Toxicology Urine Test



Product Description	Format	Cut-off Value	Registration
Acetaminophen (ACE) Test	Strip/Cassette/Dip Card/Cup	5000 ng/mL	CE
Alprazolam (ALP) Test	Strip/Cassette/Dip Card/Cup	150 ng/mL	/
Amphetamine (AMP) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500/300/250 ng/mL	CE 510(k)
Barbiturates (BAR) Test	Strip/Cassette/Dip Card/Cup	2000/600/300/200 ng/mL	CE 510(k)
Benzodiazepines (BZO) Test	Strip/Cassette/Dip Card/Cup	600/400/300/200/100 ng/mL	CE 510(k)
Buprenorphine (BUP) Test	Strip/Cassette/Dip Card/Cup	10/5 ng/mL	CE 510(k)
Caffeine (CAF) Test	Strip/Cassette/Dip Card/Cup	8000 ng/mL	/
Carisoprodol (SOMA) Test	Strip/Cassette/Dip Card/Cup	1000 ng/mL	CE
Clonazepam (CLO) Test	Strip/Cassette/Dip Card/Cup	500/100 ng/mL	CE
Cocaine (COC) Test	Strip/Cassette/Dip Card/Cup	600/300/150/100 ng/mL	CE 510(k)
Codeine (COD) Test	Strip/Cassette/Dip Card/Cup	2000 ng/mL	CE
Cotinine (COT) Test	Strip/Cassette/Dip Card/Cup	400/300/200/100/50 ng/mL	CE
Ecstasy (MDMA) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500/300/250/100 ng/mL	CE 510(k)
Ethyl Glucuronide (EtG) Test	Strip/Cassette/Dip Card/Cup	500/300ng/mL	CE
Fentanyl (FEN) Test	Strip/Cassette/Dip Card/Cup	300/200/100/50/1 ng/mL	CE
Norfentanyl (FEN) Test	Strip/Cassette/Dip Card/Cup	200/50/20/10/5 ng/mL	CE
2-Fluorodeschloroketamine (FKE) Test	Strip/Cassette/Dip Card/Cup	1000 ng/mL	/
Gabapentin (GAB) Test	Strip/Cassette/Dip Card/Cup	3750/2000/1000 ng/mL	CE
Hydrocodone (HCO) Test	Strip/Cassette/Dip Card/Cup	300/10 ng/mL	CE
Hydromorphone (HMO) Test	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 510(k)
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	300/100ng/mL	CE
Methcathinone (MTC) Test	Strip/Cassette/Dip Card/Cup	500/300 ng/mL	CE
3,4-Methylenedioxypyrovalerone (MDPV) Test	Strip/Cassette/Dip Card/Cup	1000/500/300 ng/mL	CE
Methylphenidate (MPD) Test	Strip/Cassette/Dip Card/Cup	300 ng/mL	CE
6-Monoacetylmorphine (6-MAM) Test	Strip/Cassette/Dip Card/Cup	20 ng/mL	CE
Morphine (MOP) Test	Strip/Cassette/Dip Card/Cup	2/1.5/1.0 ng/mL	CE
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
Pinacol& (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 New	Strip/Cassette/Dip Card/Cup	50 ng/mL	/
Xylazine (XYL) Test New	Strip/Cassette/Dip Card/Cup	100/50 ng/mL	/
Zolpidem (ZOL) Test	Strip/Cassette/Dip Card/Cup	50 ng/mL	/
Zopiclone (ZOP) Test	Strip/Cassette/Dip Card/Cup	50 ng/mL	/
Alcohol (ALC) Test	Strip/Cassette/Dip Card/Cup	0.04%	CE

Toxicology Saliva Test




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

Toxicology Hair Test

Product Description	Format	Cut-off Value	Registration
Amphetamine (AMP) Test	Cassette	5 ng/mg	/
Barbiturates (BAR) Test	Cassette	5 ng/mg	/
Benzodiazepines (BZO) Test	Cassette	1 ng/mg	/
Caffeine (CAF) Test	Cassette	20 ng/mg	/
Cocaine (COC) Test	Cassette	5/2 ng/mg	CE
Codeine (COD) Test	Cassette	5/2 ng/mg	/
Cotinine (COT) Test	Cassette	5/2 ng/mg	/
Ecstasy (MDMA) Test	Cassette	5/2 ng/mg	/
Etomidate (ETO) Test	Cassette	5 ng/mg	/
Fentanyl (FEN) Test	Cassette	2 ng/mg	/
Ketamine (KET) Test	Cassette	2.5/2.1/1.0 .5 ng/mg	CE
Marijuana (THC) Test	Cassette	5/2/1 ng/mg	CE
Methamphetamine (MET) Test	Cassette	5/2/1 ng/mg	CE
Methcathinone (MTC) Test	Cassette	5/2/1 ng/mg	/
Methadone (MTD) Test	Cassette	2 ng/mg	/
6-Monoacetylmorphine (6-MAM) Test	Cassette	2 ng/mg	CE
Morphine (MOP) Test	Cassette	5/2/0.5 ng/mg	CE
Oxycodone (OXY) Test	Cassette	4/1 ng/mg	/
Phencyclidine (PCP) Test	Cassette	1 ng/mg	CE
Pinacol& (K3) Test	Cassette	0.5 ng/mg	/
Synthetic Marijuana (K2) Test	Cassette	5/2/1 ng/mg	/
Tramadol (TRA) Test	Cassette	5/2 ng/mg	/
UR-144 Test	Cassette	2 ng/mg	/
Xylazine (XYL) Test	Cassette	10 ng/mg	/

Powder Test

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

Instrument

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

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

Digitally signed by Dolgopol Iulian
Date: 2025.09.04 08:53:25 EEST
Reason: MoldSign Signature
Location: Moldova

Infectious Disease


Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
Adenovirus Antigen Test	Swab	GCADE-022a√	Cassette	/	20 Tests/Kit
Adenovirus Test	Feces	GCADE-402a√	Cassette	/	20 Tests/Kit
Brucella Antibody Test	WB/S/P	GCBRU-402a√	Cassette	/	25 Tests/Kit
Candida albicans Test	Vaginal Secretion	GCCDA-502a√	Cassette	10^ CFU/mL	20 Tests/Kit
Chagas Antibody Test	S/P	GCCHA-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCCHA-402a√	Cassette	/	25 Tests/Kit
Clostridium difficile GDH Test	Feces	GCCDI(GDH)-602a√	Cassette	2 ng/mL	20 Tests/Kit
Clostridium difficile Toxin A/B Test	Feces	GCCDI(Toxin A/B)-602a√	Cassette	Toxin A: 2 ng/mL; Toxin B: 2 ng/mL	20 Tests/Kit
Clostridium difficile GDH & Toxin A/B Combo Test	Feces	GCCDI-625a√	Cassette	GDH: 2 ng/mL; Toxin A: 2 ng/mL; Toxin B: 2 ng/mL	20 Tests/Kit
Chikungunya 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	/	50 Tests/Kit
Chlamydia Test	Swab/Urine	GCCHL-502a√	Cassette	4.8×10^ IFU/mL	20 Tests/Kit
CMV IgG Test	S/P	GCCMV(IgG)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCCMV(IgG)-402a	Cassette	/	25 Tests/Kit
CMV IgM Test	S/P	GCCMV(IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCCMV(IgM)-402a	Cassette	/	25 Tests/Kit
CMV IgG/IgM Test	S/P	GCCMV(IgG/IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCCMV(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
COVID-19 IgM/IgG Test	WB/S/P	GCCOV-402a√	Cassette	/	25 Tests/Kit
COVID-19 Neutralizing Antibody Test	WB/S/P	GCCOV(NAb)-402b√	Cassette	/	25 Tests/Kit
	Nasopharyngeal Swab	GCCOV-502a√	Cassette	/	20 Tests/Kit
		GCCOV-502Ca√	Cassette	/	20 Tests/Kit
COVID-19 Antigen Test		GCCOV-551a√ New	Strip	/	20 Tests/Kit
	Nasal Swab	GCCOV-502-NA√	Cassette	/	1/2/5/7/10/120 Tests/Kit
		GCCOV-553a√ New	Device	/	1/2/5/10 Tests/Kit
	NA & NP Swab	GCCOV-502-NN√	Cassette	/	20 Tests/Kit
	Oral Fluid	GCCOV-702a√	Cassette	/	20 Tests/Kit
	Nasal Swab	GCCOV-552a-Hxx√	Cassette	/	1/2/5/7/10/120 Tests/Kit
COVID-19 Antigen Self-Test		GCCOV-602a-HxxCG√	Cassette	/	1/2/5/7/10/120 Tests/Kit
	Oral Fluid	GCCOV-702a-Hxx√ New	Cassette	/	1/2/5/7/10/120 Tests/Kit
Digital COVID-19 Antigen Test	Nasal Swab	GCCOV-D-553a√ New	Reader	/	1/2/5/7/10/120 Tests/Kit
COVID-19 Antigen & B.1.1.7 Mutant Strain Combo Test	Nasal Swab	GCCOV(B.1.1.7)-523a√	Cassette	/	20 Tests/Kit
COVID-19/Flu A&B /RSV Antigen Combo Test	Nasal Swab	GCFCR-T525a√ New	Cassette	/	20 Tests/Kit
SARS-CoV-2 Delta-series Mutant Strain Antigen Test	Nasal Swab	GCCOV(DM)-T552a√	Cassette	/	20 Tests/Kit
SARS-CoV-2 Ag Fluorescence Rapid Test	Nasal Swab	FCCOV-502a√ New	Cassette	/	20 Tests/Kit
Dengue IgG/IgM Antibody Test	WB/S/P	GCDEN(IgG/IgM)-402a√	Cassette	/	25 Tests/Kit
Dengue NS 1 Antigen Test	WB/S/P	GCDEN(NS)-402c√	Cassette	/	25 Tests/Kit
Dengue NS1 & IgG/IgM Combo Test	WB/S/P	GCDEN-625a√	Cassette	/	20 Tests/Kit
EV71 IgM Test	S/P	GCEV71(IgM)-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCEV71(IgM)-402a√	Cassette	/	25 Tests/Kit
Giardia lamblia Test	Feces	GCGIA-602a√	Cassette	/	20 Tests/Kit
Gonorrhoeae Test	Swab	GCGON-502b√	Cassette	1.0E^7	20 Tests/Kit
Chlamydia/Gonorrhoeae Combo Test	Swab	GCCHN(GT)502a New	Cassette	/	20 Tests/Kit
HAV IgM Test	S/P	GCHAV(IgM)-302Ba√	Cassette	/	25 Tests/Kit
HAV IgG/IgM Test	WB/S/P	GCHAV(IgG/IgM)-402a√	Cassette	/	25 Tests/Kit
HAVAntigenTest	Feces	GCHAV-652a√	Cassette	/	25 Tests/Kit
HBcAb Hepatitis B Core Antibody Test	S/P	GCHBcb-302a	Cassette	2 NCU	25 Tests/Kit
		GCHBcb-302b	Cassette	8 NCU	25 Tests/Kit
	WB/S/P	GCHBcb-402a	Cassette	2 NCU	25 Tests/Kit
		GCHBcb-402b	Cassette	8 NCU	25 Tests/Kit
HBeAb Hepatitis B Envelope Antibody Test	S/P	GCHBeb-302a	Cassette	2 NCU	25 Tests/Kit
		GCHBeb-302b	Cassette	8 NCU	25 Tests/Kit
	WB/S/P	GCHBeb-402a	Cassette	2 NCU	25 Tests/Kit
HBsAg Hepatitis B Envelope Antigen Test	S/P	GCHBsg-302a	Cassette	0.5 NCU	25 Tests/Kit
	WB/S/P	GCHBsg-402a	Cassette	0.5 NCU	25 Tests/Kit
	S/P	GCHBsb-301a	Strip	30 mIU/mL	50 Tests/Kit
		GCHBsb-302a	Cassette	30 mIU/mL	25 Tests/Kit
HBsAb Hepatitis B Surface Antibody Test		GCHBsb-401a	Strip	30 mIU/mL	50 Tests/Kit
	WB/S/P	GCHBsb-402a	Cassette	30 mIU/mL	25 Tests/Kit
		GCHBsb-402b	Cassette	20 mIU/mL	25 Tests/Kit
	S/P	GCHBsg-301a	Strip	1 ng/mL	50 Tests/Kit
HBsAg Hepatitis B Surface Antigen Rapid Test		GCHBsg-302a	Cassette	1 ng/mL	25 Tests/Kit
		GCHBsg-401a	Strip	1 ng/mL	50 Tests/Kit
	WB/S/P	GCHBsg-402a	Cassette	1 ng/mL	25 Tests/Kit
HBsAg/HCV Combo Test	WB/S/P	GCHBC-412a	Cassette	/	25 Tests/Kit
HBsAg/HCV/HIV/Syphilis Combo Test	S/P	GCHBCSY-345a	Cassette	/	20 Tests/Kit
	WB/S/P	GCHBCSY-445a	Cassette	/	20 Tests/Kit
HBV HBsAb/HBeAb/HBcAb IgG/IgM Test	S/P	GCHBV-355a	Cassette	/	20 Tests/Kit
HBsAg Combo Test	WB/S/P	GCHBV-455a	Cassette	/	20 Tests/Kit
HCV Hepatitis C Virus Test	S/P	GCHCV-301a	Strip	/	50 Tests/Kit
		GCHCV-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCHCV-401a	Strip	/	50 Tests/Kit
		GCHCV-402a√	Cassette	2 ng/ml	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
	WB/S/P	GCHEV-402a√	Cassette	/	25 Tests/Kit
HIV 1/2 Antibody Test	S/P	GCHIV-301a	Strip	/	50 Tests/Kit
		GCHIV-302a√	Cassette	/	25 Tests/Kit
	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-3T402a	Cassette	/	25 Tests/Kit
HIV 1/2/Oantibody Test	S/P	GCHIV-T302b	Cassette	/	25 Tests/Kit
	WB/S/P	GCHIV-T402a	Cassette	/	25 Tests/Kit
HIV Antigen/Antibody Combo Test	WB/S/P	GCHIV(Ag/Ab)-402a	Cassette	/	25 Tests/Kit
HPV E7 Protein Test	Swab	GCPPV-502a New	Cassette	1 ng/mL	20 Tests/Kit
HSV IgG Test	S/P	GCHSV(IgG)-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCHSV(IgG)-402a√	Cassette	/	25 Tests/Kit
HSV IgM Test	S/P	GCHSV(IgM)-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCHSV(IgM)-402a√	Cassette	/	25 Tests/Kit
HSV IgG/IgM Test	S/P	GCHSV(IgG/IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCHSV(IgG/IgM)-402a	Cassette	/	50 Tests/Kit
H. pylori Antibody Test	S/P	GCHP-302a√	Cassette	/	25 Tests/Kit
		GCHP-401a√	Strip	/	50 Tests/Kit
	WB/S/P	GCHP-402a√	Cassette	/	25 Tests/Kit
		GCHP-401a√	Strip	/	25 Tests/Kit
H. pylori Antigen Test	Feces	GCHP-601Ca√	Strip	/	25 Tests/Kit
		GCHP-602a√	Cassette	/	20 Tests/Kit
		GCHP-602Ca√	Cassette	/	20 Tests/Kit
Influenza A Antigen Test	Nasal/Throat Swabs	GCFLU(A)-501a√	Strip	1.5 x 10^ TCID$_{50}$	25 Tests/Kit
		GCFLU(A)-502a√	Cassette	1.5 x 10^ TCID$_{50}$	20 Tests/Kit
Influenza A/B Antigen Test		GCFLU(A/B)-501a√	Strip	1.5 x 10^ TCID$_{50}$ /1.5 x 10^ TCID$_{50}$	25 Tests/Kit
	Nasal/Throat Swabs	GCFLU(A/B)-502√	Cassette	1.5x 10^ TCID$_{50}$ /1.5 x 10^ TCID$_{50}$	20 Tests/Kit
		GCFLU(A/B)-502Ca√	Cassette	1.5x 10^ TCID$_{50}$ /1.5 x 10^ TCID$_{50}$	20 Tests/Kit
Influenza & COVID-19 Antigen Combo Test	Nasopharyngeal Swab	GCFC-525a√	Cassette	/	20 Tests/Kit
	NA & NP Swab	GCFC-525a-NN√	Cassette	/	20 Tests/Kit
		GCFC-525a-NA√	Cassette	/	20 Tests/Kit
	Nasal Swab	GCFC-T502a New	Cassette	/	1/5/20 Tests/Kit
		GCFC-T512a New	Device	/	1/2/10/15/Box/Kit
Flu, COVID-19, RSV & Adeno Antigen Combo Test	Nasopharyngeal Swab	GCFCRA-545a√	Cassette	/	20 Tests/Kit
	Nasal Swab	GCFCRA-T525a√ New	Cassette	/	20 Tests/Kit
Leishmania Antibody Test	S/P	GCKAI-302a	Cassette	/	50 Tests/Kit
		GCKAI-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCKAI-401a	Strip	/	50 Tests/Kit
		GCKAI-402a	Cassette	/	25 Tests/Kit
		GCKAI-T402a	Cassette	/	25 Tests/Kit
Malaria Pan Antigen Test	Whole Blood	GCMAL(pan)-402a√	Cassette	200 parasites	25 Tests/Kit
Malaria P.f Antigen Test	Whole Blood	GCMAL(pf)-402a√	Cassette	200 parasites	25 Tests/Kit
Malaria P.f.P.Pan Antigen Test	Whole Blood	GCMAL(pf/pan)-402a√	Cassette	200 parasites	25 Tests/Kit
Malaria P.f./P.v Antigen Test	Whole Blood	GCMAL(pf/pv)-402a√	Cassette	200 parasites	25 Tests/Kit
Malaria P.f./P.v Antibody Test	WB/S/P	GCMAL(pf/pv)-Ab-402a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCMAL(pf/pv)-Ab-402a√	Cassette	/	25 Tests/Kit
Monkeypox IgG/IgM Antibody Test	WB/S/P	GCMKP-402a New	Cassette	/	25 Tests/Kit
Monkeypox Antigen Test	Throat swab or vesicle / acne swab focus swab	GCMKP-502b√ New	Cassette	/	1/2/5/7/20 Tests/Kit
Mononucleosis Test	S/P	GCMON-325a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCMON-425a√	Cassette	/	25 Tests/Kit
M. pneumonia IgM Test	S/P	GCMPI(IgM)-302a√	Cassette	/	25 Tests/Kit
Respiratory Syncytial Virus Antigen Test	Swab	GCRSV-502a√	Cassette	/	20 Tests/Kit
Rapid Check RSV Antigen Test	Swab	GCRSV-502Sa√ New	Cassette	/	20 Tests/Kit
Rotavirus Test	Feces	GCROA-602a√	Cassette	/	20 Tests/Kit
Rotavirus/Adenovirus Test	Feces	GCROA/AD6-602a√	Cassette	/	20 Tests/Kit
Rubella IgG Test	S/P	GCRUB(IgG)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCRUB(IgG)-402a	Cassette	/	25 Tests/Kit
Rubella IgM Test	S/P	GCRUB(IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCRUB(IgM)-402a	Cassette	/	25 Tests/Kit
Rubella IgG/IgM Test	S/P	GCRUB(IgG/IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCRUB(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
		GCRUB(IgG/IgM)-T402a	Cassette	/	25 Tests/Kit
Strep A Test	Throat Swab	GCSTR-551a√	Strip	/	25 Tests/Kit
		GCSTR-501Ca√	Strip	/	25 Tests/Kit
		GCSTR-502a√	Cassette	/	20 Tests/Kit
		GCSTR-502Ca√	Cassette	/	20 Tests/Kit
Syphilis Test	S/P	GCSYP-301a	Strip	/	50 Tests/Kit
		GCSYP-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCSYP-401a	Strip	/	50 Tests/Kit
		GCSYP-402a√	Cassette	/	25 Tests/Kit
S. typhi Antigen Test	S/P/Feces	GCSAL(ST)-602a√	Cassette	/	20 Tests/Kit
TOXO IgG Test	S/P	GCTOX(IgG)-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCTOX(IgG)-402a	Cassette	/	25 Tests/Kit
TOXO IgM Test	S/P	GCTOX(IgM)-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCTOX(IgM)-402a	Cassette	/	25 Tests/Kit
Toxo IgG/IgM Test	S/P	GCTOX-302b	Cassette	/	25 Tests/Kit
		GCTOX(IgG/IgM)-302a√	Cassette	/	20 Tests/Kit
	WB/S/P	GCTOX-402b	Cassette	/	25 Tests/Kit
ToRCH Toxo/Rubella/CMV/HSV IgG Combo Test	S/P	GCTOG-345a	Cassette	/	20 Tests/Kit
ToRCH Toxo/Rubella/CMV/HSV IgM Combo Test	S/P	GCTOM-345a	Cassette	/	20 Tests/Kit
Trichomonas vaginalis Test	Vaginal Swab	GCTV-502a√	Cassette	/	20 Tests/Kit
Tuberculosis IgG/IgM Test	S/P	GCTB-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCTB-402a√	Cassette	/	25 Tests/Kit
Typhoid IgG/IgM Test	S/P	GCTYP-301a	Strip	/	50 Tests/Kit
		GCTYP-302a√	Cassette	/	25 Tests/Kit
V. cholerae O1 Antigen Test	Feces	GCVCO(O1)-602a√	Cassette	/	20 Tests/Kit
V. cholerae O1/O139 Antigen Test	Feces	GCVCO(O1/O9)-602a√	Cassette	/	20 Tests/Kit
ZIKA IgM Test	WB/S/P	GCZIK(IgM)-402a	Cassette	/	25 Tests/Kit
ZIKA IgG Test	WB/S/P	GCZIK(IgG)-402a	Cassette	/	25 Tests/Kit
ZIKA NS1 Test	WB/S/P	GCZIKN301-402a	Cassette	/	25 Tests/Kit

