



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

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 exclusive authorized representative for Orient Gene Brand product in correspondence with the conditions of directive 98/79/EEC in Moldova only. The detailed product list is in the Annex 1 in the following pages.

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.10th,2025to Mar.09th, 2027.

Zhejiang Orient Gene Biotech Co., Ltd

General Manager

Date:2025/3/10



地址：浙江省湖州市安吉县递铺镇阳光大道东段 3787 号
Add: 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China
电话 Tel:+86-572-5226111 传真 Fax: +86-572-5226222 邮编 P.C.:313300



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

Annex 1

Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul
GCCOV-702a-H1	TEST RAPID	Orient Gene	Rapid COVID-19 Antigen Oral Fluid Self-Test
GCCOV-702a-H5	TEST RAPID	Orient Gene	Rapid COVID-19 Antigen Oral Fluid Self-Test
GCCOV-702a-H20	TEST RAPID	Orient Gene	Rapid COVID-19 Antigen Oral Fluid Self-Test
GCCOV-502a-H1OGE	TEST RAPID	Orient Gene	Rapid COVID-19 (Antigen) Self-test
GCCOV-502a-H5OGE	TEST RAPID	Orient Gene	Rapid COVID-19 (Antigen) Self-test
GCCOV-502a-H20OGE	TEST RAPID	Orient Gene	Rapid COVID-19 (Antigen) Self-test

GIHSA-102a	TEST RAPID	Orient Gene	One Step Microalbumin Test Cassette
GIHSA-101a	TEST RAPID	Orient Gene	One Step Microalbumin Test Strip (Urine)
GCROA-602a	TEST RAPID	Orient Gene	Rotavirus rapid test cassette (feces)
GCMAL(pf/pv)-402a	TEST RAPID	Orient Gene	Malaria P.f./P.v. Ag Rapid Test Cassette (Whole Blood)
GCROA/ADE-602a	TEST RAPID	Orient Gene	Rotavirus and Adenovirus Combo Rapid Test Cassette (Feces)
GASPE-902a	TEST RAPID	Orient Gene	Male Fertility Rapid Test Cassette (Semen)
GAFSH-101a	TEST RAPID	Orient Gene	One Step Menopause Test Strip (Urine)
GAFSH-102a	TEST RAPID	Orient Gene	One Step Menopause Test Cassette (Urine)
GAIGF1-502a	TEST RAPID	Orient Gene	iGFBP-1 Rapid test Cassette (Swab)

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GAIGF1-501a	TEST RAPID	Orient Gene	iGFBP-1 Rapid Test Strip (Cervical Secretion)
GALH-101a	TEST RAPID	Orient Gene	One Step Ovulation Test Strip (Urine) (25mlU)
GALH-101b	TEST RAPID	Orient Gene	One Step Ovulation Test Strip (Urine) (40mlU)
GALH-102a	TEST RAPID	Orient Gene	One Step Ovulation Test Cassette (Urine) (25mlU)
GALH-102b	TEST RAPID	Orient Gene	One Step Ovulation Test Cassette (Urine) (40mlU)
GCTYP-302a	TEST RAPID	Orient Gene	Typhoid IgG/IgM Rapid Test Cassette (serum/plasma)
GCMAL(pf/pan)-402a	TEST RAPID	Orient Gene	Malaria P.f./Pan Ag Rapid Test Cassette (Whole Blood)
GCDEN-425a	TEST RAPID	Orient Gene	Dengue NS1+IgM/IgG Combo Rapid Test Cassette (Whole blood/serum/plasma)
GCDEN(NS)-402c	TEST RAPID	Orient Gene	Dengue NS1 Antigen Rapid Test Cassette (Whole blood/serum/plasma)
GCDEN(ab)-402c	TEST RAPID	Orient Gene	Dengue IgM/IgG Rapid Test Cassette (Whole blood/serum/plasma)
GCVCH(O1/O9)-602a	TEST RAPID	Orient Gene	V.cholerae O1/O139 Ag Combo Rapid Test Cassette (Feces)
GCMAL(pf)-402a	TEST RAPID	Orient Gene	Malaria Pf Ag Rapid Test Cassette (Whole blood)
GCSAL(ST)-602a	TEST RAPID	Orient Gene	S. typhi Ag Rapid Test Cassette (Serum/plasma/Feces)
GCCHK(IgM)-402a	TEST RAPID	Orient Gene	Chikungunya IgM Rapid Test Cassette (Whole blood/Serum/Plasma)
GCCOV-502a-NN	TEST RAPID	Orient Gene	Coronavirus Ag Rapid Test Cassette (Swab)
GCCOV (Nab)-402b	TEST RAPID	Orient Gene	SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette (Whole blood/Serum/Plasma)
GCCOV-502a-NA	TEST RAPID	Orient Gene	Coronavirus Ag Rapid Tests Cassette (Swab)

