Toxicology Urine Test

Product Description	Format	Cut-off Value	Qualification
Acetaminophen (ACE) Test	Strip/Cassette/Dip Card/Cup	5000 ng/mL	CE
Amphetamine (AMP) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500/300/250 ng/mL	CE 510(k)
Barbiturates (BAR) Test	Strip/Cassette/Dip Card/Cup	2000/600/300/200 ng/mL	CE 510(k)
Benzodiazepines (BZO) Test	Strip/Cassette/Dip Card/Cup	600/400/300/200/100 ng/mL	CE 510(k)
Buprenorphine (BUP) Test	Strip/Cassette/Dip Card/Cup	10/5 ng/mL	CE 510(k)
Caffeine (CAF) Test	Strip/Cassette/Dip Card/Cup	6000 ng/mL	/
Carisoprodol (SOMA) Test	Strip/Cassette/Dip Card/Cup	1000 ng/mL	CE
Clonazepam (CLO) Test	Strip/Cassette/Dip Card/Cup	500/100 ng/mL	CE
Cocaine (COC) Test	Strip/Cassette/Dip Card/Cup	600/300/150/100 ng/mL	CE 510(k)
Codeine (COD) Test	Strip/Cassette/Dip Card/Cup	2000 ng/mL	CE
Cotinine (COT) Test	Strip/Cassette/Dip Card/Cup	400/300/200/100/50 ng/mL	CE
Ecstasy (MDMA) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500/300/250/150 ng/mL	CE 510(k)
Ethyl Glucuronide (EtG) Test	Strip/Cassette/Dip Card/Cup	500/300ng/mL	CE
Fentanyl (FEN) Test	Strip/Cassette/Dip Card/Cup	300/200/100/50 ng/mL	CE
Norfentanyl (FEN) Test	Strip/Cassette/Dip Card/Cup	200/50/20/10/5 ng/mL	CE
Gabapentin (GAB) Test	Strip/Cassette/Dip Card/Cup	3750/2000/1000 ng/mL	CE
Hydrocodone (HCD) Test	Strip/Cassette/Dip Card/Cup	300/10 ng/mL	CE
Hydromorphone (HMO) Test	Strip/Cassette/Dip Card/Cup	300 ng/mL	CE
Ketamine (KET) Test	Strip/Cassette/Dip Card/Cup	3000/2000/1000/500/100 ng/mL	CE
Kratom (KRA) Test	Strip/Cassette/Dip Card/Cup	250/150/100 ng/mL	CE
Lysergic acid diethylamide (LSD) Test	Strip/Cassette/Dip Card/Cup	20 ng/mL	CE
Marijuana (THC) Test	Strip/Cassette/Dip Card/Cup	600/300/200/150/100/50/40/25/20/18/15 ng/mL	CE 510(k)
Methadone Metabolite (EDDP) Test	Strip/Cassette/Dip Card/Cup	300/100 ng/mL	CE 510(k)
Methadone (MTD) Test	Strip/Cassette/Dip Card/Cup	1000/600/300/200/50 ng/mL	CE 510(k)
Methamphetamine (MET) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500/300/250 ng/mL	CE 510(k)
Methaqualone (MQL) Test	Strip/Cassette/Dip Card/Cup	300/1000 ng/mL	CE
Methcathinone (MTC) Test	Strip/Cassette/Dip Card/Cup	500/300 ng/mL	CE
3,4-Methylenedioxypyrovalerone (MDPV) Test	Strip/Cassette/Dip Card/Cup	1000/500/50 ng/mL	CE
Methylphenidate (MPD) Test	Strip/Cassette/Dip Card/Cup	300 ng/mL	CE
6-Monoacetylmorphine (6-MAM) Test	Strip/Cassette/Dip Card/Cup	20/10 ng/mL	CE
Morphine (MOP) Test	Strip/Cassette/Dip Card/Cup	2000/600/300/150/100 ng/mL	CE 510(k)
Opiate (OPI) Test	Strip/Cassette/Dip Card/Cup	2000/300/100 ng/mL	CE 510(k)
Oxycodone (OXY) Test	Strip/Cassette/Dip Card/Cup	300/100 ng/mL	CE 510(k)
Phencyclidine (PCP) Test	Strip/Cassette/Dip Card/Cup	50/25 ng/mL	CE 510(k)
Pinaca Ab (K3) Test	Strip/Cassette/Dip Card/Cup	10 ng/mL	CE
Pregabalin (PGB) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500 ng/mL	CE
Propoxyphene (PPX) Test	Strip/Cassette/Dip Card/Cup	600/300 ng/mL	CE 510(k)
Synthetic Marijuana (K2) Test	Strip/Cassette/Dip Card/Cup	75/50/25/20/10 ng/mL	CE
Tramadol (TRA) Test	Strip/Cassette/Dip Card/Cup	200/100 ng/mL	CE
Tricyclic Antidepressants (TCA) Test	Strip/Cassette/Dip Card/Cup	1000/300 ng/mL	CE 510(k)
UR-144 Test	Strip/Cassette/Dip Card/Cup	50 ng/mL	CE
Zolpidem (ZOL) Test [New]	Strip/Cassette/Dip Card/Cup	50 ng/mL	/
Zopiclone (ZOP) Test [New]	Strip/Cassette/Dip Card/Cup	50 ng/mL	/
Alcohol (ALC) Test	Strip/Cassette/Dip Card/Cup	0.04%	CE

Toxicology Saliva Test

Product Description	Format	Cut-off Value	Qualification
7-Aminonitrazepam (ACL) Test [New]	Device	100 ng/mL	/
Amphetamine (AMP) Test	Device	50/40 ng/mL	CE
Barbiturates (BAR) Test	Device	300/50/40 ng/mL	CE
Benzodiazepines (BZO) Test	Device	50/20/10 ng/mL	CE
Buprenorphine (BUP) Test	Device	10/5 ng/mL	CE
Carisoprodol (SOMA) Test	Device	300 ng/mL	/
Cocaine (COC) Test	Device	50/20 ng/mL	CE
Codeine (COD) Test	Device	10 ng/mL	CE
Cotinine (COT) Test	Device	50/30/10 ng/mL	CE
Diphenhydramine (DIP) Test [New]	Device	150/100 ng/mL	/
Ecstasy (MDMA) Test	Device	60/50 ng/mL	CE
Ethyl Glucuronide (EtG) Test [New]	Device	150/100 ng/mL	/
Fentanyl (FEN) Test	Device	10 ng/mL	CE
Hydrocodone (HCD) Test [New]	Device	10 ng/mL	/
Hydromorphone (HMO) Test [New]	Device	300/150 ng/mL	/
Ketamine (KET) Test	Device	100/50 ng/mL	CE
Lysergic acid diethylamide (LSD) Test	Device	25/10 ng/mL	CE
Marijuana (THC) Test	Device	50/40/30/25/15/12/10/5/4/3 ng/mL	CE
Methadone Metabolite (EDDP) Test	Device	20 ng/mL	CE
Mephedrone (MEP) Test [New]	Device	50 ng/mL	/
Methadone (MTD) Test	Device	75/50/30 ng/mL	CE
Methamphetamine (MET) Test	Device	50 ng/mL	CE
Methaqualone (MQL) Test	Device	150/100 ng/mL	CE
Methcathinone (MTC) Test	Device	50 ng/mL	/
3,4-Methylenedioxypyrovalerone (MDPV) Test	Device	200/100/50 ng/mL	CE
Methylphenidate (MPD) Test	Device	50 ng/mL	/
6-Monoacetylmorphine (6-MAM) Test	Device	25/15/10/5/4 ng/mL	CE
Morphine (MOP) Test	Device	15 ng/mL	CE
Opiate (OPI) Test	Device	50/40 ng/mL	CE
Oxycodone (OXY) Test	Device	50/40/20 ng/mL	CE
Phencyclidine (PCP) Test	Device	10 ng/mL	CE
Phenytoin (PHEN) Test [New]	Device	150/100 ng/mL	/
Pinaca Ab (K3) Test [New]	Device	10 ng/mL	/
Pregabalin (PGB) Test [New]	Device	100 ng/mL	/
Propoxyphene (PPX) Test	Device	50/20 ng/mL	CE
Synthetic Marijuana (K2) Test	Device	25/10/5 ng/mL	CE
Tramadol (TRA) Test	Device	100/50 ng/mL	CE
Tricyclic Antidepressants (TCA) Test	Device	1000/500/300/150 ng/mL	CE
XLR-11 Test [New]	Device	100 ng/mL	/
Zolpidem (ZOL) Test [New]	Device	25 ng/mL	/
Zopiclone (ZOP) Test [New]	Device	25 ng/mL	/
Alcohol (ALC) Test	Device	0.05,0.02%	CE

Toxicology Hair Test

Product Description	Format	Label	Cut-off Value	Qualification
Amphetamine (AMP) Test	Cassette	Fluorescence	0.5/0.2 ng/mg	CE
		Gold	5 ng/mg	/
Benzodiazepines (BZO) Test	Cassette	Fluorescence	0.2 ng/mg	/
		Gold	1 ng/mg	/
Cocaine (COC) Test	Cassette	Fluorescence	0.5/0.2 ng/mg	CE
		Gold	5/2 ng/mg	CE
Ecstasy (MDMA) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	5 ng/mg	/
2-Fluorodeschloroketamin (FKE) Test	Cassette	Fluorescence	0.2 ng/mg	/
Ketamine (KET) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	2/1.0,5 ng/mg	CE
Marijuana (THC) Test	Cassette	Fluorescence	0.05 ng/mg	CE
		Gold	2/1.5 ng/mg	CE
Methamphetamine (MET) Test	Cassette	Fluorescence	0.5/0.2 ng/mg	CE
		Gold	5/2/1 ng/mg	CE
Methcathinone (MTC) Test	Cassette	Fluorescence	0.2 ng/mg	CE
6-Monoacetylmorphine (6-MAM) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	2 ng/mg	CE
Morphine (MOP) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	5/2.0,5 ng/mg	CE
Oxycodone (OXY) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	4 ng/mg	/
Phencyclidine (PCP) Test	Cassette	Fluorescence	0.3 ng/mg	CE
		Gold	1 ng/mg	CE
Pinaca Ab (K3) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	0.5 ng/mg	/
Synthetic Marijuana (K2) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	1 ng/mg	/
Tramadol (TRA) Test	Cassette	Fluorescence	0.2 ng/mg	/
UR-144 Test	Cassette	Fluorescence	0.05 ng/mg	/