Women's health & Fertility


Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
hCG Pregnancy Test	Urine	GAHCG-101a√	Strip	25 mIU/mL	100 Tests/Kit
		GAHCG-101b√	Strip	10 mIU/mL	100 Tests/Kit
		GAHCG-101c√	Strip	25 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 Tests/Kit
		GAHCG-103b√	Midstream	10 mIU/mL	1/2 Tests/Kit
		GAHCG-103d√	Midstream	20 mIU/mL	1/2 Tests/Kit
		GAHCG-103e√	Midstream	15 mIU/mL	1/2 Tests/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-D-103a√	Midstream	25 mIU/mL	1/2 Tests/Kit
LH Ovulation Test	Urine	GALH-101a√	Strip	25 mIU/mL	100 Tests/Kit
		GALH-101b√	Strip	40 mIU/mL	100 Tests/Kit
		GALH-101d	Strip	30 mIU/mL	100 Tests/Kit
		GALH-102a√	Cassette	25 mIU/mL	25 Tests/Kit
		GALH-103a√	Midstream	25 mIU/mL	1/5 Tests/Kit
		GALH-103b√	Midstream	40 mIU/mL	1/5 Tests/Kit
		GALH-103d	Midstream	30 mIU/mL	1/5 Tests/Kit
FSH Menopause Test	Urine	GAFSH-101a√	Strip	25 mIU/mL	100 Tests/Kit
		GAFSH-102a√	Cassette	25 mIU/mL	25 Tests/Kit
		GAFSH-103a√	Midstream	25 mIU/mL	1/5 Tests/Kit
IGFBP-1 PROM Test	Cervical Secretion	GAIGF-1-501a√	Strip	25 ng/mL	25 Tests/Kit
		GAIGF1-502a√	Cassette	25 ng/mL	20 Tests/Kit
Male Fertility Test	Semen	GASPE-902a√	Cassette	15M/mL	1 Test/Kit
Vaginal pH Test	Vaginal Secretion	VPH-501a√	Strip	3.8-4.4	25 Tests/Kit
		VPH-502a√	Cassette	3.8-4.4	20 Tests/Kit

Metabolism

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

Cardiac Marker

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

Urinalysis

Product Description	Specimen	Format	Cut-off Value	Kit Size
Ascorbate-†	Urine	Strip	0.3~0.6 mmol/L	100 Tests/Canister
Bilirubin-†	Urine	Strip	3.3~8.6 μmol/L	100 Tests/Canister
Blood-†	Urine	Strip	5~15 Ery/μL	100 Tests/Canister
Ca-‡	Urine	Strip	2.5~5 mmol/L	100 Tests/Canister
Creatinine-‡	Urine	Strip	25~75 mg/dL	100 Tests/Canister
Glucse-†	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 cells/μL	100 Tests/Canister
Micro Albumin-‡	Urine	Strip	0.08~0.15 g/L	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. 15 cells/μL NIT. 0.05 μmol/L	6/3/1 Tests/Kit

Instrument

Product Description	Model
Urine Analyzer	Healgen 500‹
Urine Analyzer	Healgen 501‹
Urine Analyzer	Healgen 800

Autoimmunity

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

Oncology

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
AFP Alpha Fetal Protein Test	S/P	GEAFP-301a	Strip	20 ng/mL	50 Tests/Kit
		GEAFP-302a	Cassette	20 ng/mL	25 Tests/Kit
	WB/S/P	GEAFP-401a‹	Strip	20 ng/mL	50 Tests/Kit
		GEAFP-402a‹	Cassette	20 ng/mL	25 Tests/Kit
BTA Bladder Tumor Antigen Test	Urine	GEBTA-102a ‹New	Cassette	/	25 Tests/Kit
CEA Carcinoembryonic Antigen Test	S/P	GECEA-301a	Strip	5 ng/mL	50 Tests/Kit
		GECEA-302a	Cassette	5 ng/mL	25 Tests/Kit
	WB/S/P	GECEA-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-604Cb‹	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-602i‹	Cassette	10 ng/mL	20 Tests/Kit
FOB /Transferrin Combo Test	Feces	GEFOBTF-402a‹ ‹New	Cassette	50/10 ng/mL	20 Tests/Kit
Nuclear Matrix Protein 22 Test	Urine	GENMP22-102a‹	Cassette	10 U/mL	25 Tests/Kit
PSA Prostate SpecificAntigen Test	S/P	GEPSA-301a‹	Strip	4 ng/mL	50 Tests/Kit
		GEPSA-302a‹	Cassette	4 ng/mL	25 Tests/Kit
	WB/S/P	GEPSA-401a‹	Strip	4 ng/mL	50 Tests/Kit
		GEPSA-402a‹	Cassette	4 ng/mL	25 Tests/Kit
PSA Prostate Specific Antigen Semi-QuantitativeTest	S/P	GEPSA-302b	Cassette	4 ng/mL, 10 ng/mL	25 Tests/Kit
	WB/S/P	GEPSA-402b	Cassette	4 ng/mL, 10 ng/mL	25 Tests/Kit
Transferrin Test	Feces	GETF-601a‹	Strip	10 ng/mL	25 Tests/Kit
		GETF-602a‹	Cassette	10 ng/mL	20 Tests/Kit

Animal Health

Product Description	Specimen	Catalog No.	Format	Label	Cut-off Value	Kit Size
Canine Adenovirus (CAV) Antigen Test	Secretions	GFCAV-502a	Cassette	Gold	/	10 Tests/Kit
Canine Coronavirus (CCV) Antigen Test	Feces	GFCCV-602a	Cassette	Gold	/	10 Tests/Kit
		FFCCV-602a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Canine Coronavirus (CCV) & Parvovirus (CPV) Antigen Combo Test	Feces	GFCCP-T602a	Cassette	Gold	/	10 Tests/Kit
		FFCCP-T602a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Canine C-Reactive Protein (cCRP) Test	WB/S/P	FFCCR-402a	Cassette	Fluorescence	10 mg/L	10 Tests/Kit
Canine Distemper Virus (CDV) Antigen Test	Secretions	GFCDV-502a	Cassette	Gold	/	10 Tests/Kit
Canine Distemper Virus (CDV), Influenza Virus (CIV) & Adenovirus (CAV) Antigen Combo Test	Secretions	GFCDA-532a	Cassette	Gold	/	10 Tests/Kit
Canine Influenza Virus (CIV) Antigen Test	Secretions	GFCIV-502a	Cassette	Gold	/	10 Tests/Kit
Canine Parvovirus (CPV) Antigen Test	Feces	GFCPV-602a	Cassette	Gold	/	10 Tests/Kit
Canine Progesterone (cProg) Test	WB/S/P	FFCPR-402a	Cassette	Fluorescence	15 ng/mL	10 Tests/Kit
Feline Calicivirus (FCV) Antigen Test	Secretions	GFFCV-502a	Cassette	Gold	/	10 Tests/Kit
		FFFCV-502a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Feline Coronavirus (FCoV) Antigen Test	Feces	GFFCO-602a	Cassette	Gold	/	10 Tests/Kit
Feline Herpes Virus (FHV) Antigen Test	Secretions	GFFHV-502a	Cassette	Gold	/	10 Tests/Kit
		FFFHV-502a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Feline Parvovirus (FPV) Antigen Test	Feces	GFFPV-602a	Cassette	Gold	/	10 Tests/Kit
		FFFPV-602a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Feline Parvovirus (FPV) & Coronavirus (FCoV) Antigen Combo Test	Feces	GFFPC-822a	Cassette	Gold	/	10 Tests/Kit
Feline Serum Amyloid A (SAA) Test	WB/S/P	FFFSA-402a	Cassette	Fluorescence	5 mg/L	10 Tests/Kit
Toxoplasma (Tgnd) IgG/IgM Test	WB/S/P	GFTOX-402a	Cassette	Gold	/	10 Tests/Kit

