

Troponin I

Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) Package Insert

A rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens.
For professional in vitro diagnostic use only.

INTENDED USE

The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens. This kit is intended to be used as an aid in the diagnosis of myocardial infarction (MI).

SUMMARY

Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa.¹ Troponin I is part of a three subunit complex comprising of Troponin T and Troponin C. Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle.² After cardiac injury occurs, Troponin I is released into the blood 4-6 hours after the onset of pain. The release pattern of cTnI is similar to CK-MB, but while CK-MB levels return to normal after 72 hours, Troponin I remains elevated for 6-10 days, thus providing for a longer window of detection for cardiac injury. The high specificity of cTnI measurements for the identification of myocardial damage has been demonstrated in conditions such as the perioperative period, after marathon runs, and blunt chest trauma.³ cTnI release has also been documented in cardiac conditions other than acute myocardial infarction (AMI) such as unstable angina, congestive heart failure, and ischemic damage due to coronary artery bypass surgery.⁴ Because of its high specificity and sensitivity in the myocardial tissue, Troponin I has recently become the most preferred biomarker for myocardial infarction.⁵

PRINCIPLE

The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) has been designed to detect cardiac Troponin I through visual interpretation of color development in the strip. The membrane was immobilized with anti-cTnI antibodies on the test region. During the test, the specimen is allowed to react with colored anti-cTnI antibodies colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interact with reagents on the membrane. If there were enough cTnI in specimens, a colored band will form at the test region of the membrane.

Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

PRECAUTIONS

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

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 off the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND PREPARATION

- The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is intended only for use with human whole blood, serum, or plasma specimens.
- Only clear, non-hemolyzed specimens are recommended for use with this test.
- Serum or plasma should be separated with soonest possible opportunity to avoid hemolysis.
- Perform the testing immediately after the specimen collection. 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.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.

- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.
- Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.
- There is a slight possibility that some whole blood specimens with very high viscosity or which have been stored for more than 2 days may not run properly on the test device. Repeat the test with a serum or plasma specimen from the same patient using a new test device.

MATERIALS

Materials Provided

- Test devices
- Buffer

- Disposable Droppers
- Package insert

Materials Required But Not Provided

- Specimen collection containers
- Centrifuge (for plasma only)

- Clock or Timer

DIRECTIONS FOR USE

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

- Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. To obtain a best result, the assay should be performed within one hour.
- Transfer 2 drops of serum or plasma to the specimen well of the device with a disposable pipette provided in the kit, and then start the timer.

OR

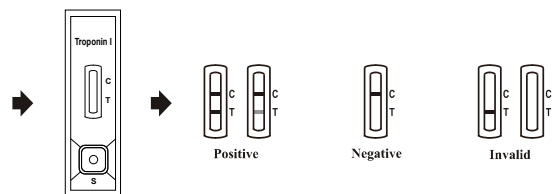
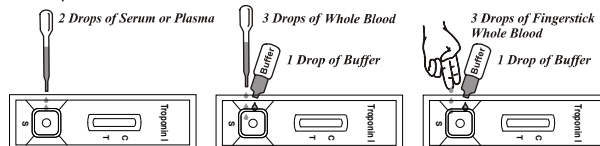
Transfer 3 drops of whole blood specimen to the specimen well of the device with a disposable pipette provided in the kit, then add 1 drop of buffer, and start the timer.

OR

Allow 3 hanging drops of fingerstick whole blood specimen to fall into the center of the specimen well (S) on the device, then add 1 drop of buffer, and start the timer. Avoid trapping air bubbles in the specimen well (S), and do not drop any solution in observation window.

As the test begins to work, you will see color move across the membrane.

- Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded.

Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

- The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level can not be determined by this qualitative test.
- Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

External controls are not supplied with this kit. 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

- The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is for professional in vitro diagnostic use, and should be used for the qualitative detection of cardiac Troponin I only. There is no meaning attributed to linen color intensity or width.
- The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of Troponin I in the specimen and should not be used as the sole criteria for the diagnosis of tuberculosis.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. The test cannot detect less than 0.5 ng/mL of cTnI in specimens. Thus, a negative result does not at anytime rule out the existence of Troponin I in blood, because the antibodies may be absent or below the minimum detection level of the test.
- Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
- Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Table: Troponin I Rapid Test vs. EIA

Method	Troponin I Rapid Test Device		Total Results
	Results	Positive	Negative
	Positive	138	2
EIA	Negative	1	315
	Total Results	139	317

Relative Sensitivity: 98.6% (94.9%-99.8%)*

Relative Specificity: 99.7% (98.3%-99.9%)*

Overall Agreement: 99.3% (98.1%-99.9%)*

*95% Confidence Interval

BIBLIOGRAPHY

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- Hossein-Nia M, et al. Cardiac troponin I release in heart transplantation. Ann. Thorac. Surg. 61: 227, 1996.
- Alpert JS, et al. Myocardial Infarction Redefined, Joint European Society of Cardiology American College of Cardiology: J. Am. Coll. Cardio., 36(3):959, 2000.

Toxicology Urine Test



Product Description	Format	Cut-off Value	Qualification
Acetaminophen (ACE) Test	Strip/Cassette/Dip Card/Cup	5000 ng/mL	CE
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	6000 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 ng/mL	CE
Norfentanyl (FEN) Test	Strip/Cassette/Dip Card/Cup	200/50/20/10/5 ng/mL	CE
Gabapentin (GAB) Test	Strip/Cassette/Dip Card/Cup	3750/2000/1000 ng/mL	CE
Hydrocodone (HCD) Test	Strip/Cassette/Dip Card/Cup	300/10 ng/mL	CE
Hydromorphone (HMO) Test	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-Methylenedioxypropylvalerone (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	2000/300/100 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)
Pinaca Ab (K3) Test	Strip/Cassette/Dip Card/Cup	10 ng/mL	CE
Pregabalin (PGB) Test	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	Strip/Cassette/Dip Card/Cup	50 ng/mL	CE
Zolpidem (ZOL) Test ^{New}	Strip/Cassette/Dip Card/Cup	50 ng/mL	/
Zopiclone (ZOP) Test ^{New}	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	Qualification
7-Aminoclonazepam (ACL) Test ^{New}	Device	100 ng/mL	/
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 ng/mL	CE
Codeine (COD) Test	Device	10 ng/mL	CE
Cotinine (COT) Test	Device	50/30/10 ng/mL	CE
Diphenhydramine (DIP) Test ^{New}	Device	150/100 ng/mL	/
Ecstasy (MDMA) Test	Device	60/50 ng/mL	CE
Ethyl Glucuronide (EtG) Test ^{New}	Device	150/100 ng/mL	/
Fentanyl (FEN) Test	Device	10 ng/mL	CE
Hydrocodone (HCD) Test ^{New}	Device	10 ng/mL	/
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-Methylenedioxypropylvalerone (MDPV) Test	Device	200/100/50 ng/mL	CE
Methylphenidate (MPD) 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 ng/mL	CE
Oxycodone (OXY) Test	Device	50/40/20 ng/mL	CE
Phencyclidine (PCP) Test	Device	10 ng/mL	CE
Phenytoln (PHEN) Test ^{New}	Device	150/100 ng/mL	/
Pinaca Ab (K3) Test ^{New}	Device	10 ng/mL	/
Pregabalin (PGB) Test ^{New}	Device	100 ng/mL	/
Propoxyphene (PPX) Test	Device	50/20 ng/mL	CE
Synthetic Marijuana (K2) Test	Device	25/10/5 ng/mL	CE
Tramadol (TRA) Test	Device	100/50 ng/mL	CE
Tricyclic Antidepressants (TCA) Test	Device	100 ng/mL	CE
XLR-11 Test ^{New}	Device	100 ng/mL	/
Zolpidem (ZOL) Test ^{New}	Device	25 ng/mL	/
Zopiclone (ZOP) Test ^{New}	Device	25 ng/mL	/
Alcohol (ALC) Test	Device	0.05/0.02%	CE