Infectious Disease

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
Adenovirus Antigen Test	Swab	GCADE-502a/	Cassette	/	20 Tests/Kit
Adenovirus Test	Feces	GCADE-602a/	Cassette	/	20 Tests/Kit
Brucella Antibody Test	WB/S/P	GCBRU-402a/	Cassette	/	25 Tests/Kit
Candida albicans Test	Vaginal Secretion	GCCA-502a/	Cassette	10⁵ CFU/mL	20 Tests/Kit
Chagas Antibody Test	S/P	GCCHA-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCCHA-402a/	Cassette	/	25 Tests/Kit
Clostridium difficile GDH Test	Feces	GCCD(GDH)-602a/	Cassette	2 ng/mL	20 Tests/Kit
Clostridium difficile Toxin A/B Test	Feces	GCCD(Toxin A/B)-602a/	Cassette	Toxin A: 2 ng/mL Toxin B: 2 ng/mL	20 Tests/Kit
Clostridium difficile GDH & Toxin A/B Combo Test	Feces	GCCD-625a/	Cassette	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	/	25 Tests/Kit
Chlamydia Test	Swab/Urine	GCCHL-502a/	Cassette	4.8×10⁵ 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
COVID-19 Antigen Test	Nasopharyngeal Swab	GCCOV-502a/	Cassette	/	20 Tests/Kit
		GCCOV-502Ca/	Cassette	/	20 Tests/Kit
		GCCOV-501a/ [New]	Strip	/	20 Tests/Kit
	Nasal Swab	GCCOV-502a-NA/	Cassette	/	1/2/3/5/7/10/15/20 Tests/Kit
		GCCOV-503a/ [New]	Device	/	1/2/5/10 Tests/Kit
	NA & NP Swab	GCCOV-502a-NN/	Cassette	/	20 Tests/Kit
	Oral Fluid	GCCOV-702a/	Cassette	/	20 Tests/Kit
COVID-19 Antigen Self-Test	Nasal Swab	GCCOV-502a-Hxx/	Cassette	/	1/2/3/5/7/10/15/20 Tests/Kit
		GCCOV-502a-HxxOGE/	Cassette	/	1/2/3/5/7/8/10/15/20/25 Tests/Kit
	Oral Fluid	GCCOV-702a-Hxx/ [New]	Cassette	/	1/2/3/5/7/10/15/20 Tests/Kit
Digital COVID-19 Antigen Test	Nasal Swab	GCCOV-D503a/ [New]	Reader	/	1/2/3/5/7/10/15/20 Tests/Kit
COVID-19 Antigen & B.1.1.7 Mutant Strain Combo Test	Nasal Swab	GCCOV(B1117)-525a/	Cassette	/	20 Tests/Kit
COVID-19/Flu A&B /RSV Antigen Combo Test	Nasal Swab	GCFCR-7525a/ [New]	Cassette	/	20 Tests/Kit
SARS-CoV-2 Delta-series Mutant Strain Antigen Test	Nasal Swab	GCCOV(Del)-T502a/	Cassette	/	20 Tests/Kit
SARS-CoV-2 Ag Fluorescence Rapid Test	Nasal Swab	FCCOV-502a/ [New]	Cassette	/	20 Tests/Kit
Dengue IgG/IgM Antibody Test	WB/S/P	GCDEN(abi)-402c/	Cassette	/	25 Tests/Kit
Dengue NS 1 Antigen Test	WB/S/P	GCDEN(NS)-402c/	Cassette	/	25 Tests/Kit
Dengue NS1 & IgG/IgM Combo Test	WB/S/P	GCDEN-425a/	Cassette	/	20 Tests/Kit
EV71 IgM Test	S/P	GCEV71(IgM)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCEV71(IgM)-402a/	Cassette	/	25 Tests/Kit
Giardia lamblia Test	Feces	GCGIA-602a/	Cassette	/	20 Tests/Kit
Gonorrhoeae Test	Swab	GCGON-502b	Cassette	1.0E+7	20 Tests/Kit
HAV IgM Test	S/P	GCHAV(IgM)-302Ba/	Cassette	/	25 Tests/Kit
HAV IgG/IgM Test	WB/S/P	GCHAV(IgG/IgM)-402a/	Cassette	/	25 Tests/Kit
HAV AntigenTest	Feces	GCHAV-602a/	Cassette	/	25 Tests/Kit
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
HBeAb Hepatitis B Envelope Antibody Test	S/P	GCHBeb-302a	Cassette	2 NCU	25 Tests/Kit
		GCHBeb-302b	Cassette	8 NCU	25 Tests/Kit
	WB/S/P	GCHBeb-402a	Cassette	2 NCU	25 Tests/Kit
HBeAg Hepatitis B Envelope Antigen Test	S/P	GCHBeg-302a	Cassette	0.5 NCU	25 Tests/Kit
	WB/S/P	GCHBeg-402a	Cassette	0.5 NCU	25 Tests/Kit
HBsAb Hepatitis B Surface Antibody Test	S/P	GCHBsb-301a	Strip	30 mIU/mL	50 Tests/Kit
		GCHBsb-302a	Cassette	30 mIU/mL	25 Tests/Kit
		GCHBsb-401a	Strip	30 mIU/mL	50 Tests/Kit
	WB/S/P	GCHBsb-402a	Cassette	20 mIU/mL	25 Tests/Kit
		GCHBsb-402b	Cassette	20 mIU/mL	25 Tests/Kit
HBsAg Hepatitis B Surface Antigen Rapid Test	S/P	GCHBsg-301a	Strip	1 ng/mL	50 Tests/Kit
		GCHBsg-302a	Cassette	1 ng/mL	25 Tests/Kit
	WB/S/P	GCHBsg-401a	Strip	1 ng/mL	50 Tests/Kit
		GCHBsg-402a	Cassette	1 ng/mL	25 Tests/Kit
HBsAg/HCV Combo Test	WB/S/P	GCHBC-402a	Cassette	/	25 Tests/Kit
HBsAg/HCV/HIV/Syphilis Combo Test	S/P	GCHBCISY-345a	Cassette	/	20 Tests/Kit
	WB/S/P	GCHBCISY-445a	Cassette	/	20 Tests/Kit
HBV HBcAb/HBeAb/HBeAg/HBsAb /HBsAg Combo Test	S/P	GCHBV-355a	Cassette	/	20 Tests/Kit
	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	/	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
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-GT402a	Cassette	/	25 Tests/Kit
HIV 1/2/O Antibody 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
HSV IgG Test	S/P	GCHSV(IgG)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCHSV(IgG)-402a/	Cassette	/	25 Tests/Kit
HSV IgM Test	S/P	GCHSV(IgM)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCHSV(IgM)-402a/	Cassette	/	25 Tests/Kit
HSV IgG/IgM Test	S/P	GCHSV(IgG/IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCHSV(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
H. pylori Antibody Test	S/P	GCHP-301a/	Strip	/	50 Tests/Kit
		GCHP-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCHP-401a/	Strip	/	50 Tests/Kit
		GCHP-402a/	Cassette	/	25 Tests/Kit
H. pylori Antigen Test	Feces	GCHP-601a/	Strip	/	25 Tests/Kit
		GCHP-601Ca/	Strip	/	25 Tests/Kit
		GCHP-602a/	Cassette	/	20 Tests/Kit
		GCHP-602Ca/	Cassette	/	20 Tests/Kit
Influenza A Antigen Test	Nasal/Throat Swabs	GCFLU(A)-501a/	Strip	1.5 x 10⁵ TCID$_{50}$	25 Tests/Kit
		GCFLU(A)-502a/	Cassette	1.5 x 10⁵ TCID$_{50}$	20 Tests/Kit
Influenza A/B Antigen Test	Nasal/Throat Swabs	GCFLU(A/B)-501a/	Strip	1.5x 10⁵ TCID$_{50}$ / 1.5 x 10⁵ TCID$_{50}$	25 Tests/Kit
		GCFLU(A/B)-502a/	Cassette	1.5x 10⁵ TCID$_{50}$ / 1.5 x 10⁵ TCID$_{50}$	20 Tests/Kit
		GCFLU(A/B)-502Ca/	Cassette	1.5x 10⁵ TCID$_{50}$ / 1.5 x 10⁵ 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-T503a/ [New]	Device	/	1/2/5/10 Tests/Kit
Flu, COVID-19, RSV & Adeno Antigen Combo Test	Nasopharyngeal Swab	GCFCRA-545a/	Cassette	/	20 Tests/Kit
	Nasal Swab	GCFCRA-T525a/ [New]	Cassette	/	20 Tests/Kit
Leishmania Antibody Test	S/P	GCKAI-301a	Strip	/	50 Tests/Kit
		GCKAI-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCKAI-401a/	Strip	/	50 Tests/Kit
		GCKAI-402a	Cassette	/	25 Tests/Kit
Malaria Pan Antigen Test	Whole Blood	GCMAL(pan)-402a/	Cassette	200 parasites	25 Tests/Kit
Malaria P.f. Antigen Test	Whole Blood	GCMAL(pf)-402a/	Cassette	200 parasites	25 Tests/Kit
Malaria P.f./Pan Antigen Test	Whole Blood	GCMAL(pf/pan)-402a/	Cassette	200 parasites	25 Tests/Kit
Malaria P.f./P.v. Antigen Test	Whole Blood	GCMAL(pf/pv)-402a/	Cassette	200 parasites	25 Tests/Kit
Malaria P.f./P.v. Antibody Test	S/P	GCMAL(pf/pv Ab)-302a/	Cassette	/	25 Tests/Kit
	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	WB/S/P or Throat swab	GCMKP-502a/ [New]	Cassette	/	25 Tests/Kit
Mononucleosis Test	S/P	GCMON-325a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCMON-402a/	Cassette	/	25 Tests/Kit
		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
Rotavirus Test	Feces	GCROA-602a/	Cassette	/	25 Tests/Kit
Rotavirus/Adenovirus Test		GCROA/ADE-602a/	Cassette	/	25 Tests/Kit
Rubella IgG Test	S/P	GCRUB(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-501a/	Strip	/	25 Tests/Kit
		GCSTR-501Ca/†	Strip	/	25 Tests/Kit
		GCSTR-502a/	Cassette	/	20 Tests/Kit
		GCSTR-502Ca/	Cassette	/	20 Tests/Kit
Syphilis Test	S/P	GCSYP-301a/	Strip	/	50 Tests/Kit
		GCSYP-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCSYP-401a/	Strip	/	50 Tests/Kit
		GCSYP-402a/	Cassette	/	25 Tests/Kit
S. typhi Antigen Test	S/P/Feces	GCSAL(ST)-602a/	Cassette	/	20 Tests/Kit
TOXO IgG Test	S/P	GCTOX(IgG)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCTOX(IgG)-402a	Cassette	/	25 Tests/Kit
TOXO IgM Test	S/P	GCTOX(IgM)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCTOX(IgM)-402a	Cassette	/	25 Tests/Kit
Toxo IgG/IgM Test	S/P	GCTOX-302b	Cassette	/	25 Tests/Kit
		GCTOX(IgG/IgM)-302a/	Cassette	/	25 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	GCVCHO(O1)-602a/	Cassette	/	20 Tests/Kit
V. cholerae O1/O139 Antigen Test	Feces	GCVCHO(O1/O9)-602a/	Cassette	/	25 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	GCZIK(NS1)-402a	Cassette	/	25 Tests/Kit

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

Fertility


Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
hCG Pregnancy Test	Urine	GAHCG-101a/†	Strip	25 mIU/mL	100 Tests/Kit
		GAHCG-101b/	Strip	10 mIU/mL	100 Tests/Kit
		GAHCG-101d/	Strip	20 mIU/mL	100 Tests/Kit
		GAHCG-102a/†	Cassette	25 mIU/mL	25 Tests/Kit
		GAHCG-102b/	Cassette	10 mIU/mL	25 Tests/Kit
		GAHCG-102d/	Cassette	20 mIU/mL	25 Tests/Kit
		GAHCG-103a/†	Midstream	25 mIU/mL	1/2 Test(s)/Kit
		GAHCG-103b/	Midstream	10 mIU/mL	1/2 Test(s)/Kit
		GAHCG-103d/	Midstream	20 mIU/mL	1/2 Test(s)/Kit
		GAHCG-105a	Panel	25 mIU/mL	25 Tests/Kit
	Urine/Serum	GAHCG-201a/	Strip	25 mIU/mL	100 Tests/Kit
		GAHCG-201b/	Strip	10 mIU/mL	100 Tests/Kit
		GAHCG-202a/	Cassette	25 mIU/mL	25 Tests/Kit
		GAHCG-202b/	Cassette	10 mIU/mL	25 Tests/Kit
Digital Pregnancy Test	Urine	GAHCG-D103a/	Midstream	25 mIU/mL	1/2 Test(s)/Kit
LH Ovulation Test	Urine	GALH-101a/	Strip	25 mIU/mL	100 Tests/Kit
		GALH-101b/	Strip	40 mIU/mL	100 Tests/Kit
		GALH-101d	Strip	30 mIU/mL	100 Tests/Kit
		GALH-102a/	Cassette	25 mIU/mL	25 Tests/Kit
		GALH-102b/	Cassette	40 mIU/mL	25 Tests/Kit
		GALH-103a/	Midstream	25 mIU/mL	1/5 Test(s)/Kit
		GALH-103b/	Midstream	40 mIU/mL	1/5 Test(s)/Kit
		GALH-103d	Midstream	30 mIU/mL	1/5 Test(s)/Kit
FSH Menopause Test	Urine	GAFSH-101a/	Strip	25 mIU/mL	100 Tests/Kit
		GAFSH-102a/	Cassette	25 mIU/mL	25 Tests/Kit
IGFBP-1 PROM Test	Cervical Secretion	GAIGF1-501a/	Strip	25 ng/mL	25 Tests/Kit
		GAIGF1-502a/	Cassette	25 ng/mL	20 Tests/Kit
Male Fertility Test	Semen	GASPE-902a/	Cassette	15M/mL	1 Test/Kit

Cardiac Marker

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
CK-MB Test	S/P	GDCKM-302a/	Cassette	5 ng/mL	25 Tests/Kit
	WB/S/P	GDCKM-402a/	Cassette	5 ng/mL	25 Tests/Kit
CRP C-Reactive Protein Semi -Quantitative Test	WB/S/P	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	GDCAR-335a/	Cassette	50/5/0.5 ng/mL	25 Tests/Kit
	WB/S/P	GDCAR-435a/	Cassette	50/5/0.5 ng/mL	25 Tests/Kit
		GDCAR-W435a/	Cassette	50/5/0.5 ng/mL	20 Tests/Kit

Urinalysis


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

Tumor Marker

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
AFP Alpha Fetal Protein Test	S/P	GEAFP-301a/	Strip	20 ng/mL	50 Tests/Kit
		GEAFP-302a/	Cassette	20 ng/mL	25 Tests/Kit
	WB/S/P	GEAFP-401a/	Strip	20 ng/mL	50 Tests/Kit
		GEAFP-402a/	Cassette	20 ng/mL	25 Tests/Kit
CEA Carcinoembryonic Antigen Test	S/P	GECEA-301a	Strip	5 ng/mL	50 Tests/Kit
		GECEA-302a	Cassette	5 ng/mL	25 Tests/Kit
	WB/S/P	GECEA-401a/	Strip	5 ng/mL	50 Tests/Kit
		GECEA-402a/	Cassette	5 ng/mL	25 Tests/Kit
FOB Fecal Occult Blood Test	Feces	GEFOB-601b/†	Strip	50 ng/mL	25 Tests/Kit
		GEFOB-601Cb/	Strip	50 ng/mL	25 Tests/Kit
		GEFOB-601c/	Strip	100 ng/mL	25 Tests/Kit
		GEFOB-601d	Strip	200 ng/mL	25 Tests/Kit
		GEFOB-602b/†	Cassette	50 ng/mL	20 Tests/Kit
		GEFOB-602Cb/	Cassette	50 ng/mL	20 Tests/Kit
		GEFOB-602c/	Cassette	100 ng/mL	20 Tests/Kit
		GEFOB-602d	Cassette	200 ng/mL	20 Tests/Kit
		GEFOB-602h	Cassette	150 ng/mL	20 Tests/Kit
		GEFOB-602j/	Cassette	10 ng/mL	20 Tests/Kit
FOB /Transferrin Combo Test	Feces	GEFOB/TF-602a/	Cassette	50/10 ng/mL	20 Tests/Kit
Nuclear Matrix Protein 22 Test	Urine	GENMP22-102a/ New	Cassette	10 U/mL	25 Tests/Kit
PSA Prostate Specific Antigen Test	S/P	GEPSA-301a/	Strip	4 ng/mL	50 Tests/Kit
		GEPSA-302a/	Cassette	4 ng/mL	25 Tests/Kit
	WB/S/P	GEPSA-401a/	Strip	4 ng/mL	50 Tests/Kit
		GEPSA-402a/	Cassette	4 ng/mL	25 Tests/Kit
PSA Prostate Specific Antigen Semi-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

Veterinary

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

Non-Infectious Disease

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

Autoimmunity

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

Instrument



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

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

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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Rev.08/2022

PRODUCT CATALOG

Enhancing Global Health

HEALGEN®

Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)

CE

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 device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test is not stable out off the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND PREPARATION

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

MATERIALS

Materials Provided

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

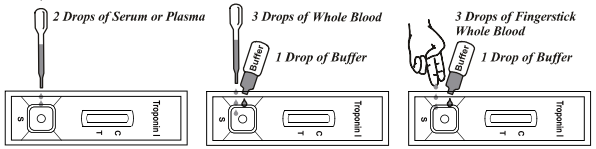
Materials Required But Not Provided

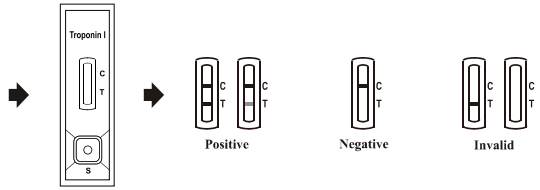
- Specimen collection containers
- Clock or timer
- Centrifuge (for plasma only)

DIRECTIONS FOR USE

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

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. To obtain a best result, the assay should be performed within one hour.
2. Transfer 2 drops of serum or plasma to the specimen well of the device with a disposable pipette provided in the kit, and then start the timer.
   OR
   Transfer 3 drops of whole blood specimen to the specimen well of the device with a disposable pipette provided in the kit, then add 1 drop of buffer, and start the timer.
   OR
   Allow 3 hanging drops of fingerstick whole blood specimen to fall into the center of the specimen well (S) on the device, then add 1 drop of buffer, and start the timer. Avoid trapping air bubbles in the specimen well (S), and do not drop any solution in observation window.
   As the test begins to work, you will see color move across the membrane.
3. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.