Instrument

Product Description	Model
Veterinary Fluorescent Immunoassay Analyzer	OG-V200
Automatic Biochemistry Analyzer	Diag-Y100

Fluorescence Immunoassay

Product Line	Product Description	Catalog No.	Specimen	Format	Cut-off Value	Kit Size	Registration
Metabolism	HbA1c Test	FHBA-402a	WB	Cassette	2-14%	10/25 Tests/Kit	CE
	25-OH VD Test	FVD-402a	WB/S/P	Cassette	5.0~100 (ng/mL	10/25 Tests/Kit	CE
	T3 Test	FKT3-402a	WB/S/P	Cassette	0.61-9.22nmol/L	10/25 Tests/Kit	CE
	T4 Test	FKT4-402a	WB/S/P	Cassette	12.87-210nmol/L	10/25 Tests/Kit	CE
	TSH Test	FKTSH-402a	WB/S/P	Cassette	0.1~100mIU/L	10/25 Tests/Kit	CE
Toxicology	Amphetamine (AMP) Test	FBAMP-1102a	Hair	Cassette	0.5 ng/mg	25 Tests/Kit	CE
		FBAMP-1102b	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	/
	Benzodiazepines (BZO) Test	FBBZO-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	/
	Cocaine (COC) Test	FBCOC-1102a	Hair	Cassette	0.5 ng/mg	25 Tests/Kit	CE
		FBCOC-1102b	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	/
	Ecstasy (MDMA) Test	FBMDM-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	CE
	2-Fluorodeschloroketamin	FBKE-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	/
	(FAC) Test	FBKE-1102b	Hair	Cassette	3 ng/mg	25 Tests/Kit	/
	Ketamine (KET) Test	FBKET-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	CE
	Lysergic acid diethylamide (LSD) Test	FBLSD-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	/
	Marijuana (THC) Test	FBTHC-1102a	Hair	Cassette	0.05 ng/mg	25 Tests/Kit	CE
	Methamphetamine (MET) Test	FBMET-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	CE
		FBMET-1102b	Hair	Cassette	0.5 ng/mg	25 Tests/Kit	/
	Methcathinone (MTC) Test	FBMTC-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	CE
	3,4-Monoacetylmorphine (6-MAM) Test	FBMAM-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	CE
	Morphine (MOP) Test	FBMOP-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	CE
	Oxycodone (OXY) Test	FBOXY-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	CE
	Phencyclidine (PCP) Test	FBPCP-1102a	Hair	Cassette	0.3 ng/mg	25 Tests/Kit	CE
	Pinacaikb (KE) Test	FBKE-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	CE
	Synthetic Marijuana (K2) Test	FBK2-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	CE
	Tramadol (TRA) Test	FBTRA-1102a	Hair	Cassette	0.2 ng/mg	25 Tests/Kit	/
	UR-144 Test	FBUR-1102a	Hair	Cassette	0.05 ng/mg	25 Tests/Kit	/
Respiratory	SARS-CoV-2 Ag Test	FCOCIV-502a	Nasal Swab	Cassette	/	20 Tests/Kit	CE
	RSV Ag Test	FCRSV-502a	Nasal Swab	Cassette	/	20 Tests/Kit	/
	Influenza A&Bag Test	FCFLUA/B)-502a	Nasal Swab	Cassette	/	20 Tests/Kit	/
Oncology	PSA Quantitative Test	FEPSA-402a	WB/S/P	Cassette	4/10 ng/mL	10/25 Tests/Kit	CE
	Procalcitonin (PCT) Test	FDPCT-402a	WB/S/P	Cassette	0.1-50 ng/mL	25 Tests/Kit	CE
	C-Reactive Protein (CRP) Test	FDCRP-402a	WB/S/P	Cassette	0.5-200 mg/L	25 Tests/Kit	CE
	Serum Amyloid A Protein (SAA) Test	FDSAA-402a	WB/S/P	Cassette	0.5-200 mg/L	25 Tests/Kit	CE
	Interleukin-6 (IL-6) Test	FDL6-402a	WB/S/P	Cassette	5-4000 pg/mL	25 Tests/Kit	CE
Cardiovascular & Inflammation	Troponin I/Myoglobin/CK-MB (cTnI/MYO/CK-MB) Combo Test	FDCAR-T402a	WB/S/P	Cassette	*cTnI: 0.1-50 ng/mL MYO: 30-900 ng/mL CK-MB: 2.5-80 ng/mL*	25 Tests/Kit	CE
	Troponin I and NT-proBNP (cTnI/NT-proBNP) Test	FDCTB-T402a	WB/S/P	Cassette	*cTnI: 0.1-50 ng/mL NT-proBNP:30-35000 pg/mL*	25 Tests/Kit	CE
	Troponin I (cTnI) Test	FDTRO-402a	WB/S/P	Cassette	0.1-50 ng/mL	25 Tests/Kit	CE
	hsTroponin I (cTnI) Test	FDTRO-4027a	WB/S/P	Cassette	0.05-50 ng/mL	25 Tests/Kit	CE
	CK-MB Test	FDCKM-402a	WB/S/P	Cassette	2.5-80 ng/mL	25 Tests/Kit	CE
	Myoglobin (MYO) Test	FDMYO-402a	WB/S/P	Cassette	30-800 ng/mL	25 Tests/Kit	CE
	NT-proBNP Test	FDBNP-402a	WB/S/P	Cassette	30-35000 pg/mL	25 Tests/Kit	CE
	D-Dimer Test	FDDDI-402a	WB/S/P	Cassette	0.1-10 mg/L	25 Tests/Kit	CE
Women's health & Fertility	b-HCG Test	FAHCG-412a	WB/S/P	Cassette	5-100 mIU/mL	25 Tests/Kit	CE
	Follicle-Stimulating Hormone (FSH) Test	FAFSH-402a	WB/S/P	Cassette	5-100000 ng/mL	25 Tests/Kit	CE

Instrument

Product Description	Model
Mini Fluorescent Immunoassay Analyzer	OG-H100
Handheld Fluorescent Immunoassay Analyzer	OG-H180
Fluorescent Immunoassay Analyzer	OG-G200
Multiplex Fluorescent Immunoassay Analyzer	OG-G290
Handheld Fluorescent Immunoassay Analyzer	OG-G300

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

HEALGEN®

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 Global Health

HEALGEN®

Urinalysis Strips

CE

SUMMARY AND INTENDED USE

The content of the instruction includes usage, reaction principle, and notification.
Urinalysis strips are intended for qualitative and semi-quantitative urinalysis and for *in vitro* diagnostics use.
The strips are for professional use only.
The strips may be read visually or instrumentally. Please read the instruction carefully before use.
There are the test items of every products type.

Products type	Packaging	Test item
URS 14	25/50/100 strips per canister	Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite, Leukocytes, Glucose, Specific Gravity, pH, and Ascorbic Acid, Microalbumin, Creatinine, Calcium
URS 13, URS 12, URS 11, URS 10, URS 9, URS 8, URS 7, URS 6, URS 5, URS 4, URS 3, URS 2, URS 1	25/50/100 strips per canister	The items of product type from URS 2 to URS 13 can be combined randomly from URS 14 test items mentioned above. US1 item can be any item from URS 14.

SPECIMEN COLLECTION AND PREPARATION

Collect fresh urine in a clean dry container. Use uncentrifuged urine and mix the sample before testing. The sample should not be more than 2 hours old at the time of testing. Always handle specimens under sanitary conditions.
Note: Water should not be used as negative control. Preservatives will not prevent the deterioration of ketones, bilirubin or urobilinogen. Bacterial growth from contaminating organisms may affect glucose, pH, nitrite and blood test results.

VISUAL READING TECHNIQUE

1. Immerse all reagent areas in specimen and remove strip immediately.
2. Run edge of strip against the rim of the container to remove excess urine.
3. Hold strip horizontally and compare test areas closely with color chart on bottle label. Record the results.

For a semi-quantitative result read the reagent areas at the time specified on the color chart. The pH and Protein areas may also be read immediately or at any time up to 60 seconds after dipping. For a qualitative result read the reagent areas between 1 and 2 minutes. If a positive result is obtained, repeat the test, reading each reagent at the time specified on the color chart.
Color changes after 2 minutes are of no diagnostic value.

INSTRUMENT READING TECHNIQUE

Follow the directions given in the appropriate instrument-operating manual.

STORAGE AND HANDLING PROCEDURES

Store only in original bottle. Do not use after expiry date. Every strip can be used only once. Do not remove desiccant(s). Do not remove strip from the bottle until immediately before it is to be used for testing. Replace cap immediately and tightly after removing reagent strip. Shelf life: 24 months. Stability period after opening: 3 months
Store at temperatures between 2℃-30℃.Don't store in refrigerator. Keep away from direct sunlight.
Do not touch test areas of reagent strips. PROTECTION AGAINST AMBIENT MOISTURE, LIGHT AND HEAT IS ESSENTIAL TO GUARD AGAINST ALTERED REAGENT REACTIVITY. Deterioration may result in discoloration or darkening of the reagent areas. If this is evident or if test results are questionable or inconsistent with expected results, confirm that strips are within the expiry dates and compare with control urine. Please deal with the waste strips according to "Treatment Regulations of Lab Biohazard Materials".

LIMITATIONS OF PROCEDURES

As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be made or based on any single result or method.

TEST PRINCIPLES

Glucose: One enzyme, glucose oxidize catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. Hydrogen peroxide releases neo-ecotypes oxide [O] under the function of peroxidase, [O] oxidates potassium. iodides chromogen, so that it makes the color change.
Bilirubin: This test is based on coupling the direct bilirubin with diazotized dichloroaniline in a strongly acid medium, which produce the diazotizing colors.
Ketone: This test is based on that acetoacetate acid react with sodium nitroprusside in an alkaline medium, producing violet color.
Specific gravity: Electrolyte (M+X-) in the form of salt in urine reacts with poly (methyl vinyl ether/maleic anhydride (-COOH), which is weakly acid ionic exchanger. And then hydrogenous ion is replaced from it and reacts with pH indicator in order to make the color change.
Blood: This test is based on the peroxidase activity of hemoglobin and myoglobin, which makes peroxide release neo-ecotypic Oxide [O]. Indicator is oxidized by [O] and shows color change subsequently.
pH: This test is based on a double indicator principle.
Protein: The test is based on the protein-error-of-indicators principle. Anion on the specific pH indicator is absorbed by cation on protein molecule, which make the indicator ionize and present color change at critical point of color.
Urobilinogen: This test is based on coupling the urobilinogen with diazotized salt in a strongly acid medium, which produce the pink-red azo dye.
Nitrite: This test depends upon the nitrite diazotize with aromatic amino sulphanilamide to form a diazonium compound. This diazonium compound in turn couples with 1,2,3,4-tetrahydro-benzo(h)quinolin-3-phenol to produce a pink color.
Leucocytes: Granulocytic leukocytes in urine contain esterase's that catalyze the hydrolysis of the privatized pyrrole amino acid ester to liberate 3-hydroxy-5-pheny pyrrole. This pyrrole then reacts with a diazonium salt to form a purple color.
Ascorbic acid: Ascorbic acid, with 1,2-dihydroxy alkenes, under alkaline condition, deoxidizes blue 2,6-dichloroindophenolate form into colorless N-(P-phenol)-2,6-dichloro–P- amine phenol.
Microalbumin: Based on the protein deviation method, utilizing the sulfone phthalein dyestuff only specific to Microalbumin.
Creatinine： Creatinine can act with 3, 5-2 nitro benzoic acid in strong alkalinity, generating colored compound.
Calcium： Calcium can with o-Cresol phthalein complex one in an alkaline medium, producing violet color.

Note:

GLUCOSE: The test is specific for glucose, no substance excreted in urine other than glucose is known to give a positive result. In dilute urine containing less than 0.28 mmol/L ascorbic acid, as little as 2.2 mmol/L glucose may produce a color change that might be interpreted as positive. Ascorbic acid concentrations of 2.8 mmol/L or greater and/or high acetoacetic concentrations (1.0 mmol/L) may influence test. Small amounts of glucose may normally be excreted by the kidney. These amounts are usually below the sensitivity of this test.
BILIRUBIN: Normally no bilirubin is detectable in urine by even the most sensitive methods. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation. Medicines that color the urine red or that are themselves red in an acid medium, e.g., phenazopyridine may influence the test. Large ascorbic acid concentration may cause false negatives.
KETONES: The test reacts with acetoacetic acid in urine. It does not react with acetone or β-hydroxybutyric acid. Normal urine specimens usually yield negative results with this reagent. False positive results may occur with highly pigmented urine specimens or those containing large amounts or levodopa metabolites.
SPECIFIC GRAVITY: The specific gravity permits determination of urine specific gravity between 1.000 and 1.030. In general, it correlates within 0.005 with values obtained with the refractive index method. For increased accuracy, 0.005 may be added to readings from urines with pH equal to or greater than 6.5. Strips read instrumentally are automatically adjusted for pH by the instrument. The SG test is not affected by certain nonionic urine constituents such as glucose or by the presence of radiopaque dye. Highly buffered alkaline urines may cause low readings relative to other methods. Elevated specific gravity readings may be obtained in the presence of moderate quantities (1-7.5 g/L) of protein.
BLOOD: The significance of the 'Trace' reaction may vary among patients, and clinical judgment is required for assessment in an individual case. Development of green spots (intact erythrocytes) or green color (free hemoglobin/ myoglobin) on the reagent area within 60 seconds indicates the need for further investigation. Blood is often found in the urine of menstruating females. Hemoglobin concentration of 150-620 μg/L is approximately equivalent to 5-15/μL intact red blood cells per microlite.
This test is highly sensitive to hemoglobin and thus complements the microscopic examination. The sensitivity of this test may be reduced in urines with high specific gravity. This test is equally sensitive to myoglobin as to hemoglobin. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction. Levels of 5.0 mmol/L ascorbic acid normally found in urine do not interfere with this test.
pH: The pH test area measures pH values generally to within 1 unit in the range of 5.0-8.5 visually and 5.0-9.0 instrumentally.

PROTEIN and MICROALBUMIN:

The Protein reagent area can detect albumin in urine and has low sensitivity to mucoprotein, generally up to 0.6 g/L concentration.

