzodiazepines (BZO) Test	Strip/Cassette/Dip Card/Cup	600/400/300/200/100 ng/mL	CE 510(k)
Buprenorphine (BUP) Test	Strip/Cassette/Dip Card/Cup	10/5 ng/mL	CE 510(k)
Caffeine (CAF) Test	Strip/Cassette/Dip Card/Cup	8000 ng/mL	/
Carisoprodol (SOMA) Test	Strip/Cassette/Dip Card/Cup	1000 ng/mL	CE
Clonazepam (CLO) Test	Strip/Cassette/Dip Card/Cup	500/100 ng/mL	CE
Cocaine (COC) Test	Strip/Cassette/Dip Card/Cup	600/300/150/100 ng/mL	CE 510(k)
Codeine (COD) Test	Strip/Cassette/Dip Card/Cup	2000 ng/mL	CE
Cotinine (COT) Test	Strip/Cassette/Dip Card/Cup	400/300/200/100/50 ng/mL	CE
Ecstasy (MDMA) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500/300/250/150 ng/mL	CE 510(k)
Ethyl Glucuronide (EtG) Test	Strip/Cassette/Dip Card/Cup	500/300ng/mL	CE
Fentanyl (FEN) Test	Strip/Cassette/Dip Card/Cup	300/200/100/50/1 ng/mL	CE
Norfentanyl (FEN) Test New	Strip/Cassette/Dip Card/Cup	200/50/20/10/5 ng/mL	CE
2-Fluorodeschloroketamine (FKE) Test	Strip/Cassette/Dip Card/Cup	1000 ng/mL	/
Gabapentin (GAB) Test	Strip/Cassette/Dip Card/Cup	3750/2000/1000 ng/mL	CE
Hydrocodone (HCO) Test	Strip/Cassette/Dip Card/Cup	300/10 ng/mL	CE
Hydromorphone (HMO) Test New	Strip/Cassette/Dip Card/Cup	300 ng/mL	CE
Ketamine (KET) Test	Strip/Cassette/Dip Card/Cup	3000/2000/1000/500/100 ng/mL	CE
Kratom (KRA) Test	Strip/Cassette/Dip Card/Cup	250/150/100 ng/mL	CE
Lysergic acid diethylamide (LSD) Test	Strip/Cassette/Dip Card/Cup	20 ng/mL	CE
Marijuana (THC) Test	Strip/Cassette/Dip Card/Cup	600/300/200/150/100/50/40/25/20/18/15 ng/mL	CE 510(k)
Methadone Metabolite (EDDP) Test	Strip/Cassette/Dip Card/Cup	300/100 ng/mL	CE 510(k)
Methadone (MTD) Test	Strip/Cassette/Dip Card/Cup	1000/600/300/200/50 ng/mL	CE 510(k)
Methamphetamine (MET) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500/300/250 ng/mL	CE 510(k)
Methaqualone (MQL) Test	Strip/Cassette/Dip Card/Cup	300/1000 ng/mL	CE
Methcathinone (MTC) Test	Strip/Cassette/Dip Card/Cup	500/300 ng/mL	CE
3,4-Methylenedioxypyrovalerone (MDPV) Test	Strip/Cassette/Dip Card/Cup	1000/500/300 ng/mL	CE
Methylphenidate (MPD) Test	Strip/Cassette/Dip Card/Cup	300 ng/mL	CE
6-Monoacetylmorphine (6-MAM) Test	Strip/Cassette/Dip Card/Cup	20/10 ng/mL	CE
Morphine (MOP) Test	Strip/Cassette/Dip Card/Cup	2000/600/300/150/100 ng/mL	CE 510(k)
Opiate (OPI) Test	Strip/Cassette/Dip Card/Cup	2000/300 ng/mL	CE 510(k)
Oxycodone (OXY) Test	Strip/Cassette/Dip Card/Cup	300/100 ng/mL	CE 510(k)
Phencyclidine (PCP) Test	Strip/Cassette/Dip Card/Cup	50/25 ng/mL	CE 510(k)
Pinacol& (K3) Test	Strip/Cassette/Dip Card/Cup	10 ng/mL	CE
Pregalalin (PGB) Test New	Strip/Cassette/Dip Card/Cup	2000/1000/500 ng/mL	CE
Propoxyphene (PPX) Test	Strip/Cassette/Dip Card/Cup	600/300 ng/mL	CE 510(k)
Synthetic Marijuana (K2) Test	Strip/Cassette/Dip Card/Cup	75/50/25/20/10 ng/mL	CE
Tramadol (TRA) Test	Strip/Cassette/Dip Card/Cup	200/100 ng/mL	CE
Tricyclic Antidepressants (TCA) Test	Strip/Cassette/Dip Card/Cup	1000/300 ng/mL	CE 510(k)
UR-144 Test New	Strip/Cassette/Dip Card/Cup	50 ng/mL	/
Xylazine (XYL) Test New	Strip/Cassette/Dip Card/Cup	100/50 ng/mL	/
Zolpidem (ZOL) Test	Strip/Cassette/Dip Card/Cup	50 ng/mL	/
Zopiclone (ZOP) Test	Strip/Cassette/Dip Card/Cup	50 ng/mL	/
Alcohol (ALC) Test	Strip/Cassette/Dip Card/Cup	0.04%	CE

Toxicology Saliva Test



Product Description	Format	Cut-off Value	Registration
Amphetamine (AMP) Test	Device	50/40 ng/mL	CE
Barbiturates (BAR) Test	Device	300/50/30 ng/mL	CE
Benzodiazepines (BZO) Test	Device	50/20/10 ng/mL	CE
Buprenorphine (BUP) Test	Device	10/5 ng/mL	CE
Carisoprodol (SOMA) Test	Device	300 ng/mL	/
Cocaine (COC) Test	Device	50/20/10 ng/mL	CE
Codeine (COD) Test	Device	10 ng/mL	CE
Cotinine (COT) Test	Device	50/30/10 ng/mL	CE
Ecstasy (MDMA) Test	Device	60/50 ng/mL	CE
Fentanyl (FEN) Test	Device	10 ng/mL	CE
Hydromorphone (HMO) Test New	Device	300/150 ng/mL	/
Ketamine (KET) Test	Device	100/50 ng/mL	CE
Lysergic acid diethylamide (LSD) Test	Device	25/10 ng/mL	CE
Marijuana (THC) Test	Device	50/40/30/25/15/12/10/5/4/3 ng/mL	CE
Methadone Metabolite (EDDP) Test	Device	20 ng/mL	CE
Mephedrone (MEP) Test New	Device	50 ng/mL	/
Methadone (MTD) Test	Device	75/50/30 ng/mL	CE
Methamphetamine (MET) Test	Device	50 ng/mL	CE
Methaqualone (MQL) Test	Device	150/100 ng/mL	CE
Methcathinone (MTC) Test	Device	50 ng/mL	/
3,4-Methylenedioxypyrovalerone (MDPV) Test	Device	200/100/50 ng/mL	CE
Methylphenidate (MPD) Test	Device	50 ng/mL	/
Methylphenidate HCL (MPD HCL) Test	Device	50 ng/mL	/
6-Monoacetylmorphine (6-MAM) Test	Device	25/15/10/5/4 ng/mL	CE
Morphine (MOP) Test	Device	15 ng/mL	CE
Opiate (OPI) Test	Device	50/40/10 ng/mL	CE
Oxycodone (OXY) Test	Device	50/40/20 ng/mL	CE
Phencyclidine (PCP) Test	Device	25/15/10 ng/mL	CE
Pregalalin (PGB) Test New	Device	150/100 ng/mL	/
Propoxyphene (PPX) Test	Device	600/300 ng/mL	CE
Synthetic Marijuana (K2) Test	Device	50/20/10 ng/mL	CE
Tramadol (TRA) Test	Device	100/50 ng/mL	CE
Tricyclic Antidepressants (TCA) Test	Device	1000 ng/mL	CE
Zolpidem (ZOL) Test	Device	2000 ng/mL	/
Alcohol (ALC) Test	Device	0.05/0.02%	CE

Toxicology Hair Test

Product Description	Format	Cut-off Value	Registration
Amphetamine (AMP) Test	Cassette	5 ng/mg	/
Barbiturates (BAR) Test	Cassette	5 ng/mg	/
Benzodiazepines (BZO) Test	Cassette	2 ng/mg	/
Caffeine (CAF) Test	Cassette	20 ng/mg	/
Cocaine (COC) Test	Cassette	5/2 ng/mg	CE
Codeine (COD) Test	Cassette	2 ng/mg	/
Cotinine (COT) Test	Cassette	5/2 ng/mg	/
Ecstasy (MDMA) Test	Cassette	5/2 ng/mg	/
Etomidate (ETO) Test	Cassette	5 ng/mg	/
Fentanyl (FEN) Test	Cassette	2 ng/mg	/
Ketamine (KET) Test	Cassette	2.5/1/0.5 ng/mg	CE
Marijuana (THC) Test	Cassette	20/5 ng/mg	CE
Methamphetamine (MET) Test	Cassette	5/2/1 ng/mg	CE
Methcathinone (MTC) Test	Cassette	5/2 ng/mg	/
Methadone (MTD) Test	Cassette	2 ng/mg	/
6-Monoacetylmorphine (6-MAM) Test	Cassette	2 ng/mg	CE
Morphine (MOP) Test	Cassette	5/2/0.5 ng/mg	CE
Oxycodone (OXY) Test	Cassette	4/1 ng/mg	/
Phencyclidine (PCP) Test	Cassette	1 ng/mg	CE
Pinacol& (K3) Test	Cassette	0.5 ng/mg	/
Synthetic Marijuana (K2) Test	Cassette	5/2/1 ng/mg	/
Tramadol (TRA) Test	Cassette	5/2 ng/mg	/
UR-144 Test	Cassette	2 ng/mg	/
Xylazine (XYL) Test	Cassette	10 ng/mg	/

Powder Test

Product Description	Format	Cut-off Value	Registration
Fentanyl (FEN) Test	Strip/Cassette/Dip Card	200/5 ng/mL	/
Xylazine (XYL) Test	Strip/Cassette	50 ng/mL	/