INTERPRETATION OF RESULTS

(Please refer to the illustration above)
POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).
NEGATIVE: Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).
INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded.
Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.
NOTE:

1. 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 linen 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 diagnostic of acute myocardial infarction(AMI).
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 0.5 ng/mL of cTnI in specimens. Thus, a negative result does not at anytime rule out the existence of Troponin I in blood, because the antibodies may be absent or below the minimum detection level of the test.
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
	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

BIBLIOGRAPHY

1. Adams, et al. Biochemical markers of myocardial injury, Immunoassay Circulation 88: 750-763, 1993.
2. Mehegan JP, Tobacman LS. Cooperative interaction between troponin molecules bound to the cardiac thin filament. J.Biol.Chem. 266:966, 1991.
3. Adams, et al. Diagnosis of Perioperative myocardial infarction with measurements of cardiac troponin I. N.Eng.J.Med 330:670, 1994.
4. Hossein-Nia M, et al. Cardiac troponin I release in heart transplantation. Ann. Thorac. Surg. 61: 227, 1996.
5. Alpert JS, et al. Myocardial Infarction Redefined, Joint European Society of Cardiology American College of Cardiology: J. Am. Coll. Cardio., 36(3):959, 2000.

INDEX OF SYMBOLS

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

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

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

REF GDTRO-402a

Revision Date: 2020-01-20
B21775-02

CE IVD

zybio

Instructions for Use of α-Amylase (α-AMY) Kit

(E-pNP-G7 Method)

Package Specification

REF	Reagent	Systems
01.09.0B.00.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.0B.00.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of the catalytic activity concentration of α-amylase (α-AMY) in human samples (serum, plasma or urine).

Summary

α-Amylase activity is one of the important diagnostic markers of acute pancreatitis. Serum amylase can be increased in diseases such as chronic pancreatitis, pancreatic cancer, acute appendicitis, ulcerative perforation, intestinal obstruction, mumps, and salivary gland suppuration. When renal function decreased, serum amylase increased and urine amylase decreased. Patients with various liver diseases will show a simultaneous decrease in serum and urine amylase.

Principle

This kit uses E-pNP-G7 method (IFCC recommended method) to determine the activity of α-amylase (α-AMY) in samples. α-AMY in the sample hydrolyzes 4, 6-ethylene-4-nitrophenyl-4-a-D-maltoheptaose (E-pNP-G7) to generate 4, 6-ethylene-maltopentaose (E-G5), 4, 6-ethylene-maltotetraose (E-G4), 4, 6-ethylene-maltotriose (E-G3), and 4-nitrophenyl-maltose (G2-NP), 4-nitrophenyl-maltotriose (G3-NP), 4-nitrophenyl-maltotetraose (G4-NP) and other fragments, and the three 4-nitrophenyl-maltopolysaccharides generated are hydrolyzed to glucose and 4-nitrophenol under the action of α-glucosidase, causing an increase in absorbance at a rate directly proportional to the activity of α-AMY in the sample. The activity of α-AMY in the sample can be calculated from the working curve by continuously monitoring and comparing with the calibrator treated in the same manner.

$$\text{E-pNP-G7} + H_2O \xrightarrow{\alpha\text{-AMY}} \text{E-G5} + \text{E-G4} + \text{E-G3} + \text{G2-NP} + \text{G3-NP} + \text{G4-NP}$$

$$\text{G2-NP} + \text{G3-NP} + \text{G4-NP} + H_2O \xrightarrow{\alpha\text{-Glucosidase}} \text{Glucose (G)} + \text{4-NP}$$

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	HEPES	50 mmol/L
	Glucosidase	5.5 - 6.5 KU/L
R2	HEPES	50 mmol/L
	Ethylene-pNP-G7	7.5 - 9.5 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 °C and kept away from freezing. The unopened reagents are valid for 18 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 °C. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Sample types are serum, plasma (heparin), or urine (random or timed). Serum and plasma are stable for 4 days at room temperature, 2 weeks at 2 - 8 °C, and 1 year at - 20 °C to avoid repeated freezing and thawing. Urine is stable for 7 days at 2 - 8 °C with pH adjusted to 7.0 prior to storage.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When the blank absorbance > 0.35, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. **Parameters**

Method	Rate Method	**Sample/Reagent**	1/50
Main Wavelength	405 nm	**Reaction Temperature**	37 °C
Sub Wavelength	505 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. **Operation**

Addition	**Blank**	**Calibration**	**Detection**
Sample (μL)	/	/	5
Calibrator (μL)	/	5	/
Purified Water (μL)	5	/	/
Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 °C for 5 min			
Reagent 2 (μL)	50	50	50
Mix well, incubate at 37 °C for 1 min, measure the average absorbance change rate ΔA/min within 2 min.			

3. **Calibration**

Use Randox multi-analyte calibrator or Zybio Clinical Chemistry Multi-analyte Calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. **Quality Control**

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it

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is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The catalytic activity concentration of α-Amylase (α-AMY) in the sample can be calculated on the working curve based on its absorbance change rate.

Reference Intervals

Serum: < 140 U/L

Urine: < 640 U/L

This reference interval is determined according to the 95% distribution area of 200 healthy human specimens without related diseases in each group, and is only for reference. It is recommended that each laboratory establish its own reference interval.

Explanation of Results

1. If the catalytic activity concentration of α-AMY in the sample exceeds 1000 U/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.
2. The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by re-measuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.
3. The results obtained from tests using reagents from different manufacturers or methodologies should not be directly compared to each other to avoid incorrect medical interpretation; it is recommended that the laboratory indicate the characteristics of the reagents used in the test report sent to the clinician.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.3 g/L
Hemoglobin	1.25 g/L
Bilirubin	342 μmol/L
Triglyceride	10 mmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.35; the reagent blank absorbance change rate (ΔA/min) ≤ 0.002.
2. Analytical sensitivity: at the test catalytic activity concentration of 140 U/L, the reagent absorbance change rate (ΔA/min) ≥ 0.01.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 10%.
5. Linear Range:

[5, 1000] U/L, the correlation coefficient (r) ≥ 0.990.

[5, 50] U/L, the absolute deviation ≤ 5 U/L;

(50, 1000] U/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Current Version: 02 Date of Issue: May, 2022

CE IVD

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Instructions for Use of Albumin (ALB) Kit (Bromocresol Green Method)

Package Specification

REF	Reagent	Systems
01.09.00.04.EC.01	R 30 mL × 6	Zybio EXC200/220
01.09.00.04.EC.03	R 60 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of albumin (ALB) concentration in human samples (serum). Clinically, it is mainly used as an aid to evaluation of liver function as well as nutritional assessment.

Summary

Albumin is a carbohydrate-free protein, which constitutes 55 - 65% of total plasma protein. It maintains plasma oncotic pressure, and is also involved in the transport and storage of a wide variety of ligands and is a source of endogenous amino acids. Albumin binds and solubilizes various compounds, e g. bilirubin, calcium and long-chain fatty acids. Furthermore, albumin is capable of binding toxic heavy metal ions as well as numerous pharmaceuticals, which is the reason why lower albumin concentrations in blood have a significant effect on pharmacokinetics.

Hyperalbuminemia is of little diagnostic significance except in the case of dehydration. Hypoalbuminemia occurs during many illnesses and is caused by several factors: compromised synthesis due either to liver disease or as a consequence of reduced protein uptake; elevated catabolism due to tissue damage (severe burns) or inflammation; malabsorption of amino acids (Crohn's disease); proteinuria as a consequence of nephrotic syndrome; protein loss via the stool (neoplastic disease). In severe cases of hypoalbuminemia, the maximum albumin concentration of plasma is 2.5 g/dL (380 µmol/L). Due to the low osmotic pressure of the plasma, water permeates through blood capillaries into tissue (edema). The determination of albumin allows monitoring of a controlled patient dietary supplementation and serves also as an excellent test of liver function.

Principle

Albumin in serum binds to bromocresol green to form a blue-green complex at pH 4.2, which has an absorption peak at the wavelength of 630 nm, and the change in color intensity is directly proportional to the albumin concentration. The albumin concentration in the serum can be obtained by comparing with that in calibrator treated in the same manner.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R	Bromocresol Green	0.15 mmol/L
	Succinic Acid buffer	74.9 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Non-hemolytic serum is suitable for samples, which are stable at 2 - 8 ℃ for 14 days.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.500, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/100
Main Wavelength	630 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	2 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (µL)	/	/	3
Calibrator (µL)	/	3	/
Purified Water (µL)	3	/	/
Reagent (µL)	300	300	300
Mix well, measure absorbance *A* after 2 min.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality

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control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of albumin (ALB) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

35.0~55.0 g/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of ALB in the sample exceeds 60.00 g/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Chyle	0.30%
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.500.
2. Analytical sensitivity: at the test concentration of 40.0 g/L, the reagent absorbance change (ΔA) ≥ 0.50.
3. Accuracy: relative deviation ≤ 6.0%.
4. Precision: within-run CV ≤ 2.0%, between-run relative range ≤ 5.0%.
5. Linear Range:

[10.0, 60.0] g/L, the correlation coefficient (r) ≥ 0.990.

[10.0, 20.0] g/L, the absolute deviation ≤ 4.0 g/L;

(20.0, 60.0] g/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Guo J, Xie J, Zhao H. Design of method comparison study and bias estimation for albumin assays[J]. Chin J Lab Med, 2000, 23:343-345.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
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	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Instructions for Use of Alkaline Phosphatase (ALP) Kit (Enzymatic Method)

Package Specification

REF	Reagent	Systems
01.09.00.13.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.00.13.EC.03	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of the catalytic activity concentration of alkaline phosphatase (ALP) in human samples (serum or plasma). Clinically, it is mainly used as an aid to diagnosis of hepatobiliary diseases and bone diseases.

Summary

Alkaline phosphatase in serum consists of four structural genotypes: the liver-bone-kidney type, the intestinal type, the placental type and the variant from the germ cells. It occurs in osteoblasts, hepatocytes, leukocytes, the kidneys, spleen, placenta, prostate and the small intestine. The liver-bone-kidney type is particularly important.

A rise in the alkaline phosphatase occurs with all forms of cholestasis, particularly with obstructive jaundice. It is also elevated in diseases of the skeletal system, such as Paget's disease, hyperparathyroidism, rickets and osteomalacia, as well as with fractures and malignant tumors. A considerable rise in the alkaline phosphatase activity is sometimes seen in children and juveniles. It is caused by increased osteoblast activity following accelerated bone growth.

Principle

P-nitrophenyl phosphate + H_2O $\xrightarrow{ALP}$ P-Nitrophenol + Phosphate

The catalytic activity concentration of alkaline phosphatase in the sample shall be calculated by measuring the increasing rate of the absorbance at 405 nm.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	2-Amino-2-methyl-1-propanol (AMP) buffer	597 mmol/L
	Magnesium Acetate	2.0 mmol/L
R2	Disodium 4-nitrophenylphosphate (PNPP)	81.5 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Non-hemolytic serum or plasma (heparin anticoagulation) is suitable for samples, which are stable for 2 days at 2 - 8 ℃ and for 1 month at - 20 ℃.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 1.000, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	Rate Method	Sample/Reagent	1/50
Main Wavelength	405 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	505 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	5
Calibrator (μL)	/	5	/
Purified Water (μL)	5	/	/
Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 ℃ for 5 min			
Reagent 2 (μL)	50	50	50
Mix well, after 2 min, measure the absorbance change within 3 min, and calculate the absorbance change rate ΔA/ min.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The catalytic activity concentration of alkaline phosphatase (ALP) in the sample can be calculated on the working curve based on its absorbance change rate.

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Reference Intervals

Age: 1 - 12, < 500 U/L

Male (Age: 12 - 15): < 750 U/L Adult Male: 45 - 125 U/L

Female (Age: 15 - 20): 40 - 150 U/L Female (Age: 20 - 49): 35 - 100 U/L

Female (Age: 50 - 79): 50 - 135 U/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases per group, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the catalytic activity concentration of ALP in the sample exceeds 1000 U/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Chyle	0.30%
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 1.000, the reagent blank absorbance change rate (ΔA/min) ≤ 0.005.

2. Analytical sensitivity: at the test catalytic activity concentration of 120 U/L, the reagent absorbance change rate (ΔA/min) ≥ 0.010.

3. Accuracy: the relative deviation ≤ 10%.

4. Precision: within-run CV ≤ 5%, between-run relative range ≤ 10%.

5. Linear range:

[25, 1000] U/L, the correlation coefficient (r) ≥ 0.990.

[25, 100] U/L, the absolute deviation ≤ 10 U/L;

(100, 1000] U/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Bowers G, McComb R. Measurement of total alkaline phosphatase activity in human serum[J]. Clin Chem, 1975, 21:1988-1995.

[2] Price P, Toroian D, Chan W. Tissue-nonspecific alkaline phosphatase is required for the calcification of collagen in serum: a possible mechanism for biomineralization[J]. J Biol Chem, 2009, 284:4594-46.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
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Current Version: 02 Date of Issue: May, 2022

CE IVD

zybio

Instructions for Use of Alanine Aminotransferase (ALT) Kit (Enzymatic Method)

Package Specification

REF	Reagent	Systems
01.09.00.05.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.00.05.EC.03	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of alanine aminotransferase activity in human samples (serum or plasma). Clinically, it is mainly used as an aid to diagnosis of hepatobiliary diseases.

Summary

The enzyme alanine aminotransferase (ALT) has been widely reported as present in a variety of tissues. The major source of ALT is the liver, which has led to the measurement of ALT activity for the diagnosis of hepatic diseases. Elevated serum ALT is found in hepatitis, cirrhosis, obstructive jaundice, carcinoma of the liver, and chronic alcohol abuse. ALT is only slightly elevated in patients who have an uncomplicated myocardial infarction. Although both serum aspartate aminotransferase (AST) and ALT become elevated whenever disease processes affect liver cell integrity, ALT is the more liver-specific enzyme. Moreover, elevations of ALT activity persist longer than elevations of AST activity. In patients with vitamin B6 deficiency, serum aminotransferase activity maybe decreased. The apparent reduction in aminotransferase activity may be related to decreased pyridoxal phosphate, the prosthetic group for aminotransferases, resulting in an increase in the ratio of apoenzyme to holoenzyme.

Principle

This kit uses the method recommended by the International Federation of Clinical Chemistry (IFCC):

1. Alanine + α -Ketoglutaric Acid $\xrightarrow{ALT}$ Pyruvic Acid + L-Glutamic Acid

2. Pyruvic Acid + NADH + H^+ $\xrightarrow{LDH}$ L-Lactic Acid + NAD^+ + H_2O

Oxidation of NADH to NAD^+ causes a decrease in absorbance at 340 nm, which is directly proportional to the ALT activity in the sample.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Trometamol (Tris) buffer	62 mmol/L
	Nicotinamide adenine dinucleotide (NADH)	0.4 mmol/L
R2	Trometamol (Tris) buffer	512 mmol/L
	α -Ketoglutaric Acid	79.6 mmol/L
	L-Alanine	898 mmol/L
	Lactate Dehydrogenase (LDH)	≥8.5 kU/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.