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GCCOV (Ag)-PN10	TEST RAPID	Orient Gene	COVID-19 Antigen Control Kit
GCCOV (Ag)-PN20	TEST RAPID	Orient Gene	COVID-19 Antigen Control Kit
GCF CRA-545a	TEST RAPID	Orient Gene	Flu, COVID-19,RSV&Adeno Ag Combo Tests Cassette (Swab)
GCTV-502a	TEST RAPID	Orient Gene	Trichomonas Ag Rapid Test Cassette (Swab)
GCVCH(O1)-602a	TEST RAPID	Orient Gene	V.cholerae O1 Ag Rapid Test Cassette (Feces)
GCCHA-402a	TEST RAPID	Orient Gene	Chagas Ab Rapid Test Cassette (Whole blood/serum/plasma)
GCMAL(pf/pv Ab)-302a	TEST RAPID	Orient Gene	Malaria Pf/Pv Ab Rapid Test Cassette (Serum/plasma)
GCMAL(pf/pv Ab)-402a	TEST RAPID	Orient Gene	Malaria Pf/Pv Ab Rapid Test Cassette (Whole blood/Serum/plasma)
GCMKP-502b	TEST RAPID	Orient Gene	Monkeypox Ag Rapid Test Cassette (Swab)
GCCOV(Del)-T502a	TEST RAPID	Orient Gene	SARS-CoV-2 Delta-series Mutant Strain Ag Rapid Test cassette (Swab)
GCCOV-PN10	TEST RAPID	Orient Gene	COVID-19 IgG/IgM Control kit
GCCOV-PN20	TEST RAPID	Orient Gene	COVID-19 IgG/IgM Control kit
GCF CR-T525a	TEST RAPID	Orient Gene	COVID-19/Flu A&B/ RSV Ag Combo Rapid Test Cassette (Swab)
GCCOV(B117)-525a	TEST RAPID	Orient Gene	COVID-19 Ag&B.1.1.7 Mutant Strain Combo Test Cassette (Swab)
GCF CRA-T525a	TEST RAPID	Orient Gene	COVID-19/Flu A&B/ RSV/Adeno Ag Combo Rapid Test Cassette (Swab)
GCCOV-702a	TEST RAPID	Orient Gene	COVID-19 Ag Rapid Test Cassette (Oral fluid)
GCF C-T502a	TEST RAPID	Orient Gene	COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab)

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GCMKP-402a	TEST RAPID	Orient Gene	Monkeypox IgG/IgM Rapid Test Cassette (Whole blood/serum/plasma)
GCKa1-401a	TEST RAPID	Orient Gene	Leishmania Ab Rapid Test strip (Whole blood/serum/plasma)
GCKa1-T402a	TEST RAPID	Orient Gene	Leishmania IgG/IgM Rapid test cassette (whole blood/serum/plasma)
GCCOV-503a	TEST RAPID	Orient Gene	Smart Rapid COVID-19 Ag Test Device
GCBRU-402a	TEST RAPID	Orient Gene	Brucella Antibody Rapid Test Cassette (Whole blood/serum/plasma)
GCCHA-302a	TEST RAPID	Orient Gene	Chagas Ab Rapid Test Cassette (Serum/plasma)
GCCHK(IgM)-302a	TEST RAPID	Orient Gene	Chikungunya IgM Rapid Test Cassette (Serum/Plasma)
GCCOV-501a	TEST RAPID	Orient Gene	Rapid COVID-19 Antigen Test Strip
GCMON-352a	TEST RAPID	Orient Gene	Mononucleosis IgG/IgM Rapid Test Cassette (Serum/plasma)
GCMON-402a	TEST RAPID	Orient Gene	Mononucleosis Rapid Test Cassette (Whole blood/Serum/plasma)
GCMON-425a	TEST RAPID	Orient Gene	Mononucleosis IgG/IgM Rapid Test Cassette (Whole blood/Serum/plasma)
GCEV71 (IgM)-302a	TEST RAPID	Orient Gene	EV71 IgM Rapid Test Cassette (Serum/plasma)
GCEV71 (IgM)-402a	TEST RAPID	Orient Gene	EV71 IgM Rapid Test Cassette (Whole blood/Serum/plasma)
GENMP22-102a	TEST RAPID	Orient Gene	One Step Nuclear Matrix Protein 22 Test Cassette (Urine)
GEFOB/TF-602a	TEST RAPID	Orient Gene	Fecal Occult Blood and Transferrin Combo Rapid Test Cassette (Feces)
GCHEV-302a	TEST RAPID	Orient Gene	HEV IgM Rapid Test Cassette (Serum/Plasma)
GCMP (IgM)-302a	TEST RAPID	Orient Gene	M.pneumonia IgM Rapid Test Cassette (Serum/plasma)

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FCCOV-502a	TEST RAPID	Orient Gene	SARS-CoV-2 Ag Fluorescence Rapid Test Cassette (Swab)
GCCOV-402Ba	TEST RAPID	Orient Gene	COVID-19 IgG/IgM Rapid test cassette (whole blood/serum/plasma)
GCCOV-402a	TEST RAPID	Orient Gene	COVID-19 IgG/IgM Rapid test cassette (whole blood/serum/plasma)
GCCOV-502a	TEST RAPID	Orient Gene	Coronavirus Ag Rapid Test Cassette (Swab)
GCFC-T503a	TEST RAPID	Orient Gene	Smart Rapid COVID-19 &Flu A/B Ag Test Device
GAHCG-101a	TEST RAPID	Orient Gene	One step pregnancy test strip (urine)
GAHCG-101d	TEST RAPID	Orient Gene	One step pregnancy test strip (urine)
GAHCG-101b	TEST RAPID	Orient Gene	One step pregnancy test strip (urine)
GAHCG-102a	TEST RAPID	Orient Gene	One step pregnancy test cassette (urine)
GAHCG-102d	TEST RAPID	Orient Gene	One step pregnancy test cassette (urine)
GAHCG-102b	TEST RAPID	Orient Gene	One step pregnancy test cassette (urine)

GEFOB-602c	TEST RAPID	Orient Gene	Fecal Occult Blood Rapid Test Cassette (Feces)
GEFOB-602b	TEST RAPID	Orient Gene	Fecal Occult Blood Rapid Test Cassette (Feces)
GEFOB-601c	TEST RAPID	Orient Gene	Fecal Occult Blood Rapid Test Strip (Feces)
GEFOB-601b	TEST RAPID	Orient Gene	Fecal Occult Blood Rapid Test Strip (Feces)
GECEA-402a	TEST RAPID	Orient Gene	Carcinoembryonic Antigen Rapid Test Cassette (Whole blood/serum/plasma)