Instrument

Product Description	Model
Colloidal Gold Test Reader	OG-D180
Urine Drug Test Cup Reader	OG-D600

√ CE Marked *Cleared for US 510(k) In Specimen column: WB: Whole Blood S: Serum P: Plasma

Infectious Disease


Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
Adenovirus Antigen Test	Swab	GCADE-502a√	Cassette	/	20 Tests/Kit
Adenovirus Test	Feces	GCADE-602a√	Cassette	/	20 Tests/Kit
Brucella Antibody Test	WB/S/P	GCBRU-402a√	Cassette	/	25 Tests/Kit
Candida albicans Test	Vaginal Secretion	GCCAL-502a√	Cassette	10⁵ CFU/mL	20 Tests/Kit
Chagas Antibody Test	S/P	GCCHA-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCCHA-402a√	Cassette	/	25 Tests/Kit
Clostridium difficile GDH Test	Feces	GCCDI(GDH)-602a√	Cassette	2 ng/mL	20 Tests/Kit
Clostridium difficile Toxin A/B Test	Feces	GCCDI(Toxin A/B)-602a√	Cassette	Toxin A: 2 ng/mL; Toxin B: 2 ng/mL	20 Tests/Kit
Clostridium difficile GDH & Toxin A/B Combo Test	Feces	GCCDI-625a√	Cassette	GDH: 2 ng/mL; Toxin A: 2 ng/mL; Toxin B: 2 ng/mL	20 Tests/Kit
Chikungunya Ig M Test	S/P	GCCHK(IgM)-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCCHK(IgM)-402a√	Cassette	/	25 Tests/Kit
Chikungunya IgG/IgM Test	WB/S/P	GCCHK(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
Chlamydia Test	Swab/Urine	GCCHL-502a√	Cassette	4.8×10⁴ IFU/mL	20 Tests/Kit
CMV IgG Test	S/P	GCCMV(IgG)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCCMV(IgG)-402a	Cassette	/	25 Tests/Kit
CMV IgM Test	S/P	GCCMV(IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCCMV(IgM)-402a	Cassette	/	25 Tests/Kit
CMV IgG/IgM Test	S/P	GCCMV(IgG/IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCCMV(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
COVID-19 IgM/IgG Test	WB/S/P	GCCOV-402a√	Cassette	/	25 Tests/Kit
COVID-19 Neutralizing Antibody Test	WB/S/P	GCCOV(NAb)-402b√	Cassette	/	25 Tests/Kit
	Nasopharyngeal Swab	GCCOV-552a√	Cassette	/	20 Tests/Kit
		GCCOV-552Ca√	Cassette	/	20 Tests/Kit
COVID-19 Antigen Test	Nasal Swab	GCCOV-557a√ New	Strip	/	20 Tests/Kit
		GCCOV-502a-NA√	Cassette	/	1/20/5/1/0.5/0.2 Tests/Kit
		GCCOV-552a-NA√	Cassette	/	1/20/5/1/0.5/0.2 Tests/Kit
	NA & NP Swab	GCCOV-502a-NN√	Cassette	/	20 Tests/Kit
	Oral Fluid	GCCOV-782a√	Cassette	/	1/20/5/1/0.5/0.2 Tests/Kit
	Nasal Swab	GCCOV-552a-Hox√	Cassette	/	1/20/5/1/0.5/0.2 Tests/Kit
COVID-19 Antigen Self-Test		GCCOV-602a-HoxOG&T	Cassette	/	1/20/5/1/0.5/0.2 Tests/Kit
	Oral Fluid	GCOV-782a-Hox√ New	Cassette	/	1/20/5/1/0.5/0.2 Tests/Kit
Digital COVID-19 Antigen Test	Nasal Swab	GCCOV-D-503a√ New	Reader	/	1/20/5/1/0.5/0.2 Tests/Kit
COVID-19 Antigen & B.1.1.7 Mutant Strain Combo Test	Nasal Swab	GCOVN(B1.1.7)-523a√	Cassette	/	20 Tests/Kit
COVID-19/Flu A&B /RSV Antigen Combo Test	Nasal Swab	GCFCR-T525a√ New	Cassette	/	20 Tests/Kit
SARS-CoV-2 Delta series Mutant Strain Antigen Test	Nasal Swab	GCCOVD(MT)-T552a√	Cassette	/	20 Tests/Kit
SARS-CoV-2 Ag Fluorescence Rapid Test	Nasal Swab	FCCOV-502a√ New	Cassette	/	20 Tests/Kit
Dengue IgG/IgM Antibody Test	WB/S/P	GCDEN(NS1)-402a√	Cassette	/	25 Tests/Kit
Dengue NS 1 Antigen Test	WB/S/P	GCDEN(NS)-402c√	Cassette	/	25 Tests/Kit
Dengue NS1 & IgG/IgM Combo Test	WB/S/P	GCDEN-625a√	Cassette	/	20 Tests/Kit
EV71 IgM Test	S/P	GCEV71(IgM)-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCEV71(IgM)-402a√	Cassette	/	25 Tests/Kit
Giardia lamblia Test	Feces	GCGIA-602a√	Cassette	/	20 Tests/Kit
Gonorrhoeae Test	Swab	GCGON-502b√	Cassette	1.0E^7	20 Tests/Kit
Chlamydia/Gonorrhoeae Combo Test	Swab	GCCTN/G-T502a New	Cassette	/	20 Tests/Kit
HAV IgM Test	S/P	GCHAV(IgM)-302Ba√	Cassette	/	25 Tests/Kit
HAV IgG/IgM Test	WB/S/P	GCHAV(IgG/IgM)-402a√	Cassette	/	25 Tests/Kit
HAVAntigenTest	Feces	GCHAV-652a√	Cassette	/	25 Tests/Kit
HBcAb Hepatitis B Core Antibody Test	S/P	GCHBcb-302a	Cassette	2 NCU	25 Tests/Kit
		GCHBcb-302b	Cassette	8 NCU	25 Tests/Kit
	WB/S/P	GCHBcb-402a	Cassette	2 NCU	25 Tests/Kit
		GCHBcb-402b	Cassette	8 NCU	25 Tests/Kit
HBeAb Hepatitis B Envelope Antibody Test	S/P	GCHBeb-302a	Cassette	2 NCU	25 Tests/Kit
		GCHBeb-302b	Cassette	8 NCU	25 Tests/Kit
	WB/S/P	GCHBeb-402a	Cassette	2 NCU	25 Tests/Kit
HBeAg Hepatitis B Envelope Antigen Test	S/P	GCHBeg-302a	Cassette	0.5 NCU	25 Tests/Kit
	WB/S/P	GCHBeg-402a	Cassette	0.5 NCU	25 Tests/Kit
HBsAb Hepatitis B Surface Antibody Test	S/P	GCHBsb-301a	Strip	30 mIU/mL	50 Tests/Kit
		GCHBsb-302a	Cassette	30 mIU/mL	25 Tests/Kit
		GCHBsb-401a	Strip	30 mIU/mL	50 Tests/Kit
	WB/S/P	GCHBsb-402a	Cassette	30 mIU/mL	25 Tests/Kit
		GCHBsb-402b	Cassette	20 mIU/mL	25 Tests/Kit
HBsAg Hepatitis B Surface Antigen Rapid Test	S/P	GCHBsg-301a	Strip	1 ng/mL	50 Tests/Kit
		GCHBsg-302a	Cassette	1 ng/mL	25 Tests/Kit
	WB/S/P	GCHBsg-401a	Strip	1 ng/mL	50 Tests/Kit
		GCHBsg-402a	Cassette	1 ng/mL	25 Tests/Kit
HBsAg/HCV Combo Test	WB/S/P	GCHBC-412a	Cassette	/	20 Tests/Kit
HBsAg/HCV/HIV/Syphilis Combo Test	S/P	GCHBCSY-345a	Cassette	/	20 Tests/Kit
	WB/S/P	GCHBCSY-445a	Cassette	/	20 Tests/Kit
HBV HBsAb/HBeAb/HBeAg/HBsAb	S/P	GCHBV-355a	Cassette	/	20 Tests/Kit
/HBsAg Combo Test	WB/S/P	GCHBV-455a	Cassette	/	20 Tests/Kit
HCV Hepatitis C Virus Test	S/P	GCHCV-302a√	Cassette	/	25 Tests/Kit
		GCHCV-302a√	Strip	/	50 Tests/Kit
	WB/S/P	GCHCV-402a	Cassette	/	25 Tests/Kit
		GCHCV-402a√	Strip	/	50 Tests/Kit
HCV/HIV Combo Test	WB/S/P	GCHCI-402a	Cassette	/	25 Tests/Kit
HEV Hepatitis E Virus IgM Test	S/P	GCHEV-302a√	Cassette	/	25 Tests/Kit
		GCHEV-301a	Strip	/	50 Tests/Kit
	WB/S/P	GCHEV-402a	Cassette	/	25 Tests/Kit
HIV 1/2 Antibody Test		GCHIV-301a	Strip	/	50 Tests/Kit
	WB/S/P	GCHIV-401a	Strip	/	50 Tests/Kit
HIV 1/2 Antibody Tri-line Test	WB/S/P	GCHIV-D7402a	Cassette	/	25 Tests/Kit
HIV 1/O/2Antibody Test	S/P	GCHIV-T302b	Cassette	/	25 Tests/Kit
	WB/S/P	GCHIV-T402a	Cassette	/	25 Tests/Kit
HIV Antigen/Antibody Combo Test	WB/S/P	GCHIV(Ag/Ab)-402a	Cassette	/	25 Tests/Kit
HPV E7 Protein Test	Swab	GCHPV-502a New	Cassette	1 ng/mL	20 Tests/Kit
HSV IgG Test	S/P	GCHSV(IgG)-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCHSV(IgG)-402a√	Cassette	/	25 Tests/Kit
HSV IgM Test	S/P	GCHSV(IgM)-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCHSV(IgM)-402a√	Cassette	/	25 Tests/Kit
HSV IgG/IgM Test	S/P	GCHSV(IgG/IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCHSV(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
H. pylori Antibody Test	S/P	GCHP-302a√	Cassette	/	25 Tests/Kit
		GCHP-401a√	Strip	/	50 Tests/Kit
	WB/S/P	GCHP-402a√	Cassette	/	25 Tests/Kit
		GCHP-601a√	Strip	/	25 Tests/Kit
H. pylori Antigen Test	Feces	GCHP-607Ca√	Cassette	/	25 Tests/Kit
		GCHP-602a√	Cassette	/	20 Tests/Kit
		GCHP-602Ca√	Cassette	/	20 Tests/Kit
Influenza A Antigen Test	Nasal/Throat Swabs	GCFLU(A)-501a√	Strip	1.5 x 10⁵ TCID$_{50}$/mL	25 Tests/Kit
		GCFLU(A)-502a√	Cassette	1.5 x 10⁵ TCID$_{50}$/mL	20 Tests/Kit
Influenza A/B Antigen Test	Nasal/Throat Swabs	GCFLU(A/B)-501a√	Strip	1.5x 10⁵ TCID$_{50}$/mL; 1.5 x 10⁵ TCID$_{50}$/mL	25 Tests/Kit
		GCFLU(A/B)-502Ca√	Cassette	1.5x 10⁵ TCID$_{50}$/mL; 1.5 x 10⁵ TCID$_{50}$/mL	20 Tests/Kit
		GCFLU(A/B)-502Ca√	Strip	1.5x 10⁵ TCID$_{50}$/mL; 1.5 x 10⁵ TCID$_{50}$/mL	20 Tests/Kit
Influenza & COVID-19 Antigen Combo Test	Nasopharyngeal Swab	GCFC-525a√	Cassette	/	20 Tests/Kit
	NA & NP Swab	GCFC-525a-NN√	Cassette	/	20 Tests/Kit
		GCFC-525a-NA√	Cassette	/	20 Tests/Kit
	Nasal Swab	GCFC-T502a√ New	Cassette	/	1/5/20 Tests/Kit
		GCFC-T502a-N√ New	Device	/	1/2/5/10 Tests/Kit
Flu, COVID-19, RSV & Adeno Antigen Combo Test	Nasopharyngeal Swab	GCFCRA-545a√	Cassette	/	20 Tests/Kit
	Nasal Swab	GCFCRA-T525a√ New	Cassette	/	20 Tests/Kit
Leishmania Antibody Test	S/P	GCKAH-301a	Strip	/	50 Tests/Kit
		GCKAH-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCKAH-401a	Strip	/	50 Tests/Kit
		GCKAH-402a	Cassette	/	25 Tests/Kit
		GCKAH-T402a	Cassette	/	25 Tests/Kit
Malaria Pan Antigen Test	Whole Blood	GCMAL(pan)-402a√	Cassette	200 parasites	25 Tests/Kit
Malaria P.f. Antigen Test	Whole Blood	GCMAL(pf)-402a√	Cassette	200 parasites	25 Tests/Kit
Malaria P.f.P.Pan Antigen Test	Whole Blood	GCMAL(pf/pan)-402a√	Cassette	200 parasites	25 Tests/Kit
Malaria P.f./P.v. Antigen Test	Whole Blood	GCMAL(pf/pv)-402a√	Cassette	200 parasites	25 Tests/Kit
Malaria P.f./P.v. Antibody Test	S/P	GCMAL(pf/pv-Ab)-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCMAL(pf/pv-Ab)-402a√	Cassette	/	25 Tests/Kit
Monkeypox IgG/IgM Antibody Test	WB/S/P	GCMKP-402a New	Cassette	/	25 Tests/Kit
Monkeypox Antigen Test	Throat swab or vesicle / acne swab Tecus swab	GCMKP-502b√ New	Cassette	/	1/2/5/7/20 Tests/Kit
Mononucleosis Test	S/P	GCMON-325a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCMON-425a√	Cassette	/	25 Tests/Kit
M. pneumonia IgM Test	S/P	GCMP(IgM)-302a√	Cassette	/	25 Tests/Kit
Respiratory Syncytial Virus Antigen Test	Swab	GCRSV-552a√	Cassette	/	20 Tests/Kit
Rapid Check RSV Antigen Test	Swab	GCRSV-502Sat New	Cassette	/	20 Tests/Kit
Rotavirus Test	Feces	GCROA-602a√	Cassette	/	20 Tests/Kit
Rotavirus/Adenovirus Test	Feces	GCROAD&E-602a√	Cassette	/	20 Tests/Kit
Rubella IgG Test	S/P	GCRUB(IgG)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCRUB(IgG)-402a	Cassette	/	25 Tests/Kit
Rubella IgM Test	S/P	GCRUB(IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCRUB(IgM)-402a	Cassette	/	25 Tests/Kit
Rubella IgG/IgM Test	S/P	GCRUB(IgG/IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCRUB(IgG/IgM)-T402a	Cassette	/	25 Tests/Kit
Strep A Test	Throat Swab	GCSTR-501a√	Strip	/	25 Tests/Kit
		GCSTR-501Ca√	Strip	/	25 Tests/Kit
		GCSTR-502a√	Cassette	/	20 Tests/Kit
		GCSTR-502Ca√	Cassette	/	20 Tests/Kit
Syphilis Test	S/P	GCSYP-301a√	Strip	/	50 Tests/Kit
		GCSYP-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCSYP-401a√	Strip	/	50 Tests/Kit
		GCSYP-402a√	Cassette	/	25 Tests/Kit
S. typhi Antigen Test	S/P/Feces	GCSAL(ST)-602a√	Cassette	/	20 Tests/Kit
TOXO IgG Test	S/P	GCTOX(IgG)-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCTOX(IgG)-402a	Cassette	/	25 Tests/Kit
TOXO IgM Test	S/P	GCTOX(IgM)-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCTOX(IgM)-402a	Cassette	/	25 Tests/Kit
		GCTOX-302b	Cassette	/	25 Tests/Kit
Toxo IgG/IgM Test	S/P	GCTOX(IgG/IgM)-302a√	Cassette	/	20 Tests/Kit
	WB/S/P	GCTOX-402b	Cassette	/	25 Tests/Kit
ToRCH Toxo/Rubella/CMV/HSV IgG Combo Test	S/P	GCTOG-345a	Cassette	/	20 Tests/Kit
ToRCH Toxo/Rubella/CMV/HSV IgM Combo Test	S/P	GCTOM-345a	Cassette	/	20 Tests/Kit
Trichomonas vaginalis Test	Vaginal Swab	GCTV-502a√	Cassette	5 ng/mL	20 Tests/Kit
Tuberculosis IgG/IgM Test	S/P	GCTB-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCTB-402a√	Cassette	/	25 Tests/Kit
Typhoid IgG/IgM Test	S/P	GCTYP-301a	Strip	/	50 Tests/Kit
		GCTYP-302a√	Cassette	/	25 Tests/Kit
V. cholerae O1 Antigen Test	Feces	GCVCH(O1)-602a√	Cassette	/	20 Tests/Kit
V. cholerae O1/O139 Antigen Test	Feces	GCVCH(O1/O9)-602a√	Cassette	/	20 Tests/Kit
ZIKA IgM Test	WB/S/P	GCZK(IgM)-402a	Cassette	/	25 Tests/Kit
ZIKA IgG Test	WB/S/P	GCZIK(IgG)-402a	Cassette	/	25 Tests/Kit
ZIKA NS1 Test	WB/S/P	GCZIK(NS1)-402a	Cassette	/	25 Tests/Kit