The Microalbumin reagent area is to detect the microalbumin. Beyond 0.15 g/L indicate albuminuria clinically. The Microalbumin reagent can detect specifically microalbumin, and 9 times more sensitive than other protein.
Visible blood urine (⩾0.05 g/L) can be false negative action.

UROBILINOGEN: This test area will detect urobilinogen in concentrations as low as 3 μmol/L (approximately 0.2 Ehrlich unit/dL) in urine. The normal range with this test is 3-16 μmol/L. a result of 33 μmol/L represents the transition from normal to abnormal, and the patient and/or urine specimen should be evaluated further. The absence of urobilinogen cannot be determined with this test.

NITRITE: This test depends upon the conversion of nitrate (derived from the diet) to nitrite by the action of principally Gram-negative bacteria in the urine. The test is specific for nitrite and will not react with any other substance normally excreted in urine. Pink spots or pink edges should not be interpreted as a positive result. Any degree of uniform pink color development should be interpreted as a positive nitrite test suggesting the presence of 10^5 or more organisms per mL, but color development is not proportional to the number of bacteria present. A negative result does not prove that there is no significant bacteriuria. Negative results may occur ① when urinary tract infections are caused by organisms which do not contain reductase to convert nitrate to nitrite; ② when urine has not been retained in the bladder long enough (four hours or more) for reduction of nitrate to occur, ③ or when dietary nitrate is absent. Sensitivity of the nitrite test is reduced for urines with high specific gravity. It may resist 2.8mmol/L Ascorbic Acid.

LEUKOCYTES: Test area react with esterase in leucocytes (granulocytic leukocytes). Normal urine specimens generally yield negative result; positive results (+ or greater) are clinically significant. Individually observed 'Trace' results may be of questionable clinical significance; however, 'Trace' results observed repeatedly may be clinically significant. 'Positive' results may occasionally be found with random specimens from females due to contamination of the specimen by vaginal discharge. Elevated glucose concentrations (160 mmol/L) or high specific gravity may cause decreased test results.

ASCORBIC ACID: The test area can detect the ascorbic acid in urine. Through the ascorbic acid detection, we will know the level of ascorbic acid in the body and the effect degree that the ascorbic acid brings to the test on glucose, bilirubin, blood and nitrite. It will reduce the sensitivity when the oxidant (such as potassium permanganate, hypochlorite) in the urine.

Creatinine: Adult normal urine creatinine is 0.6-2.0 g/24 hour (the Creatinine reagent area results is about 50-200 mg/dL). Result of random urine sample differ largely, from 10 mg/dL to 300 mg/dL. Concentrated urine and morning urine have high concentration (possibly over 200 mg/dL). Because of diuresis, excessive drinking water, or other urine dilution, resulting in testing analyte concentration decrease (result can be less than 50 mg/dL).

SPECIFIC PERFORMANCE CHARACTERISTICS

Specific performance characteristics are based on clinical and analytical studies. In clinical specimens, the sensitivity depends upon several factors; the variability of color perception, the presence or absence of inhibitory factors typically found in urine, specific gravity, pH, and the lighting conditions when the product is read visually. Each color block or instrumental display value represents a range of values. Because of specimen and reading variability, specimens with analyte concentrations that fall between nominal levels may give results at either level. Results at levels greater than the second positive level for the Protein, Glucose, Ketone, and Urobilinogen tests will usually be within one level of the true concentration. Exact agreement between visual results and instrumental results might not be found because of the inherent differences between the perception of the human eye and the optical system of the instruments.

Sensitivity and test range of urinalysis strips

Item	Sensitivity	Instrumental test range	Visual test range
Glucose (mmol/L)	2.8-5.5	Neg-55	
Protein (g/L)	0.15-0.3	Neg -3.0	Neg – 20.0
Microalbumin (g/L)	0.08-0.15	0-0.15	
Ketone (acetoacetic acid) (mmol/L)	0.5-1.0	Neg-7.8	Neg-16
Blood (Ery/uL)	5-15	Neg.- 200	
Bilirubin (μmol /L)	3.3-8.6	Neg.-100	
Nitrite (μmol /L)	13-22	Neg. or Pos.	
Leukocytes (cells/μL)	5-15	Neg. - 500	
Urobilinogen (μmol /L)	3.3-16	3.3-131	
Ascorbic acid (mmol/L)	0.3-0.6	0-5.0	
Creatinine (mg/dL)	25-75	10-300	
pH	——	5.0-9.0	5.0-8.5
Specific Gravity	——	1.005-1.030	1.000-1.030
Calcium (mmol/L)	2.5-3.5	2.5-10.0	2.5-10.0

REACTIVE INGREDIENTS (based on dry weight at time of impregnation)

Protein: 0.1% m/m tetrabromphenol blue; 97.4% w/w buffer; 2.5% w/w nonreactive ingredients

Blood: 26.0% w/w diisopropylbenzene dihydro peroxide; 1.5% w/w tetramethylbenzidine; 35.3% w/w buffer; 37.2 % nonreactive ingredients.

Glucose: 1.7% w/w glucose oxidase (microbial.123U); 0.2 % w/w peroxidase (horseradish. 203 IU); 0.1% w/w potassium iodide; 71.8% w/w buffer; 26.2% w/w nonreactive ingredients.

Ketone: 5.7% w/w sodium nitroprusside; 29.9% w/w nonreactive ingredients;64.4% w/w buffer;

Leukocytes: 4.3% w/w pyrrole amino acid ester; 0.4% w/w diazonium salt; 92.6% w/w buffer; 2.7% w/w nonreactive ingredients.

Nitrite: 1.3% w/w1,2,3,4-Tetrahydrobenzo(h)quinolin-3-ol; 89.6% w/w buffer; 9.1% w/w nonreactive ingredients**.**

Specific Gravity: 4.8% w/w bromothymol blue; 90.2% w/w poly (methyl vinyl ether co maleic anhydride); 5.0% w/w sodium hydroxide.

pH: 3.3% w/w bromocresol green; 55.0% w/w bromothymol blue; 41.7% w/w nonreactive ingredients.

Bilirubin: 0.6% w/w 2.4-dichlorbenzene amine diazonium salt; 57.3% w/w buffer; 42.1% w/w nonreactive ingredients.

Urobilinogen: 0.2% w/w fast B blue; 98.0% w/w buffer; 1.8% w/w nonreactive ingredients.

Ascorbic acid: 0.8% w/w 2,6-dichloroindophenolate hydrate; 40.7% w/w buffer; 58.5% w/w nonreactive ingredients.

Microalbumin: 2.2% w/w sulfone phthalein dyestuff; 96.0% w/w buffer; 1.8 w/w nonreactive ingredients.

Creatinine: 4.8% w/w 3, 5-2 nitro benzoic acid; 85.2% w/w buffer; 10% w/w nonreactive ingredients.

Calcium: 2.5% W/W o-Cresol phthalein Complex one; 87.5% w/w buffer; 10% w/w nonreactive ingredients.

INDEX OF SYMBOLS

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

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

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

Revision Date：2023-02-28
B20952-05

Reference number	Measured parameters	Reference number	Measured parameters
URS-1T-ASC	ASC	URS-4T-004	GLU-01，PH-01，SG-01，PRO-01
URS-1T-BIL	BIL	URS-4T-005	LEU-01，NIT-01，BLO-01，PH-01
URS-1T- BLO	BLO	URS-4T-006	LEU-01, NIT-01,BLO-01,PRO-01
URS-1T- CA	CA	URS-5T-001	PRO/PH/BLO/KET/GLU
URS-1T-CRE	CRE	URS-5T-002	GLU/PRO/BLO/LEU/NIT
URS-1T-GLU	GLU	URS-5T-003	GLU/KET/MA/PH/SG
URS-1T-KET	KET	URS-5T-004	GLU/PRO/PH/BLO/KET
URS-1T-LEU	LEU	URS-5T-005	MA/BLO/ASC/CRE/CA
URS-1T-MA	MA	URS-6T-001	LEU/NIT/PRO/BLO/GLU/KET
URS-1T- NIT	NIT	URS-6T-002	OXI/SG/PH/NIT/GLUT/CRE
URS-1T- PH	PH	URS-8T-001	LEU/NIT/PRO/PH/BLO/SG/KET/GLU
URS-1T-PRO	PRO	URS-9T-001	LEU/NIT/URO/PRO/PH/BLO/KET/BIL/GLU
URS-1T- SG	SG	URS-9T-002	BLO/BIL/URO/KET/PRO/NIT/GLU/PH/SG
URS-1T- URO	URO	URS-10T-001	LEU/NIT/URO/PRO/PH/BLO/SG/KET/BIL/GLU
URS-1T-ASC	ASC	URS-10T-002	LEU/NIT/URO/PRO/PH/BLO/SG/KET/BIL/GLU
URS-1T-BIL	BIL	URS-10T-003	URO/GLU/BIL/KET/SG/BLO/PH/PRO/NIT/LEU
URS-1T- BLO	BLO	URS-10T-004	LEU/NIT/URO/PRO/PH/BLO/SG/KET/BIL/GLU
URS-1T- CA	CA	URS-11T-001	LEU/NIT/URO/PRO/PH/BLO/SG/ASC/KET/BIL/GLU
URS-1T-CRE	CRE	URS-11T-002	URO/BLO/BIL/KET/LEU/GLU/PRO/PH/NIT/SG/MA
URS-2T-001	GLU/PRO	URS-11T-003	LEU/NIT/URO/PRO/PH/BLO/SG/ASC/KET/BIL/GLU
URS-2T-002	LEU/NIT	URS-11T-004	URO/BIL/KET/BLO/PRO/NIT/LEU/GLU/SG/PH/ASC
URS-2T-003	GLU/KET	URS-11T-005	31ET/URO/GLU/BIL/KET/SG/BLD/pH/PRO/NIT/LEU
URS-2T-004	pH/pH	URS-12T-001	(LEU/NIT/URO/MA/PRO/PH/BLO/SG/ASC/KET/BIL/GLU)
URS-3T-001	GLU/PRO/PH	URS-12T-002	URO/BIL/KET/BLO/PRO/MA/NIT/LEU/GLU/SG/PH/ASC
URS-3T-002	GLU/KET/PRO	URS-13T-001	LEU/NIT/URO/MA/PRO/PH/BLO/SG/ASC/CRE/KET/BIL/GLU
URS-4T-001	GLU-01，PRO-01，pH-01，BLO-01	URS-14T-001	LEU/NIT/URO/MA/PRO/PH/BLO/SG/ASC/CRE/KET/BIL/GLU/CA
URS-4T-002	PRO-01，GLU-01，pH-01，SG-01b	URS-14T-002	URO/BIL/KET/CRE/BLO/PRO/MA/NIT/LEU/GLU/SG/PH/ASC/CA
URS-4T-003	KET-01，BLO-01，BIL-01，NIT-01		

Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma)

CE

A rapid test for the Semi-Quantitative detection of Procalcitonin in whole blood, serum or plasma specimens.

For professional *in vitro* diagnostic use only.

INTENDED USE

The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is used for semi-quantitative determination and monitoring of PCT concentrations in whole blood/serum/plasma specimens.

SUMMARY

The Procalcitonin (PCT) is a peptide hormone mainly produced by the C cells of the thyroid and certain endocrine cells of the lung. Under normal expression conditions, procalcitonin is immediately cleaved into three specific fragments, an N terminal residue, calcitonin and katacalcin, Levels of unprocessed procalcitonin rise significantly after bacterial infection, trauma or shock.

The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test that semi-qualitatively detects the presence of Procalcitonin in whole blood, plasma or serum specimens at the sensitivity of 0.5ng/mL, 2ng/mL and 10ng/mL. The test utilizes a combination of monoclonal antibodies to selectively detect elevated levels of Procalcitonin in whole blood, plasma or serum. At the level of claimed sensitivity, the Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) shows no cross-reactivity interference from the structurally related CRP or others at high physiological levels.

PRINCIPLE

The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) detects Procalcitonin through visual interpretation of color development on the internal strip. Anti-PCT antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with anti-PCT antibodies conjugated to colored particles and precoated on the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If Test band 3 (T3) appears, it indicates that the PCT level in the specimen is between 0.5-2.0ng/ml. If the Test band 3 and 2 (T3 and T2) appear, it indicates that the PCT level in the specimen is between 2.0-10.0 ng/ml. If all the Test bands (T1, T2, T3), it indicates that the PCT level is above 10.0 ng/ml. The appearance of control line serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENT

The test contains anti- Procalcitonin particles and anti- Procalcitonin coated on the membrane.

MATERIALS PROVIDED

25 Sealed pouches each containing a test cassette, a dropper and a desiccant

1 Buffer, 4.0 mL

1 Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection container 2. Timer 3. Centrifuge

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to any testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.

Do not freeze.

Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

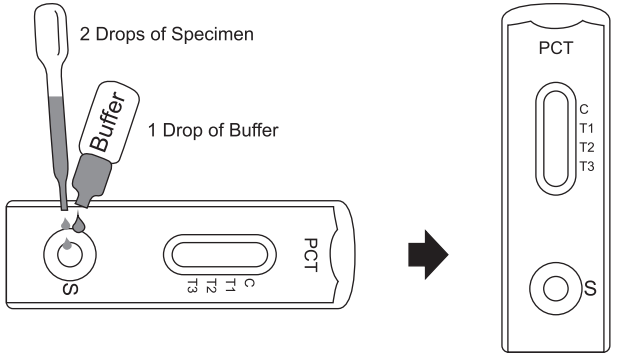
SPECIMEN COLLECTION AND PREPARATION

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

DIRECTIONS FOR USE

Bring tests, specimens, buffer, and/or controls to room temperature (15-30°C) before use.

1. Remove the test from its 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 within one hour.
2. Add **2 drops of specimen** above to the specimen well and then add **1 drop of buffer**, start the timer.
3. Wait for the colored bands to appear. The result should be **read at 10 minutes**. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

POSITIVE RESULT:

Possible Interpretation of Procalcitonin Levels

A Control band (C) and a test band (T3) appears indicates a PCT level 0.5 mg/L at least.

A Control band (C) and two test bands (T3 and T2) appear indicates a PCT level 2.0 mg/L at least.

A Control band (C) and three test bands (T1, T2 and T3) appears indicates a PCT level 10.0 mg/L at least.

NEGATIVE RESULT:

Only a Control band (C) appears and no colored band appears in the test region (T) indicates a PCT level is lower than 0.5 mg/L.