Toxicology Hair Test



Product Description	Format	Label	Cut-off Value	Qualification
Amphetamine (AMP) Test	Cassette	Fluorescence	0.5/0.2 ng/mg	CE
		Gold	5 ng/mg	/
Benzodiazepines (BZO) Test	Cassette	Fluorescence	0.2 ng/mg	/
		Gold	1 ng/mg	/
Cocaine (COC) Test	Cassette	Fluorescence	0.5/0.2 ng/mg	CE
		Gold	5/2 ng/mg	CE
Ecstasy (MDMA) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	5 ng/mg	/
2-Fluorodeschloroketamin (FKE) Test	Cassette	Fluorescence	0.2 ng/mg	/
Ketamine (KET) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	2/1/0.5 ng/mg	CE
Marijuana (THC) Test	Cassette	Fluorescence	0.05 ng/mg	CE
		Gold	2/1.5 ng/mg	CE
Methamphetamine (MET) Test	Cassette	Fluorescence	0.5/0.2 ng/mg	CE
		Gold	5/2/1 ng/mg	CE
Methcathinone (MTC) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Fluorescence	0.2 ng/mg	CE
6-Monoacetylmorphine (6-MAM) Test	Cassette	Gold	2 ng/mg	CE
		Fluorescence	0.2 ng/mg	CE
Morphine (MOP) Test	Cassette	Gold	5/2/0.5 ng/mg	CE
		Fluorescence	0.2 ng/mg	CE
Oxycodone (OXY) Test	Cassette	Gold	4 ng/mg	/
		Fluorescence	0.3 ng/mg	CE
Phencyclidine (PCP) Test	Cassette	Gold	1 ng/mg	CE
		Fluorescence	0.2 ng/mg	CE
Pinaca Ab (K3) Test	Cassette	Gold	0.5 ng/mg	/
		Fluorescence	0.2 ng/mg	CE
Synthetic Marijuana (K2) Test	Cassette	Gold	1 ng/mg	/
Tramadol (TRA) Test	Cassette	Fluorescence	0.2 ng/mg	/
UR-144 Test	Cassette	Fluorescence	0.05 ng/mg	/