Women's health & Fertility


Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
HCG Pregnancy Test	Urine	GAHCG-101a√	Strip	25 mIU/mL	100 Tests/Kit
		GAHCG-101b√	Strip	10 mIU/mL	100 Tests/Kit
		GAHCG-101c√	Strip	10 mIU/mL	100 Tests/Kit
		GAHCG-102a√	Cassette	25 mIU/mL	25 Tests/Kit
		GAHCG-102b√	Cassette	10 mIU/mL	25 Tests/Kit
		GAHCG-102c√	Cassette	20 mIU/mL	25 Tests/Kit
		GAHCG-103a√	Midstream	25 mIU/mL	1/2 Tests/Kit
		GAHCG-103b√	Midstream	10 mIU/mL	1/2 Tests/Kit
		GAHCG-103d√	Midstream	20 mIU/mL	1/2 Tests/Kit
		GAHCG-103c√	Midstream	10 mIU/mL	1/2 Tests/Kit
	Urine/Serum	GAHCG-105a	Panel	25 mIU/mL	25 Tests/Kit
		GAHCG-201a√	Strip	25 mIU/mL	100 Tests/Kit
		GAHCG-201b√	Strip	10 mIU/mL	100 Tests/Kit
		GAHCG-202a√	Cassette	25 mIU/mL	25 Tests/Kit
		GAHCG-202b√	Cassette	10 mIU/mL	25 Tests/Kit
Digital Pregnancy Test	Urine	GAHCG-D103a√	Midstream	25 mIU/mL	1/2 Tests/Unit
LH Ovulation Test	Urine	GALH-101a√	Strip	25 mIU/mL	100 Tests/Kit
		GALH-101b√	Strip	40 mIU/mL	100 Tests/Kit
		GALH-101d	Strip	30 mIU/mL	100 Tests/Kit
		GALH-102a√	Cassette	25 mIU/mL	25 Tests/Kit
		GALH-102b√	Cassette	40 mIU/mL	25 Tests/Kit
		GALH-103a√	Midstream	25 mIU/mL	1/5 Tests/Kit
		GALH-103b√	Midstream	40 mIU/mL	1/5 Tests/Kit
		GALH-103d	Midstream	30 mIU/mL	1/5 Tests/Unit
FSH Menopause Test	Urine	GAFSH-101a√	Strip	25 mIU/mL	100 Tests/Kit
		GAFSH-102a√	Cassette	25 mIU/mL	25 Tests/Kit
		GAFSH-103a√	Midstream	25 mIU/mL	1/5 Tests/Kit
IGFBP-1 PROM Test	Cervical Secretion	GAIGF-L-501a√	Strip	25 ng/mL	25 Tests/Kit
		GAIGF-L-502a√	Cassette	25 ng/mL	20 Tests/Kit
Male Fertility Test	Semen	GASPE-902a√	Cassette	/	1 Tests/Kit
Vaginal pH Test	Vaginal Secretion	VPH-501a√	Strip	3.8-4.4	25 Tests/Kit
		VPH-502a√	Cassette	3.8-4.4	20 Tests/Kit