2. Once opened, the reagents are stable for 4 weeks at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.

3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Non-hemolytic serum or plasma is suitable for samples, which are stable for 3 days at 2 - 8 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.

2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.

3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.

4. When reagent becomes turbid or the blank absorbance < 1.000, the reagent is failed and should be discarded.

5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.

6. The same sample tested with reagents from different manufacturers may lead to different measured values.

7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	Rate Method	**Sample/Reagent**	6/125
Main Wavelength	340 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	405 nm	**Reaction Time**	10 min
Reaction Direction	-		

2. Operation

Addition	**Blank**	**Calibration**	**Detection**
Sample (μL)	/	/	12
Calibrator (μL)	/	12	/
Purified Water (μL)	12	/	/
Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 ℃ for 5 min			
Reagent 2 (μL)	60	60	60
Mix well, after 2 min, accurately measure the absorbance change rate ΔA/min within 3 min.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

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4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of alanine aminotransferase (ALT) in the sample can be calculated on the working curve based on its absorbance change rate.

Reference Intervals

Male: 9~50 U/L

Female: 7~40 U/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy males and 200 healthy females specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of ALT in the sample exceeds 1000 U/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Hemoglobin	5 g/L
Chyle	0.30%
Bilirubin	300 μmol/L
Triglyceride	11.3 mmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≥ 1.000; the reagent blank absorbance change rate (ΔA/min) ≤ 0.004.

2. Analytical sensitivity: at the test concentration of 130 U/L, the reagent absorbance change rate (ΔA/min) ≥ 0.01.

3. Accuracy: relative deviation ≤ 10%.

4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 10%.

5. Linear Range:

[5, 1000] U/L, the correlation coefficient (*r*) ≥ 0.990.

[5, 40] U/L, the absolute deviation ≤ 4 U/L;

(40, 1000] U/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Prati D, Taioli E, Zanella A, et al. Updated definitions of healthy ranges for serum alanine aminotransferase levels[J]. Ann Intern Med, 2002, 137:1-10.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Current Version: 03 Date of Issue: April, 2023

CE IVD

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Instructions for Use of Aspartate Aminotransferase (AST) Kit (Enzymatic Method)

Package Specification

REF	Reagent	Systems
01.09.00.16.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.00.16.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of aspartate aminotransferase activity in human samples (serum or plasma). Clinically, it is mainly used as an aid to diagnosis of viral hepatitis, obstructive jaundice, and myocardial infarction.

Summary

The enzyme aspartate aminotransferase (AST) is widely distributed in tissue, principally hepatic, cardiac, muscle, and kidney. Elevated serum levels are found in diseases involving these tissues. Hepatobiliary diseases, such as cirrhosis, metastatic carcinoma, and viral hepatitis also increase serum AST levels. Following myocardial infarction, serum AST is elevated and reaches a peak two days after onset. In patients undergoing renal dialysis or those with vitamin B6 deficiency, serum AST may be decreased. The apparent reduction in AST may be related to decreased pyridoxal phosphate, the prosthetic group for AST, resulting in an increase in the ratio of apoenzyme to holoenzyme. Two isoenzymes of AST have been detected, cytoplasmic and mitochondrial. Only the cytoplasmic isoenzyme occurs in normal serum, while the mitochondrial, together with the cytoplasmic isoenzyme, has been detected in the serum of patients with coronary and hepatobiliary disease.

Principle

This kit uses the method recommended by the International Federation of Clinical Chemistry (IFCC):

1. Aspartic Acid + α-Ketoglutaric Acid $\xrightarrow{AST}$ Oxaloacetic Acid + L-Glutamic Acid

2. Oxaloacetic Acid + NADH + H^+ $\xrightarrow{MDH}$ L-Lactic Acid + NAD^+ + H_2O

Oxidation of NADH to NAD^+ causes a decrease in absorbance at 340 nm, which is directly proportional to the AST activity in the sample.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Trometamol (Tris) buffer	62 mmol/L
	Nicotinamide adenine dinucleotide (NADH)	0.4 mmol/L
R2	Trometamol (Tris) buffer	439 mmol/L
	α-Ketoglutaric Acid	37.1 mmol/L
	L-Aspartic Acid	>800 mmol/L
	Malate Dehydrogenase (MDH)	>2.5 kU/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.

2. Once opened, the reagents are stable for 4 weeks at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.

3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Non-hemolytic serum or plasma is suitable for samples, which are stable for 3 days at 2 - 8 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.

2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.

3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.

4. When reagent becomes turbid or the blank absorbance < 1.000, the reagent is failed and should be discarded.

5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.

6. The same sample tested with reagents from different manufacturers may lead to different measured values.

7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	Rate Method	Sample/Reagent	6/125
Main Wavelength	340 nm	Reaction Temperature	37 ℃
Sub Wavelength	405 nm	Reaction Time	10 min
Reaction Direction	-		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	12
Calibrator (μL)	/	12	/
Purified Water (μL)	12	/	/
Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 ℃ for 5 min			
Reagent 2 (μL)	50	50	50
Mix well, after 2 min, measure the average absorbance change rate ΔA/min within 3 min.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

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4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of aspartate aminotransferase (AST) in the sample can be calculated on the working curve based on its absorbance change rate.

Reference Intervals

≤ 40 U/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of AST in the sample exceeds 1000 U/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Chyle	0.30%
Bilirubin	300 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≥ 1.000; the reagent blank absorbance change rate (ΔA/min) ≤ 0.004.

2. Analytical sensitivity: at the test concentration of 130.0 U/L, the reagent absorbance change rate (ΔA/min) ≥ 0.01.

3. Accuracy: relative deviation ≤ 10%.

4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 10%.

5. Linear Range:

[10, 1000] U/L, the correlation coefficient (*r*) ≥ 0.990.

[10, 100] U/L, the absolute deviation ≤ 10 U/L;

(100, 1000] U/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Abdalla D. Clinical chemistry: theory, analysis, correlations[J]. Revista Brasileira de Ciências Farmacêuticas, 2003, 39:348-349.

[2] Tietz N. Fundamentals of clinical chemistry[M]. Saunders, 1987.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Current Version: 02 Date of Issue: May, 2022

CE IVD

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Instructions for Use of Calcium (Ca) Kit (Arsenazo III Method)

Package Specification

REF	Reagent	Systems
01.09.0C.01.EC.01	R 30 mL × 6	Zybio EXC200/220
01.09.0C.01.EC.02	R 60 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of calcium (Ca) concentration in human samples (serum or plasma). Clinically, it is mainly used as an aid to diagnosis of calcium metabolism disorders.

Summary

Calcium is the most abundant mineral element in the body with about 99% in the bones primarily as hydroxyapatite. The remaining calcium is distributed between the various tissues and the extracellular fluids where it performs a vital role for many life sustaining processes. Among the extra skeletal functions of calcium are involvement in blood coagulation, neuromuscular conduction, excitability of skeletal and cardiac muscle, enzyme activation, and the preservation of cell membrane integrity and permeability. Serum calcium levels and hence the body content are controlled by parathyroid hormone (PTH), calcitonin, and vitamin D. An imbalance in any of these modulators leads to alterations of the body and serum calcium levels. Increases in serum PTH or vitamin D are usually associated with hypercalcemia. Increased serum calcium levels may also be observed in multiple myeloma and other neoplastic diseases. Hypocalcemia may be observed e g. in hypoparathyroidism, nephrosis, and pancreatitis.

Principle

The Arsenazo III is combined with calcium ions, forming a purple-colored complex. The color of the complex is proportional to the concentration of calcium ion in the sample, which can be calculated by measuring the absorbance change at 660 nm.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R	Arsenazo III	129 μmol/L
	MES Buffer	4.25 g/L
	Surfactant	0.2% (v/v)

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 4 weeks at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

1. Fresh and nonhemolytic serum or plasma (heparin) is suitable for samples.
2. Samples should be analyzed as soon as possible after collection, which can be stable for 2 days at 20 - 25 ℃, for 14 days at 2 - 8 ℃, and for 3 months at - 20 ℃. Repeated freezing and thawing should be avoided.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. Strict measures shall be taken to avoid contamination since calcium ion is almost omnipresent.
4. When reagent becomes turbid or the blank absorbance > 1.500, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. Trace chelating agents (such as EDTA) present in the detergent can hinder the generation of chromogens. It is recommended to use disposable tubes and pipettes, etc.
7. The same sample tested with reagents from different manufacturers may lead to different measured values.
8. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/100
Main Wavelength	660 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Direction**	+

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent (μL)	300	300	300
Mix well, incubate at 37 ℃ for 2 min, then zero the system at 660 nm as blank and measure absorbance *A*.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

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5. Calculation

Linear calibration was used to draw the working curve. The concentration of calcium ion (Ca) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

Adults Serum: 2.10 - 2.60 mmol/L

Children Serum: 2.50 - 3.00 mmol/L

This reference interval is determined based on 95% distribution interval obtained from 210 healthy human specimens without related diseases per group, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of Ca in the sample exceeds 4.00 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is within ± 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Bilirubin	280 μmol/L
Mg^{2+}	3 mmol/L
K^{+}	8 mmol/L
Na^{+}	180 mmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 1.500.

2. Analytical sensitivity: at the test concentration of 2.50 mmol/L, the absorbance change (ΔA) ≥ 0.20.

3. Accuracy: relative deviation ≤ 5%.

4. Precision: within-run CV ≤ 3%, between-run relative range ≤ 5%.

5. Linear range:

[1.00, 4.00] mmol/L, the correlation coefficient (r) ≥ 0.990.

Within the specified test range, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Massry S, Coburn J, Chapman L, et al. Role of serum Ca, parathyroid hormone, and NaCl infusion on renal Ca and Na clearances[J]. Am J Physiol, 1968, 214:1403-1409.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Current Version: 02 Date of Issue: May, 2022

Instructions for Use of Total Cholesterol (CHOL) Kit (Single) (Enzymatic Method)

Package Specification

REF	Reagent
01.09.02.11.EC.01	R 30 mL × 6
01.09.02.11.EC.02	R 60 mL × 2

Intended Use

In vitro test for the quantitative determination of cholesterol concentration in human samples (serum). Clinically, it is mainly used as an aid to diagnosis of hypercholesterolemia.

Summary

Cholesterol is a steroid with a secondary hydroxyl group in the C3 position. It is synthesized in many types of tissue, but particularly in the liver and intestinal wall. Approximately three quarters of cholesterol is newly synthesized and a quarter originates from dietary intake. Cholesterol assays are used for screening for atherosclerotic risk and in the diagnosis and treatment of disorders involving elevated cholesterol levels as well as lipid and lipoprotein metabolic disorders. Cholesterol analysis was first reported by Liebermann in 1885 followed by Burchard in 1889. In the Liebermann-Burchard reaction, cholesterol forms a blue-green dye from polymeric unsaturated carbohydrates in an acetic acid/acetic anhydride/concentrated sulfuric acid medium. The Abell and Kendall method is specific for cholesterol, but is technically complex and requires the use of corrosive reagents. In 1974, Roeschlau and Allain described the first fully enzymatic method. This method is based on the determination of Δ4-cholestenone after enzymatic cleavage of the cholesterol ester by cholesterol esterase, conversion of cholesterol by cholesterol oxidase, and subsequent measurement by the Trinder reaction of the hydrogen peroxide formed. Optimization of ester cleavage (> 99.5%) allows standardization using primary and secondary standards and a direct comparison with the CDC and NIST reference methods. Nonfasting sample results may be slightly lower than fasting results. The Roche cholesterol assay meets the 1992 National Institutes of Health (NIH) goal of less than or equal to 3% for both precision and bias. The assay is optionally standardized against Abell/Kendall and isotope dilution/mass spectrometry. The performance claims and data presented here are independent of the standardization.

Principle

Cholesteryl Ester $\xrightarrow{\text{Cholesterol Esterase}}$ Cholesterol + Fatty Acid

Cholesterol + O_2 $\xrightarrow{\text{Cholesterol Oxidase}}$ 3-cholestenone + H_2O_2

H_2O_2 + 4-AAP + Phenol $\xrightarrow{\text{Peroxidase}}$ Quinonimine + H_2O

The content of total cholesterol in the sample could be calculated by comparing the absorbance change measured at 505 nm with calibrator treated in the same manner.

Reagents Components and Concentration

Composition: R

R	Hepes Buffer	50 mmol/L
	$MgCl_2$	10 mmol/L
	4-AAP	0.3 mmol/L
	Peroxidase	2000 U/L
	Cholesterol Esterase	3000 U/L
	Cholesterol Oxidase	300 U/L
	Phenol	1.5 mmol/L

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The reagents could be stable for 2 weeks at 2 - 8 ℃ in transportation.
4. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

1. Serum is suitable for samples and is stable for 3 days at 2 - 8 ℃ and for 30 days at -20 ℃.
2. Repeated freezing and thawing should be avoided.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or blank absorbance > 0.100, the reagent is invalid and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. **Parameters**

Method	End-Point Method	**Sample / Reagent**	1/100
Main Wavelength	505 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. **Operations**

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water	3	/	/

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Reagent (μL)	300	300	300
Mix well, incubate at 37 ℃ for 10 min, and measure absorbance *A*.			

3. Calibration

Use Zybio clinical chemistry multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

Indoor quality control is recommended. Values obtained should fall within the limited range. If there is a failure of any of controls, the laboratory should take appropriate corrective measures.

5. Calculation

CHOL (mmol/L) = (*A* Sample / *A* Calibrator) × C Calibrator

Reference Intervals

≤ 5.2 mmol/L (≤ 200 mg/dL)

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration exceeds 20.0 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, gender or weight. The measured values within the critical range should be re-determined and confirmed, if it is obviously beyond the reference range or if it is still beyond the reference range after confirmation, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations-Interference

The deviation of test results caused by interferents is within ± 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
VC	500 mg/L
Hemoglobin	5 g/L
Bilirubin	342 μmol/L

Performance Characteristics

1. The reagent blank absorbance: ≤ 0.100.

2. Analytical sensitivity: at the test concentration of 5.0 mmol/L, the absorbance change (Δ*A*) > 0.10.

3. Accuracy: relative deviation ≤ 10%.

4. Precision: within-run *CV* ≤ 4%, between-run relative range ≤ 6%.

5. Linear range:

[1.0, 20.0] mmol/L, the correlation coefficient (*r*) ≥ 0.990.

[1.0, 4.0] mmol/L, the absolute deviation ≤ 0.4 mmol/L;

(4.0, 20.0] mmol/L, the relative deviation ≤ 10%.

References

[1] Allain C C, Poon L S, Chan C S G, et al. Enzymatic Determination of Total Serum Cholesterol[J]. Clinical Chemistry, 1974, 20(4):470-475.