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	GCCA-502a√	Cassette	10 ⁶ 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	GCDD(GDH)-602a√	Cassette	2 ng/mL	20 Tests/Kit
Clostridium difficile Toxin A/B Test	Feces	GCDD(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	GCCD-625a√	Cassette	Toxin A: 2 ng/mL Toxin B: 2 ng/mL	20 Tests/Kit
Chikungunya IgM 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	4.8×10 ³ 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
	S/P	GCCMV(IgM)-302a	Cassette	/	25 Tests/Kit
CMV IgM Test	WB/S/P	GCCMV(IgM)-402a	Cassette	/	25 Tests/Kit
	S/P	GCCMV(IgG/IgM)-302a	Cassette	/	25 Tests/Kit
CMV IgG/IgM Test	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
		GCCOV-502a√	Cassette	/	20 Tests/Kit
	Nasopharyngeal Swab	GCCOV-502Ca√	Cassette	/	20 Tests/Kit
		GCCOV-501a√ ^{New}	Strip	/	20 Tests/Kit
	Nasal Swab	GCCOV-502a-NA√	Cassette	/	1/2/3/5/7/10/15/20 Test(s)/Kit
		GCCOV-503a√ ^{NA}	Device	/	1/2/5/10 Tests/Kit
	NA & NP Swab	GCCOV-502a-NN√	Cassette	/	20 Tests/Kit
	Oral Fluid	GCCOV-702a√	Cassette	/	20 Tests/Kit
		GCCOV-502a-Hxx√	Cassette	/	1/2/3/5/7/10/15/20 Test(s)/Kit
COVID-19 Antigen Self-Test	Nasal Swab	GCCOV-502a-HxxOGE√	Cassette	/	1/2/3/5/8/10/15/20/25 Test(s)/Kit
	Oral Fluid	GCCOV-702a-Hxx√ ^{New}	Cassette	/	1/2/3/5/7/10/15/20 Test(s)/Kit
Digital COVID-19 Antigen Test	Nasal Swab	GCCOV-D503a√ ^{New}	Reader	/	1/2/3/5/7/10/15/20 Test(s)/Kit
COVID-19 Antigen & B.1.1.7 Mutant Strain Combo Test	Nasal Swab	GCCOV(B117)-525a√	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	GCCOV(Del)-T502a√	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(lab)-402c√	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-425a√	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	GCGLA-602a√	Cassette	/	20 Tests/Kit
Gonorrhoeae Test	Swab	GCGON-502b	Cassette	1.0E+7	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
HAV AntigenTest	Feces	GCHAV-602a√	Cassette	/	25 Tests/Kit
	S/P	GCH8cb-302a	Cassette	2 NCU	25 Tests/Kit
HBCAb Hepatitis B Core Antibody Test	S/P	GCH8cb-302b	Cassette	8 NCU	25 Tests/Kit
	WB/S/P	GCH8cb-402a	Cassette	2 NCU	25 Tests/Kit
	S/P	GCH8eb-302a	Cassette	2 NCU	25 Tests/Kit
		GCH8eb-302b	Cassette	8 NCU	25 Tests/Kit
	WB/S/P	GCH8eb-402a	Cassette	2 NCU	25 Tests/Kit
	S/P	GCH8eg-302a	Cassette	0.5 NCU	25 Tests/Kit
HBeAg Hepatitis B Envelope Antigen Test	WB/S/P	GCH8eg-402a	Cassette	0.5 NCU	25 Tests/Kit
	S/P	GCH8sb-301a	Strip	30 mIU/mL	50 Tests/Kit
		GCH8sb-302a	Cassette	30 mIU/mL	25 Tests/Kit
		GCH8sb-401a	Strip	30 mIU/mL	50 Tests/Kit
		GCH8sb-402a	Cassette	30 mIU/mL	25 Tests/Kit
		GCH8sb-402b	Cassette	20 mIU/mL	25 Tests/Kit
		GCH8sg-301a	Strip	1 ng/mL	50 Tests/Kit
	S/P	GCH8sg-302a	Cassette	1 ng/mL	25 Tests/Kit
		GCH8sg-401a	Strip	1 ng/mL	50 Tests/Kit
		GCH8sg-402a	Cassette	1 ng/mL	25 Tests/Kit
HBSAg Hepatitis B Surface Antigen Rapid Test	WB/S/P	GCHBC-402a	Cassette	/	25 Tests/Kit
	S/P	GCHBCISY-345a	Cassette	/	20 Tests/Kit
HBSAg/HCV/HIV/Syphilis Combo Test	WB/S/P	GCHBCISY-445a	Cassette	/	20 Tests/Kit
HBV HBCAb/HBeAb/HBeAg/HBsAb	S/P	GCHBV-355a	Cassette	/	20 Tests/Kit
/HBsAg Combo Test	WB/S/P	GCHBV-455a	Cassette	/	20 Tests/Kit
	S/P	GCHCV-301a	Strip	/	50 Tests/Kit
		GCHCV-302a√	Cassette	/	25 Tests/Kit
		GCHCV-401a	Strip	/	50 Tests/Kit
HCV Hepatitis C Virus Test	WB/S/P	GCHCV-402a√	Cassette	/	25 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
	S/P	GCHIV-301a	Strip	/	50 Tests/Kit
		GCHIV-302a√	Cassette	/	25 Tests/Kit
HIV 1/2 Antibody Test	WB/S/P	GCHIV-401a	Strip	/	50 Tests/Kit
		GCHIV-402a√	Cassette	/	25 Tests/Kit
HIV 1/2 Antibody Tri-line Test	WB/S/P	GCHIV-GT402a	Cassette	/	25 Tests/Kit
	S/P	GCHIV-T302b	Cassette	/	25 Tests/Kit
HIV 1/2/O Antibody Test	WB/S/P	GCHIV-T402a	Cassette	/	25 Tests/Kit
HIV Antigen/Antibody Combo Test	WB/S/P	GCHV(Ag/Ab)-402a	Cassette	/	25 Tests/Kit
	S/P	GCHSV(IgG)-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCHSV(IgG)-402a√	Cassette	/	25 Tests/Kit
	S/P	GCHSV(IgM)-302a√	Cassette	/	25 Tests/Kit
HSV IgM Test	WB/S/P	GCHSV(IgM)-402a√	Cassette	/	25 Tests/Kit
	S/P	GCHSV(IgG/IgM)-302a	Cassette	/	25 Tests/Kit
HSV IgG/IgM Test	WB/S/P	GCHSV(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
	S/P	GCHP-301a√	Strip	/	50 Tests/Kit
		GCHP-302a√	Cassette	/	25 Tests/Kit
		GCHP-401a√	Strip	/	50 Tests/Kit
	WB/S/P	GCHP-402a√	Cassette	/	25 Tests/Kit