Metabolism

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
Micro-Albumin Test	Urine	GHSA-101a√	Strip	20 ug/mL	100 Tests/Kit
		GHSA-102a√	Cassette	20 ug/mL	25 Tests/Kit

Cardiac Marker

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
CK-MB Test	S/P	GDCKM-302a√	Cassette	5 ng/mL	25 Tests/Kit
	WB/S/P	GDCKM-422a√	Cassette	5 ng/mL	25 Tests/Kit
CRP C-Reactive Protein Semi -Quantitative Test	WB/S/P	GDCRP-402a√	Cassette	1~3~10 mg/L	25 Tests/Kit
		GDCRP-T402a√	Cassette	10~40~80 mg/L	25 Tests/Kit
D-dimer Test	WB/P	GDDDI-402a√	Cassette	500 ng/mL	25 Tests/Kit
Myoglobin Test	WB/S/P	GDMYO-402a√	Cassette	50 ng/mL	25 Tests/Kit
Procalcitonin Test	WB/S/P	GDPCT-T402a√	Cassette	0.5~2~10 ng/mL	25 Tests/Kit
Troponin I Test	S/P	GDTRO-302a√	Cassette	0.5 ng/mL	25 Tests/Kit
	WB/S/P	GDTRO-402a√	Cassette	0.5 ng/mL	25 Tests/Kit
		GDTRO-402b√	Cassette	0.5 ng/mL	25 Tests/Kit
Cardiac Myoglobin/CK - MB/cTnI Combo Test	S/P	GDCAR-335a√	Cassette	50/5/0.5 ng/mL	25 Tests/Kit
	WB/S/P	GDCAR-435a√	Cassette	50/5/0.5 ng/mL	25 Tests/Kit
		GDCAR-W435a√	Cassette	50/5/0.5 ng/mL	20 Tests/Kit

Urinalysis

Product Description	Specimen	Format	Cut-off Value	Kit Size
Ascorbate-I†	Urine	Strip	0.3~0.6 mmol/L	100 Tests/Canister
Bilirubin-I†	Urine	Strip	3.3~8.6 μmol/L	100 Tests/Canister
Blood-I†	Urine	Strip	5~15 Ery/μL	100 Tests/Canister
Ca-I	Urine	Strip	2.5~5 mmol/L	100 Tests/Canister
Creatinine-I	Urine	Strip	25~75 mg/dL	100 Tests/Canister
Glucose-I†	Urine	Strip	2.8~5.5 mmol/L	100 Tests/Canister
Ketone-I†	Urine	Strip	0.5~1.0 mmol/L	100 Tests/Canister
Leukocytes-I†	Urine	Strip	5~15 cells/μL	100 Tests/Canister
Micro Albumin-I	Urine	Strip	0.08~0.15 g/L	100 Tests/Canister
Nitrite-I	Urine	Strip	13~22 μmol/L	100 Tests/Canister
pH-I†	Urine	Strip	0.5	100 Tests/Canister
Protein-I†	Urine	Strip	0.15~0.3 g/L	100 Tests/Canister
Specific Gravity-I†	Urine	Strip	0.005	100 Tests/Canister
Urobilinogen-I†	Urine	Strip	3.3~16 μmol/L	100 Tests/Canister
Urinary Tract Infection Test Strip†	Urine	Strip	LEU. 15 cells/μL NIT. 0.05 μmol/L	6/3/1 Tests/Kit

Instrument

Product Description	Model
Urine Analyzer	Healgen 500-I
Urine Analyzer	Healgen 501-I
Urine Analyzer	Healgen 800

Autoimmunity

Product Description	Specimen	Catalog No.	Format	Kit Size
Rheumatoid Factor IgM Test	S/P	GDRF(gM)-302a√	Cassette	25 Tests/Kit
Total IgE Test	S/P	GDGE-302a√	Cassette	25 Tests/Kit

Oncology

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
AFP Alpha Fetal Protein Test	S/P	GEAFP-301a	Strip	20 ng/mL	50 Tests/Kit
		GEAFP-302a	Cassette	20 ng/mL	25 Tests/Kit
	WB/S/P	GEAFP-S07a√	Strip	20 ng/mL	50 Tests/Kit
		GEAFP-402a√	Cassette	20 ng/mL	25 Tests/Kit
BTA Bladder Tumor Antigen Test	Urine	GEBTA-102a New	Cassette	/	25 Tests/Kit
CEA Carcinoembryonic Antigen Test	S/P	GECEA-301a	Strip	5 ng/mL	50 Tests/Kit
		GECEA-302a	Cassette	5 ng/mL	25 Tests/Kit
	WB/S/P	GECEA-S07a√	Strip	5 ng/mL	50 Tests/Kit
		GECEA-402a√	Cassette	5 ng/mL	25 Tests/Kit
FOB Fecal Occult Blood Test	Feces	GEFOB-601b√†	Strip	50 ng/mL	25 Tests/Kit
		GEFOB-S3b√	Strip	50 ng/mL	25 Tests/Kit
		GEFOB-601c√	Strip	100 ng/mL	25 Tests/Kit
		GEFOB-601d	Strip	200 ng/mL	25 Tests/Kit
		GEFOB-602b√†	Cassette	50 ng/mL	20 Tests/Kit
		GEFOB-602b2√	Cassette	50 ng/mL	20 Tests/Kit
		GEFOB-602c√	Cassette	100 ng/mL	20 Tests/Kit
		GEFOB-602d	Cassette	200 ng/mL	20 Tests/Kit
		GEFOB-602h	Cassette	150 ng/mL	20 Tests/Kit
		GEFOB-602i	Cassette	10 ng/mL	20 Tests/Kit
FOB /Transferrin Combo Test	Feces	GEFOBTF-602a New	Cassette	50/10 ng/mL	20 Tests/Kit
Nuclear Matrix Protein 22 Test	Urine	GENMP22-102a√	Cassette	10 U/mL	25 Tests/Kit
PSA Prostate SpecificAntigen Test	S/P	GEPSA-301a√	Strip	4 ng/mL	50 Tests/Kit
		GEPSA-302a√	Cassette	4 ng/mL	25 Tests/Kit
	WB/S/P	GEPSA-407a√	Strip	4 ng/mL	50 Tests/Kit
		GEPSA-402a√	Cassette	4 ng/mL	25 Tests/Kit
PSA Prostate Specific Antigen Semi-QuantitativeTest	S/P	GEPSA-302b	Cassette	4 ng/mL、10 ng/mL	25 Tests/Kit
	WB/S/P	GEPSA-402b	Cassette	4 ng/mL、10 ng/mL	25 Tests/Kit
Transferrin Test	Feces	GETF-601a√	Strip	10 ng/mL	25 Tests/Kit
		GETF-602a√	Cassette	10 ng/mL	20 Tests/Kit

Animal Health

Product Description	Specimen	Catalog No.	Format	Label	Cut-off Value	Kit Size
Canine Adenovirus (CAV) Antigen Test	Secretions	GFCAV-502a	Cassette	Gold	/	10 Tests/Kit
Canine Coronavirus (CCV) Antigen Test	Feces	GFCCV-602a	Cassette	Gold	/	10 Tests/Kit
		FFCCV-602a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Canine Coronavirus (CCV) & Parvovirus (CPV) Antigen Combo Test	Feces	GFCCP-T602a	Cassette	Gold	/	10 Tests/Kit
		FFCCP-T602a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Canine C-Reactive Protein (cCRP) Test	WB/S/P	FFCCR-402a	Cassette	Fluorescence	10 mg/L	10 Tests/Kit
Canine Distemper Virus (CDV) Antigen Test	Secretions	GFCDV-502a	Cassette	Gold	/	10 Tests/Kit
Canine Distemper Virus (CDV), Influenza Virus (CIV) & Adenovirus (CAV) Antigen Combo Test	Secretions	GFCDA-532a	Cassette	Gold	/	10 Tests/Kit
Canine Influenza Virus (CIV) Antigen Test	Secretions	GFCIV-502a	Cassette	Gold	/	10 Tests/Kit
Canine Parvovirus (CPV) Antigen Test	Feces	GFCPV-602a	Cassette	Gold	/	10 Tests/Kit
Canine Progesterone (cProg) Test	WB/S/P	FFCPR-402a	Cassette	Fluorescence	15 ng/mL	10 Tests/Kit
Feline Calicivirus (FCV) Antigen Test	Secretions	GFFCV-502a	Cassette	Gold	/	10 Tests/Kit
		FFFCV-502a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Feline Coronavirus (FCoV) Antigen Test	Feces	GFFCO-602a	Cassette	Gold	/	10 Tests/Kit
Feline Herpes Virus (FHV) Antigen Test	Secretions	GFFHV-502a	Cassette	Gold	/	10 Tests/Kit
		FFFHV-502a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Feline Parvovirus (FPV) Antigen Test	Feces	GFFPV-602a	Cassette	Gold	/	10 Tests/Kit
		FFFPV-602a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Feline Parvovirus (FPV) & Coronavirus (FCoV) Antigen Combo Test	Feces	GFFPC-622a	Cassette	Gold	/	10 Tests/Kit
Feline Serum Amyloid A (fSAA) Test	WB/S/P	FFFSA-402a	Cassette	Fluorescence	5 mg/L	10 Tests/Kit
Toxoplasma (Toxo) IgG/IgM Test	WB/S/P	GFTOX-402a	Cassette	Gold	/	10 Tests/Kit

Instrument

Product Description	Model
Veterinary Fluorescent Immunoassay Analyzer	OG-V200
Automatic Biochemistry Analyzer	Diag-V100