[2] Trinder, P. Determination of Glucose in Blood Using Glucose Oxidase with an Alternative Oxygen Acceptor[J]. Ann.clin.biochem, 1969, 6(1):24-27.

[3] Siedel J, EO Hägele, Ziegenhorn J et al. Reagent for the enzymatic determination of serum total cholesterol with improved lipolytic efficiency[J]. Clinical Chemistry, 2019(6):6.

[4] Wiebe D A Bernert J T Influence of incomplete cholesteryl ester hydrolysis on enzymic measurements of cholesterol [J]. Clinical Chemistry, 1984(3):352-356.

[5] Cohn J S, Mcnamara J R, Schaefer E J. Lipoprotein cholesterol concentrations in the plasma of human subjects as measured in the fed and fasted states [J]. Clinical Chemistry, 1988(12):2456-2459.

Label Interpretation

	In Vitro Diagnostic Medical Device		Batch Code
	Consult Instructions for Use		Use-By Date
	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture

 **Manufacturer Information**

Zybio Inc.

Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA.

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CE IVD

Instructions for Use of Total Cholesterol (CHOL) Kit (Enzymatic Method)

Package Specification

REF	Reagent	Systems
01.09.02.10.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.02.10.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of total cholesterol (CHOL) concentration in human samples (serum).

Summary

Total cholesterol is the sum of cholesterol contained in all lipoproteins in the blood and is an important index for the prevention and treatment of dyslipidemia. There are primary hypercholesterolemia and secondary hypercholesterolemia. Primary hypercholesterolemia is mainly caused by genetic factors, while secondary hypercholesterolemia is common in diabetes mellitus, nephrotic syndrome, fatty liver, and hypothyroidism. Hypercholesterolemia is one of the major risk factors for coronary heart disease.

The kit uses enzymatic method to determine the concentration of total cholesterol (CHOL) in the sample. The cholesterol ester in the sample was hydrolyzed by cholesterol esterase into free fatty acid and free cholesterol, the latter was oxidized by cholesterol oxidase to cholestenone and produces H_2O_2. Finally, the Trinder reaction was coupled to produce a colored quinonimine, causing an increase in absorbance. The degree of increase is proportional to the concentration of CHOL in the sample. By monitoring the change of absorbance and comparing with the calibrator of the same treatment, the concentration of CHOL in the sample can be calculated according to the working curve.

Principle

1. Cholesteryl Ester + H_2O $\xrightarrow{\text{Cholesterol Esterase}}$ Cholesterol + Fatty Acid
2. Cholesterol + O_2 $\xrightarrow{\text{Cholesterol Oxidase}}$ Cholestenone + H_2O_2
3. $2H_2O_2$ + 4-AAP + TOOS $\xrightarrow{\text{Peroxidase}}$ Quinonimine + $4H_2O$

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	N-2-hydroxyethylpiperazine-N'-2-ethanesulfonic acid	40-60 mmol/L
	Phenol	1-2 mmol/L
	Cholesterol Esterase	2-4 kU/L
R2	N-2-hydroxyethylpiperazine-N'-2-ethanesulfonic acid	40-60 mmol/L
	Peroxidase	8-12 kU/L
	Cholesterol Esterase	2-4 kU/L
	Cholesterol Oxidase	1-2 kU/L
	4-Aminoantipyrine (4-AAP)	1-2 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 18 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum is suitable for samples, which shall be separated in time after collection to avoid hemolysis. Samples are stable for 3 days at 2 - 8 ℃ and 30 days at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.080, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. **Parameters**

Method	End-Point Method	**Sample/Reagent**	1/100
Main Wavelength	546 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. **Operation**

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent 1 (μL)	240	240	240
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	60	60	60
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

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3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of total cholesterol (CHOL) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

≤ 5.2 mmol/L (≤ 200 mg/dL)

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of CHOL in the sample exceeds 20.0 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
VC	0.5 g/L
Hemoglobin	5 g/L
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.080.

2. Analytical sensitivity: at the test concentration of 5.0 mmol/L, the reagent absorbance change (ΔA) > 0.10.

3. Accuracy: relative deviation ≤ 10%.

4. Precision: within-run *CV* ≤ 3%, between-run relative range ≤ 5%.

5. Linear Range:

[1.0, 20.0] mmol/L, the correlation coefficient (*r*) ≥ 0.990.

[1.0, 4.0] mmol/L, the absolute deviation ≤ 0.4 mmol/L;

(4.0, 20.0] mmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Allain C, Poon L, Chan C, et al. Enzymatic Determination of Total Serum Cholestero[J]. Clinical Chemistry, 1974, 20:470-475.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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EC REP Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Current Version: 02 Date of Issue: May, 2022

CE IVD

zybio

Instructions for Use of Creatine Kinase (CK) Kit (Rate Method)

Package Specification

REF	Reagent	Systems
01.09.04.03.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.04.03.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of the catalytic activity concentration of creatine kinase (CK) in human samples (serum or plasma). Clinically, serum creatine kinase levels increased in certain tissue damage or diseases, such as myocardial infarction, muscular dystrophy, acute cerebrovascular accident, etc.

Summary

Creatine kinase (CK), also known as creatine phosphokinase. The contents of creatine kinase in skeletal muscle, myocardium, and smooth muscle were more, followed by brain tissue, and the contents in gastrointestinal tract, lung and kidney were less. CK is an important kinase that is directly related to intracellular energy transport, muscle contraction, and ATP regeneration. When the striated muscle of the human body is damaged and necrotic, creatine kinase is released into the blood and abnormally elevated during detection. However, the increase of creatine kinase lacks specificity.

If it is combined with the increase of creatine kinase isoenzyme and troponin, it shall be judged that the myocardium is damaged. If abnormal elevation of myoglobin is also combined, it shall be judged that skeletal muscle injury occurs.

Principle

This kit uses rate method (improved based on the method recommended by IFCC) to determine the catalytic activity concentration of CK in samples. Creatine kinase (CK) catalyzes the conversion of phosphocreatine to creatine, while ADP is phosphorylated to ATP. Hexokinase (HK) catalyzes the reaction between ATP and glucose to generate glucose-6-phosphate. Glucose-6-phosphate dehydrogenase (G6PDH) catalyzes glucose-6-phosphate to generate 6-phosphogluconic acid, and simultaneously converts oxidative nicotinamide adenine dinucleotide phosphate ($NADP^+$) into reduced nicotinamide adenine dinucleotide phosphate (NADPH), causing the increase of the absorbance. The rate of increase is directly proportional to the catalytic activity concentration of CK in the sample. By continuously monitor the absorbance change rate, the catalytic activity concentration of CK in the sample can be calculated from the calibration curve generated by the calibrator treated in the same manner.

1. Phosphocreatine + ADP $\xrightarrow{CK}$ Creatine + ATP
2. ATP + Glucose $\xrightarrow{HK}$ Glucose-6-phosphate + ADP
3. Glucose-6-phosphate + $NADP^+$ $\xrightarrow{G6PDH}$ 6-phosphogluconic acid + NADPH + H^+

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	D-Glucose	20-30 mmol/L
	Nicotinamide adenine dinucleotide phosphate oxidized form ($NADP^+$)	1.5-2.0 g/L
	Hexokinase	4-8 kU/L
	Imidazole buffer	100 mmol/L
R2	Glucose-6-phosphate dehydrogenase (G6PDH)	12-16 kU/L
	Phosphocreatine	80-120 mmol/L
	Adenosine-5'-diphosphate (ADP) potassium salt	7-9 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from freezing. The unopened reagents are valid for 18 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum or plasma (heparin for anticoagulation) is suitable for samples, which shall be separated in time after collection to avoid hemolysis. Samples containing EDTA, citrate, and chloride should not be used. Samples are stable for 1 day at 2 - 8 ℃ and 30 days at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When the blank absorbance > 0.400, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	Rate Method	**Sample/Reagent**	1/25
Main Wavelength	340 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	546 nm	**Reaction Time**	10 min
Reaction Direction	+		

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2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	10
Calibrator (μL)	/	10	/
Purified Water (μL)	10	/	/
Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 ℃ for 5 min			
Reagent 2 (μL)	50	50	50
Mix well, after adding R2 for 45 s, continuously monitor the absorbance change within 4 min and 15 s, and calculate the absorbance change rate Δ*A*/min.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The catalytic activity concentration of creatine kinase (CK) in the sample can be calculated on the working curve based on its absorbance change rate.

Reference Intervals

Male: 38~174 U/L Female: 26~140 U/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases per group, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the catalytic activity concentration of CK in the sample exceeds 1000 U/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is ≤ 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	1.0 g/L
Hemoglobin	5 g/L
Bilirubin	342 μmol/L
Triglyceride	10 mmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.400; the reagent blank absorbance change rate (Δ*A*/min) ≤ 0.002.
2. Analytical sensitivity: at the test catalytic activity concentration of 100 U/L, the reagent absorbance change rate (Δ*A*/min) > 0.002.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 10%.
5. Linear Range:

[25, 1000] U/L, the correlation coefficient (*r*) ≥ 0.990.

[25, 100) U/L, the absolute deviation ≤ 10 U/L;

[100, 1000] U/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Kitzenberg D, Colgan S, Glover L. Creatine kinase in ischemic and inflammatory disorders[J]. Clin Transl Med, 2016, 5:31.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Current Version: 02 Date of Issue: May, 2022

CE IVD

zybio

Instructions for Use of Creatinine (CREA) Kit (Enzymatic Method)

Package Specification

REF	Reagent	Systems
01.09.01.05.EC.01	R1 30 mL × 2 R2 10 mL × 2	Zybio EXC200/220
01.09.01.05.EC.02	R1 30 mL × 1 R2 10 mL × 1	Zybio EXC200/220
01.09.01.05.EC.03	R1 45 mL × 2 R2 15 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of creatinine (CREA) concentration in human samples (serum, plasma or urine). Clinically, it is mainly used as one of the evaluation indicators of renal function.

Summary

Chronic kidney disease is a worldwide problem that carries a substantial risk for cardiovascular morbidity and death. Current guidelines define chronic kidney disease as kidney damage or glomerular filtration rate (GFR) less than 60 mL/min per 1.73 m^2 for three months or more, regardless of cause. The assay of creatinine in serum or plasma is the most commonly used test to assess renal function. Creatinine is a break-down product of creatine phosphate in muscle, and is usually produced at a fairly constant rate by the body (depending on muscle mass). It is freely filtered by the glomeruli and, under normal conditions, is not re-absorbed by the tubules to any appreciable extent. A small but significant amount is also actively secreted. Since a rise in blood creatinine is observed only with marked damage of the nephrons, it is not suited to detect early stage kidney disease. A considerably more sensitive test and better estimation of glomerular filtration rate (GFR) is given by the creatinine clearance test based on creatinine's concentration in urine and serum or plasma, and urine flow rate. For this test a precisely timed urine collection (usually 24 hours) and a blood sample are needed. However, since this test is prone to error due to the inconvenient collection of timed urine, mathematical attempts to estimate GFR based only on the creatinine concentration in serum or plasma have been made. Among the various approaches suggested, two have found wide recognition: that of Cockroft and Gault and that based on the results of the MDRD trial. While the first equation was derived from data obtained with the conventional Jaffé method, a newer version of the second is usable for IDMS-traceable creatinine methods. Both are applicable for adults. In children, the Schwartz formula should be used. In addition to the diagnosis and treatment of renal disease, the monitoring of renal dialysis, creatinine measurements are used for the calculation of the fractional excretion of other urine analytes (e g, albumin, α -amylase). Numerous methods were described for determining creatinine. Automated assays established in the routine laboratory include the Jaffé alkalinepicrate method in various modifications, as well as enzymatic tests.

Principle

This kit uses an enzymatic method to determine the concentration of creatinine (CREA) in samples.

Creatinine (CREA) in the sample is hydrolyzed by creatininase to creatine, which is hydrolyzed to sarcosine and carbamide catalyzed by creatinase. Sarcosine is oxidized to glycine, formaldehyde, and H_2O_2 catalyzed by sarcosine oxidase, and finally coupled with Trinder reaction to form colored quinonimine, causing an increase in absorbance. The degree of increase is proportional to the concentration of CREA in the sample. By monitoring the change of absorbance and comparing it with that of the calibrator treated in the same manner, the concentration of CREA in the sample can be calculated according to the working curve.

1. Creatinine + H_2O $\xrightarrow{\text{Creatininase}}$ Creatine
2. Creatine + H_2O $\xrightarrow{\text{Creatinase}}$ Sarcosine + Carbamide
3. Sarcosine + H_2O + O_2 $\xrightarrow{\text{Sarcosine Oxidase}}$ Glycine + HCHO + H_2O_2
4. $2H_2O_2$ + 4-AAP + TOOS $\xrightarrow{\text{Peroxidase}}$ Quinonimine + $4H_2O$

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Creatinase	≥10 kU/L
	Sarcosine Oxidase	≥7.5 kU/L
	Sodium 3-(N-Ethyl-3-Methylanilino)-2-Hydroxypro Panesulfonate（TOOS）	≥1 mmol/L
R2	Creatininase	≥100 kU/L
	4-Aminoantipyrine (4-AAP)	≥1 mmol/L
	Peroxidase	≥2 kU/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum, plasma (heparin for anticoagulation) or urine is suitable for samples, which shall be separated as soon as possible after collection to avoid hemolysis.

Serum or plasma (heparin for anticoagulation) are stable for 7 days at 2 - 8 ℃ and for 30 days at - 20 ℃. Avoid repeated freezing and thawing.

Urine are stable for 3 days at room temperature, for 6 days at 2 - 8 ℃ and for 30 days at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When the blank absorbance > 0.300, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

(1) Basic parameters (Blood)

Method	End-Point Method	Sample/Reagent	1/60
Main Wavelength	540 nm	Reaction Temperature	37 ℃
Sub Wavelength	700 nm	Reaction Time	10 min
Reaction Direction	+		

(2) Basic parameters (Urine)

Method	End-Point Method	Sample/Reagent	1/160
Main Wavelength	600 nm	Reaction Temperature	37 ℃
Sub Wavelength	700 nm	Reaction Time	10 min
Reaction Direction	+		

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2. Operation

(1) Operation (Blood)

Addition	Blank	Calibration	Detection
Sample (Blood) (μL)	/	/	5
Calibrator (μL)	/	5	/
Purified Water (μL)	5	/	/
Reagent 1 (μL)	225	225	225
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	75	75	75
Mix well, incubate at 37 ℃ for 5 min, then measure absorbance A_2, calculate $\Delta A = A_2 - A_1$.			

