



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, Chișinău 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





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)

地址：浙江省湖州市安吉县递铺镇阳光大道东段 3787 号

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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) (25mIU)
GALH-101b	TEST RAPID	Orient Gene	One Step Ovulation Test Strip (Urine) (40mIU)
GALH-102a	TEST RAPID	Orient Gene	One Step Ovulation Test Cassette (Urine) (25mIU)
GALH-102b	TEST RAPID	Orient Gene	One Step Ovulation Test Cassette (Urine) (40mIU)
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
GCFCRA-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
GCFCR-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)
GCFCRA-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)
GCFC-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)
GCKal-401a	TEST RAPID	Orient Gene	Leishmania Ab Rapid Test strip (Whole blood/serum/plasma)
GCKal-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-Methylenedioxypyrovalerone 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

GBMDP-101a	TEST RAPID	Orient Gene	One step 3,4-Methylenedioxypyrovalerone 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-XXXXXLX	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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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
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VPH-502a	TEST RAPID	Orient Gene	Vaginal pH test cassette (Vaginal secretions)
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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.



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Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

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

Report No.: SH2398804

Valid from: 2024-03-17
Valid until: 2027-03-16

Date: 2024-03-01

Christoph Dicks
Head of Certification/Notified Body



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 092305 0001 Rev. 02

Applied Standard(s):

ISO 13485:2016

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

Medical devices - Quality management systems -
Requirements for regulatory purposes

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



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



CE-DOC-OG039
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 Ag Rapid Test Strip (Feces)	GCHP-601a
H. pylori Ag Rapid Test Cassette (Feces)	GCHP-602a

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

H. pylori Ag Rapid Test Cassette (Feces)

CE

INTENDED USE

H. pylori Ag Rapid Test Cassette (Feces) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of H. Pylori antigen in feces. It is for professional *in vitro* diagnostic use only.

INTRODUCTION

H. 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

PRINCIPLE

H. pylori Ag Rapid Test Cassette (Feces) is a lateral flow chromatographic immunoassay based on the principle of the double antibody-sandwich technique. The test cassette consists of: 1) a burgundy colored conjugate pad containing H. Pylori antibodies conjugated with color particles (H. Pylori 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 antibodies.

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 antigen of H. Pylori if present in the specimen will bind to the H. Pylori antibodies conjugates. The immunocomplex is then captured on the membrane by the pre-coated H. Pylori antibodies, forming a burgundy colored T band, indicating a H. Pylori antigen positive test result. 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. Otherwise, the test result is invalid and the specimen must be retested with another device.

PRODUCT CONTENTS

H. pylori Ag Rapid Test Cassette (Feces) containing anti- H. pylori antibodies particles and anti-H. pylori antibodies coated on the membrane.

MATERIALS SUPPLIED

20 Sealed pouches each containing a test cassette and a desiccant

20 Specimen collection tubes with extraction buffer, 2.0 mL

1 Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or timer

2. Specimen collection containers.

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test is not stable out of the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use if the tube/pouch is damaged or broken.
3. Test is for single use only. Do not re-use under any circumstances.
4. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
6. Humidity and temperature can adversely affect results

SPECIMEN COLLECTION

Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours. For long term storage, specimens should be kept below -20°C.

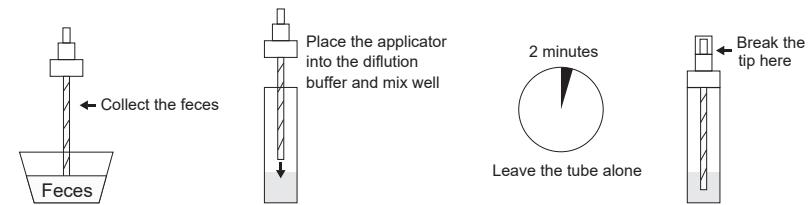
To process fecal specimens:

• For Solid Specimens:

Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.