INVALID RESULT:

No Control band appears. Results from any test which has not produced Control band at the specified read 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:

1. The intensity of the color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Please note that this is a semi-quantitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. Control band appearing in the control regions is considered an internal positive procedural control, confirming 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

1. The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should only be used for the semi-quantitative detection of Patent Cooperation Treaty.
2. The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the semi-quantitative level of PCT in the specimen and should not be used as the sole criteria for evaluating inflammatory conditions.
3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. PCT values near the cut-off level Test line 3 (T3: 0.5 ng/ml), Test line 2 (T2: 2.0 ng/ml), and Test line 1 (T1: 10.0 ng/ml) should be reported with caution as with all quantitative assays there exists some level of variation. Therefore, a T line with slightly higher intensity than T1 can also represent a value slightly below 10.0 ng/ml. Similar observations may occur with values near 2.0 ng/ml and 0.5 ng/ml. A repeat test or further quantitative test is recommended in such cases.

EXPECTIED VALUES

The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial Procalcitonin EIA test, demonstrating an overall accuracy of 98.9%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) has been evaluated with a leading commercial Procalcitonin EIA test using clinical specimens. The results show that the sensitivity of the Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is 98.8% and the specificity is 99.0% relative to the leading EIA test.

Procalcitonin Semi-Quantitative Rapid Test Cassette vs. EIA

Method		**EIA Test**		Total Results
Semi-Quantitative Rapid Test Cassette	Results	Positive	Negative	
	Positive	84	2	86
	Negative	1	193	194
Total Results		85	195	280

Relative Sensitivity: 98.8%(93.6%-99.9%)*

Relative Specificity: 99.0%(96.3%-99.9%)*

Accuracy: 98.9%(96.9%-99.8%)* *95% Confidence Interval

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INDEX OF SYMBOLS

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

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

EC REP CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº 18, CP29006, Málaga, Spain
Fax: +34952330100
Email-info@cmcmedicaldevices.com

REF GDPCT-T402a

Revision Date: 2022-03-03
B23104-01

One Step Multi-Drug Screen Cassette Test (Urine) Package Insert

CE

Package insert for testing of any combination of the following drugs: Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Cotinine, Ecstasy, Ethyl Glucuronide, Fentanyl, Lysergic acid diethylamide, Marijuana, Methadone, EDDP (Methadone Metabolites), Ketamine, Methamphetamine, Methaqualone, Methylenedioxypyrovalerone, 6-Monoacetylmorphine, Morphine, Oxycodone, Phencyclidine, Propoxyphene, K2 (Synthetic Cannabinoid), Tramadol and Tricyclic Antidepressants.

A rapid, one step screening test for the simultaneous, qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Cotinine, Ecstasy, Ethyl Glucuronide, Fentanyl, Lysergic acid diethylamide, Marijuana, Methadone, EDDP (Methadone Metabolites), Ketamine, Methamphetamine, Methaqualone, Methylenedioxypyrovalerone, 6-Monoacetylmorphine, Morphine, Oxycodone, Phencyclidine, Propoxyphene, K2 (Synthetic Cannabinoid), Tramadol and Tricyclic Antidepressants and the metabolites in human urine.

For healthcare professional in vitro diagnostic use only.

INTENDED USE

Urine based Drug tests for multiple drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method to screen urine for multiple drugs of abuse.

The **One Step Multi-Drug Screen Cassette Test (Urine)** is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs, drug metabolites and alcohol at the following cut-off concentrations in urine:[1]

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	D-Amphetamine	1,000
Amphetamine (AMP)	D-Amphetamine	500
Amphetamine (AMP)	D-Amphetamine	300
Barbiturates (BAR)	Secobarbital	300
Barbiturates (BAR)	Secobarbital	200
Benzodiazepines (BZO)	Oxazepam	300
Benzodiazepines (BZO)	Oxazepam	200
Buprenorphine (BUP)	Buprenorphine	10
Cocaine (COC)	Benzoylecgonine	300
Cocaine (COC)	Benzoylecgonine	150
Cotinine (COT)	Cotinine	200
MDMA (Ecstasy)	D,L-3,4-Methylenedioxymethamphetamine (MDMA)	500
Ethyl Glucuronide (ETG)	Ethyl Glucuronide	500
Ethyl Glucuronide (ETG)	Ethyl Glucuronide	300
Fentanyl (FEN)	Fentanyl	300
Fentanyl (FEN)	Fentanyl	200
Fentanyl (FEN)	Fentanyl	100
Fentanyl (FEN)	Norfentanyl	20
Ketamine (KET)	Ketamine	1,000
Ketamine (KET)	Ketamine	100
Lysergic acid diethylamide (LSD)	D-lysergic acid diethylamide	20
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	25
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	20
Methadone (MTD)	Methadone	300
EDDP (Methadone Metabolites)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)	300
EDDP (Methadone Metabolites)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)	100
Methamphetamine (MET, mAMP)	D-Methamphetamine	1,000
Methamphetamine (MET, mAMP)	D-Methamphetamine	500
Methamphetamine (MET, mAMP)	D-Methamphetamine	300
Methaqualone (MQL)	Methaqualone	300
Methylenedioxypyrovalerone	3,4-Methylenedioxypyrovalerone	1,000
(MDPV)		
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	10
Morphine (MOP 300)	Morphine	300
Morphine (OPI, MOP 2000)	Morphine	2,000
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	300
K2 Synthetic Cannabinoid	JWH-073/JWH-018	50
K2 Synthetic Cannabinoid	JWH-073/JWH-018	25
Tramadol (TRA)	Tramadol	200
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000
Alcohol (ALC)	Ethanol	>0.04% B.A.C

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

SUMMARY

AMPHETAMINE (AMP)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use, and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

BARBITURATES (BAR)

Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence. Short acting Barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death. Only a small amount (less than 5%) of most Barbiturates are excreted unaltered in the urine.

The approximate detection time limits for Barbiturates are:

Short acting (e.g. Secobarbital) 100 mg PO (oral) 4.5 days

Long acting (e.g. Phenobarbital) 400 mg PO (oral) 7 days.

BENZODIAZEPINES (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal. Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception. Only trace amounts (less than 1%) of most Benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for the Benzodiazepines in the urine is 3-7 days.

BUPRENORPHINE (BUP)

Buprenorphine is a semisynthetic opioid analgesic derived from thebain, a component of opium. It has a longer duration of action than morphine when indicated for the treatment of moderate to severe pain, peri-operative analgesia, and opioid dependence. Low doses buprenorphine produces sufficient agonist effect to enable opioid-addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms. Buprenorphine carries a lower risk of abuse, addiction, and side effects compared to full opioid agonists because of the "ceiling effect", which means no longer continue to increase with further increases in dose when reaching a plateau at moderate doses. However, it has also been shown that Buprenorphine has abuse potential and may itself cause dependency. Subutex® and a Buprenorphine/Naloxone combination product, Suboxone® are the only two forms of Buprenorphine that have been approved by FDA in 2002 for use in opioid addiction treatment. Buprenorphine was rescheduled from Schedule V to Schedule III drug just before FDA approval of Suboxone and Subutex.

COCAINE (COC)

Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as Benzoylecgonine.[1,2] Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.[2]

COTININE (COT)

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%.[1] While cotinine is thought to be an inactive metabolite, it's elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration.[2] Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2-3 days after nicotine use.

MDMA (ECSTASY)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

ETHYL GLUCURONIDE (ETG)

Ethyl Glucuronide (EtG) is a direct metabolite of ethanol alcohol. The presence of EtG in the urine can be used to detect recent alcohol consumption, even after the ethanol alcohol is no longer measurable. Consequently, the presence of EtG in the urine is a definitive indicator that alcohol has been ingested. Traditional laboratory practices typically measure the amount of alcohol present in the body. Depending on the amount of alcohol that has been consumed, this method usually reveals alcohol ingestion within the past few hours.

The presence of EtG in the urine, on the other hand, demonstrates that ethanol alcohol was ingested within the past three or four days, or roughly 80 hours after the ethanol alcohol has been metabolized by the body. As a result, it can be determined that a urine alcohol test employing EtG is a more accurate indicator of the recent consumption of alcohol as opposed to simply measuring for the existence of ethanol alcohol.

FENTANYL (FEN)

Fentanyl is a synthetic opioid. It has the brand names of Sublimaze, Actiq, Durogestic, Fentora and others. The Fentanyl drug is approximately 100 times more potent than morphine, with 100 micrograms of fentanyl approximately equivalent to 10 mg. of morphine or 75 mg. of meperidine in analgesic activity. The Fentanyl drug is a potent narcotic analgesic with rapid onset and short duration of action. Historically, the fentanyl drug has been used to treat chronic breakthrough pain and is commonly used pre-procedures. Illicit use of pharmaceutical fentanyl drugs first appeared in the mid-1970s. Because the effects of the fentanyl drug last for only a very short time, it is even more addictive than heroin. Regular users may become addicted very quickly. The Fentanyl drug is much more potent than heroin, and tends to produce significantly worse respiratory depression, making it somewhat more dangerous than heroin to users. Overdose of the fentanyl drug has caused death. In the United States, the fentanyl drug is classified as a Schedule II controlled substance.

KETAMINE (KET)

Ketamine is a short-acting "dissociative" anesthetic due to its ability to separate perception from sensation. It also has hallucinogenic and painkilling qualities that seem to affect people in very different ways. Ketamine is chemically related to PCP ('Angel Dust'). Ketamine is occasionally administered to people but, more commonly, is used by vets for pet surgery. Generally street K is

most often diverted in liquid form from vets' offices or medical suppliers. Ketamine generally takes 1-5 minutes to take effect. Snorted ketamine takes a little longer at 5-15 minutes. Depending on how much and how recently one has eaten, oral ketamine can take between 5 and 30 minutes to take effect. The primary effects of ketamine last approximately a 30-45 minutes if injected, 45-60 minutes when snorted, and 1-2 hours if used orally. The Drug Enforcement Administration reports that the drug can still affect the body for up to 24 hours.

LYSERGIC ACID DIETHYLAMIDE (LSD)

D-lysergic acid diethylamide (LSD) is the most potent hallucinogenic substance known to man. Dosages of LSD are measured in micrograms, or millionths of a gram. By comparison, dosages of cocaine and heroin are measured in milligrams, or thousandths of a gram. Compared to other hallucinogenic substances, LSD is 100 times more potent than psilocybin and psilocin and 4,000 times more potent than mescaline. The dosage level that will produce a hallucinogenic effect in humans generally is considered to be 25 micrograms. Over the past several years, the potency of LSD obtained during drug law enforcement operations has ranged between 20 and 80 micrograms per dosage unit. The Drug Enforcement Administration (DEA) recognizes 50 micrograms as the standard dosage unit equivalency.

MARIJUANA (THC)

THC (Δ^9-tetrahydrocannabinol) is the primary active ingredient in cannabinoids (marijuana). When smoked or orally administered, it produces euphoric effects. Users have impaired short term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long term relatively heavy use may be associated with behavioral disorders. The peak effect of smoking marijuana occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid (Δ^9-THC-COOH).

METHADONE (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of Morphine dependence (heroin, Vicodin, Percocet, Morphine). The pharmacology of Oral Methadone is very different from IV Methadone. Oral Methadone is partially stored in the liver for later use. IV Methadone acts more like heroin. In most states you must go to a pain clinic or a Methadone maintenance clinic to be prescribed Methadone. Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, Methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from Methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.

EDDP

EDDP is the primary metabolite of methadone. Methadone is a controlled substance and is used for detoxification and maintenance of opiate-dependent patients. Patients on methadone maintenance may exhibit methadone (parent) levels that account for 5-50% of the dosage and 3-25% of EDDP in urinary excretion during the first 24 hours. The tampering of specimens by spiking the urine with methadone can be prevented. Also, renal clearance of EDDP is not affected by urinary pH; therefore the EDDP test provides a more accurate result of methadone ingestion than the methadone test. Methadone is an unusual drug in a sense that its primary urinary metabolites (EDDP and EMDP) are cyclic in structure. Thus, they are very difficult to detect with immunoassays targeted to the native compound. Exacerbating this problem, there is a subsection of the population classified as "extensive metabolizers" of methadone. In these individuals, a urine specimen may not contain enough parent methadone to yield a positive drug screen even if the individual is in compliance with their methadone maintenance.

METHAMPHETAMINE (MET, mAMP)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulaDtion of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion. The effects of Methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine as amphetamine and oxidized and delaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use.

METHAQUALONE (MQL)

Methaqualone (Quaalude, Sopor) is a quinazoline derivative that was first synthesized in 1951 and found clinically effective as a sedative and hypnotic in 1956. It soon gained popularity as a drug of abuse and in 1984 was removed from the US market due to extensive misuse. It is occasionally encountered in illicit form, and is also available in Europeon countries in combination with diphenhydramine (Mandrax). Methaqualone is extensively metabolized in vivo principally by hydroxylation at every possible position on the molecule. At least 12 metabolites have been identified in the urine.

METHYLENEDIOXYPYROVALERONE (MDPV)

Bath salts', a form of designer drugs, also promoted as 'plant food' or 'research chemicals', is sold mainly in head shops, on the Internet, and at other retail locations. Designer drugs were developed in recent years to subvert law enforcement and drug testing agencies and are advertised a'legal'highs. The technical term for 'bath salts' is substituted cathinone. Substituted cathinone is synthetic, concentrated version of the stimulant chemical in Khat. Khat is a plant that is cultivated and used in East Africa and the Middle East. It has a stimulant effect on the user and can be quite dangerous. The white crystals resemble legal bathing salts, thus the name of 'bath salts'. In 2009 and 2010 there was a significant rise in the abuse of synthetic cathinone, initially in the United Kingdom and the rest of Europe, and subsequently in the US and Canada,

Established as one of the main ingredients for 'bath salts', among other synthetic stimulants like Mephedrone, Methylone, Butylone and Methedrone, MDPV started appearing around 2004 when it was popularized as a club drug, often used in combination with alcohol, GHB, cannabis and other abused drugs, for its desired effects such as euphoria, alertness, talkativeness, and sexual arousal. There are currently no prescribed used for the synthetic stimulants.

While synthetic stimulants appear to affect users in ways similar to amphetamines, ecstasy and cocaine, reports concerning aggression, tachycardia, paranoia and suicide suggest that they may be more acutely toxic. These negative effects have resulted in an increase of ER visits and hospitalizations, severe psychotic and violent episodes, self-inflicted wounds, suicide and an alarming increase in abuse-related deaths. U.S. Poison Control and National Drug Intelligence have all issued health warnings, noting nationwide emergency room visits related to these drugs. In October 2011, the DEA announced an emergency ban on MDPV, Methylone and Mephedrone, making testing for these substances more vital than ever.