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GECEA-401a	TEST RAPID	Orient Gene	Carcinoembryonic Antigen Rapid Test Strip (Whole blood/serum/plasma)
GETF-602a	TEST RAPID	Orient Gene	Transferrin Rapid Test Cassette (Feces)
GETF-601a	TEST RAPID	Orient Gene	Transferrin Rapid Test Strip (Feces)
GEAFP-401a	TEST RAPID	Orient Gene	Alpha-Fetoprotein Rapid Test Strip (Whole blood/serum/plasma)
GEAFP-402a	TEST RAPID	Orient Gene	Alpha-Fetoprotein Rapid Test Cassette (Whole blood/serum/plasma)
GIHSA-101a	TEST RAPID	Orient Gene	One step microalbumin test strip (urine)
GIHSA-102a	TEST RAPID	Orient Gene	One step microalbumin test cassette (urine)
GDCAR-335a	TEST RAPID	Orient Gene	Myoglobin/CK-MB/Troponin I Combo Test Cassette (Serum/plasma)
GDCKM-302a	TEST RAPID	Orient Gene	One step CK-MB Test Cassette (Serum/Plasma)
GDCKM-402a	TEST RAPID	Orient Gene	CK-MB Rapid Test Cassette (Whole blood/serum/plasma)
GDCRP-402a	TEST RAPID	Orient Gene	C-Reactive Protein Semi-Quantitative Rapid Test Cassette (Whole Blood/serum/plasma)
GDTRO-302a	TEST RAPID	Orient Gene	Troponin I Rapid Test Cassette (Serum/Plasma)
GDTRO-402a	TEST RAPID	Orient Gene	Troponin I Rapid Test Cassette (Whole blood/Serum/Plasma) (Except the tender No. ocds-b3wdp1-MD-1722410248839 din 05.09.2024, limited to the quantity 28060 pcs only, as per the tender)
GDTRO-402b	TEST RAPID	Orient Gene	Troponin I Rapid Test Cassette (Whole blood/Serum/Plasma)

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GDMYO-402a	TEST RAPID	Orient Gene	Myoglobin Rapid Test Cassette (Whole blood/serum/plasma)
GDCAR-W435a	TEST RAPID	Orient Gene	Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (whole blood/Serum/plasma)
GDPCT-402a	TEST RAPID	Orient Gene	Procalcitonin Rapid Test Cassette (Whole blood/serum/plasma)
GDPCT-T402a	TEST RAPID	Orient Gene	Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole blood/serum/plasma)
GDPCT-T401a	TEST RAPID	Orient Gene	Procalcitonin Semi-Quantitative Rapid Test Strip (Whole blood/serum/plasma)
FDPCT -302a	TEST RAPID	Orient Gene	Procalcitonin Rapid Test Kit (serum/plasma)
GDDDI-402b	TEST RAPID	Orient Gene	D-Dimer Rapid Test Cassette (Whole blood/plasma)
FDCAR-T302a	TEST RAPID	Orient Gene	Troponin I/CK-MB/Myoglobin Fluorescence Combo Test Kit (Serum/plasma)
FDTRO-302a	TEST RAPID	Orient Gene	Troponin I Fluorescence Rapid Test Kit (Serum/plasma)
FDBNP-302a	TEST RAPID	Orient Gene	NT-ProBNP Fluorescence Rapid Test Kit (Serum/plasma)
FDCRP-402a	TEST RAPID	Orient Gene	C-Reactive Protein Rapid Test Kit (Whole blood/serum/plasma)
GDCKM-402a	TEST RAPID	Orient Gene	CK-MB Rapid Test Cassette (whole blood/serum/plasma)
GAHCG-201a	TEST RAPID	Orient Gene	One step pregnancy test strip (Urine/serum)
GAHCG-202a	TEST RAPID	Orient Gene	One step pregnancy test cassette (Urine/serum)
GAHCG-201b	TEST RAPID	Orient Gene	One step pregnancy test strip (Urine/serum)
GAHCG-202b	TEST RAPID	Orient Gene	One step pregnancy test cassette (Urine/serum)
GCHAV(IgM)-302Ba	TEST RAPID	Orient Gene	HAV IgM Rapid Test Cassette (Serum/plasma)
GCHAV-602a	TEST RAPID	Orient Gene	HAV Ag Rapid Test Cassette (Feces)