H. pylori Antigen Test	Feces	GCHP-601a/	Strip	/	25 Tests/Kit
		GCHP-601Ca/	Strip	/	25 Tests/Kit
		GCHP-602a/	Cassette	/	20 Tests/Kit
Influenza A Antigen Test	Nasal/Throat Swabs	GCHP-602Ca/	Cassette	/	20 Tests/Kit
		GCFLU(A)-501a/	Strip	1.5 x 10 ⁴ TCID ₅₀	25 Tests/Kit
		GCFLU(A)-502a/	Cassette	1.5 x 10 ⁴ TCID ₅₀	20 Tests/Kit
Influenza A/B Antigen Test	Nasal/Throat Swabs	GCFLU(A/B)-501a/	Strip	1.5x 10 ⁴ TCID ₅₀ / 1.5 x 10 ³ TCID ₅₀	25 Tests/Kit
		GCFLU(A/B)-502a/	Cassette	1.5x 10 ⁴ TCID ₅₀ / 1.5 x 10 ³ TCID ₅₀	20 Tests/Kit
		GCFLU(A/B)-502Ca/	Cassette	1.5x 10 ⁴ TCID ₅₀ / 1.5 x 10 ³ TCID ₅₀	20 Tests/Kit
Influenza & COVID-19 Antigen Combo Test	Nasopharyngeal Swab	GCFC-525a/	Cassette	/	20 Tests/Kit
	NA & NP Swab	GCFC-525a-NA/	Cassette	/	20 Tests/Kit
	Nasal Swab	GCFC-525a-NA/	Cassette	/	20 Tests/Kit
		GCFC-7502a/ ^{New}	Cassette	/	1/5/20 Tests/Kit
Flu, COVID-19, RSV & Adeno Antigen Combo Test	Nasopharyngeal Swab	GCFC-T503a/ ^{New}	Device	/	1/2/5/10 Test(s)/Kit
		GCFCRA-545a/	Cassette	/	20 Tests/Kit
	Nasal Swab	GCFCRA-T525a/ ^{New}	Cassette	/	20 Tests/Kit
	S/P	GCKal-301a	Strip	/	50 Tests/Kit
Leishmania Antibody Test	S/P	GCKal-302a	Cassette	/	25 Tests/Kit
		GCKal-401a/	Strip	/	50 Tests/Kit
	WB/S/P	GCKal-402a	Cassette	/	25 Tests/Kit
		GCKal-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./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
Monkeypox IgG/IgM Antibody Test	WB/S/P	GCMAL(pf/pv Ab)-402a/	Cassette	/	25 Tests/Kit
Monkeypox Antigen Test	WB/S/P	GCMPK-402a/ ^{New}	Cassette	/	25 Tests/Kit
Monkeypox Antigen Test	WB/S/P or Throat swab	GCMPK-502a/ ^{New}	Cassette	/	25 Tests/Kit
Mononucleosis Test	S/P	GCMON-325a/	Cassette	/	25 Tests/Kit
		GCMON-402a/	Cassette	/	25 Tests/Kit
		GCMON-425a/	Cassette	/	25 Tests/Kit
M. pneumonia IgM Test	S/P	GCMP(lgM)-302a/	Cassette	/	25 Tests/Kit
Respiratory Syncytial Virus Antigen Test	Swab	GCRSV-502a/	Cassette	/	20 Tests/Kit
Rotavirus Test	Feces	GCROA-602a/	Cassette	/	25 Tests/Kit