6-MONOACETYLMORPHINE (6-MAM)

6-Monoacetylmorphine (6-MAM) is one of three active metabolites of heroin (diacetylmorphine), the others being morphine and the much less active 3-acetylmorphine (3-ACM). 6-MAM is rapidly created from heroin in the body, and then is either metabolized into morphine or excreted in the urine. Since 6-ACM is a unique metabolite to heroin, its presence in the urine confirms that heroin was the opioid used. This is significant because on a urine immunoassay drug screen, the test typically tests for morphine, which is a metabolite of a number of legal and illegal opiates/opioids such as codeine, morphine sulphate, and heroin. 6-MAM remains in the urine for no more than 24 hours so a urine specimen must be collected soon after the last heroin use, but the presence of 6-MAM guarantees that heroin was in fact used as recently as within the last day.

MORPHINE (MOP)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor. Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.[4]

OXYCODONE (OXY)

Oxycodone, [4,5-epoxy-14-hydroxy-3-methoxy-17-methyl-morphinan-6-one, dihydrohydroxycodeinone] is a semi-synthetic opioid agonist derived from thebaine, a constituent of opium. Oxycodone is a Schedule II narcotic analgesic and is widely used in clinical medicine. The pharmacology of oxycodone is similar to that of morphine, in all respects, including its abuse and dependence liabilities. Pharmacological effects include analgesia, euphoria, feelings of relaxation, respiratory depression, constipation, papillary constriction, and cough suppression. Oxycodone is prescribed for the relief of moderate to high pain under pharmaceutical trade names as OxyContin® (controlled release), OxyIR®, OxyFast® (immediate release formulations), or Percodan® (aspirin) and Percocet® (acetaminophen) that are in combination with other nonnarcotic analgesics. Oxycodone's behavioral effects can last up to 5 hours. The controlled-release product, OxyContin®, has a longer duration of action (8-12 hours).

PHENCYCLIDINE (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations. Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of Phencyclidine. PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.[5] Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).

PROPOXYPHENE (PPX)

Propoxyphene (PPX) is a mild narcotic analgesic found in various pharmaceutical preparations, usually as the hydrochloride or napsylate salt. These preparations typically also contain large amounts of acetaminophen, aspirin, or caffeine. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels. In human, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

SYNTHETIC MARIJUANA (K2)

Synthetic Marijuana or K2 is a psychoactive herbal and chemical product that, when consumed, mimics the effects of Marijuana. It is best known by the brand names K2 and Spice, both of which have largely become genericized trademarks used to refer to any synthetic Marijuana product. The studies suggest that synthetic marijuana intoxication is associated with acute psychosis, worsening of previously stable psychotic disorders, and also may have the ability to trigger a chronic (long-term) psychotic disorder among vulnerable individuals such as those with a family history of mental illness.

Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 72 hours after smoking (depending on usage/dosage).

As of March 1, 2011, five cannabinoids, JWH-018, JWH-073, CP-47, JWH-200 and cannabicyclo hexanol are now illegal in the US because these substances have the potential to be extremely harmful and, therefore, pose an imminent hazard to the public safety. JWH-018 was developed and evaluated in basic scientific research to study structure activity relationships related to the cannabinoid receptors. JWH-073 has been identified in numerous herbal products, such as "Spice", "K2", K3" and others. These products may be smoked for their psychoactive effects.

TRAMADOL (TRA)

Tramadol is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine, but has a low binding affinity to the mu-opioid receptors. It has been prescribed off-label for the treatment of diabetic neuropathy and restless leg syndrome.[2] Large doses of Tramadol could develop tolerances and physiological dependency and lead to its abuse. Both Δ (d) and L forms of the isomers are controlled substances. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% is excreted as metabolites. The major pathways appear to be N- and O- demethylation, glucoronidation or sulfation in the liver.

TRICYCLIC ANTIDEPRESSANTS (TCA)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

ALCOHOL (ALC)

Excess or inappropriate consumption of alcohol is a common and pervasive social problem. It is a contributory factor to many accidents, injuries and medical conditions. Screening of individuals for alcohol consumption is an important method for the identification of individuals who might be at risk due to alcohol use or intoxication. Screening is also an important deterrent against inappropriate alcohol consumption. The blood alcohol concentration at which a person becomes impaired is variable dependent on the individual. Parameters specific to the individual such as physical size, weight, activity level, eating habits and alcohol tolerance all affect the level of impairment. Determination of ethyl alcohol in urine, blood and saliva is commonly used for measuring legal impairment, alcohol poisoning, etc. Gas chromatography techniques and enzymatic methods are commercially available for the determination of ethyl alcohol in human fluids. Alcohol Test is designed to detect ethyl alcohol in urine specimens.

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) SUMMARY

The Adulterant Test Strip contains chemically treated reagent pads. Observation of the color change on the strip compared to the color chart provides a semi-quantitative screen for Oxidants, Specific Gravity, pH, Creatinine, Nitrite and Glutaraldehyde in human urine which can help to assess the integrity of the urine specimen.

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants in the urine specimen can cause false negative results by either interfering with the test and/or destroying the drugs present in the urine. Dilution may also be used to produce false negative drug test results. To determine certain urinary characteristics such as specific gravity and pH, and to detect the presence of oxidants, Nitrite, Glutaraldehyde and Creatinine in urine are considered to be the best ways to test for adulteration or dilution.

- **Oxidants (OX)**: Tests for the presence of oxidizing agents such as bleach and peroxide in the urine.
- **Specific Gravity (S.G.)**: Tests for sample dilution. Normal levels for specific gravity will range from 1.003 to 1.030. Specific gravity levels of less than 1.003 or higher than 1.030 may be an indication of adulteration or specimen dilution.
- **pH:** tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in

the range of 4.0 to 9.0. Values below pH 4.0 or above pH 9.0 may indicate the sample has been altered.

- **Nitrite (NIT)**: Tests for commercial adulterants such as Klear and Whizzies. Normal urine specimens should contain no trace of nitrite. Positive results for nitrite usually indicate the presence of an adulterant.
- **Glutaraldehyde (GLU):** Tests for the presence of an aldehyde. Glutaraldehyde is not normally found in a urine specimen. Detection of glutaraldehyde in a specimen is generally an indicator of adulteration.
- **Creatinine (CRE):** Creatinine is one way to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine may indicate dilute urine.

PRINCIPLE

(1) The **One Step Multi-Drug Screen Cassette Test (Urine)** is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody coated on the particles. The antibody coated particles will then be captured by the immobilized drug conjugate and a visible colored line will show up in the test line region of the specific drug strip. The colored line will not form in the test line region if the drug level is above its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

(2) Alcohol Test: A pad coated with enzymes, turns to color shades of green and blue on contact with alcohol in urine. The alcohol pad employs a solid phase chemistry which uses the following highly specific enzymatic reaction:

$$CH_3CH_2OH + O_2 \xrightarrow{\text{Alcohol Oxidase}} CH_3CHO + H_2O_2$$

$$H_2O_2 + DH_2 \xrightarrow[\text{Blue}]{\text{Peroxidase}} D + 2H_2O$$

REAGENTS

Each test line in the test panel contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

ADULTERANT TESTS (SPECIMEN VALIDITY TEST) REAGENTS

Adulteration Pad	Reactive Indicator	Buffers and Non-reactive Ingredients
Oxidants (OX)	0.30%	99.70%
Specific Gravity (S.G.)	0.21%	99.79%
pH	0.06%	99.94%
Nitrite (NIT)	0.06%	99.94%
Glutaraldehyde (GLU)	0.02%	99.98%
Creatinine (CRE)	0.03%	99.97%

PRECAUTIONS

- For healthcare professional *in vitro* diagnostic use only.
- Do not use after the expiration date.
- The test dip card should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test dip card should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test dip card is stable through the expiration date printed on the sealed pouch. The test dip card must remain in the sealed pouch until use. Keep away from direct sunlight, moisture and heat. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

MATERIALS

Materials Provided

1. 25 Sealed pouches each containing a test dip card and a desiccant
2. 1 Package insert
3. 2 Color Chart Cards for Adulterant Interpretation (when applicable)
4. 2 Color Chart Cards for Alcohol (when applicable)

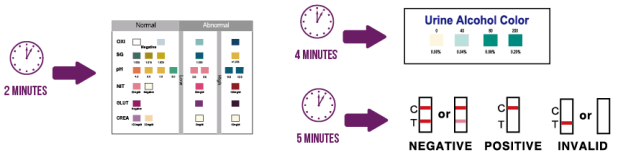
Materials Required But Not Provided

- Timer

DIRECTIONS FOR USE

Allow the test dip card, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.

1) Remove the test dip card from the foil pouch.
2) Remove the cap from the test dip card. Label the dip card with patient or control identifications.
3) Immerse the absorbent tip into the urine sample for 10-15 seconds. Urine sample should not touch the plastic dip card.
4) Replace the cap over the absorbent tip and lay the dip card flatly on a non-absorptive clean surface.
5) Read the adulteration strip at 2 minutes by comparing the colors on the adulteration strip to the enclosed color chart. If the result indicates adulteration, do not interpret the drug test results. Either retest the urine or collect another specimen.
6) Read the alcohol strip in 4 minutes by comparing the colors on the alcohol strip to the enclosed color chart.
7) Read the drug strip results at 5 minutes. **DO NOT INTERPRET RESULT AFTER 5 MINUTES.**



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* Two lines appear. One red line should be in the control region (C), and another apparent red or pink line adjacent should be in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level.

*NOTE: The shade of red in the test line region (Drug/T) will vary, but it should be considered negative whenever there is even a faint pink line.

POSITIVE: One red line appears in the control region (C). No line appears in the test region (Drug/T). This positive result indicates that the drug concentration is above the detectable level.

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 using a new test panel. If the problem persists, discontinue using the lot immediately and contact your manufacturer.

Note: There is no meaning attributed to line color intensity or width.

A preliminary positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

IMPORTANT: The result you obtained is called preliminary for a reason. The sample must be tested by laboratory in order to determine if a drug of abuse is actually present. Send any sample which does not give a negative result to a laboratory for further testing.

What Is A False Positive Test?

The definition of a false positive test would be an instance where a substance is identified incorrectly by One Step Multi-Drug Screen Test Dip Card (Urine). The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What Is A False Negative Test?

The definition of a false negative test is that the initial substance is present but isn't detected by One Step Multi-Drug Screen Test Dip Card (Urine). If the sample is diluted, or the sample is adulterated that may cause false negative result.

ALCOHOL/ADULTERANT INTERPRETATION

(Please refer to the color chart)

Semi-quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the color chart. No instrumentation is required.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. The One Step Multi-Drug Screen Cassette Test (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result might be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

80 clinical urine specimens were analyzed by GC-MS and by the **One Step Multi-Drug Screen Cassette Test (Urine)**. Each test was performed by three operators. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Specimen	AMP	AMP 500	AMP 300	BAR	BAR 200	BUP	BZO
Positive	91.7%	95.8%	96.7%	95.0%	94.2%	93.3%	91.7%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	95.8%	97.9%	98.3%	97.5%	97.1%	96.7%	95.8%

Specimen	BZO 200	COC	COC 150	COT	EDDP	EDDP 100	ETG
Positive	92.5%	95.8%	95.0%	92.5%	94.2%	93.3%	95.0%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	96.3%	97.9%	97.5%	96.3%	97.1%	96.7%	97.5%

Specimen	ETG 300	FEN	FEN 200	FEN 100	FEN 20	K2	K2 25
Positive	95.8%	97.5%	95.8%	93.3%	97.5%	93.3%	95.8%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	97.9%	98.8%	97.9%	96.7%	98.8%	96.7%	97.9%

Specimen	KET	KET 100	LSD	MET	MET 500	MET 300	MDMA
Positive	95.8%	91.7%	91.7%	95%	95.8%	95.8%	95.0%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	97.9%	95.8%	95.8%	97.5%	97.9%	97.9%	97.5%

Specimen	MOP	MQL	6-MAM	MTD	OPI	OXY	PCP
Positive	96.7%	91.7%	92.5%	95.0%	88.3%	93.3%	91.7%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	98.3%	95.8%	96.3%	97.5%	94.2%	96.7%	95.8%

Specimen	PPX	THC	THC 25	THC 20	TCA	TRA	MDPV
Positive	95.0%	95.8%	94.2%	91.7%	95.0%	93.3%	94.2%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	97.5%	97.9%	97.1%	95.8%	97.5%	96.7%	97.1%

Analytical Sensitivity

Total 150 samples equally distributed at concentrations of -50% Cut-Off; -25% Cut-Off; Cut-Off; +25% Cut-Off; +50% Cut-Off were tested using three different lots of each dip card by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for Methamphetamine, Amphetamine, Cocaine, Morphine, Ecstasy, EDDP (Methadone Metabolites), Tricyclic Antidepressants, Oxycodone, Barbiturates, Buprenorphine, Phencyclidine, K2 (Synthetic Cannabinoid), Ketamine, Methaqualone, Methadone, Fentanyl, Tramadol, Ethyl Glucuronide, Cotinine, 6-Monoacetylmorphine, Methylenedioxypyrovalerone, Lysergic acid diethylamide, Marijuana and Benzodiazepines. The cut-off value for the dip card is verified.

Analytical Specificity

The following table lists compounds that are positively detected in urine by the **One Step Multi-Drug Screen Cassette Test (Urine)** at 5 minutes.