Fluorescence Immunoassay

Product Line	Product Description	Catalog No.	Specimen	Format	Cut-off Value	Kit Size	Registration
Metabolism	HbA1c Test	FHBA-402a	WB	Cassette	2-14%	10/25 Tests/Kit	CE
	25-OH-VD Test	FVD-402a	WB/S/P	Cassette	5.0~100.0ng/mL	10/25 Tests/Kit	CE
	T3 Test	FKT3-402a	WB/S/P	Cassette	0.61~9.22nmol/L	10/25 Tests/Kit	CE
	T4 Test	FKT4-402a	WB/S/P	Cassette	12.87~210nmol/L	10/25 Tests/Kit	CE
	TSH Test	FKTSH-402a	WB/S/P	Cassette	0.1~100mIU/L	10/25 Tests/Kit	CE
Toxicology	Amphetamine (AMP) Test	FBMP-1102a	Hair	Cassette	0.5 ng/mg	25 Tests/Kit	CE
		FBMP-1102b	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	/
	Benzodiazepines (BZO) Test	FBBZO-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	/
	Cocaine (COC) Test	FBCOC-1102a	Hair	Cassette	0.5 ng/mg	25 Tests/Kit	CE
		FBCOC-1102b	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	/
	Ecstasy (MDMA) Test	FBMDM-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	CE
	2-Fluorodeschloroketamin	FBKE-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	/
	(FAK) Test	FBKE-1102b	Hair	Cassette	3 ng/mg	25 Tests/Kit	/
	Ketamine (KET) Test	FBKET-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	CE
	Lysergic acid diethylamide (LSD) Test	FBLSD-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	/
	Marijuana (THC) Test	FBTHC-1102a	Hair	Cassette	0.05 ng/mg	25 Tests/Kit	CE
		FBTHC-1102b	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	CE
	Methamphetamine (MET) Test	FBMET-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	CE
		FBMET-1102b	Hair	Cassette	0.5 ng/mg	25 Tests/Kit	/
	Methcathinone (MTC) Test	FBMTC-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	CE
	6-Monoacetylmorphine (6-MAM) Test	FBMAM-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	CE
	Morphine (MOP) Test	FBMOP-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	CE
	Oxycodone (OXY) Test	FBOXY-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	CE
	Phencyclidine (PCP) Test	FBPCP-1102a	Hair	Cassette	0.3 ng/mg	25 Tests/Kit	CE
	Pinacainb (K1) Test	FBK1-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	CE
	Synthetic Marijuana (K2) Test	FBK2-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	CE
	Tramadol (TRA) Test	FBTRA-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	/
	Ub-144 Test	FBUB-1102a	Hair	Cassette	0.05 ng/mg	25 Tests/Kit	/
Respiratory	SARS-CoV-2 Ag Test	FCCOV-502a	Nasal Swab	Cassette	/	20 Tests/Kit	CE
	RSV Ag Test	FCRSV-502a	Nasal Swab	Cassette	/	20 Tests/Kit	/
	Influenza A&Ag Test	FCFLUA(B)-502a	Nasal Swab	Cassette	/	20 Tests/Kit	/
Oncology	PSA Quantitative Test	FDPSA-402a	WB/S/P	Cassette	4/10 ng/mL	10/25 Tests/Kit	CE
	Procalcitonin (PCT) Test	FDPCT-402a	WB/S/P	Cassette	0.1~50 ng/mL	25 Tests/Kit	CE
	C-Reactive Protein (CRP) Test	FDCRP-402a	WB/S/P	Cassette	0.5~200 mg/L	25 Tests/Kit	CE
	Serum Amyloid A Protein (SAA) Test	FDSAA-402a	WB/S/P	Cassette	0.5~200 mg/L	25 Tests/Kit	CE
	Interleukin-6 (IL-6) Test	FDIL6-402a	WB/S/P	Cassette	5~4000 pg/mL	25 Tests/Kit	CE
Cardiovascular & Inflammation	Troponin I/Myoglobin/CK-MB (cTnI/MYO/CK-MB) Combo Test	FDCAR-T402a	WB/S/P	Cassette	*cTnI: 0.1-50 ng/mL MYO: 30-600 ng/mL CK-MB: 2.5-80 ng/mL*	25 Tests/Kit	CE
	Troponin I and NT-proBNP (cTnI/NT-proBNP) Test	FDCTB-T402a	WB/S/P	Cassette	*cTnI: 0.1-50 ng/mL NT-proBNP:30-35000 pg/mL*	25 Tests/Kit	CE
	Troponin I (cTnI) Test	FDTRO-402a	WB/S/P	Cassette	0.1~50 ng/mL	25 Tests/Kit	CE
	hsTroponin I (cTnI) Test	FDTRO-407a	WB/S/P	Cassette	0.05~50 ng/mL	25 Tests/Kit	CE
	CK-MB Test	FDCKM-402a	WB/S/P	Cassette	2.5~80 ng/mL	25 Tests/Kit	CE
	Myoglobin (MYO) Test	FDMYO-402a	WB/S/P	Cassette	30~650 ng/mL	25 Tests/Kit	CE
	NT-proBNP Test	FDBNP-402a	WB/S/P	Cassette	30~35000 pg/mL	25 Tests/Kit	CE
	D-Dimer Test	FDDDI-402a	WB/S/P	Cassette	0.1~10 mg/L	25 Tests/Kit	CE
	β-hCG Test	FAHCG-402a	WB/S/P	Cassette	5~1,000 mIU/mL	25 Tests/Kit	CE
Women's health & Fertility	Follicle-Stimulating Hormone (FSH) Test	FAFSH-402a	WB/S/P	Cassette	5~100000 ng/mL	25 Tests/Kit	CE

Instrument

Product Description	Model
Mini Fluorescent Immunoassay Analyzer	OG-H100
Handheld Fluorescent Immunoassay Analyzer	OG-H180
Fluorescent Immunoassay Analyzer	OG-G200
Multiplex Fluorescent Immunoassay Analyzer	OG-G350
Handheld Fluorescent Immunoassay Analyzer	OG-G300

√CE Marked †Cleared for US 510(k) In Specimen column: WB: Whole Blood S: Serum P: Plasma

PRODUCT CATALOG

Enhancing Global Health

Zhejiang Orient Gene Biotech Co., Ltd was founded in December 2005 and listed on the SEE STAR Market on February 5, 2020 (securities code: 688298).
Orient Gene specializes in R&D, production and sales of in vitro diagnostic products, mainly covering infectious diseases (including COVID-19 test series), toxicology, tumor markers, cardiac markers and fertility testing, etc. Through 16 years of technology accumulation and continuous investment in R&D, the Company has independently developed hundreds of products. The company own more than 200 authorized patents, and has obtained more than 500 product medical device certifications at home and abroad. The Company's sales network covers more than 100 countries, products are mainly sold to Europe, America and other developed countries.

Healgen Scientific LLC, a wholly owned subsidiary of Zhejiang Orient Gene Biotech Co., Ltd develops, manufactures and commercializes in vitro diagnostic test systems worldwide. Our product portfolio spans multiple testing categories and analytes to meet various clinical and laboratory needs.

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Rev.01/2024

Hepatitis B Surface Antigen Rapid Test Cassette (Whole blood/Serum/Plasma)

INTENDED USE

The Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the qualitative detection of Hepatitis B surface antigen (HBsAg) in human whole blood, serum or plasma. It is intended to be used as a. screening test and as an aid in the diagnosis of infection with Hepatitis B virus (HBV). Any reactive specimen with the HBsAg Rapid Test Cassette must be confirmed with alternative testing method(s) and clinical findings.

INTRODUCTION

Viral hepatitis is a systemic disease primarily involving the liver. Most cases of acute viral hepatitis are caused by Hepatitis A virus, Hepatitis B virus (HBV) or Hepatitis C virus. The complex antigen found on the surface of HBV is called HBsAg. The presence of HBsAg in serum or plasma is an indication of an active Hepatitis B infection, either acute or chronic. In a typical Hepatitis B infection, HBsAg will be detected 2 to 4 weeks before the ALT level becomes abnormal and 3 to 5 weeks before symptoms or jaundice develop. HBsAg has four principal subtypes: adw, ayw, adr and ayr. Because of antigenic heterogeneity of the determinant, there are 10 major serotypes of Hepatitis B virus. The HBsAg Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of HBsAg in whole blood, serum or plasma specimens. The test utilizes a combination of double monoclonal antibodies to selectively detect elevated levels of HBsAg in whole blood, serum or plasma.

PRINCIPLE

The Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay based on the principle of the double antibody-sandwich technique. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the test. During testing, Hepatitis B Surface Antigen in the whole blood, serum or plasma specimen reacts with the particle coated with anti-HBsAg antibody. The mixture migrates upward on the membrane, chromatographically by capillary action to react with anti-HBsAg antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that the proper volume of specimen has been added and membrane wicking has occurred.

PRODUCT CONTENTS

The Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) containing anti-HBsAg antibodies particles and anti-HBsAg antibodies coated on the membrane.

MATERIALS SUPPLIED

Test cassette Dropper Buffer Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Lancets (for fingerstick whole blood only)
3. Centrifuge (for plasma only)
4. Timer
5. Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

1. For professional In Vitro diagnostic use only. Do not use after expiration date.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results.
8. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning.

SPECIMEN COLLECTION AND PREPARATION

1. Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
2. To collect Fingerstick Whole Blood specimens:

- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a new sterile lancet for each person. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the test cassette by using a capillary tube:
  - Touch the end of the capillary tube to the blood until filled to approximately 50µL. Avoid air bubbles.
  - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the specimen well (S) of the test cassette.
- Add the Fingerstick Whole Blood specimen to the test cassette by using hanging drops:
  - Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test cassette.
  - Allow 2 hanging drops of fingerstick whole blood to fall into the center of specimen well (S) on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen well (S). Avoid touching the finger directly to the specimen well (S).