Rotavirus/Adenovirus Test		GCROA/ADE-602a/	Cassette	/	25 Tests/Kit
Rubella IgG Test	S/P	GCRUB(lgG)-302a	Cassette	/	25 Tests/Kit
Rubella IgM Test	WB/S/P	GCRUB(lgG)-402a	Cassette	/	25 Tests/Kit
	S/P	GCRUB(lgM)-302a	Cassette	/	25 Tests/Kit
Rubella IgG/IgM Test	WB/S/P	GCRUB(lgM)-402a	Cassette	/	25 Tests/Kit
	S/P	GCRUB(lgG/IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCRUB(lgG/IgM)-402a	Cassette	/	25 Tests/Kit
Strep A Test	Throat Swab	GCRUB(lgG/IgM)-T402a	Cassette	/	25 Tests/Kit
		GCSTR-501a/	Strip	/	25 Tests/Kit
		GCSTR-501Ca/†	Strip	/	25 Tests/Kit
		GCSTR-502a/	Cassette	/	20 Tests/Kit
Syphilis Test	S/P	GCSTR-502Ca/	Cassette	/	20 Tests/Kit
		GCSYP-301a/	Strip	/	50 Tests/Kit
		GCSYP-302a/	Cassette	/	25 Tests/Kit
		GCSYP-401a/	Strip	/	50 Tests/Kit
S. typhi Antigen Test	WB/S/P	GCSYP-402a/	Cassette	/	25 Tests/Kit
		GCSAL(ST)-602a/	Cassette	/	20 Tests/Kit
		GCTOX(lgG)-302a/	Cassette	/	25 Tests/Kit
TOXO IgG Test	WB/S/P	GCTOX(lgG)-402a	Cassette	/	25 Tests/Kit
TOXO IgM Test	S/P	GCTOXO(lgM)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCTOXO(lgM)-402a	Cassette	/	25 Tests/Kit
	S/P	GCTOX-302b	Cassette	/	25 Tests/Kit
Toxo IgG/IgM Test	S/P	GCTOX(lgG/IgM)-302a/	Cassette	/	20 Tests/Kit
ToRCH Toxo/Rubella/CMV/HSV IgG Combo Test	WB/S/P	GCTOX-402b	Cassette	/	25 Tests/Kit
	S/P	GCTOG-345a	Cassette	/	20 Tests/Kit
	S/P	GCTOM-345a	Cassette	/	20 Tests/Kit
Trichomonas vaginalis Test	Vaginal Swab	GCTV-502a/	Cassette	/	20 Tests/Kit
Tuberculosis IgG/IgM Test	S/P	GCTB-302a/	Cassette	/	25 Tests/Kit
Typhoid IgG/IgM Test	WB/S/P	GCTB-402a/	Cassette	/	25 Tests/Kit
	S/P	GCTYP-301a	Strip	/	50 Tests/Kit
V. cholerae O1 Antigen Test	S/P	GCTYP-302a/	Cassette	/	25 Tests/Kit
V. cholerae O1/O139 Antigen Test	Feces	GCVC(O1)-602a/	Cassette	/	25 Tests/Kit
ZIKA IgM Test	Feces	GCVC(O1/O9)-602a/	Cassette	/	25 Tests/Kit
ZIKA IgG Test	WB/S/P	GCZIK(lgM)-402a	Cassette	/	25 Tests/Kit
ZIKA NS1 Test	WB/S/P	GCZIK(lgG)-402a	Cassette	/	25 Tests/Kit
	WB/S/P	GCZIK(NS1)-402a	Cassette	/	25 Tests/Kit