Drug	Concentration (ng/mL)
AMPHETAMINE (AMP)	
D-Amphetamine	1,000
D,L - Amphetamine (Amphetamine Sulfate)	1,000
Phentermine	1,250
(+/-)-4-Hydroxyamphetamine HCL	600
L-Amphetamine	20,000
3,4-Methylenedioxyamphetamine HCl (MDA)	1,500
d-Methamphetamine	>100,000 ng/mL
1-Methamphetamine	>100,000 ng/mL
ephedrine	>100,000 ng/mL
3,4-Methylenedioxyethylamphetamine (MDE)	>100,000 ng/mL
3,4-methylenedioxy-methamphetamine (MDMA)	>100,000 ng/mL
AMPHETAMINE (AMP 500)	
D-Amphetamine	500
D,L-Amphetamine	750
L-Amphetamine	16,000
Phentermine	650
(+/-)-Methylenedioxyamphetamine (MDA)	800
d-Methamphetamine	>100,000
1-Methamphetamine	>100,000
ephedrine	>100,000
3,4-Methylenedioxyethylamphetamine (MDE)	>100,000
3,4-methylenedioxy-methamphetamine (MDMA)	>100,000
AMPHETAMINE (AMP 300)	
D-Amphetamine	300
D,L-Amphetamine	450
L-Amphetamine	9,000
Phentermine	450
(+/-)-Methylenedioxyamphetamine (MDA)	600
BARBITURATES (BAR)	
Secobarbital	300
Amobarbital	300
Alphenal	750
Aprobarbital	250
Butabarbital	2,500
Butethal	2,500
Cyclopentobarbital	500
Pentobarbital	2,500
Phenobarbital	25,000
BARBITURATES (BAR 200)	
Secobarbital	200
Amobarbital	200
Alphenal	500
Aprobarbital	200
Butabarbital	2,000
Butethal	2,000
Butalbital	2,000
Cyclopentobarbital	300
Pentobarbital	2,000
BENZODIAZEPINES (BZO)	
Alprazolam	200
Bromazepam	1,560
Chlordiazepoxide HCL	1,560
Clobazam	100

Drug	Concentration (ng/mL)
Clonazepam	780
Clorazepate Dipotassium	200
Delorazepam	1,560
Desalkylflurazepam	400
Diazepam	200
Estazolam	2,500
Flunitrazepam	400
a-Hydroxyalprazolam	1260
(±) Lorazepam	1,560
RS-Lorazepam glucuronide	160
Midazolam	12,500
Nitrazepam	100
Norchlordiazepoxide	200
Nordiazepam	400
Oxazepam	300
Temazepam	100
Triazolam	2,500
BENZODIAZEPINES (BZO200)	
Alprazolam	200
Bromazepam	1,000
Chlordiazepoxide HCL	1,000
Clobazam	80
Clonazepam	500
Clorazepate Dipotassium	100
Delorazepam	1,000
Desalkylflurazepam	300
Diazepam	100
Estazolam	2,000
Flunitrazepam	300
a-Hydroxyalprazolam	840
(±) Lorazepam	1,000
RS-Lorazepam glucuronide	100
Midazolam	10,000
Nitrazepam	100
Norchlordiazepoxide	100
Nordiazepam	300
Oxazepam	200
Temazepam	800
Triazolam	2,000
BUPRENORPHINE (BUP)	
Buprenorphine	10
Norbuprenorphine	20
COCAINE (COC)	
Benzoylecogonine	300
Cocaethylene	300
Cocaine HCl	300
COCAINE (COC 150)	
Benzoylecogonine	150
Cocaethylene	2,500
Cocaine	500
Ecgonine	12,500
Ecgonine methylester	50,000
COTININE (COT)	
Cotinine	200

Drug	Concentration (ng/mL)
Nicotine	6,250
MDMA (ECSTASY)	
D,L-3,4-Methylenedioxymethamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethyla-amphetamine (MDEA)	300
d-methamphetamine	2500
d-amphetamine	>100,000
l-amphetamine	>100,000
l-methamphetamine	>100,000
ETHYL GLUCURONIDE (EtG 500)	
Ethyl-β-D-glucuronide	500
Ethyl-β-D-glucuronide-D5	500
ETHYL GLUCURONIDE (EtG 300)	
Ethyl-β-D-glucuronide	300
Ethyl-β-D-glucuronide-D5	300
FENTANYL (FEN)	
Norfentanyl	20
Fentanyl	300
FENTANYL (FEN20)	
Norfentanyl	20
Fentanyl	300
FENTANYL (FEN200)	
Norfentanyl	15
Fentanyl	200
Sufentanyl	50,000
Fenfluramine	50,000
FENTANYL (FEN 100)	
Norfentanyl	10
Fentanyl	100
Buspirone	>100,000
Sufentanyl	25,000
Fenfluramine	25,000
KETAMINE (KET)	
Ketamine	1,000
Norketamine	3,000
Methoxy-amphetamine	12,500
Promethazine	25,000
4-hydroxyphenyl cyclohexyl piperidine	50,000
KETAMINE (KET 100)	
Ketamine	100
Norketamine	100
Methoxy-amphetamine	1,250
Promethazine	2,500
4-hydroxyphenyl cyclohexyl piperidine	5,000
LYSERGIC ACID DIETHYLAMIDE (LSD)	
D-lysergic acid diethylamide	20
Fentanyl	75
Norfentanyl	300

Drug	Concentration (ng/mL)
MARIJUANA (THC)	
Delta-9-Tetrahydrocannabinol	50,000
11-nor-delta-9-THC-carboxyglucuronide	75
(-)-11-nor-9-carboxy-delta9-THC	75
11-Nor-Δ^9-Tetrahydrocannabinol	50
11-Hydroxy-Δ^9-Tetrahydrocannabinol	5,000
11-Nor-Δ^8-Tetrahydrocannabinol	50
Δ^8-THC-COOH	50,000
MARIJUANA (THC 25)	
Delta-9-Tetrahydrocannabinol	25,000
11-nor-delta-9-THC-carboxyglucuronide	37.5
(-)-11-nor-9-carboxy-delta9-THC	37.5
11-Nor-Δ^9-Tetrahydrocannabinol	25
11-Hydroxy-Δ^9-Tetrahydrocannabinol	2,500
11-Nor-Δ^8-Tetrahydrocannabinol	25
Δ^8-THC-COOH	25,000
MARIJUANA (THC 20)	
Delta-9-Tetrahydrocannabinol	20,000
11-nor-delta-9-THC-carboxyglucuronide	30
(-)-11-nor-9-carboxy-delta9-THC	30
11-Nor-Δ^9-Tetrahydrocannabinol	20
11-Hydroxy-Δ^9-Tetrahydrocannabinol	2,000
11-Nor-Δ^8-Tetrahydrocannabinol	20
Δ^8-THC-COOH	20,000
METHADONE (MTD)	
Methadone	300
Doxylamine	5,000
EDDP (Methadone Metabolites)	
EDDP	300
Disopyramide	50,000
Methadone	>100,000
EMDP	500
EDDP100 (Methadone Metabolites)	
EDDP	100
Disopyramide	20,000
Methadone	>100,000
EMDP	200
METHAMPHETAMINE (mAMP)	
D-Methamphetamine	1,000
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	20,000
Procaine (Novocaine)	60,000
Trimethobenzamide	20,000
Methamphetamine	1,000
Ranitidine (Zantac)	50,000
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	2,500
Chloroquine	50,000
Ephedrine	100,000
Fenfluramine	50,000
p-Hydroxymethamphetamine	10,000
METHAMPHETAMINE (MET 500)	
p-Hydroxymethamphetamine	15,000
l-Methamphetamine	4,000

Drug	Concentration (ng/mL)
Mephentermine	25,000
d,l-Amphetamine	75,000
(1R,2S)-(-)-Ephedrine	50,000
β-Phenylethylamine	75,000
d-Methamphetamine	500
3,4-Methylenedioxymethamphetamine (MDMA)	1,000
d-Amphetamine	50,000
Chloroquine	12,500
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	20,000
Procaine (Novocaine)	50,000
Trimethobenzamide	20,000
Ranitidine (Zantac)	50,000
Fenfluramine	50,000
METHAMPHETAMINE (MET 300)	
p-Hydroxymethamphetamine	10,000
l-Methamphetamine	3,000
Mephentermine	15,000
d,l-Amphetamine	50,000
(1R,2S)-(-)-Ephedrine	50,000
β-Phenylethylamine	50,000
d-Methamphetamine	300
3,4-Methylenedioxymethamphetamine (MDMA)	1,000
d-Amphetamine	30,000
Chloroquine	7,500
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	12,000
Procaine (Novocaine)	30,000
Trimethobenzamide	12,000
Ranitidine (Zantac)	30,000
Fenfluramine	30,000
METHAQUALONE (MQL)	
Methaqualone	300
METHYLENEDIOXYPYROVALERONE (MDPV)	
3,4-Methylenedioxypyrovalerone	1,000
Ethylone HCl	1,200
Methylone	50,000
Pyrovalerone	50,000
6-MONOACETYLMORPHINE (6-MAM)	
6-Moonacetylmorphine	10
Morphine	>500,000
Codeine	>600,000
Dextromethorphan	>100,000
Dihydrocodeine	>100,000
Heroin HCl	250
Hydrocodone	>100,000
Hydromorphone	>100,000
Imipramine	>100,000
Levorphanol	>10,000
NorMeperidine	>10,000
Normorphine	>100,000
Nalorphine	>100,000
Naloxone	>100,000
Naltrexone	>100,000
Norcodeine	>100,000
Oxycodone	>100,000
Oxymorphone	>100,000

Drug	Concentration (ng/mL)
MORPHINE (MOP)	
Morphine	300
O6-Acetylmorphine	400
Codeine	300
EthylMorphine	100
Heroin	600
Hydromorphone	500
Hydrocodone	50,000
Levorphanol	1,500
Oxycodone	30,000
Procaine	15,000
Thebaine	6,240
MORPHINE (OPI, MOP2000)	
Morphine	2,000
O6-Acetylmorphine	2,500
Codeine	1,000
EthylMorphine	250
Heroin	5,000
Hydromorphone	2,500
Hydrocodone	5,000
Oxycodone	75,000
Thebaine	13,000
OXYCODONE (OXY)	
Naloxone hydrochloride	10,000
Naltrexone hydrochloride	50,000
Oxycodone	100
Hydrocodone	5,000
Hydromorphone	5,000
Oxymorphone-D3	5,000
Oxymorphone	200
N-Benzylisopropylamine	2,500
PHENCYCLIDINE (PCP)	
Phencyclidine	25
4-Hydroxy Phencyclidine	90
PROPOXYPHENE (PPX)	
Norpropoxyphene	300
d-Propoxyphene	300
K2 (SYNTHETIC CANNABINOID)	
JWH-018 5-Pentanoic acid metabolite	50
JWH-018 5-Hydroxypentyl metabolite	500
JWH-018 4-Hydroxypentyl metabolite	400
JWH-018 N-(4-hydroxypentyl) metabolite solution	5,000
JWH-019 5-hydroxyhexylmetabolite	<10,000
JWH-019 6-Hydroxyhexyl	5,000
JWH-073 4-butanoic acid metabolite	50
JWH-073 4-Hydroxybutyl metabolite	500
JWH-210 5-Hydroxypentyl metabolite solution	<10,000
JWH-122 5-Hydroxypentyl metabolite solution	<10,000
Spice Cannabinoid Mix 3 solution	<10,000
JWH-122 4-Hydroxypentyl metabolite solution	<10,000
JWH-122 4-Hydroxypentyl metabolite-D5 solution	<10,000
JWH-019 5-hydroxyhexylmetabolite	<10,000
JWH-018 N-(4-hydroxypentyl) metabolite solution	<10,000

Drug	Concentration (ng/mL)
JWH-073 N-(3-Hydroxybutyl) metabolite solution	<10,000
K2 (SYNTHETIC CANNABINOID) 25 ng/mL	
JWH-018 5-Pentanoic acid metabolite	25
JWH-018 5-Hydroxypentyl metabolite	250
JWH-018 4-Hydroxypentyl metabolite	200
JWH-018 N-(4-hydroxypentyl) metabolite solution	2,500
JWH-019 5-hydroxyhexylmetabolite	<10,000
JWH-019 6-Hydroxyhexyl	2,500
JWH-073 4-butanoic acid metabolite	25
JWH-073 4-Hydroxybutyl metabolite	250
JWH-210 5-Hydroxypentyl metabolite solution	<10,000
JWH-122 5-Hydroxypentyl metabolite solution	<10,000
Spice Cannabinoid Mix 3 solution	<10,000
JWH-122 4-Hydroxypentyl metabolite solution	<10,000
JWH-122 4-Hydroxypentyl metabolite-D5 solution	<10,000
JWH-019 5-hydroxyhexylmetabolite	<10,000
JWH-018 N-(4-hydroxypentyl) metabolite solution	<10,000
JWH-073 N-(3-Hydroxybutyl) metabolite solution	<10,000
TRAMADOL (TRA)	
Tramadol	200
N-desmethyl-tramadol	500
O-desmethyl-tramadol	20,000
Tricyclic Antidepressants (TCA)	
Nortriptyline	1,000
Amitriptyline	1,500
Clomipramine	50,000
Desipramine	5,000
Doxepine	10,000
Imipramine	10,000
Maprotiline	100,000
Nordoxepin	10,000
Promazine	50,000
Promethazine	2,500
Trimipramine	50,000
Cyclobenzaprine Hydrochloride	5,000
Norclomipramine	50,000

Precision

This study is performed 2 runs/day and lasts 25 days for each format with three lots. Three operators who don't know the sample number system participate in the study. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs/day). A total of 50 determinations by each operator, at each concentration, were made. The results are given below:

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

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

REF GBDOA-1X5

Drug Conc. (Cut-off range)	AMP		AMP 500		AMP 300		BAR		BAR 200		BZO		BZO 200		BUP	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-75% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-50% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-25% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cut-off	20	30	20	30	22	28	23	27	23	27	18	32	24	26	28	22
+25% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+50% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+75% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc. (Cut-off range)	COC		COC150		COT		EDDP		EDDP 100		ETG		ETG 300		FEN	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-75% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-50% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-25% Cut-off	50	0	50	0	50	0	50	0	41	9	44	6	42	8	50	0
Cut-off	20	30	24	26	20	30	21	29	30	20	23	27	23	27	22	28
+25% Cut-off	0	50	0	50	0	50	0	50	3	47	8	42	4	46	0	50
+50% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+75% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc. (Cut-off range)	FEN 200		FEN 100		FEN 20		K2		K2 25		KET		KET 100		MET		MET 500	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-75% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-50% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-25% Cut-off	46	4	43	7	50	0	50	0	50	0	45	5	44	6	50	0	50	0
Cut-off	28	22	20	30	22	28	18	32	22	28	18	32	30	20	24	26	25	25
+25% Cut-off	5	45	2	48	0	50	0	50	0	50	6	44	3	47	0	50	0	50
+50% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+75% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc. (Cut-off range)	OXY		MET 300		MDMA		MOP		MQL		6-MAM		MTD		OPI	
	-	+	-	+	-	+	-	-	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	50	50	50	0	50	0	50	0
-75% Cut-off	50	0	50	0	50	0	50	0	50	50	50	0	50	0	50	0
-50% Cut-off	50	0	50	0	50	0	50	0	50	50	50	0	50	0	50	0
-25% Cut-off	50	0	50	0	50	0	50	0	48	50	50	0	50	0	50	0
Cut-off	24	26	25	25	24	26	22	28	24	22	22	27	28	22	22	28
+25% Cut-off	0	50	0	50	0	50	0	50	6	0	5	45	0	50	0	50
+50% Cut-off	0	50	0	50	0	50	0	50	0	0	0	50	0	50	0	50
+75% Cut-off	0	50	0	50	0	50	0	50	0	0	0	50	0	50	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	0	0	50	0	50	0	50