3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
4. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
6. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE

Allow test cassette, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

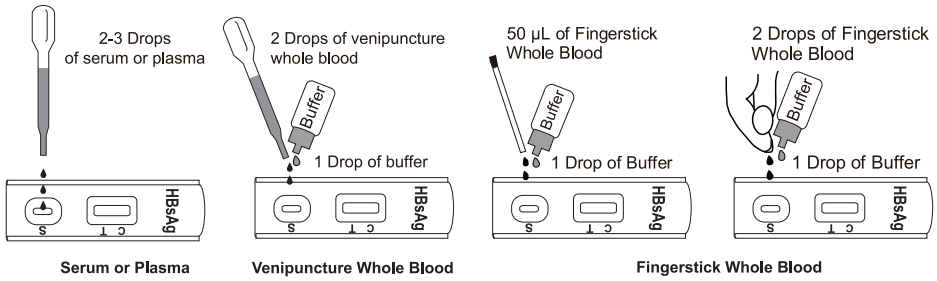
1. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean and level surface.

For Serum or Plasma Specimens: Hold the dropper vertically and transfer 2-3 drops of serum or plasma (approximately 60-90µL) to the specimen well (S) of the test cassette. See illustration below.

For Venipuncture Whole Blood Specimens: Hold the dropper vertically and transfer 2 drops of venipuncture whole blood (approximately 50µL) to the specimen well (S) of the test cassette, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

For Fingerstick Whole Blood Specimens: Allow 2 hanging drops of fingerstick whole blood (approximately 50 µL) to fall into the center of the specimen well (S) on the test cassette, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

3. Wait for the red line(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 15 minutes



INTERPRETATION OF RESULTS

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).
NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test Cassette. If the problem persists discontinue using the test kit immediately and contact your local distributor

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. Though the Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) is a reliable screening assay, it should not be used as a sole criterion for diagnosis of HBV infection.
2. The HBsAg Rapid Test Cassette is limited to the qualitative detection of HBsAg in human whole blood, serum or plasma. The intensity of the test band does not have linear correlation with HBsAg titer in the specimen.
3. A negative test result does not preclude the possibility of exposure to or infection with HBV. Infection through recent exposure (seroconversion) to HBV may not be detectable.
4. A negative result can occur if the quantity of HBsAg present in the specimen is below the detection limits of the assay (lower than1 ng/mL), or the HBsAg that are detected are not present during the stage of disease in which a sample is collected.
5. Interference due to heterophile antibodies, Rheumatoid Factors and other nonanalyte substances in patient's serum, capable of binding antibodies multivalently and providing erroneous analyte detection in immunoassays, has been reported in various studies. Both laboratory professionals and clinicians must be vigilant to this possibility of antibody interference. Results that appear to be internally inconsistent or incompatible with the clinical presentation should invoke suspicion of the presence of an endogenous artifact and lead to appropriate in vitro investigative action.
6. This kit is intended ONLY for testing of individual samples. Do not use it for testing of cadaver samples, saliva, urine or other body fluids, or pooled (mixed) blood.
7. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Sensitivity:

The Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested with a sensitivity panel ranging from 0 to 300 ng/mL. All 10 HBsAg subtypes produced positive results on the Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma). The test can detect 5ng/mL of HBsAg in 10 minutes, and 1 ng/mL of HBsAg in 15 minutes.

Specificity:

Antibodies used for the Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) were developed against whole Hepatitis B antigen isolated from Hepatitis B virus. Specificity of the Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) was also tested with laboratory strains of Hepatitis A and Hepatitis C. They all yielded negative results.

Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) **vs. EIA test**

Method		EIA		Total Results
Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	345	5	350
	Negative	2	980	982
Total Results		347	985	1332

Relative sensitivity: 99.4%
Relative specificity 99.5%
Accuracy: 99.5%

REFERENCE

1. Blumberg, B. S. The Discovery of Australian Antigen and its relation to viral hepatitis. Vitro. 1971; 7: 223

Effective Date: 2023-08-22
B20137-05

H. pylori Ab Rapid Test Cassette (Whole blood/Serum/Plasma)

CE

INTENDED USE

The H. pylori Ab Rapid Test Cassette (Whole blood/Serum/Plasma) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM, and IgA) anti- *Helicobacter pylori* （*H.pylori*）in human whole blood, serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with *H.pylori.* Any reactive specimen with the H.pylori Ab Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY

Helicobacter pylori is associated with a variety of gastrointestinal diseases included non-ulcer dyspepsia, duodenal and gastric ulcer and active, chronic gastritis[1,2]. The prevalence of H.pylori infection could exceed 90% in patients with signs and symptoms of gastrointestinal diseases. Recent studies indicate an association of H.pylori infection with stomach cancer[3].

H.pylori colonizing in the gastrointestinal system elicits specific antibody responses[4,5,6] which aids in the diagnosis of H.pylori infection and in monitoring the prognosis of the treatment of H.pylori related diseases. Antibiotics in combination with bismuth compounds have been shown to be effective in treating active H.pylori infection. Successful eradication of H.pylori is associated with clinical improvement in patients with gastrointestinal diseases providing a further evidence[7].

The H. pylori Ab Rapid Test Cassette (Whole blood/Serum/Plasma) is a latest generation of chromatographic immunoassay which utilizes recombinant antigens to detect the antibodies to H.pylori in human whole blood, serum or plasma. The test is user friendly, highly sensitive and specific.

PRINCIPLE

The H. pylori Ab Rapid Test Cassette (Whole blood/Serum/Plasma) is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The test cassette consists of: 1) a burgundy colored conjugate pad containing H.pylori antigens conjugated with colloidal gold (H.pylori conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated H.pylori antigens, and the C band is pre-coated with goat anti-rabbit IgG.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. The antibodies: either the IgG, the IgM, or the IgA, to H.pylori if present in the specimen will bind to the H.pylori conjugates. The immunocomplex is then captured on the membrane by the pre-coated H.pyloriantigens, forming a burgundy colored T band, indicating a H.pylori Ab positive test result. Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless the presence of any antibodies to H. pylori. Otherwise, the test result is invalid and the specimen must be retested with another device.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use beyond expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against micro-biological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Humidity and temperature can adversely affect test results.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

1.The H.pylori Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.

2.To collect Fingerstick Whole Blood specimens:

◦Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.

◦Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.

◦ Puncture the skin with a new sterile lancet for each person. Wipe away the first sign of blood.

◦ Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.

◦ Add the Fingerstick Whole Blood specimen to the test device by using a capillary tube:

・Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.

・ Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the specimen well (S) of the test device.

◦ Add the Fingerstick Whole Blood specimen to the test device by using hanging drops:

・Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.

・Allow 2 hanging drops of fingerstick whole blood to fall into the center of specimen well (S) on the test device, or move the patient's finger so that the hanging drop touches the center of the specimen well (S). Avoid touching the finger directly to the specimen well (S).

3.Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.

4.Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.

5.Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

6.If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS PROVIDED

25 sealed pouches each containing a test cassette, a dropper and a desiccant
1 Buffer, 4.0 mL
1 package insert

MATERIAL REQUIRED BUT NOT PROVIDED

1.Specimen collection containers 2.Lancets (for fingerstick whole blood only)
3.Centrifuge (for plasma only) 4.Timer
5.Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

DIRECTIONS FOR USE

Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1.Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

2. Place the test device on a clean and level surface.

For Serum or Plasma Specimens: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 30 µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

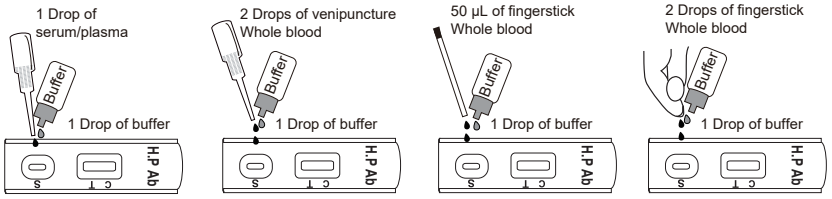
For Venipuncture Whole Blood Specimens: Hold the dropper vertically and transfer 2 drops of venipuncture whole blood (approximately 50µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

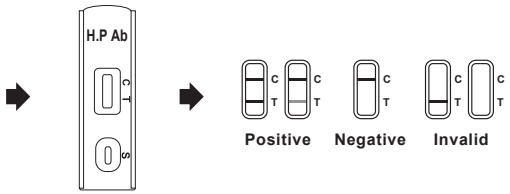
For Fingerstick Whole Blood Specimens: Allow 2 hanging drops of fingerstick whole blood (approximately 50 µL) to fall into the center of the specimen well (S) on the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

3. Wait for the red line(s) to appear. The result should be read in 15 minutes.

Note: Low levels of H.plori antibodies might result in a faint line appearing in the test region(T) after an extended period of time; therefore ,do not interpret the result after 15 minutes.

H. pylori Ab Rapid Test Cassette
(Whole Blood/Serum/Plasma)





INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE*: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

***NOTE:** *The intensity of the red color in the test line region (T) will vary depending on the concentration of H.p antibodies in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.*

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1.H. pylori Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of H.pylori antibodies in whole blood, serum or plasma specimen only.

2.H. pylori Ab Rapid Test Cassette (Whole blood/Serum/Plasma) will only indicate the presence of H.pylori antibodies in the specimen and should not be used as the sole criteria for the diagnosis of H.pylori infection.

3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of H.pylori infection.

PERFORMANCE CHARACTERISTICS

Clinical Performance

A study was performed with 175 patient specimen including both symptomatic gastrointestinal disorders and samples from non-symptomatic patients and 100 normal specimen. Comparison for all subjects with the H.pylori Ab Rapid Test Cassette (Whole Blood / Serum/Plasma) and reference ELISA kit is showed in the following table:

Method		H.pylori Ab Rapid Test		Total Results
ELISA	Results	Positive	Negative	
	Positive	170	5	175
	Negative	1	99	100
Total Results		171	104	275

Relative Sensitivity: 97.1%
Relative Specificity: 99.0%
Accuracy: 97.8%

REFERENCE

1. Marshall,B.J.et.al.1985. Med. J. Australia. 149:439-44,
2. Soll,A.H. 1990. New England J. Med.322:909-916.
3. Parsonnet,J.et.al.1991. New England J. Med. 325:1127-31.
4. Ansong,R. et.al.1991. J.Clin.Micro. 29:51-53,
5. Pronovost,A.P.et.al. 1994. J.Clin.Microbiol.32:46-50.
6. Megraud,F.et.al.1989. 27:1870-3,1989
7. Marshall,B.J.et.al. 1988. Lancet. Dec.1437-42

INDEX OF SYMBOLS

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

Zhejiang Orient Gene Biotech Co., Ltd.
Address: 3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com

EC REP Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany

REF GCHP-402a

Revision Date: 2024-04-09
B21762-02

Hepatitis B Core Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma)

A rapid, one step test for the qualitative detection of Hepatitis B Core Antibody (HBcAb) in whole blood, serum or plasma. It is for professional in vitro diagnostic use only.