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GCHAV(IgG/IgM) -302a	TEST RAPID	Orient Gene	HAV IgG/IgM Rapid Test Cassette (Serum/plasma)
GCHSV(IgG)-402a	TEST RAPID	Orient Gene	HSV IgG Rapid Test Cassette (Whole blood/serum/plasma)
GCHSV(IgM)-302a	TEST RAPID	Orient Gene	HSV IgM Rapid test Cassette (serum/plasma)
GCHP-601a	TEST RAPID	Orient Gene	H.pylori Ag Rapid Test Strip (feces)
GCHP-602a	TEST RAPID	Orient Gene	H.pylori Ag Rapid Test Cassette(feces)
GCTB-302a	TEST RAPID	Orient Gene	Tuberculosis IgG/IgM Rapid Test Cassette (serum/plasma)
GCTB-402a	TEST RAPID	Orient Gene	Tuberculosis IgG/IgM Rapid Test Cassette (whole blood/serum/plasma)
GCFLU(A/B)-501a	TEST RAPID	Orient Gene	Influenza A&B Ag Rapid Test Strip (Swab)
GCFLU(A/B)-502a	TEST RAPID	Orient Gene	Influenza A&B Ag Rapid Test Cassette (Swab)
GCFLU(A/B)-502Ca	TEST RAPID	Orient Gene	Influenza A&B Ag Rapid Test Cassette (Swab)
GCFLU(A)-501a	TEST RAPID	Orient Gene	Influenza A Ag Rapid Test Strip (Swab)
GCFLU(A)-502a	TEST RAPID	Orient Gene	Influenza A Ag Rapid Test Cassette (Swab)
GCHP-301a	TEST RAPID	Orient Gene	H.Pylori Ab Rapid Test Strip (serum/plasma)
GCHP-302a	TEST RAPID	Orient Gene	H.pylori Ab Rapid Test Cassette (serum/plasma)
GCHP-401a	TEST RAPID	Orient Gene	H.pylori Ab Rapid Test Strip (Whole blood/serum/plasma)
GCHP-402a	TEST RAPID	Orient Gene	H.pylori Ab Rapid Test Cassette (Whole blood/serum/plasma)
GCCA-502a	TEST RAPID	Orient Gene	Candida albicans Antigen rapid test cassette (swab)
GCGON-502b	TEST RAPID	Orient Gene	Gonorrhea Rapid Test Cassette (Swab)
GCGIA-602a	TEST RAPID	Orient Gene	Giardia lamblia Antigen Rapid tests cassette (feces)

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GCSTR-501a	TEST RAPID	Orient Gene	Strep A Rapid Test Strip (Throat swab)
GCSTR-502a	TEST RAPID	Orient Gene	Strep A Rapid Test Cassette (Throat swab)
GCFC-525a	TEST RAPID	Orient Gene	Rapid COVID-19 + Influenza Antigen Test
GCRSV-502a	TEST RAPID	Orient Gene	RSV Antigen Rapid Test Cassette (swab)
GCADE-502a	TEST RAPID	Orient Gene	Adenovirus antigen rapid test cassette (swab)
GCADE-602a	TEST RAPID	Orient Gene	Adenovirus Rapid test cassette (feces)
GCCD(GDH)-602a	TEST RAPID	Orient Gene	Clostridium difficile Antigen GDH Rapid Test cassette (feces)
GCCD (Toxin A/B)-602a	TEST RAPID	Orient Gene	Clostridium difficile Toxin A&B rapid test cassette (feces)
GCCD-602a	TEST RAPID	Orient Gene	Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces)
GCHSV (IgM)-402a	TEST RAPID	Orient Gene	HSV IgM Rapid test Cassette (whole blood/serum/plasma)
GCHSV(IgG)-302a	TEST RAPID	Orient Gene	HSV IgG Rapid Test Cassette (serum/plasma)
GCSYP-301a	TEST RAPID	Orient Gene	Syphilis Ab Rapid Test Strip (serum/plasma)
GCSYP-302a	TEST RAPID	Orient Gene	Syphilis Ab Rapid Test Cassette (serum/plasma)
GCSYP-401a	TEST RAPID	Orient Gene	Syphilis Ab Rapid test strip (whole blood/serum/plasma)
GCSYP-402a	TEST RAPID	Orient Gene	Syphilis Ab Rapid test cassette (whole blood/serum/plasma)
GBBAR-101a	TEST RAPID	Orient Gene	One Step Barbiturates Test Strip (Urine)
GBBAR-102a	TEST RAPID	Orient Gene	One Step Barbiturates Test Cassette (Urine)
GBAMP-101a	TEST RAPID	Orient Gene	One Step Amphetamine Test Strip (Urine)
GBAMP-102a	TEST RAPID	Orient Gene	One Step Amphetamine Test Cassette (Urine)
GBAMP-105a	TEST RAPID	Orient Gene	One Step Amphetamine Dip Card (Urine)

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GBPPX-101a	TEST RAPID	Orient Gene	One Step Propoxyphene Test Strip (Urine)
GBPPX-102a	TEST RAPID	Orient Gene	One Step Propoxyphene Test Cassette (Urine)
GBDSA-XXXXFX	TEST RAPID	Orient Gene	Oral Fluid Drug test Cube
GBDSA-XXXXEX	TEST RAPID	Orient Gene	Oral Fluid Drug test
GBDSA-XXXXFSI	TEST RAPID	Orient Gene	Oral Fluid Drug test Cube
GBDSA-XXXXCX	TEST RAPID	Orient Gene	Oral Fluid Drug test cylinder
GBOPI-102a	TEST RAPID	Orient Gene	One Step Opiate Test Cassette (Urine)
GBOPI-101a	TEST RAPID	Orient Gene	One Step Opiate Test Strip (Urine)
GBETG-101b	TEST RAPID	Orient Gene	One Step Ethyl Glucoronide Test Strip (urine)
GBETG-102b	TEST RAPID	Orient Gene	One Step Ethyl Glucoronide Test Cassette (urine)
GBMOP-101a	TEST RAPID	Orient Gene	One step Morphine Test strip (urine)
GBMOP-102a	TEST RAPID	Orient Gene	One step Morphine Test Cassette (urine)
GBMOP-105a	TEST RAPID	Orient Gene	One step Morphine Test dip card (urine)
GBTHC-101a	TEST RAPID	Orient Gene	One Step Marijuana Test Strip (Urine)
GBTHC-102a	TEST RAPID	Orient Gene	One Step Marijuana Test Cassette (Urine)
GBTHC-105a	TEST RAPID	Orient Gene	One Step Marijuana Test Dip Card (Urine)
GBMTD-101a	TEST RAPID	Orient Gene	One step Methadone Test strip (urine)
GBMTD-102a	TEST RAPID	Orient Gene	One step Methadone Test cassette (urine)
GBXXX-101	TEST RAPID	Orient Gene	One Step Drugs of Abuse Test Strip (Urine)
GBXXX-102	TEST RAPID	Orient Gene	One Step Drugs of Abuse Test Cassette (Urine)
GBXXX-105	TEST RAPID	Orient Gene	One Step Drugs of Abuse Test Dip Card (Urine)