Drug Conc. (Cut-off range)	PCP		PPX		THC		THC 25		THC 20		TCA		TRA		LSD		MDPV	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-75% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-50% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-25% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	47	3	44	6	48	2
Cut-off	22	28	26	24	20	30	23	27	25	25	22	28	25	25	21	29	24	26
+25% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	1	49	5	45	7	43
+50% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+75% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Effect of Urinary Specific Gravity

Twelve (12) urine samples of normal, high, and low specific gravity from 1.000 to 1.035 were spiked with drugs at 25% below and 25% above cut-off levels respectively. The **One Step Multi-Drug Screen Cassette Test (Urine)** was tested in duplicate using drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquot of negative urine pool is adjusted in the range of 4.00 to 9.00 in 1 pH unit increment and spiked with the target drug at 25% below and 25% above Cutoff levels. The spiked, pH-adjusted urine was tested with The **One Step Multi-Drug Screen Cassette Test (Urine)**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Methamphetamine, Amphetamine, Cocaine, Morphine, Ecstasy, EDDP (Methadone Metabolites), Tricyclic Antidepressants, Oxycodone, Barbiturates, Buprenorphine, Phencyclidine, K2(Synthetic Cannabinoid), Ketamine, Methaqualone, Methadone, Fentanyl, Tramadol, Ethyl Glucuronide, Cotinine, 6-Monoacetylmorphine, Methylenedioxypyrovalerone, Lysergic acid diethylamide, Marijuana and Benzodiazepines positive urine. The following compounds show no cross-reactivity when tested with the **One Step Multi-Drug Screen Cassette Test (Urine)** at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

Acetophenetidin	Cortisone	Pseudoephedrine	Quinidine
N-Acetylprocainamide	Creatinine	Kynurenic Acid	Quinine
Acetylsalicylic acid	Dexamethasone	Labetalol	Salicylic acid
Amiloride	Dextromethorphan	Loperamide	Serotonin
Amoxicillin	Desipramine	Meprobamate	Sulfamethazine
Ampicillin	Diflunisal	Methoxyphenamine	Sulindac
l-Ascorbic acid	Digoxin	Methylphenidate	Tetracycline
Apomorphine	Droperidol	Nalidixic acid	Tetrahydrocortisone,
Aspartame	Ethyl-p-aminobenzoate	Naproxen	3-Acetate
Atropine	Ethopropazine	Niacinamide	Theobromine
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tolazamide
p-Aminobenzoic Acid	Erythromycin	Norethindrone	Tetrahydrozoline
Bilirubin	Fenoprofen	Noscapine	Thiamine
Beclomethasone	Furosemide	Octopamine	Thioridazine Hydrochloride
Caffeine	Gentisic acid	Oxalic acid	D/L-Tyrosine
Cannabidiol	Hemoglobin	Oxyphenbutazone	Tolbutamide
Carbamazepine	Hydralazine	Oxymetazoline	Triamterene
Chloramphenicol	Hydrochlorothiazide	Papaverine	Trifluoperazine
Chlorothiazide	Hydrocortisone	Paclitaxel	Trimethoprim
Chlorpheniramine	α-Hydroxyhippuric acid	Perphenazine	D,L-Tryptophan
Chlorpromazine	Hydroxyprogesterone	Phenelzine	Uric acid
Cholesterol	Isoproterenol-(+/-)	Prednisone	Verapamil
Clonidine	Isoxsuprine	Prilocaine	Zomepirac

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3. *Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.*
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INDEX OF SYMBOLS

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

Revision Date: 2022-05-31
B21769-03

Fecal Occult Blood Rapid Test Cassette (Feces) CE

INTENDED USE

Fecal Occult Blood Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in feces by professional laboratories or physician's offices. It is useful to detect bleeding caused by a number of gastrointestinal disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer.
Fecal Occult Blood Rapid Test Cassette (Feces) is recommended for use in1) routine physical examinations, 2) hospital monitoring for bleeding in patients, and 3) screening for colorectal cancer or gastrointestinal bleeding from any source.

INTRODUCTION

Most of diseases can cause hidden blood in the stool. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. Traditional guaiac-based method lacks sensitivity and specificity, and has diet-restriction prior to the testing.
Fecal Occult Blood Rapid Test Cassette (Feces) is a rapid test to qualitatively detect low levels of fecal occult blood in feces. The test uses double antibod- sandwich assay to selectively detect as low as 50 ng/mL of hemoglobin or 6 µg hemoglobin/g feces. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the patients.

PRINCIPLE

Fecal Occult Blood Rapid Test Cassette (Feces) is a lateral flow chromatographic immunoassay based on the principle of the double antibody-sandwich technique. The membrane is pre-coated with anti-hemoglobin antibodies on the test line region of the device. During testing, the specimen reacts with the colloidal gold coated withl anti-hemoglobin antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hemoglobin antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS PROVIDED

20 Test cassettes
20 Specimen collection tubes with buffer
1 Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers 2. Clock or timer

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.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Do not use specimen with visible blood for the testing.
6. Handel all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens.
7. Specimen extraction buffer contains Sodium Azide (0.1%). Avoid contact with skin or eyes. Do not ingest.
8. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
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.

PATIENT PREPARATION

1. A specimen should not be collected from a patient with following conditions that may interfere with the test results:

- Menstrual bleeding
- Bleeding hemorrhoids
- Constipating bleeding
- Urinary bleeding.

2. Dietary restrictions are not necessary.
3. Alcohol and certain medications such as aspirin, indomethacin, phenylbutazone, reserpine, cortocosteroids, and nonsteroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding, thus gives positive reactions. On the advice of the physician, such substances should be discontinued at least 48 hours prior to testing.

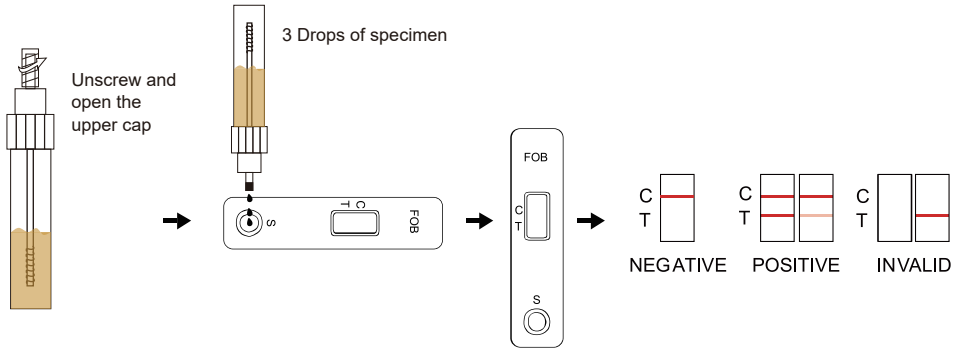
SPECIMEN COLLECTION AND PREPARATION

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.
2. Unscrew the top of the collection tube and remove the applicator stick.
3. Randomly pierce the fecal specimen in at least five (5) different sites.
4. Remove excess sample off the shaft and outer grooves. Be sure sample remains on inside grooves.
5. Replace the stick in the tube and tighten securely.
6. Shake the specimen collection bottle so that there is proper homogenisation of feces in buffer solution.

Note: Specimens prepared in the specimen collection tube may be stored at room temperature (15-30°C) for 3 days maximum, at 2-8°C for 7 days maximum or at -20°C for 3 months maximum if not tested within 1 hour after preparation.

TEST PROCEDURE

Allow the test cassette, specimen, and/or controls to reach room temperature (15-30°C) prior to testing.
1. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean, flat surface.
3. Shake the specimen collection tube several times.
4. Hold the specimen collection tube upright and then unscrew and open the upper cap.
5. Squeeze 3 drops (~90 µL) of the sample solution in the sample well of the cassette and start the timer.
6. Wait for the colored line(s) to appear. Read results in 5 minutes. Do not interpret the result after 5 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)
Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
Negative: One colored line appears in the control line region(C). No line appears in the test line region (T).
Invalid: Control line fails to appear. The test should be repeated using a new cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.
NOTE:
1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and

Fecal Occult Blood Rapid Test Cassette (Feces)

cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

An internal 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 correctl 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. This test kit is to be used for the qualitative detection of human hemoglobin in fecal samples. A positive result suggests the presence of human hemoglobin in fecal samples. In addition to intestinal bleeding the presence of blood in stools may have other causes such as hemorrhoids, blood in urine etc.
2. Not all colorectal bleedings are due to precancerous or cancerous polyps. The information obtained by this test should be used in conjunction with other clinical findings and testing methods, such as colonoscopy gathered by the physician.
3. Negative results do not exclude bleeding since some polyps and colorectal region cancers can bleed intermittently or not at all. Additionally, blood may not be uniformly distributed in fecal samples. Colorectal polyps at an early stage may not bleed.
4. Urine and excessive dilution of sample with water from toilet bowl may cause erroneous test results. The use of a receptacle is recommended.
5. Feces specimens should not collect during the menstrual period and not three day before or afterwards, at bleeding due to constipation, bleeding haemorrhoids,or at taking rectally administered medication. It could cause false positive results.
6. This test may be less sensitive for detecting upper g.i. Bleeding because blood degrades as it passes through the g.i. Track.
7. The Fecal Occult Blood Rapid Test Cassette (Feces) is to aid indiagnosis and is not intended to replace other diagnostic procedures such as G.I. fibroscope, endoscopy, colonoscopy, or X-ray analysis. Test results should not be deemed conclusive with respect to the presence or absence of gastrointestinal bleeding or pathology. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source for the occult blood in the feces.

PERFORMANCE CHARACTERISTICS

1. Sensitivity: 99.6%
Fecal Occult Blood Rapid Test Cassette (Feces) can detect the levels of human occult blood as low as 50 ng/mL hemoglobin or 6 µg hemoglobin/g feces.
2. Prozone Effect:
It is observed that this FOB test can detect 2 mg/mL hemoglobin.
3. Specificity: 99.9%
Fecal Occult Blood Rapid Test Cassette (Feces) is specific to human hemoglobin. Specimen containing the following substances at the standard concentration was tested on both positive and negative controls and showed no effects on test results at standards concentration.

Substances	Concentrations (Diluted with the extraction buffer)
Beef hemoglobin	2 mg/mL
Chicken hemoglobin	0.5 mg/mL
Pig hemoglobin	0.5 mg/mL
Goat hemoglobin	0.5 mg/mL
Horse hemoglobin	20 mg/mL
Rabbit hemoglobin	0.06 mg/mL

REFERENCES

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2. Blebea J. and Ncpherson RA. False-Positive Guaiac Testing With Iodine, Arch Pathol Lab Med, 1985;109:437-40.

INDEX OF SYMBOLS

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

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

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

REF GEFOB-602b

Revision Date: 2023-04-18
B21056-04

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

CE 0123

REF GCHCV-402a

INTENDED USE

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

INTRODUCTION

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

PRINCIPLE

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

PRODUCT CONTENTS

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

MATERIALS SUPPLIED

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

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

MATERIAL REQUIRED BUT NOT PROVIDED

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

STORAGE AND STABILITY

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

WARNINGS AND PRECAUTIONS

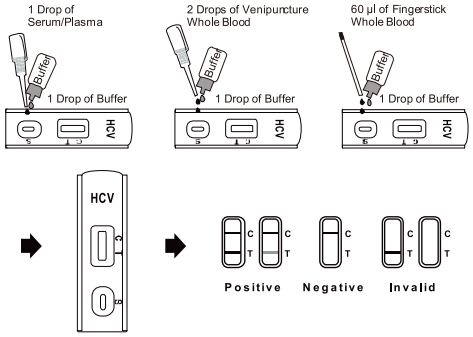
1. For professional *in vitro* diagnostic use only. Do not use after expiration date.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of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

SPECIMEN COLLECTION

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

TEST PROCEDURE

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



INTERPRETATION OF RESULTS

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

QUALITY CONTROL

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

LIMITATIONS

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

PERFORMANCE CHARACTERISTICS

Relative Sensitivity

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

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

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

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

Relative Specificity

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

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

Whole Blood vs. Serum vs. Plasma

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

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

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

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

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

Precision

Intra Assay

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

Inter-Assay

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

Cross Reactivity

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

Interfering Substances

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

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

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INDEX OF SYMBOLS

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

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

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

B21304-05
Revision Date: 2022-11-10

Troponin I

Troponin I Rapid Test Cassette (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 Cassette (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 Cassette (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

1. For professional *in vitro* diagnostic use only.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re- use under any circumstances.
5. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
7. Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test cassette unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test cassette 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.

SPECIMEN COLLECTION AND PREPARATION

- The Troponin I Rapid Test Cassette (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 cassette. Repeat the test with a serum or plasma specimen from the same patient using a new test cassette.

Materials Provided

1. Test cassettes 2. Droppers 3. Package insert

Materials Required But Not Provided

1. Specimen collection containers 2. Centrifuge (for plasma only)
3. Clock or Timer

DIRECTIONS FOR USE

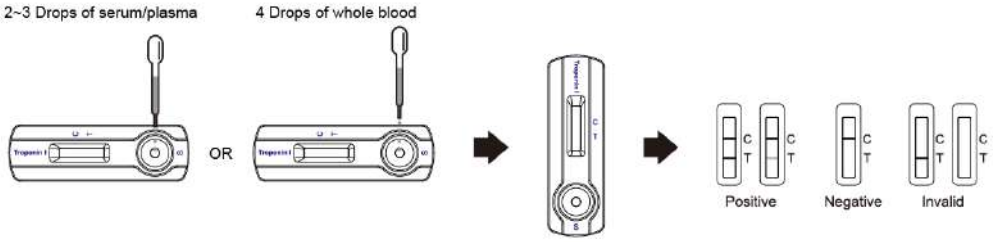
Allow test cassette, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the cassette with patient or control identification. To obtain a best result, the assay should be performed within one hour.
2. Transfer **2-3 drops of serum or plasma** to the specimen well(S) of the cassette with a disposable pipette provided in the kit, and then start the timer.

OR

Transfer **4 drops of whole blood** specimen to the specimen well(S) of the cassette with a disposable pipette provided in the kit, and then start the timer.

2. Wait for the colored band(s) to appear. The result should be read at 15 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: 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

1. The Troponin I Rapid Test Cassette (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 line color intensity or width.
2. The Troponin I Rapid Test Cassette (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.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. The test cannot detect less than 0.25 ng/mL of cTnI in specimens. Thus, a negative result does not at any time rule out the existence of Troponin I in blood, because the antibodies may be absent or below the minimum detection level of the test.
4. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. 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 Cassette		Total Results
		Positive	Negative	
EIA	Positive	138	2	140
	Negative	1	315	316
Total Results		139	317	456

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

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