(2) Operation (Urine)

Addition	Blank	Calibration	Detection
Sample (Urine) (μL)	/	/	2
Calibrator (μL)	/	2	/
Purified Water (μL)	2	/	/
Reagent 1 (μL)	240	240	240
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	80	80	80
Mix well, incubate at 37 ℃ for 5 min, then measure absorbance A_2, calculate $\Delta A = A_2 - A_1$.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of creatinine (CREA) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

Serum: Male: 44~97 μmol/L; Female: 35~80 μmol/L;
Morning urine: Male: 3540~24600 μmol/L; Female: 2550~20000 μmol/L;
24-hour urine: Male: 9000~19000 μmol/L; Female: 6000~13000 μmol/L;

Explanation of Results

1. If the concentration of CREA in the blood sample exceeds 2000 μmol/L or the concentration of CREA in the urine sample exceeds 40000 μmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.
2. The system can be configured to initiate automatic repetition, and setting the automatic repetition conditions (when the test result exceeds 40000 μmol/L, it is recommended to use a triple dilution for automatic repeated detection) can extend the urine detection range to 120000 μmol/L. Automatic repetition results will be marked as automatic repetition.
3. The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is ≤ 10% if the concentrations of the following interferents are at or below the given values:

Sample	Substances	Concentrations
Blood	Bilirubin	342 μmol/L
	Hemoglobin	1 g/L
	Triglyceride	10 mmol/L
	Vc	500 mg/L
Urine	Bilirubin	342 μmol/L
	Hemoglobin	5 g/L
	Triglyceride	11 mmol/L
	Vc	4 g/L
	Glucose	150 mmol/L
	Urea	1600 mmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.300.
2. Analytical sensitivity:
Blood: at the test concentration of 100 μmol/L, the reagent absorbance change (ΔA) ≥ 0.010.
Urine: at the test concentration of 2000 μmol/L, the reagent absorbance change (ΔA) ≥ 0.040.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run CV ≤ 3%, between-run relative range ≤ 6%.
5. Linear Range:
Correlation coefficient:
Blood: [20, 2000] μmol/L, the correlation coefficient (r) ≥ 0.990.
Urine: [100, 40000] μmol/L, the correlation coefficient (r) ≥ 0.990.
Linearity deviation:
Blood: [20, 70) μmol/L, the absolute deviation ≤ 7 μmol/L;
[70, 2000] μmol/L, the relative deviation ≤ 10%.
Urine: [100, 3000) μmol/L, the absolute deviation ≤ 300 μmol/L;
[3000, 40000] μmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Huidobro E, Tagle R, Guzmán A. Estimation of glomerular filtration rate with creatinine[J]. Rev Med Chil, 2018, 146:344-350.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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CE IVD

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Instructions for Use of Direct Bilirubin (DBIL) Kit (Vanadate Oxidation Method)

Package Specification

REF	Reagent	Systems
01.09.00.20.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.00.20.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of direct bilirubin concentration in human samples (serum or plasma). Clinically, it is mainly used as an evaluation indicator of bilirubin metabolism disorders.

Summary

Bilirubin is formed in the reticuloendothelial system during the degradation of aged erythrocytes. The heme portion from hemoglobin and from other heme-containing proteins is removed, metabolized to bilirubin, and transported as a complex with serum albumin to the liver. In the liver, bilirubin is conjugated with glucuronic acid for solubilization and subsequent transport through the bile duct and elimination via the digestive tract.

Diseases or conditions which, through hemolytic processes, produce bilirubin faster than the liver can metabolize it, cause the levels of unconjugated (indirect) bilirubin to increase in the circulation. Liver immaturity and several other diseases in which the bilirubin conjugation mechanism is impaired cause similar elevations of circulating unconjugated bilirubin. Bile duct obstruction or damage to hepatocellular structure causes increases in the levels of both conjugated (direct) and unconjugated (indirect) bilirubin in the circulation.

Principle

The direct bilirubin in the sample is oxidized to biliverdin, which causes a decrease in absorbance at 450 nm.

1. Bilirubin $\xrightarrow{\text{Vanadate}}$ Biliverdin

The concentration of direct bilirubin in the sample shall be calculated by measuring the absorbance change at 450 nm and comparing with that in calibrator treated in the same manner.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Citric Acid buffer	100 mmol/L
	Surfactant 1	>0.1% (v/v)
R2	Citric Acid buffer	4.9 mmol/L
	Sodium Metavanadate	>5 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum or plasma (heparin anticoagulation) is suitable for samples, which are stable for 3 days at 2 - 8 ℃. Samples should be protected from direct light.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.300, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/35
Main Wavelength	450 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	546 nm	**Reaction Time**	10 min
Reaction Direction	-		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	10
Calibrator (μL)	/	10	/
Purified Water (μL)	10	/	/
Reagent 1 (μL)	280	280	280
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	70	70	70
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is

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out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of direct bilirubin (DBIL) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

≤ 6.89 μmol/L (≤ 0.4mg/dL)

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of DBIL in the sample exceeds 300.00 μmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Hemoglobin	5 g/L
Chyle	0.30%

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.300.
2. Analytical sensitivity: at the test concentration of 15.00 μmol/L, the reagent absorbance change (ΔA) ≥ 0.008.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 10%.
5. Linear Range:

[2.00, 300.00] μmol/L, the correlation coefficient (*r*) ≥ 0.990.

[2.00, 20.00] μmol/L, the absolute deviation ≤ 2.00 μmol/L;

(20.00, 300.00] μmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Gu D, Wang Y, Ren B, et al. Comparison of Three Routine Methods for the Measurement of Serum Bilirubin in a China Laboratory[J]. Clin Lab, 2018, 64:1485-1490.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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CE IVD

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Instructions for Use of Gamma-Glutamyl Transferase (GGT) Kit (Enzymatic Method)

Package Specification

REF	Reagent	Systems
01.09.00.03.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.00.03.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of the catalytic activity concentration of γ-glutamyl transferase in human samples (serum or plasma). Clinically, it is mainly used as an aid to diagnosis of hepatobiliary diseases.

Summary

γ-Glutamyl transferase is used in the diagnosis and monitoring of hepatobiliary diseases. Enzymatic activity of GGT is often the only parameter with increased values when testing for such diseases, and is one of the most sensitive indicators known. γ-Glutamyl transferase is also a sensitive screening test for occult alcoholism. Elevated GGT activities are found in the serum of patients requiring long-term medication with phenobarbital and phenytoin. In 1969, Szasz published the first kinetic procedure for GGT in serum using γ-glutamyl-p-nitroanilide as substrate and glycylglycine as acceptor. In order to circumvent the poor solubility of γ-glutamyl-p-nitroanilide, Persijn and van der Slik investigated various derivatives and found the water soluble substrate L-γ-glutamyl-3-carboxy-4-nitroanilide to be superior in terms of stability and solubility. The results correlate with those derived using the original substrate. In 2002, the International Federation of Clinical Chemistry (IFCC) recommended the standardized method for determining GGT including optimization of substrate concentrations, employment of NaOH, glycylglycine buffer and sample start.

Principle

The kit uses a modified version of the method recommended by the International Federation of Clinical Chemistry (IFCC):

L-γ-Glutamyl-3-Carboxy-4-Nitroaniline + Glycylglycine $\xrightarrow{\text{GGT}}$ L-γ-Glutamyl Glycylglycine + 5-Amino-2-Nitrobenzoate

This causes an increase in absorbance at 405 nm, which is directly proportional to the catalytic activity concentration of GGT in the sample.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Glycylglycine	127.8 mmol/L
	Trometamol (Tris) buffer	154.6 mmol /L
R2	L-γ-Glutamyl-3-Carboxy-4-Nitroaniline	6 g/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 4 weeks at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Non-hemolytic serum or plasma (EDTA for anticoagulation) is suitable for samples. The γ-glutamyl transferase in samples is stable for 7 days at 2 - 8 ℃.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.800, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. Considering the reaction solution turbidity caused by heparin and inhibition of GGT by citrate, oxalate, and fluoride, plasma with these substances as anticoagulant is not suitable for GGT determination.
7. The same sample tested with reagents from different manufacturers may lead to different measured values.
8. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. **Parameters**

Method	Rate Method	**Sample/Reagent**	1/10
Main Wavelength	405 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	505 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. **Operation**

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	25
Calibrator (μL)	/	25	/
Purified Water (μL)	25	/	/
Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 ℃ for 3 ~ 5 min			
Reagent 2 (μL)	50	50	50
After 1 min, continuously monitor the absorbance change within 2 min, and calculate the absorbance change rate ΔA/min.			

3. **Calibration**

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

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4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The catalytic activity concentration of γ-glutamyl transferase (GGT) in the sample can be calculated on the working curve based on its absorbance change rate.

Reference Intervals

Male: 11 - 50 U/L Female: 7 - 32 U/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases per group, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the catalytic activity concentration of GGT in the sample exceeds 600 U/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Hemoglobin	5 g/L
Bilirubin	684 μmol/L
Triglyceride	10 g/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.800, the reagent blank absorbance change rate (Δ*A*/min) ≤ 0.005.
2. Analytical sensitivity: at the test catalytic activity concentration of 50 U/L, the absorbance change rate (Δ*A*/min) ≥ 0.010.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 10%.
5. Linear range:

[10, 600] U/L, the correlation coefficient (*r*) ≥ 0.990.

[10, 50] U/L, the absolute deviation ≤ 5 U/L;

(50, 600] U/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Szasz G. A kinetic photometric method for serum gamma-glutamyl transpeptidase[J]. Clin Chem, 1969, 15:124-136.

[2] Schumann G, Bonora R, Ceriotti F, et al. IFCC primary reference procedures for the measurement of catalytic activity concentrations of enzymes at 37 degrees C. International Federation of Clinical Chemistry and Laboratory Medicine. Part 4. Reference procedure for the measurement of catalytic concentration of alanine aminotransferase[J]. Clin Chem Lab Med, 2002, 40:718-724.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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CE IVD

Instructions for Use of Glucose (GLU) Kit (Hexokinase Method)

Package Specification

REF	Reagent	Systems
1080201	R1 30 mL × 1 R2 7.5 mL × 1	Zybio EXC200/220
1080202	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
1080203	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of glucose in human samples (serum or plasma). Clinically, the measurements are used as an aid to diagnosis of diabetes mellitus.

Summary

Glucose(GLU) is a kind of hexose containing aldehyde group, whose molecular formula is $C_6H_{12}O_6$, and it is the most important monosaccharide in organisms. Its main function is to provide energy needed for physiological activities.

Glucose and energy homeostasis are maintained through multiple interacting complex feed-back systems that involves neuronal, hormonal, and metabolic components.

Glucose is of central metabolic importance in virtually all organisms, from microbes to humans. Glycolytic metabolism of glucose is a major pathway for the generation of energy (ATP). The phosphorylation of glucose is the first step in glycolysis. A family of hexose phosphorylating enzymes, the hexokinases, carry out this important process. Glucose, glucose 6-phosphate (G-6-P), and α-glucose 1-phosphate (α-G1P) are three essential molecules. When glucose enters a cell, it is first converted to G-6-P upon phosphorylation at C6 by hexokinase (HK).

Principle

The kit uses hexokinase method to determine glucose in serum or plasma.

1. GLU + ATP $\xrightarrow{\text{Hexokinase}}$ G-6-P + ADP

2. G-6-P + NAD^+ $\xrightarrow{\text{G6PDH}}$ 6-Phosphogluconic Acid + NADH + H^+

The glucose content in the sample could be calculated by comparing the variation value of NADH absorbance measured at 340 nm with calibrator treated by the same way.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Adenosine triphosphate (ATP)	8-10 mmol/L
R2	Nicotinamide adenine dinucleotide (NAD^+)	5-8 mmol/L
	Hexokinase	5-10 kU/L
	Glucose-6-phosphate dehydrogenase (G6PDH)	8-15 kU/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 18 months.
2. Once opened, the reagents are stable for 35 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum and plasma (Na-heparin or K_2-EDTA) are the recommended specimen types. The serum and plasma (Na-heparin) samples are stable for 24 hours at 2 - 8 °C, for 30 days at - 20 °C, and for 3 freezing-thawing cycles.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.600, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/100
Main Wavelength	340 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	405 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent 1 (μL)	240	240	240
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	60	60	60
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

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4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of glucose (GLU) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

3.9~6.1 mmol/L

This reference interval is determined based on 95% distribution interval obtained from 132 healthy human specimens without related diseases and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of GLU in the sample exceeds 40.0 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is within ± 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Hemoglobin	5 g/L
Chyle	0.30%
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests, and treatment response. To achieve diagnostic purposes, the test results should be combined with clinical tests, medical history, and other test results.

Performance Characteristics

1. The product has a limit of blank (LoB) of 0.06 mmol/L.
2. The product has a limit of detection (LoD) of 0.13 mmol/L.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: ≤ 5%CV for specimen from 2.0 - 7.0 mmol/L, and ≤ 4%CV for specimen > 7.0 mmol/L.
5. Linear Range:

[2.0, 40.0] mmol/L, the correlation coefficient (r) ≥ 0.990.

[2.0, 4.0) mmol/L, the absolute deviation ≤ 0.4 mmol/L;

[4.0, 40.0] mmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Marco V, Zhao F. Viriyapong R, et al. The impact of ageing, fasting and high-fat diet on central and peripheral glucose tolerance and glucose-sensing neural networks in the arcuate nucleus [J]. J Neuroendocrinol, 2017, 29:10.1111/jne.12528.

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[3] Middleton R. Hexokinases and glucokinases[J]. Biochem Soc Trans, 1990, 18: 180-183.

[4] Tang Y, Cheng F, Feng Z, et al. Stereostructural Elucidation of Glucose Phosphorylation by Raman Optical Activity[J]. J Phys Chem B, 2019, 123:7794-7800.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Current Version: 02 Date of Issue: May, 2022

CE IVD

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Instructions for Use of Glycated Hemoglobin A1c (HbA1c) Kit (Immunoturbidimetric Method)

Package Specification

REF	Reagent	Systems
01.09.06.03.EC.01	R1 15 mL × 2 R2 10 mL × 1 Lyse 50 mL × 2 Calibrator 5 Levels × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	Zybio EXC200/220
01.09.06.03.EC.02	R1 15 mL × 2 R2 10 mL × 1 Lyse 50 mL × 2 Calibrator 5 Levels × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of the percentage of glycated hemoglobin A1c (HbA1c) in human samples (whole blood). Glycated hemoglobin A1c reflects the average blood glucose level 1-2 months before the test, and is a good indicator of diabetes screening and long-term glycemic control in diabetic patients. Clinically, it is mainly used as an aid to diagnosis for diabetes and monitoring blood-sugar levels.

Summary

Glycated hemoglobin A1c (HbA1c) is an important marker in the diagnosis and treatment of diabetes. Specifically glycated hemoglobin A1c (HbA1c) is an index that reflects control of blood glucose in diabetes for a long time (4-10 weeks). Poor long-term control of blood glucose will cause increased content of glycated hemoglobin. So determination of HbA1c can help to control the blood glucose in diabetics and it plays an important role in the study of peripheral vascular and cardiovascular complications of diabetes.