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GBDSA-XXXXJSI	TEST RAPID	Orient Gene	Oral fluid drug test cylinder
GBDSA-XXXXJX	TEST RAPID	Orient Gene	Oral fluid drug test cylinder
GBDSA-XXXXKX	TEST RAPID	Orient Gene	Oral fluid drug test cylinder
GBDSA-XXXXMX	TEST RAPID	Orient Gene	Oral fluid drug test device
GBDSA-XXXXA/B/G/H/I	TEST RAPID	Orient Gene	Multi-drug rapid screen test cassette (oral fluid)
GBMTC-101a	TEST RAPID	Orient Gene	One Step Methcathinone Test Strip (Urine)
GBMTC-102a	TEST RAPID	Orient Gene	One Step Methcathinone Test Cassette (Urine)
GBKRA-101a	TEST RAPID	Orient Gene	One step kratom test strip (urine)
GBKRA-102a	TEST RAPID	Orient Gene	One step kratom test cassette (urine)
GBLSD-101a	TEST RAPID	Orient Gene	One Step Lysergic Acid Diethylamide Test Strip (Urine)
GBLSD-102a	TEST RAPID	Orient Gene	One Step Lysergic Acid Diethylamide Test Cassette (Urine)
FBXXX-1102	TEST RAPID	Orient Gene	Hair Multi-drug rapid test kit
GBETG-105a	TEST RAPID	Orient Gene	One step ethyl glucuronide test dip card (urine)
GBPGB-102b	TEST RAPID	Orient Gene	One step pregabalin test cassette (urine)
GBTRA-101a	TEST RAPID	Orient Gene	One step tramadol test strip (urine)
GBTRA-102a	TEST RAPID	Orient Gene	One step tramadol test cassette (urine)
GBOXY-101a	TEST RAPID	Orient Gene	One step oxycodone Test strip (urine)
GBOXY-102a	TEST RAPID	Orient Gene	One step oxycodone Test cassette (urine)
GBMDP-101a	TEST RAPID	Orient Gene	One step 3,4-Methylenedioxypropylvalerone Test strip (urine)

地址：浙江省湖州市安吉县递铺镇阳光大道东段 3787 号

Add: 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China

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

GBMDP-101a	TEST RAPID	Orient Gene	One step 3,4-Methylenedioxypropylvalerone Test cassette (urine)
GBMQL-102a	TEST RAPID	Orient Gene	One step Methaqualone Test cassette (urine)
GBMQL-101a	TEST RAPID	Orient Gene	One step Methaqualone Test strip (urine)
GBMPD-101a	TEST RAPID	Orient Gene	One step Methylphenidate Test strip (urine)
GBMPD-102a	TEST RAPID	Orient Gene	One step Methylphenidate Test cassette (urine)
GBUR-101a	TEST RAPID	Orient Gene	One step UR-144 test strip (urine)
GBUR-102a	TEST RAPID	Orient Gene	One step UR-144 test cassette (urine)
GBBUP-101a	TEST RAPID	Orient Gene	One step buprenorphine test strip (urine)
GBBUP-102a	TEST RAPID	Orient Gene	One step buprenorphine test cassette (urine)
GBPCP-101a	TEST RAPID	Orient Gene	One step Phencyclidine Test strip (urine)
GBPCP-102a	TEST RAPID	Orient Gene	One step Phencyclidine Test cassette (urine)
GBTCA-101a	TEST RAPID	Orient Gene	One step Tricyclic Antidepressants test strip (urine)
GBTCA-102a	TEST RAPID	Orient Gene	One step Tricyclic Antidepressants test cassette (urine)
GBEDD-101a	TEST RAPID	Orient Gene	One step EDDP test strip (urine)
GBEDD-102a	TEST RAPID	Orient Gene	One step EDDP test cassette (urine)
GBFEN-101b	TEST RAPID	Orient Gene	One step Fentanyl Test strip (urine)
GBFEN-102b	TEST RAPID	Orient Gene	One step Fentanyl Test cassette (urine)
GBALC-101a	TEST RAPID	Orient Gene	Urine Alcohol Test Strip
GBMAM-S102	TEST RAPID	Orient Gene	One step 6-MAM Test cassette (urine)

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Zhejiang Orient Gene Biotech Co.,LTD