INTENDED USE

The Hepatitis B Core Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid, one step test for the qualitative detection of Hepatitis B Core Antibody (HBcAb) in whole blood, serum or plasma.

SUMMARY

Chronic hepatitis B is a serious, debilitating illness that can cause cirrhosis of the liver, liver cancer and death. Chronic hepatitis B is the main cause of liver cancer and the tenth leading cause of death worldwide, with 400,000,000 people infected with the virus. Every year, one million people worldwide are expected to die from this infection.

Most people fight off the infection themselves, but approximately 5-10 percent of those infected with the virus become carriers, and an additional 5-10 percent of those infected each year will progress to chronic liver disease, cirrhosis and possibly liver cancer.

The Hepatitis B Core Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of HBcAb in whole blood, serum or plasma without the use of an instrument.

PRINCIPLE

Hepatitis B Core Antibody (HBcAb) is also known as anti-Hepatitis B Core Antigen (anti-HBc). These tests are immunoassays based on the principle of competitive binding.

During testing, the mixture migrates upward on the membrane chromatographically by capillary action. The membrane is pre-coated with HBcAg on the test line region of the strip. During testing, anti-HBc antibody, if present in the specimen, will compete with particle coated anti-HBc antibody for limited amount of HBcAg on the membrane, and no line will form in the test line region, indicating a positive result. A visible colored line will form in the test line region if there is no anti-HBc antibody in the specimen because all the antibody coated particles will be captured by the antigen coated in the test line region. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS SUPPLIED

1. Test cassette 2. Dropper 3. Buffer 4. Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Specimen collection container 2. Centrifuge (for plasma only) 3. Timer

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30℃). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Humidity and temperature can adversely affect results.

SPECIMEN COLLECTION AND PREPARATION

1. The Hepatitis B Core Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum or plasma.
2. To collect venipuncture whole blood specimens: Collect anti-coagulated blood sample (EDTA-K2, heparin, and sodium citrate) following standard laboratory procedures.
3. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, no hemolyzed specimens can be used.
4. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
6. If specimens are to be shipped, they should be packed in compliance with local regulations for the transportation of etiologic agents.

TEST PROCEDURE

Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean and level surface.

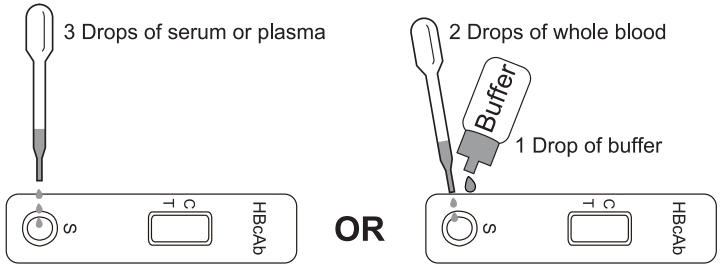
   For Serum or Plasma:

   Hold the dropper vertically and transfer 3 full drops of serum or plasma (approx. 75 µL) to each specimen well (S) of the test cassette respectively, avoid trapping air bubbles in the specimen well (S). See illustration below.

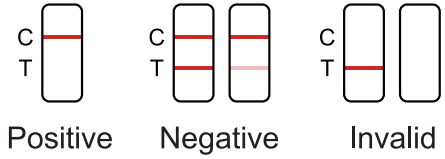
   For Venipuncture Whole Blood specimens:

   Hold the dropper vertically and transfer 2 drops of whole blood (approx. 50 µL) to the specimen well (S) of the test cassette, then add 1 drop of buffer (approximately 40 µL) and starts the time. See illustration below.

3. Wait for the red line(s) to appear. The results should be read at 15 minutes. Do not interpret the results after 20 minutes.



INTERPRETATION OF RESULTS



POSITIVE: One red line appears in the control line region (C), No apparent red or pink line appears in the test region (T).
NEGATIVE: Two red lines appear. One line should be in the control line region (C) and another line should be in the test line region (T).
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.
Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The Hepatitis B Core Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of HBcAb in whole blood, serum or plasma specimen.
   Neither the quantitative value nor the rate of increase in the concentration of HBcAb can be determined by this qualitative test.
2. The Hepatitis B Core Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of HBcAb in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Hepatitis B Virus infection.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The Hepatitis B Core Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) was compared with leading commercial EIA HBcAb test, the results show that the Hepatitis B Core Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) has a high sensitivity and specificity.

Method		ELISA		Total Results
Hepatitis B Core Antibody Rapid Test Cassette	Results	Positive	Negative	
	Positive	443	4	447
	Negative	17	120	137
Total Results		460	124	584

Relative Sensitivity: 96.3%
Relative Specificity: 96.8%
Accuracy: 96.4%

REFERENCE

1. Chizzali-Bonfadin C., Addlassnig K.P., Kreihsl M., Hatvan A., Horak W., Knowledge-based interpretation of serologic tests for hepatitis on the World Wide Web. Clin Perform Qual Health Care 1997 Apr-Jun 5: 61-3**.**
2. ter Bog F., ten Kate F.J., Cuypers H.T., Leentvaar-KuipersA., Oosting J., Wertheim-van Dillen P.M., Honkoop P, Rasch M.C., de Man R.A., vab Hattum J., Chamelueau R.A., Reesink H.W., Jones E.A., Relation between laboratory results and histological hepatitis activity in individuals positive for hepatitis B surface antigen and antibodies to hepatitis B e antigen, Lancet 1998 June 351: 1914-8ng Infect Dis. 1997; 3: 213±221. https://doi.org/10.3201/eid0302.970219 PMID: 9204307**.**

Effective Date: 2024-12-14
B22893-02

HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette)

CE 0123

REF GCHCV-402a

INTENDED USE

The HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM, and IgA) to Hepatitis C virus (HCV) in human whole blood, serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with HCV. Any reactive specimen with the HCV Hepatitis C Virus Rapid Test Cassette must be confirmed with alternative testing method(s) and clinical findings.

INTRODUCTION

Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA virus. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis. Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens (1, 2). Compared to the first generation HCV EIAs using single recombinant antigen, multiple antigens using recombinant protein and/or synthetic peptides have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests (3, 4). HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) is a rapid test to qualitatively detect the presence of antibody to HCV in a whole blood, serum or plasma specimen. The test utilizes a combination of recombinant antigen to selectively detect elevated levels of HCV antibodies in whole blood, serum or plasma.

PRINCIPLE

The HCV Hepatitis C Virus Rapid Test Cassette is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The test Cassette consists of: 1) a burgundy colored conjugate pad containing HCV antigens conjugated with colloidal gold (HCV Ag conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane Cassette containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated HCV antigens, and the C band is pre-coated with goat anti-rabbit IgG. When an adequate volume of test specimen is dispensed into the sample well of the Cassette, the specimen migrates by capillary action across the Cassette. The antibodies: either the IgG, the IgM, or the IgA, to HCV if present in the specimen will bind to the HCV Ag conjugates. The immunocomplex is then captured on the membrane by the precoated HCV antigens, forming a burgundy colored T band, indicating a HCV Ab positive test result. Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-rabbit IgG and rabbit IgG-gold conjugate regardless the presence of any antibodies to HCV. Otherwise, the test result is invalid and the specimen must be retested with another Cassette.

PRODUCT CONTENTS

HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) containing HCV antigen (HCV antigen includes core, NS3, NS4 and NS5 segment) coated particles and HCV antigen (HCV recombinant antigen includes core, NS3, NS4 and NS5 segment) coated on the membrane.

MATERIALS SUPPLIED

1. 25 sealed pouches each containing a test cassette, a pipette dropper and a desiccant
(Test Cassette T band is pre-coated with non-conjugated HCV antigens, and the C band is pre-coated with goat anti-rabbit IgG on the nitrocellulose and coupled to colloidal gold on label pad)
2. 1 Package insert

3. 1 Buffer (4 mL) (Casein-salt: 1%, NaCl: 0.9%, Na_2HPO_4: 0.286%, NaN_3: 0.5%)	Warning	Warning: 0.5% NaN_3 Harmful if swallowed; Harmful to aquatic life with long lasting effects Prevention Wash face, hands and any exposed skin thoroughly after handling Wear protective gloves/protective clothing/eye protection/face protection Do not breathe dust/fume/gas/mist/vapors/spray Do not eat, drink or smoke when using this product Avoid release to the environment. Response IF SWALLOWED: rinse mouth. Do NOT induce vomiting. Get medical attention/advice if you feel unwell

MATERIAL REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Sterile lancets (for fingerstick whole blood only)
3. Centrifuge (for plasma only)
4. Timer
5. Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test Cassette is stable through the expiration date printed on the sealed pouch. The test Cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

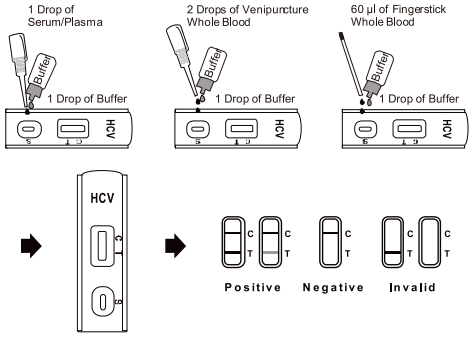
1. For professional *in vitro* diagnostic use only. Do not use after expiration date.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results.
8. Do not perform the test in a room with strong air flow, ie. an electric fan or strong airconditioning.