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-101d/	Strip	20 mIU/mL	100 Tests/Kit
		GAHCG-102a/†	Cassette	25 mIU/mL	25 Tests/Kit
		GAHCG-102b/	Cassette	10 mIU/mL	25 Tests/Kit
		GAHCG-102d/	Cassette	20 mIU/mL	25 Tests/Kit
		GAHCG-103a/†	Midstream	25 mIU/mL	1/2 Test(s)/Kit
		GAHCG-103b/	Midstream	10 mIU/mL	1/2 Test(s)/Kit
		GAHCG-103d/	Midstream	20 mIU/mL	1/2 Test(s)/Kit
		GAHCG-105a	Panel	25 mIU/mL	25 Tests/Kit
	Urine/Serum	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 Test(s)/Kit
		GALH-101a/	Strip	25 mIU/mL	100 Tests/Kit
LH Ovulation Test	Urine	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 Test(s)/Kit
		GALH-103b/	Midstream	40 mIU/mL	1/5 Test(s)/Kit
		GALH-103d	Midstream	30 mIU/mL	1/5 Test(s)/Kit
FSH Menopause Test	Urine	GAFSH-101a/	Strip	25 mIU/mL	100 Tests/Kit
		GAFSH-102a/	Cassette	25 mIU/mL	25 Tests/Kit
IGFBP-1 PROM Test	Cervical Secretion	GAIGF1-501a/	Strip	25 ng/mL	25 Tests/Kit
		GAIGF1-502a/	Cassette	25 ng/mL	20 Tests/Kit
Male Fertility Test	Semen	GASPE-002a/	Cassette	15M/mL	1 Test/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-402a/	Cassette	5 ng/mL	25 Tests/Kit
CRP C-Reactive Protein Semi-Quantitative Test	WB/S/P	GDGRP-402a/	Cassette	1-3-10 mg/L	25 Tests/Kit
		GDGRP-T402b/	Cassette	10-40-80 mg/L	25 Tests/Kit
D-dimer Test	WB/P	GDDDI-402b/	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	GDPC-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
		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	GDGAR-335a/	Cassette	50/5/0.5 ng/mL	25 Tests/Kit
		GDGAR-435a/	Cassette	50/5/0.5 ng/mL	25 Tests/Kit
	WB/S/P	GDGAR-W435a/	Cassette	50/5/0.5 ng/mL	20 Tests/Kit