GBMAM-S101	TEST RAPID	Orient Gene	One step 6-MAM Test cassette (urine)
GBHCD-101a	TEST RAPID	Orient Gene	One step Hydrocodone test strip (urine)
GBHCD-102a	TEST RAPID	Orient Gene	One step Hydrocodone test cassette (urine)
GBNFT-101c	TEST RAPID	Orient Gene	One step Norfentanyl test strip (urine)
GBNFT-102c	TEST RAPID	Orient Gene	One step Norfentanyl test cassette (urine)
GBXXX-1102	TEST RAPID	Orient Gene	Hair Multi-Drug Rapid Test Kit (ICA)
GBDSA-XXXXLX	TEST RAPID	Orient Gene	Oral Fluid Drug Test Mini Cube
GBDUA-1X4	TEST RAPID	Orient Gene	One Step Multi-Drug Screen Test Dip Card (urine)
GBDOA-1X5	TEST RAPID	Orient Gene	One Step Multi-Drug Screen Test Cassette (urine)
GBDUA-1X6	TEST RAPID	Orient Gene	One Step Multi-Drug Screen Test Cup (urine)
GBCOT-102a	TEST RAPID	Orient Gene	One step cotinine test cassette (urine)
GBK2-101a	TEST RAPID	Orient Gene	One step K2 Test strip (urine)
GBK2-102a	TEST RAPID	Orient Gene	One step K2 Test cassette (urine)
GBKET-101a	TEST RAPID	Orient Gene	One step Ketamine Test strip (urine)
GBKET-102a	TEST RAPID	Orient Gene	One step Ketamine Test cassette (urine)
GBBZO-101a	TEST RAPID	Orient Gene	One step Benzodiazepines Test Strip (urine)
GBBZO-102a	TEST RAPID	Orient Gene	One step Benzodiazepines Test Cassette (urine)
GBCOC-101a	TEST RAPID	Orient Gene	One step Cocaine Test strip (urine)
GBCOC-102a	TEST RAPID	Orient Gene	One step Cocaine Test cassette (urine)
GBCOC-105a	TEST RAPID	Orient Gene	One step Cocaine Test dip card (urine)
GBMDM-101a	TEST RAPID	Orient Gene	One step ecstasy Test strip (urine)

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

GBMDM-102a	TEST RAPID	Orient Gene	One step ecstasy Test cassette (urine)
GBMET-101a	TEST RAPID	Orient Gene	One step Methamphetamine test strip (urine)
GBMET-102a	TEST RAPID	Orient Gene	One step Methamphetamine test cassette (urine)
GBMET-105a	TEST RAPID	Orient Gene	One step Methamphetamine test dip card (urine)
GCTOXI(IgG/IgM)-302a	TEST RAPID	Orient Gene	Toxoplasma gondii test cassette (serum/plasma)
GCTOXI(IgG)-302a	TEST RAPID	Orient Gene	Toxoplasma gondii IgG test cassette (serum/plasma)
GCTOXI(IgM)-302a	TEST RAPID	Orient Gene	Toxoplasma gondii IgM test cassette (serum/plasma)
GCCHL-502a	TEST RAPID	Orient Gene	Chlamydia Trachomatis Antigen test cassette (swab/urine)
GEPSA-402a	TEST RAPID	Orient Gene	Prostate specific antigen test cassette (whole blood/serum/plasma)
GEPSA-401a	TEST RAPID	Orient Gene	Prostate specific antigen test strip (whole blood/serum/plasma)
GEPSA-302a	TEST RAPID	Orient Gene	Prostate specific antigen test cassette (serum/plasma)
GEPSA-301a	TEST RAPID	Orient Gene	Prostate specific antigen test strip (serum/plasma)
GALH-101a-1T	TEST RAPID	Orient Gene	LH Ovulation Test Strip
GALH-101a-5T	TEST RAPID	Orient Gene	LH Ovulation Test Strip
GALH-101a-7T	TEST RAPID	Orient Gene	LH Ovulation Test Strip
GALH-101b-1T	TEST RAPID	Orient Gene	LH Ovulation Test Strip
GALH-101b-5T	TEST RAPID	Orient Gene	LH Ovulation Test Strip
GALH-101b-7T	TEST RAPID	Orient Gene	LH Ovulation Test Strip
GALH-102a-1T	TEST RAPID	Orient Gene	LH Ovulation Test Cassette
GALH-102a-5T	TEST RAPID	Orient Gene	LH Ovulation Test Cassette
GALH-102a-7T	TEST RAPID	Orient Gene	LH Ovulation Test Cassette
GALH-102b-5T	TEST RAPID	Orient Gene	LH Ovulation Test Cassette
GALH-102b-1T	TEST RAPID	Orient Gene	LH Ovulation Test Cassette

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GALH-102b-7T	TEST RAPID	Orient Gene	LH Ovulation Test Cassette
VPH-502a	TEST RAPID	Orient Gene	Vaginal pH test cassette (Vaginal secretions)
URS-1T to 14T with various combination	STRIPURI DE URINA	Orient Gene	LEU/NIT/URO/MA/PRO/PH/BLO/S G/ASC/CRE/KET/BIL/GLU/CA
GCHCV-302a	TEST RAPID	Orient Gene	HCV Hepatitis C Virus Rapid Test (serum/plasma) cassette
GCHCV-402a	TEST RAPID	Orient Gene	HCV Hepatitis C Virus Rapid Test (whole blood/serum/plasma) cassette
GCHIV-302a	TEST RAPID	Orient gene	HIV 1/2 Human Immunodeficiency Virus (Serum/Plasma) cassette
GCHIV-402a	TEST RAPID	Orient gene	HIV 1/2 Human Immunodeficiency Virus (Whole blood/serum/plasma)cassette
GCHBsg-302a	TEST RAPID	Orient gene	HBsAg Hepatitis B Surface Antigen Rapid Test (Serum/Plasma)
GCHBsg-402a	TEST RAPID	Orient gene	HBsAg Hepatitis B Surface Antigen Rapid Test(Whole Blood/Serum/Plasma)

The end.





Certificate

No. Q5 092305 0001 Rev. 02

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. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_092305_0001_Rev.02)

Report No.: SH2398804

Valid from: 2024-03-17

Valid until: 2027-03-16

Date, 2024-03-01



Christoph Dicks
Head of Certification/Notified Body



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

CE-DOC-OG083
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)

HAV IgM Rapid Test Cassette (Serum/Plasma)	GCHAV(IgM)-302Ba
--	------------------

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: September 17, 2019

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



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



CE-DOC-OG260
Version 2.0

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)

Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces)	GCCD-602a
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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: CMC Medical Devices & Drugs S.L

EC Representative's Address: C/Horacio Lengo N° 18, CP 29006, Málaga, Spain

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: May 25, 2022

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

Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces)



INTENDED USE

The Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces) is a rapid visual immunoassay for the simultaneous detection and differentiation of Clostridium difficile Glutamate Dehydrogenase (GDH), Toxin A and Toxin B in human fecal specimens, as a screening test and as an aid in the diagnosis of Clostridium difficile infection.