• For Liquid Specimens:

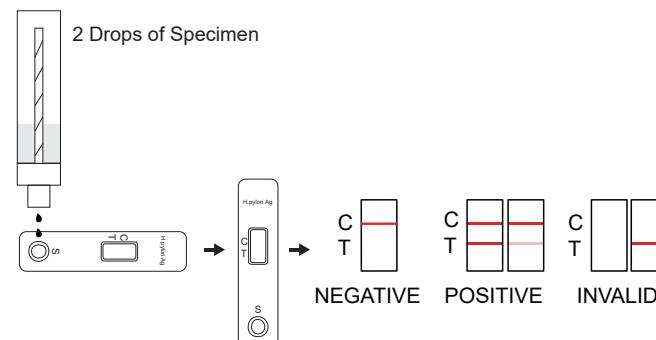
Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops (approximately 80 µL) into the specimen collection tube containing the dilution buffer. Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the dilution buffer. Leave the tube alone for 2 minutes.



TEST PROCEDURE

1. Remove the test device from its foil pouch by tearing along the notch and use it as soon as possible.
2. Specimen collection. See also specimen collection.
3. Holding the sample collection device upright, carefully break off the tip of collection device.
4. Squeeze 2 drops (~80 µL) of the sample solution in the sample well of the cassette, as in the illustration.
5. Read the test results in 10 minutes. It is important that the background is clear before the result is read. Do not read results after 10 minutes. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF RESULTS



H. pylori Ag Rapid Test Cassette (Feces)

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.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking 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. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of H. Pylori antigen in feces from individual subjects. Failure to follow the procedure may give inaccurate results.
2. H. pylori Ag Rapid Test Cassette (Feces) is limited to the qualitative detection of H. Pylori antigen in feces. The intensity of the test band does not have linear correlation with the antigen titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable H. Pylori antigen. However, a negative test result does not preclude the possibility of exposure to or infection with H. Pylori.
4. A negative result can occur if the quantity of the H. Pylori antigen present in the specimen is below the detection limits of the assay, or the antigen that are detected are not present during the stage of disease in which a sample is collected.
5. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

PERFORMANCE CHARACTERISTICS

A study was performed with 165 patient feces samples including both symptomatic gastrointestinal disorders and samples from non-symptomatic patients and 100 normal feces samples. Comparison for all subjects with H. pylori Ag Rapid Test Cassette (Feces) and reference ELISA kit is showed in the following table:

Method		EIA		Total Results
H.P Test Cassette	Results	Positive	Negative	
	Positive	163	0	163
	Negative	2	100	102
Total Results		165	100	265

Relative sensitivity: 98.8%

Relative specificity: 100%

Accuracy:98.9%

REFERENCE

1. Marshall,B.J.et.al. Pyloric Campylobacter infection and gastroduodenal disease. Med. J. Australia.149:439-44, 1985.
2. Marshall,B.J.et.al. Prospective double-blind trial of duodenal ulcer relapse after eradication of Campylobacter pylori. Lancet. Dec.1437-42,1988.
3. Megraud,F.et.al. Seroepidemiology of Campylobacter pylori infection in virious populations J.Clin.Microbiology. 27:1870-3,1989.
4. Soll,A.H. Pathogenesis of peptic ulcer and implications for therapy. New England J. Med.322:909-916,1990.

5. Parsonnet,J.et.al. Helicobacter pylori infection and the risk of gastric carcinoma. New England J.Med. 325:1127-31,1991.

6. Ansong,R. et.al. Evaluation of techniques for isolation, subcultivation and preservation of Helicobacter pylori. J.Clin.Micro. 29:51-53,1991.

7. Pronovost,A.P.et.al. Evaluation of a new immunodiagnostic assay for Helicobacter pylori antibody detection: Correlation with histopathological and microbiological results. J.Clin.Microbiol.32:46-50,1994.

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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