Principle

This kit is used to directly detect the percentage of HbA1c in total hemoglobin (Hb) by antigen-antibody reaction. Total Hb and HbA1c in the sample are solidified because of the same non-specific adsorption as latex. When the specific monoclonal antibody of HbA1c was added to form a complex of latex-HbA1c-mouse anti-human HbA1c monoclonal antibody, it would form agglutination because of goat-anti-mouse IgG. The amount of agglutination varies with that of HbA1c that is subject to latex surface immobilization. The percentage of HbA1c in total hemoglobin (Hb) in the sample is determined by measuring the absorbance and comparing it to the standard curve of HbA1c percent concentration.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Latex solution	0.06-0.18%
R2	Glycated hemoglobin A1c (HbA1c) Antibody	30-54 mg/L
	IgG antibody	42-62 mg/L
Lyse	Purified Water	/
Calibrator	Glycated hemoglobin A1c (HbA1c)	Refer to the label for marked value
	Phosphate buffer	40-60 mmol/L
Control	Glycated hemoglobin A1c (HbA1c)	Refer to the label for marked value
	Phosphate buffer	40-60 mmol/L

The components in different batches are non-interchangeable.

The measurement system can be traceable to JCCRM411-4.

The target value of control has batch specificity.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. To ensure accuracy, calibrator and control are stable for 30 days at - 20 ℃ after reconstitution and subpackage. Avoid repeated freezing and thawing.
4. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

1. Anticoagulated whole blood (EDTA or heparin for anticoagulation) shall be used as sample. Sample pretreatment: 10 μL sample is collected from the blood cell layer which has been kept static settlement for more than 3 hours or the blood cell layer which has been separated by centrifugation at 2000 rpm for 2 minutes, then 1 mL Lyse is added to the sample and mixed well for hemolysis. It is recommended that the hemolyzed sample be tested within 3 hours.
2. Anticoagulant whole blood are stable for 3 days at 15 - 20 ℃ and for 7 days at 2 - 8 ℃. Avoid freezing to prevent hemolysis.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 1.200, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. Dedicated calibrator is recommended for use to ensure the accuracy of test values.
7. The same sample tested with reagents from different manufacturers may lead to different measured values.
8. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. **Parameters**

Method	End-Point Method	**Sample/Reagent**	1/50
Main Wavelength	660 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	800 nm	**Reaction Time**	10 min
Reaction Direction	+		

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2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	8
Calibrator (μL)	/	8	/
Purified Water (μL)	8	/	/
Reagent 1 (μL)	300	300	300
Mix well, incubate at 37 ℃ for 5 min			
Reagent 2 (μL)	100	100	100
Mix well, measure absorbance A_1 after 20 s, and measure absorbance A_2 after another 4 min 40 s, calculate $\Delta A = A_2 - A_1$.			

3. Calibration

Use Zybio matched calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

Calibrator reconstitution: Reconstitution with the amount of purified water labeled on the bottle accurately absorbed, leave for 30 minutes, and mix well before use.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

Control reconstitution: Reconstitution with the amount of purified water labeled on the bottle accurately absorbed, leave for 30 minutes, and mix well before use.

5. Calculation

Multi-point nonlinear calibration was used to draw the working curve. The percentage of glycated hemoglobin A1c (HbA1c) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

Whole blood: 3.8%- 6.0%

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the percentage of HbA1c in the sample exceeds 14.0%, measured after 1 : 1 dilution of no more than 6 % of clinical samples and high-value samples, and then calculate the percentage of high-value samples by dilution ratio and percentage of low-value clinical samples.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is ≤ 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Bilirubin	500 μmol/L
Triglyceride	11 mmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 1.200.
2. Analytical sensitivity: at the test percentage of 6.0%, the reagent absorbance change (ΔA) ≥ 0.010.
3. Accuracy: relative deviation ≤ 7%.
4. Precision: within-run CV ≤ 3%, between-run relative range ≤ 10%.
5. Linear Range:

[3.6%, 14.0%], the correlation coefficient (r) ≥ 0.990.

[3.6%, 7.0%), the absolute deviation ≤ 0.5%;

[7.0%, 14.0%], the relative deviation ≤ 7%.

6. Calibrator accuracy: relative deviation ≤ 7%.
7. Calibrator homogeneity: between-vial CV ≤ 10%.
8. Control accuracy: test value is within the allowable range of the marked value.
9. Control homogeneity: between-vial CV ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, General lab equipment and consumable.

References

[1] YY/T 1605-2018. Hemoglobin Alc testing kit (latex immunoturbidimetric method)[S].

[2] Li X, Zhang T, Long Q, et al. Bias evaluation and methodological comparison of different glycosylated hemoglobin detection systems[J]. Journal of Modern Medicine & Health, 2019, 35:48-51.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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CE IVD

zybio

Instructions for Use of High Density Lipoprotein Cholesterol (HDL-C) Kit (Enzymatic Method)

Package Specification

REF	Reagent	Systems
01.09.02.03.EC.01	R1 30 mL × 3 R2 10 mL × 3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	Zybio EXC200/220
01.09.02.03.EC.02	R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of high density lipoprotein cholesterol (HDL-C) concentration in human samples (serum). Clinically, it is mainly used for diagnosing hypercholesterolemia, coronary heart disease, and atherosclerosis.

Summary

A high HDL-C protects against CHD, as HDL-C is responsible for removing cholesterol from the periphery to the liver for catabolism. In the United States, the average woman has an HDL-C of 55 mg/dL and the average man has an HDL-C of 45 mg/dL. A 1-mg/dL increase in HDL-C has generally been associated with a 2% decrease in risk of CHD. The NCEP ATP III considers an HDL-C > 60 mg/dL as a negative risk factor, whereas HDL-C < 40 mg/dL is considered a positive risk factor for CHD. However, a study of postmenopausal women with CHD found that 20% had “protective” HDL-C of > 60 mg/dL. These women actually had fewer CHD risk factors than other women in the cohort. Because only 20% of women in the study had a high HDL-C vs 30% of women in the general population, this higher level of HDL-C did have some apparent role in CHD prevention. However, as an HDL-C of > 60 mg/dL is the 85th percentile for men vs the 70th percentile in women, it seems probable that the level of HDL-C considered cardioprotective may need to be higher in women. An HDL-C of 70 mg/dL is the 85th percentile for women, and this may be a more appropriate designated “negative risk factor” than an HDL-C of 60 mg/dL in women.

Principle

The kit uses enzymatic method to determine the concentration of high density lipoprotein cholesterol (HDL-C) in samples.

The non-HDL components of serum, such as chyle (CM), low-density lipoprotein (LDL) and very low-density lipoprotein (VLDL), are consumed by hydrolysis reactions under the action of enzymes such as cholesterol oxidase and peroxidase in reagent R1. High-density lipoprotein cholesterol was released under the action of denaturant in reagent R2, and HDL-C was detected by the following reactions.

1. Cholesteryl Ester+ H_2O $\xrightarrow{\text{Cholesterol Esterase}}$ Cholesterol + Fatty acid
2. Cholesterol + O_2 $\xrightarrow{\text{Cholesterol Oxidase}}$ Cholestenone + H_2O_2
3. $2H_2O_2$ + 4-AAP + TOOS $\xrightarrow{\text{Peroxidase}}$ Quinonimine + $4H_2O$

The production of quinonimine products causes an increase in absorbance at 546 nm, which is directly proportional to the HDL-C concentration in the sample. The concentration of HDL-C in the sample shall be calculated by measuring the absorbance change at 546 nm and comparing with that in calibrator treated in the same manner.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Cholesterol Oxidase	0.8-1.2 kU /L
	4-Aminoantipyrine (4-AAP)	0.05-0.15 g/L
	Peroxidase	1.6-2.4 kU /L
	2-Morpholinoethane sulfonic Acid (MES)	5.5-7.5 g/L
R2	Sodium 3-(N-ethyl-3-methylanilino)-2-hydroxypropanesulfonate (TOOS)	0.5-1.5 g/L
	Cholesterol Esterase	0.8-1.2 kU/L
	2-Morpholinoethane sulfonic Acid (MES)	5.5-7.5 g/L
Calibrator	Bovine Serum	Refer to the label for marked value of HDL-C concentration
	Sucrose	35 g/L
Control	Bovine Serum	Refer to the label for marked value of HDL-C concentration
	Sucrose	35 g/L

The components in different batches are non-interchangeable.

The measurement system can be traceable to JCCRM 224-16.

The target value of control has batch specificity.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from freezing. The unopened reagents are valid for 18 months. Summer transportation with attention to refrigeration.
2. Once opened, the reagents are stable for 1 month at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. To ensure accuracy, calibrator and control are stored at 2 - 8 ℃ after reconstitution and used only on the same day.
4. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum is suitable for samples, which shall be separated in time after collection to avoid hemolysis. Samples are stable for 6 days at 2 - 8 ℃ and 21 days at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.05, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. Dedicated calibrator is recommended for use to ensure the accuracy of test values.
7. The same sample tested with reagents from different manufacturers may lead to different measured values.
8. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

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Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	3/320
Main Wavelength	546 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. Operation

Addition	**Blank**	**Calibration**	**Detection**
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent 1 (μL)	240	240	240
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	80	80	80
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_2, calculate $\Delta A = A_2 - A_1$.			

3. Calibration

Use Zybio matched calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

Calibrator reconstitution: Reconstitution with the amount of purified water labeled on the bottle accurately absorbed, leave for 30 minutes, and mix well before use.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

Control reconstitution: Reconstitution with the amount of purified water labeled on the bottle accurately absorbed, leave for 30 minutes, and mix well before use.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of high density lipoprotein cholesterol (HDL-C) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

0.9~2.0 mmol/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of HDL-C in the sample exceeds 4.00 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor. The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is ≤ 10% if the concentrations of the following interferents are at or below the given values:

Substances	**Concentrations**
Hemoglobin	0.5 g/L
Chyle	0.30%
Bilirubin	300 μmol/L
Intralipid	1000 mg/dL

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.05.
2. Analytical sensitivity: at the test concentration of 1.00 mmol/L, the reagent absorbance change (ΔA) ≥ 0.04.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run CV ≤ 4%, between-run relative range ≤ 10%.
5. Linear Range:

[0.20, 4.00] mmol/L, the correlation coefficient (r) ≥ 0.995.

[0.20, 1.00) mmol/L, the absolute deviation ≤ 0.10 mmol/L;

[1.00, 4.00] mmol/L, the relative deviation ≤ 10%.

6. Calibrator accuracy: relative deviation ≤ 10%.
7. Calibrator homogeneity: between-vial CV ≤ 10%.
8. Control accuracy: test value is within the allowable range of the marked value.
9. Control homogeneity: between-vial CV ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, General lab equipment and consumable.

References

[1] Gordon D, Probstfield J, Garrison R, et al. High-Density Lipoprotein Cholesterol and Cardiovascular Disease[J]. Am Heart Assoc, 1989, 79:8-15.

[2] Warnick G, Nguyen R, Albers A. Comparison of improved precipitation methods for quantification of high density lipoprotein cholesterol[J]. Clin Chem, 1985, 31:217-222.

[3] Warnick G, Cheung M, Albers J. Comparison of current methods for high-density lipoprotein cholesterol quantitation[J]. Clin Chem, 1979, 25:596-604.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Current Version: 02 Date of Issue: May, 2022

CE IVD

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Instructions for Use of Lactate Dehydrogenase (LDH) Kit (Rate Method)

Package Specification

REF	Reagent	Systems
01.09.04.06.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.04.06.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of lactate dehydrogenase activity in human samples (serum). Clinically, it is mainly used as an aid to diagnosis of myocardial infarction and hepatopathy.

Summary

Lactate dehydrogenase is a kind of NAD-dependent kinase, which has three subunits, LDHA, LDHB and LDHC, and can constitute six tetrameric isoenzymes. Animal lactate dehydrogenase is a tetramer composed of 4 subunits, 5 LDH isozymes (LDH1-5) composed of common A and B subunits, and only one LDH isozyme (LDH-C4) composed of C subunit. Lactate dehydrogenase is a metalloprotein containing zinc ions, with a molecular weight of 135-140 kD. It is one of the important enzymes for anaerobic glycolysis and gluconeogenesis of sugars. It can catalyze the reduction and oxidation reaction between propionic acid and L-lactic acid, and can also catalyze the related α-keto acid. LDH is widely present in human tissues, with the highest content in the kidney, followed by the myocardium and bony muscle. LDH in red blood cells is about 100 times higher than in normal serum.

Lactate dehydrogenase is a key enzyme in microorganisms that catalyzes the production of benzolactic acid (also known as 2-hydroxy-3-phenylpropionic acid) from phenylpyruvate. Lactate dehydrogenase is a crucial oxidoreductase in the glycolytic pathway in organisms, which can reversibly catalyze the oxidation of lactate to pyruvate, and this catalytic reaction is the end product of anaerobic glycolysis. Lactate dehydrogenase is mainly found in animal tissues such as heart muscle, liver, kidney, skeletal muscle, or lung. Lactate dehydrogenase measurements are commonly used in the diagnosis of myocardial infarction, liver disease, and certain malignancies.

Principle

L-Lactic acid + NAD^+ $\xrightarrow{LDH}$ Pyruvic acid + NADH + H^+

The activity of lactate dehydrogenase (LDH) in the sample can be detected by measuring the increase rate of the absorbance at 340 nm.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Lactate	>6 mmol/L
	Trometamol (Tris) buffer	100 mmol/L
R2	Nicotinamide adenine dinucleotide (NAD^+)	>12 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.

2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.

3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum is suitable for samples, which are stable for 3 days at 2 - 8 ℃ and for 30 days at - 20 ℃. Avoid hemolysis and repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.

2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.

3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.

4. When reagent becomes turbid or the blank absorbance > 0.500, the reagent is failed and should be discarded.

5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.

6. The same sample tested with reagents from different manufacturers may lead to different measured values.

7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	Rate Method	**Sample/Reagent**	1/50
Main Wavelength	340 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	405 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	5
Calibrator (μL)	/	5	/
Purified Water (μL)	5	/	/
Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 ℃ for 5 min			
Reagent 2 (μL)	50	50	50
Mix well, after 2 min, measure the average absorbance change rate Δ*A*/min within 3 min.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

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4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of lactate dehydrogenase (LDH) in the sample can be calculated on the working curve based on its absorbance change rate.

Reference Intervals

105~245 U/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of LDH in the sample exceeds 800 U/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Chyle	0.30%
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.500; the reagent blank absorbance change rate (Δ*A*/min) ≤ 0.002 *A*/min.