INTRODUCTION

Clostridium difficile (*C. difficile*), a Gram-positive spore bearing anaerobic bacterium is the major aetiological agent of diarrhoea and colitis associated with antibiotics. *C. difficile* is the most common cause of health care-associated diarrhoea in developed countries and is a major source of nosocomial morbidity and mortality worldwide.

Disease due to *C. difficile* develops when the organism is allowed to proliferate in the colon, most commonly after antibiotic use has eliminated competing flora. *C. difficile* can release two high-molecular-weight toxins, toxin A and toxin B, which are responsible for the clinical manifestations, which range from mild, self-limited watery diarrhoea to fulminant pseudomembranous colitis, toxic megacolon and death.

Clostridium difficile Glutamate Dehydrogenase (GDH) is an enzyme produced in large quantities by all toxigenic and non-toxigenic strains, making it an excellent marker for the organism.

The toxigenic culture (TC) is used as the gold standard technique to determine Clostridium difficile infection. This method consists in culture and isolation of *C. difficile* from feces, followed by toxin testing of the isolate, a labour-intensive assay to obtain a result.

The Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces) is a rapid test to qualitatively detect Clostridium difficile Glutamate Dehydrogenase (GDH), Toxin A and Toxin B in human feces in 10 minutes. The test can be performed by untrained or minimally skilled personnel, without cumbersome laboratory equipment.

PRINCIPLE

The Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces) is a qualitative lateral flow immunoassay for the detection of Clostridium difficile GDH, Toxin A&B in human feces samples.

For the Clostridium difficile GDH Rapid Test Cassette (Feces), the membrane is pre-coated with monoclonal antibodies against GDH on the test line region. During testing, the sample reacts with the particle coated with anti-GDH antibodies, which were pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. If there is sufficient Clostridium difficile GDH in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred. If the control line does not appear, the test result is not valid.

For the Clostridium difficile Toxin A/B Rapid Test Cassette (Feces), the membrane is pre-coated with monoclonal antibodies against Toxin A on the A test line region and monoclonal antibodies against Toxin B on the B test line region. During testing, the sample reacts with the particle coated with anti-Toxin A and anti-Toxin B antibodies, which were pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. If there is sufficient Clostridium difficile Toxin or Toxin B in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred. If the control line does not appear, the

test result is not valid.

PRODUCT CONTENTS

The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) containing Clostridium difficile GDH-specific antibodies coated particles and GDH-specific antibodies coated on the membrane.

The Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) containing Clostridium difficile Toxin A and Toxin B antibodies coated particles and Toxin A-specific antibodies and Toxin B-specific antibodies coated on the membrane.

MATERIALS SUPPLIED

20 Test cassettes
20 Extraction tubes with buffer
1 Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

Timer

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.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged.
3. Test is for single use only. Do not re-use under any circumstances.
4. Avoid cross-contamination of specimens by using a new extraction tube for each specimen obtained.
5. Read the entire procedure carefully prior to testing.
6. Do not eat, drink or smoke in any area where specimens and kits are handled.
7. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
8. Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
9. Humidity and temperature can adversely affect results.
10. Do not perform the test in a room with strong air flow, ie. electric fan or strong airconditioning.

SPECIMEN COLLECTION AND PREPARATION

- The Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces) is intended for use with human fecal specimens only.
- Stool samples should be collected in clean containers. The samples can be stored in the refrigerator (2-8°C) for 7 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen at -20°C. In this case, the sample will be totally thawed and brought to room temperature before testing. Ensure only the amount needed is thawed because of freezing and defrosting cycles are not recommended. Homogenise stool samples as thoroughly as possible prior to preparation.

SPECIMEN PREPARATION

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

1. Collect a random sample of feces in a clean, dry receptacle. Best results will be obtained if the

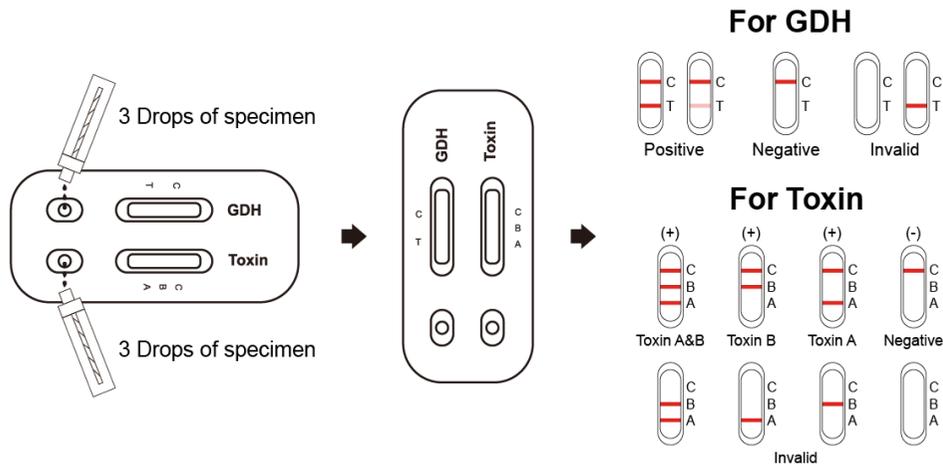
assay is performed within 6 hours after collection.