SPECIMEN COLLECTION

1. The HCV Hepatitis C Virus Rapid Test (Whole Blood/Serum/Plasma) (Cassette) can be performed using whole blood (from venipuncture and fingerstick), serum or plasma.
2. For venipuncture whole blood and plasma: K_2EDTA, Sodium Heparin, Sodium citrate Sterile, and Lithium heparin should be used as the anticoagulant. Other anticoagulants have not been tested and may give incorrect results.
3. To collect Fingerstick Whole Blood specimens:
 • Wash the patient's hand with soap and warm water or clean with an alcohol wipe . Allow to dry.
 • Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
 • Puncture the skin with a new sterile lancet for each person. Wipe away the first sign of blood.
 • Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
 • Add the Fingerstick Whole Blood specimen to the test device by using a capillary tube:
 • Touch the end of the capillary tube to the blood until filled to approximately 60 µL. Avoid air bubbles.
 • Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the specimen well (S) of the test device.
 • Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, nonhemolyzed specimens.
4. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days and may be stored at -20°C for 6 months. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
6. If specimens are to be shipped, they should be packed in compliance with usual regulations for transportation of etiological agents.

TEST PROCEDURE

Allow test cassette, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
1. Remove the test Cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test Cassette on a clean and level surface.
For Serum or Plasma Specimens: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 30 µL) to the specimen well (S) of the test Cassette, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
For Venipuncture Whole Blood Specimens: Hold the dropper vertically and transfer 2 drops of venipuncture whole blood (approximately 60 µL) to the specimen well (S) of the test Cassette, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
For Fingerstick Whole Blood specimens: To use a capillary tube: Fill the capillary tube and transfer approximately 60 µL of fingerstick whole blood specimen to the specimen well (S) of the test device, then add 1 drops of buffer (approximately 40 µL) and start the timer. See illustration below.
3. Wait for the red line(s) to appear. The result should be read at 15 minutes. Do not interpret the result after 30 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)
Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
Negative: One colored line appears in the control line region (C). No line appears in the test line region (T).
Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test Cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS

1. The HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) is for *in vitro* diagnostic use only. This test should be used for the detection of antibodies to HCV in whole blood, serum or plasma specimen.
2. The HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) will only indicate the presence of antibodies to HCV in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis C viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of Hepatitis C Virus infection.
5. A negative result can occur if the quantity of the antibodies to HCV present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
7. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
8. Results should not be used to determine the genotype of HCV infections.
9. Due to possible cross reactivity, the appearance of lines in T line does not necessarily indicate co-infection from IgG, IgM or IgA, nor can it identify the serotype.
10. The recommended anticoagulants are K_2EDTA, Sodium Heparin, Sodium citrate Sterile and Lithium heparin for venous whole blood. Other anticoagulants have not been evaluated with this test.

PERFORMANCE CHARACTERISTICS

Relative Sensitivity

A total of 506 HCV positive specimens were tested using the HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) and a commercially available test (Table 1). The relative sensitivity of the test is >99.9% (95% confidence interval: 99.27% – 100%).
Table 1: Sensitivity of HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette)

Population	Specimen Type	Number of Specimens Tested	Positive by HCV Hepatitis C Virus Rapid Test	Positive by Commercially Available Test
Anti-HCV (any genotype)	plasma	329	329/329 (100%)	329/329 (100%)
Anti-HCV (any genotype)	Serum	26	26/26 (100%)	26/26 (100%)
Anti-HCV (genotype 1, 2, 3, 4 (non-subtype A), 4, 5, 6)	Serum/Plasma	151	151/151 (100%)	151/151 (100%)
Total		506	506/506 (100%)	506/506 (100%)

30 Serocoversion panels have been done and details of the 30 seroconversion are in the table below.

No.	Panel	Specimens No.	Results
1	PHV907	7	Positive from 0 days since first bleed
2	PHV908	13	Positive from 3 days since first bleed
3	PHV206(M)	25	/
4	PHV911(M)	5	Positive from 3 days since first bleed
5	PHV919	7	Positive from 28 days since first bleed
6	PHV920	10, No. 2 can't be got because ofout of stock from the vendor	Positive from 16 days since first bleed
7	HCV9047	10	Positive from 28 days since first bleed
8	HCV9046	5	Positive from 69 days since first bleed
9	HCV6229	8	Positive from 17 days since first bleed
10	HCV10041	3	Positive from 6 days since first bleed
11	HCV9041	8	Positive from 62 days since first bleed
12	HCV9045	8	Positive from 37 days since first bleed
13	HCV6222	3	Positive from 40 days since first bleed
14	HCV6224	8	Positive from 19 days since first bleed
15	HCV6227	7	Positive from 75 days since first bleed
16	HCV6228	12	Positive from 31 days since first bleed
17	HCV10071	7	Positive from 84 days since first bleed
18	HCV6220	6	Positive from 18 days since first bleed
19	HCV10185	5	Positive from 130 days since first bleed
20	HCV10235	5	Positive from 96 days since first bleed
21	HCV6215	4	Positive from 20 days since first bleed
22	HCV9042	6	Positive from 8 days since first bleed
23	HCV9058	5	Positive from 10 days since first bleed
24	HCV9094	5	Positive from 9 days since first bleed
25	HCV9095	5	Positive from 10 days since first bleed
26	HCV9055	11	Positive from 65 days since first bleed
27	HCV9054	10	Positive from 72 days since first bleed
28	HCV9044	6	Positive from 21 days since first bleed
29	HCV10165	9	Positive from 19 days since first bleed
30	HCV6226	12	Positive from 39 days since first bleed

Relative Specificity

A total of HCV 1259 negative specimens were tested using the HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) and a commercially available test (Table 2). The relative specificity of the test is ＞99.9% (95% confidence interval: 99.71% – 100%).
Table 2: Specificity of the HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette)

Population	Specimens Tested	Number of Specimens Tested	Negative by HCV Hepatitis C Virus Rapid Test	Negative by Commercially Available Test
Clinical Negative	Serum/plasma	202	202/202 (100%)	202/202 (100%)
Potentially cross-reacting	Serum/Plasma	30	30/30 (100%)	30/30 (100%)
Unselected Donors	Serum	1000	1000/1000 (100%)	1000/1000 (100%)
Inhibition Panel	Serum	27	27/27 (100%)	27/27 (100%)
Total		1259	1259/1259 (100%)	1259/1259 (100%)

Whole Blood vs. Serum vs. Plasma

Total 25 clinical negative samples (whole blood, serum, plasma) have been collected from patients in local hospital. The whole blood collected and separated into three tubes. One was stored as whole blood. One was collected into tube for plasma, one was collected into tube for serum (Table 3). There is a very good correlation of results between whole blood, serum, and plasma with HCV negative samples.
Table 3: A Comparison of HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) Specificity in negative Whole Blood and Paired Serum and Plasma Specimens

Specimen Type	Number of Specimens Tested	Negative by HCV Ab
Serum	25	25/25 (100%)
Plasma	25	25/25 (100%)
Whole blood	25	25/25 (100%)

A total of 25 positive specimens (whole blood, serum, plasma) were tested using the HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) (Table 4). There is a very good correlation of results between whole blood and paired plasma with HCV positive samples.

Table 4: A Comparison of HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) Specificity in positive Whole Blood and Paired Serum and Plasma Specimens.

Specimen Type	Number of Specimens Tested	Positive by HCV Ab
Serum	25	25/25 (100%)
Plasma	25	25/25 (100%)
Whole blood	25	25/25 (100%)

Precision

Intra Assay

Within-run precision has been determined by using 20 replicates of four specimens: a negative, a low positive, medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 5 independent assays on the same four specimens: a negative, a low positive, medium positive and a high positive. Three different lots of the HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) have been tested using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross Reactivity

No cross-reactivity was observed when samples positive for other diseases such as HIV, Syphilis, Infectious Mononucleosis, HBV, Rheumatoid Factor, HAMA, Hyper IgG, Hyper IgM, anti-HAV, anti-HSV2, anti-HEV, anti- EBV and anti-CMV were tested.

Interfering Substances

No interference was observed in samples with high concentrations of Uric acid,Ascorbic Acid, Hemoglobin, Gentistic Acid, Acetaminnophen, Oxalic Acid, Albumin, Caffein, Bilirubin, EDTA, Aspirin and Methanol.

Analytes	Conc	Analytes	Conc
Control	0	Control	0
Uric acid	0.15 mg/mL	Albumin	20 mg/mL
Ascorbic Acid	0.2 mg/mL	Caffein	0.2 mg/mL
Hemoglobin	5.0 mg/mL	Bilirubin	0.3 mg/mL
Gentistic Acid	0.2 mg/mL	EDTA	0.2 mg/mL
Acetaminnophen	1.0 mg/mL	Aspirin	0.2 mg/mL
Oxalic Acid	0.2 mg/mL	Methanol	1.0%

REFERENCE

1. Choo, Q.L., G.Kuo, A.J. Weiner, L.R. Overby, D.W. Bradley, and M. Houghton. Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome. Science 189; 244: 359
2. Kuo, G., Q.L. Choo, H.J. Alter, and M. Houghton. An assay for circulating antibodies to a major etiolog Virus of human non-A, non-B hepatitis. Science 1989; 244: 362
3. Van der Poel, C.L., H.T.M. Cuypers, H.W. Reesink, and P.N. Lelie. Confirmation of hepatitis C Virus infection by new four-antigen recombinant immunoblot assay. Lancet 1991; 337: 317
4. Wilber, J.C. Development and use of laboratory tests for hepatitis Cinfection: a review. J. Clin. Immunoassy 1993; 16: 204

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Manufacturer		Warning		

Healgen Scientific Limited Liability Company
Address: 3818 Fuqua Street, Houston, TX 77047, USA.
Tel: +1 713-733-8088 Fax: +1 713-733-8848
Website: www.healgen.com

EC REP QARAD b.v.b.a.
Cipalstraat 3, B-2440 Geel, Belgium

B21304-05
Revision Date: 2022-11-10