Urinalysis

Product Description	Specimen	Format	Cut-off Value	Kit Size
Ascorbate/†	Urine	Strip	0.5-0.6 mmol/L	100 Tests/Canister
Bilirubin/†	Urine	Strip	8.6-17 µmol/L	100 Tests/Canister
Blood/†	Urine	Strip	5-15 Ery/µL	100 Tests/Canister
Ca/	Urine	Strip	2.5 mmol/L	100 Tests/Canister
Creatinine/	Urine	Strip	50 mg/dL	100 Tests/Canister
Glucose/†	Urine	Strip	2.8-5.5 mmol/L	100 Tests/Canister
Ketone/†	Urine	Strip	0.5-1.0 mmol/L	100 Tests/Canister
Leukocytes/†	Urine	Strip	5-15 Leuko/µL	100 Tests/Canister
Micro Albumin/	Urine	Strip	0.08-0.15 mg/dL	100 Tests/Canister
Nitrite/†	Urine	Strip	13-22 µmol/L	100 Tests/Canister
pH/†	Urine	Strip	0.5	100 Tests/Canister
Protein/†	Urine	Strip	0.15-0.3 g/L	100 Tests/Canister
Specific Gravity/†	Urine	Strip	0.005	100 Tests/Canister
Urobilinogen/†	Urine	Strip	3.3-16 µmol/L	100 Tests/Canister
Urinary Tract Infection Test Strip	Urine	Strip	LEU: 10-15 Leuko/µL NIT: 13-22 µmol/L	3 Tests/Kit

Tumor Marker

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-401a/	Strip	20 ng/mL	50 Tests/Kit
		GEAFP-402a/	Cassette	20 ng/mL	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-401a/	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-601Cb/	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-602Cb/	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-602j/	Cassette	10 ng/mL	20 Tests/Kit
FOB/Transferrin Combo Test	Feces	GEFOB/TF-602a/	Cassette	50/10 ng/mL	20 Tests/Kit
Nuclear Matrix Protein 22 Test	Urine	GENMP22-102a/ ^{New}	Cassette	10 U/mL	25 Tests/Kit
PSA Prostate Specific Antigen 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-401a/	Strip	4 ng/mL	50 Tests/Kit
		GEPSA-402a/	Cassette	4 ng/mL	25 Tests/Kit
PSA Prostate Specific Antigen Semi-Quantitative Test	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

Veterinary

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
		GFCDV-502a	Cassette	Gold	/	10 Tests/Kit
Canine Distemper Virus (CDV) Antigen Test	Secretions	FFCDV-502a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Canine Distemper Virus (CDV), Influenza Virus (CIV) & Adenovirus (CAV) Antigen Combo Test	Secretions	GFCDIA-532a	Cassette	Gold	/	10 Tests/Kit
Canine Influenza Virus (CIV) Antigen Test	Secretions	GFClV-502a	Cassette	Gold	/	10 Tests/Kit
Canine Parvovirus (CPV) Antigen Test	Feces	GFPCPV-602a	Cassette	Gold	/	10 Tests/Kit
		FFCPV-602a	Cassette	Fluorescence	10 IU	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
		GFFPV-602a	Cassette	Gold	/	10 Tests/Kit
Feline Parvovirus (FPV) Antigen Test	Feces	FFFPV-602a	Cassette	Fluorescence	10 IU	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

Non-Infectious Disease

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
Micro-Albumin Test	Urine	GIHSA-101a/	Strip	20 µg/mL	100 Tests/Kit
		GIHSA-102a	Cassette	20 µg/mL	25 Tests/Kit
Vaginal pH Test	Vaginal Secretion	VPH-501a ^{New}	Strip	3.8-4.4	100 Tests/Canister

Autoimmunity

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

Instrument

Product Description	Model
Urine Analyzer	Healgen 500/
Urine Analyzer	Healgen 501/
Colloidal Gold Test Reader	OG-D180
Handheld Oral Fluid Drug Test Reader	OG-D200
Multi-Function Colloidal Gold Test Reader	OG-D600
Fluorescence Immunoassay Analyzer	OG-G200
Handheld Fluorescence Immunoassay Analyzer	OG-G300
Mini Immunofluorescence Analyzer	OG-H100/
Veterinary Fluorescence Immunoassay Analyzer	OG-V100

✓CE Marked

†Cleared for US 510(k)

In Specimen column: WB: Whole Blood

S: Serum

P: Plasma



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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PRODUCT CATALOG

Enhancing
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