- Unscrew and remove the dilution tube applicator. Be careful not to spill or spatter solution from the tube. Collect specimens by inserting the applicator stick into at least 5 different sites of the feces to collect approximately 50 mg of feces (equivalent to 1/4 of a pea).
- For liquid specimens:** Hold the pipette vertically, aspirate fecal specimens, and then transfer 3 drops (approximately 80 µL) into the specimen collection tube containing the extraction buffer.
- Replace the stick in the tube and tighten securely.
- Shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Specimens prepared in the specimen collection tube may be stored for 6 months at -20°C if not tested within 1 hour after preparation.

TEST PROCEDURE

Bring tests, specimens, reagents and/or controls to room temperature (15-30°C) prior to testing.

- Remove the test from the sealed pouch and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed immediately after opening the foil pouch.
- Hold the specimen collection tube upright and then unscrew and open the upper cap.
- Squeeze 3 drops (~90 µL) of the sample solution in each sample well of the device and start the timer.
- Wait for the colored line(s) to appear. Read results in 10 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

For the GDH test:

- 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.

For the Toxin A&B test:

1. Positive:

1.1 Toxin A Positive:

The presence of two lines as control line (C) and A test line within the result window indicates a positive result for Toxin A.

1.2 Toxin B Positive:

The presence of two lines as control line (C) and B test line within the result window indicates a positive result for Toxin B.

1.3 Toxin A & B Positive:

The presence of three lines as control line (C), A test line and B test line within the result window indicates a positive result for both Toxin A and Toxin B.

2. Negative:

One colored line appears in the control line region (C). No line appears in the test line region (T).

3. Invalid:

If the control band (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test. 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

- The Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces) will only indicate the presence of parasites in the specimen (qualitative detection) and should be used for the detection of Clostridium difficile GDH, Toxin A&B in feces specimens only. Neither the quantitative value nor the rate of increase in antigen concentration can be determined by this test.
- An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
- The Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces) should be used only with samples from human feces. The use of other samples has not been established. The quality of the test depends on the quality of the sample; proper fecal specimens must be obtained.
- A negative result is not meaningful because of it is possible the antigen concentration in the stool samples is lower than the detection limit value. If the symptoms or situation still persist, a Clostridium difficile determination should be carried out, on a sample from an enrichment culture.
- 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.

PERFORMANCE CHARACTERISTICS

1. Clinical Sensitivity, Specificity and Accuracy

The Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces) has been evaluated with specimens obtained from patients. ELISA method was used as the reference method. The results show that the Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces) has a high overall relative accuracy.

Table 1: The Clostridium difficile GDH Rapid Test vs ELISA

Method		ELISA		Total Results
Clostridium difficile Antigen GDH Rapid Test Cassette	Results	Positive	Negative	
	Positive	62	1	63
	Negative	0	50	50
Total Results		62	51	113

Relative Sensitivity: 100%
 Relative Specificity: 98.0%
 Accuracy: 99.1%

Table 2: The Clostridium difficile Toxin A Rapid Test vs ELISA

Method		ELISA		Total Results
Clostridium difficile Toxin A&B Rapid Test Cassette	Results	Positive	Negative	
	Positive	43	1	44
	Negative	0	69	69
Total Results		43	70	113

Relative Sensitivity: 100%
 Relative Specificity: 98.6%
 Accuracy: 99.1%

Table 3: The Clostridium difficile Toxin B Rapid Test vs ELISA

Method		ELISA		Total Results
Clostridium difficile Toxin A&B Rapid Test Cassette	Results	Positive	Negative	
	Positive	36	1	37
	Negative	0	76	76
Total Results		36	77	113

Relative Sensitivity: 100%
 Relative Specificity: 98.6%
 Accuracy: 99.1%

2. Analytical Sensitivity

The Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces) was determined by testing serial dilutions of recombinant antigen. Detection limit values of Clostridium difficile GDH & Toxin A/B are 1 ng/mL for GDH, 2 ng/mL for Toxin A and 1 ng/mL for Toxin B.

3. Cross-Reactivity

Cross-reactivity to samples positive for the following pathogens was tested and found to be negative:

<i>Campylobacter coli</i>	<i>Salmonella enteritidis</i>	<i>Shigella dysenteriae</i>
<i>Campylobacter jejuni</i>	<i>Salmonella paratyphi</i>	<i>Shigella flexneri</i>
<i>E. Coli O157: H7</i>	<i>Salmonella typhi</i>	<i>Shigella sonnei</i>
<i>H. Pylori</i>	<i>Salmonella typhimurium</i>	<i>Staphylococcus aureus</i>
<i>Listeria monocytogenes</i>	<i>Shigella boydii</i>	<i>Yersinia enterocolitica</i>

REFERENCE

1. Knoop, F.C. et al.: Clostridium difficile: Clinical disease and diagnosis. Clin. Microbiol. Rev. (1993); 6: 251-265.
2. Kelly, C.P. et al.: Clostridium difficile Colitis. New Engl. J. Med. (1994); 330: 257-262.
3. Sullivan, N.M. et al.: Purification and characterization of toxins A and B of Clostridium difficile. Infect. Immun. (1982); 35: 1032-1040.

4. McDonald, L.C. et al.: An epidemic, toxin gene-variant strain of Clostridium difficile. N. Engl. J. Med. (2005); 353: 23.
5. Loo, V.G. et al.: A predominantly clonal multi-institutional outbreak of Clostridium difficile-associated diarrhea with high morbidity and mortality. N. Engl. J. Med. (2005); 353: 23.
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INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2~30°C		Lot Number		Catalog#

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