2. Analytical sensitivity: at the test concentration of 200 U/L, the reagent absorbance change rate (Δ*A*/min) ≥ 0.005.

3. Accuracy: relative deviation ≤ 10%.

4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 10%.

5. Linear Range:

[25, 800] U/L, the correlation coefficient (*r*) ≥ 0.990.

[25, 100] U/L, the absolute deviation ≤ 10 U/L;

(100, 800] U/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Eigentler T, Figl A, Krex D, et al. Number of metastases, serum lactate dehydrogenase level, and type of treatment are prognostic factors in patients with brain metastases of malignant melanoma[J]. Cancer, 2011, 117:1697-1703.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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CE IVD

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Instructions for Use of Low Density Lipoprotein Cholesterol (LDL-C) Kit (Enzymatic Method)

Package Specification

REF	Reagent	Systems
01.09.02.00.EC.01	R1 30 mL × 3 R2 10 mL ×3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	Zybio EXC200/220
01.09.02.00.EC.02	R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of low density lipoprotein cholesterol (LDL-C) concentration in human samples (serum). Clinically, it is mainly used as an aid to diagnosis of hypercholesterolemia, coronary heart disease, and atherosclerosis.

Summary

Low Density Lipoprotein (LDL) play a key role in causing and influencing the progression of atherosclerosis and, in particular, coronary sclerosis. The LDLs are derived from VLDLs (Very Low Density Lipoproteins) rich in triglycerides by the action of various lipolytic enzymes and are synthesized in the liver. The elimination of LDL from plasma takes place mainly by liver parenchymal cells via specific LDL receptors. Elevated LDL concentrations in blood and an increase in their residence time coupled with an increase in the biological modification rate results in the destruction of the endothelial function and a higher LDL-cholesterol uptake in the monocyte/macrophage system as well as by smooth muscle cells in vessel walls. The majority of cholesterol stored in atherosclerotic plaques originates from LDL. The LDL-cholesterol value is the most powerful clinical predictor among all of the single parameters with respect to coronary atherosclerosis.

Therefore, therapies focusing on lipid reduction primarily target the reduction of LDL-cholesterol which is then expressed in an improvement of the endothelial function, prevention of atherosclerosis and reducing its progression as well as preventing plaque rupture.

Principle

1. The surface-active ingredients in R1 inhibit low density lipoprotein in serum, while high-density lipoprotein and very low-density lipoprotein are consumed by the reaction catalyzed by cholesterol enzyme.

$$\text{Cholesteryl Ester} + H_2O \xrightarrow{\text{Cholesterol Esterase}} \text{Cholesterol} + \text{Fatty acid}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{Cholesterol Oxidase}} \text{Cholestenone} + H_2O_2$$

$$2H_2O_2 \xrightarrow{\text{Peroxidase}} 2H_2O + O_2$$

2. LDL-C is only measured after the surfactant in R2 has released low-density lipoprotein.

$$\text{Cholesteryl Ester} + H_2O \xrightarrow{\text{Cholesterol Esterase}} \text{Cholesterol} + \text{Fatty acid}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{Cholesterol Oxidase}} \text{Cholestenone} + H_2O_2$$

$$2H_2O_2 + \text{4-AAP} + \text{TOOS} \xrightarrow{\text{Peroxidase}} \text{Quinonimine} + 4H_2O$$

3. The absorbance of quinonimine is directly proportional to the content of cholesterol. The content of low-density lipoprotein cholesterol (LDL-C) in the sample can be calculated by measuring the absorbance change value at 546 nm.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Ascorbate Oxidase	> 3000 U/L
	Cholesterol Oxidase	> 400 U/L
	Cholesterol Esterase	> 500 U/L
	Sodium 3-(N-ethyl-3-methylanilino)-2-hydroxypropanesulfonate (TOOS)	0.8 mmol/L
	1,4-Piperazinebis (ethanesulfonic acid) buffer (PIPES)	100 mmol/L
R2	4-Aminoantipyrine (4-AAP)	4 mmol/L
	1,4-Piperazinebis (ethanesulfonic acid) buffer (PIPES)	100 mmol/L
	Peroxidase	> 1500 U/L
	Surfactant	Appropriate amount
Calibrator	Sucrose	10 g/L
	Bovine Serum	Refer to the label for marked value of LDL-C concentration
Control	Sucrose	10 g/L
	Bovine Serum	Refer to the label for marked value of LDL-C concentration

The measurement system can be traceable to JCCRM 224-16.

The components in different batches are non-interchangeable.

The target value of control has batch specificity.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 18 months. Summer transportation with attention to refrigeration.
2. Once opened, the reagents are stable for 1 month at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. To ensure accuracy, calibrator and control are stored at 2 - 8 ℃ after reconstitution and used only on the same day.
4. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum is suitable for samples, which shall be separated in time after collection to avoid hemolysis. Samples are stable for 6 days at 2 - 8 ℃ and 3 weeks at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.05, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. Dedicated calibrator is recommended for use to ensure the accuracy of test values.
7. The same sample tested with reagents from different manufacturers may lead to different measured values.
8. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

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Test Process

1. **Parameters**

Method	End-Point Method	**Sample/Reagent**	3/320
Main Wavelength	546 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. **Operation**

Addition	**Blank**	**Calibration**	**Detection**
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent 1 (μL)	240	240	240
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	80	80	80
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

3. **Calibration**

Use Zybio matched calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

Calibrator reconstitution: Reconstitution with the amount of purified water labeled on the bottle accurately absorbed, leave for 30 minutes, and mix well before use.

4. **Quality Control**

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

Control reconstitution: Reconstitution with the amount of purified water labeled on the bottle accurately absorbed, leave for 30 minutes, and mix well before use.

5. **Calculation**

Linear calibration was used to draw the working curve. The concentration of low density lipoprotein cholesterol (LDL-C) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

≤3.36 mmol/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of LDL-C in the sample exceeds 11.60 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor. The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is ≤ 10% if the concentrations of the following interferents are at or below the given values:

Substances	**Concentrations**
Vc	0.5 g/L
Hemoglobin	5 g/L
Chyle	0.30%
Bilirubin	342 μmol/L
Intralipid	1000 mg/dL

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.05.
2. Analytical sensitivity: at the test concentration of 1.00 mmol/L, the reagent absorbance change (ΔA) ≥ 0.03.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run CV ≤ 3%, between-run relative range ≤ 10%.
5. Linear Range:

[0.20, 11.60] mmol/L, the correlation coefficient (r) ≥ 0.995.

[0.20, 3.00) mmol/L, the absolute deviation ≤ 0.30 mmol/L;

[3.00, 11.60] mmol/L, the relative deviation ≤ 10%.

6. Calibrator accuracy: relative deviation ≤ 10%.
7. Calibrator homogeneity: between-vial CV ≤ 10%.
8. Control accuracy: test value is within the allowable range of the marked value.
9. Control homogeneity: between-vial CV ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, General lab equipment and consumable.

References

[1] Davidson M. Low-density lipoprotein cholesterol, non-high-density lipoprotein, apolipoprotein, or low-density lipoprotein particle: what should clinicians measure?[J]. J Am Coll Cardiol, 2012, 60:2616-2617.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Current Version: 02 Date of Issue: May, 2022

CE IVD

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Instructions for Use of Lipase (LPS) Kit (Colorimetric Method)

Package Specification

REF	Reagent	Systems
01.09.0B.01.EC.01	R1 30 mL × 3 R2 10 mL × 3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	Zybio EXC200/220
01.09.0B.01.EC.02	R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of the catalytic activity concentration of lipase (LPS) in human samples (serum or plasma). Clinically, it is used as the most important evaluation indicator for differential diagnosis of pancreatic diseases.

Summary

Lipases are glycoproteins with a molecular weight of 47000 Da. They are defined as triglyceride hydrolases which catalyze the cleavage of triglycerides to diglycerides with subsequent formation of monoglycerides and fatty acids. In addition to α-amylase, pancreatic lipases have for many years been undeniably the most important clinical chemistry parameters for the differential diagnosis of diseases of the pancreas. The lipase activity determination has gained increasing international recognition because of its high specificity and rapid response. After acute pancreatitis the lipase activity increases within 4 - 8 hours, reaches a peak after 24 hours and decreases after 8 - 14 days.

Numerous methods have been described for the determination of lipase which determine the decrease in substrate turbidimetrically or nephelometrically or determine degradation products.

The methylresorufin substrate method is based on the cleavage of a specific chromogenic lipase substrate 1,2-dilauryl glycerol-3-glutaric acid-(6-methylresorufin)-ester emulsified with bile acids. The pancreatic enzyme activity is determined specifically by the combination of bile acid and colipase used in this assay.

Virtually no lipase activity is detected in the absence of colipase. Colipase only activates pancreatic lipase, but not other lipolytic enzymes found in serum. The high amount of cholate ensures that the esterases present in the serum do not react with the chromogenic substrate due to the highly negative surface charge.

Principle

Lipase, in the presence of co-lipase and bile acids, can hydrolyze 1,2-Di-O-Lauryl-Rac-Glycero-3-Glutaric Acid-(6-Methylresorufin)-Ester to generate 1,2-O-Dilauryl-Rac-Glycerol and Glutaric Acid-(6-Methylresorufin)-Ester, and the latter continues to decompose under alkaline conditions to form glutaric acid and red methylresorufin. The increase in absorbance caused by this red dye is directly proportional to the lipase catalytic activity concentration in the sample.

1. 1,2-Di-O-Lauryl-Rac-Glycero-3-Glutaric Acid-(6-Methylresorufin)-Ester + H_2O $\xrightarrow{LPS}$ 1,2-O-Dilauryl-Rac-Glycerol + Glutaric Acid-(6-Methylresorufin)-Ester

2. Glutaric Acid-(6-Methylresorufin)-Ester + H_2O $\xrightarrow{OH^-}$ glutaric acid + Methylresorufin

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	N,N-Bis(2-hydroxyethyl)glycine	> 130 mmol/L
	Co-lipase	> 0.5 mg/L
R2	Tartaric acid buffer	9 mmol/L
	Lipase substrate	> 0.10 g/L
Calibrator	Lipase Bovine Serum	Refer to the label for marked value
Control	Lipase Bovine Serum	Refer to the label for marked value

The components in different batches are non-interchangeable.

The measurement system can be traceable to enterprise standard.

The target value of control has batch specificity.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 18 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. In order to ensure the accuracy of test results, calibrator and control are stable for 7 days at 2 - 8 ℃ after reconstitution.
4. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum or plasma (heparin for anticoagulation) is suitable for samples, which are stable for 3 days at 2 - 8 ℃ and for 90 days at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.800, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. Dedicated calibrator and control are recommended for use to ensure the accuracy of test values.
7. The same sample tested with reagents from different manufacturers may lead to different measured values.
8. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. **Parameters**

Method	Rate Method	**Sample/Reagent**	1/100
Main Wavelength	570 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	10 min
Reaction Direction	+		

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2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent 1 (μL)	225	225	225
Mix well, incubate at 37 ℃ for 5 min			
Reagent 2 (μL)	75	75	75
Mix well, incubate at 37 ℃ for 1.5 min, then continuously monitor the absorbance change rate (ΔA/min) within 2 min.			

3. Calibration

Use Zybio matched calibrator or Zybio Clinical Chemistry Multi-analyte Calibrator.
Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.
Calibrator reconstitution: Reconstitution with the amount of purified water labeled on the bottle accurately absorbed, leave for 30 minutes, and mix well before use.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.
Control reconstitution: Reconstitution with the amount of purified water labeled on the bottle accurately absorbed, leave for 30 minutes, and mix well before use.

5. Calculation

Linear calibration was used to draw the working curve. The catalytic activity concentration of lipase (LPS) in the sample can be calculated on the working curve based on its absorbance change rate.

Reference Intervals

≤ 60 U/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the catalytic activity concentration of LPS in the sample exceeds 300 U/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.
The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is ≤ 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Hemoglobin	1 g/L
Chyle	0.30%
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.800, the reagent blank absorbance change rate (ΔA/min) ≤ 0.010.
2. Analytical sensitivity: at the test catalytic activity concentration of 100 U/L, the reagent absorbance change rate (ΔA/min) ≥ 0.015.
3. Accuracy: the relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 5%; between-run relative range ≤10%.
5. Linear range:
[8, 300] U/L, the correlation coefficient (r) ≥ 0.990.
[8, 40] U/L, the absolute deviation ≤ 8 U/L;
(40, 300] U/L, the relative deviation ≤ 10%.
6. Calibrator accuracy: the relative deviation ≤ 10%.
7. Calibration homogeneity: between-vial *CV* shall be ≤ 10%.
8. Control accuracy: test value is within the allowable range of the marked value.
9. Control homogeneity: between-vial *CV* shall be ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, General lab equipment and consumable.

References

[1] Kazmierczak S, Catrou P, Lente F. Diagnostic accuracy of pancreatic enzymes evaluated by use of multivariate data analysis[J]. Clin Chem, 1993, 39:1960-1965.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
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CE IVD

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Instructions for Use of Magnesium (Mg) Kit (Xylidyl Blue Method)

Package Specification

REF	Reagent	Systems
01.09.0C.02.EC.01	R 30 mL × 6	Zybio EXC200/220
01.09.0C.02.EC.02	R 60 mL × 2	Hitachi 7180 Zybio EXC400/420
01.09.0C.02.EC.03	R 30 mL × 6 Calibrator 1 Level × 1.0 mL × 1	Zybio EXC200/220
01.09.0C.02.EC.04	R 60 mL × 2 Calibrator 1 Level × 1.0 mL × 1	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of magnesium concentration in human samples (serum or plasma). Clinically, it is mainly used as an aid to diagnosis of magnesium metabolism disorders.

Summary

Magnesium along with potassium is a major intracellular cation. Mg^{2+} is a cofactor of many enzyme systems. Thus, all ATP-dependent enzymatic reactions require Mg^{2+} as a cofactor in the ATP-magnesium complex. Approximately 69% of magnesium are stored in bone. The rest are part of the intermediary metabolism, about 70% being present in free form while the other 30% is bound to proteins (especially albumin), citrates, phosphate, and other complex formers. The Mg^{2+} serum level is kept constant within very narrow limits (0.65-1.05 mmol/L).

Regulation takes place mainly via the kidneys, especially via the ascending loop of Henle.

This assay is used as an aid to diagnosis of hypomagnesemia (magnesium deficiency) and hypermagnesemia (magnesium excess). Numerous studies have shown a correlation between magnesium deficiency and changes in calcium-, potassium- and phosphate-homeostasis which are associated with cardiac disorders such as ventricular arrhythmias that cannot be treated by conventional therapy, increased sensitivity to digoxin, coronary artery spasms, and sudden death. Additional concurrent symptoms include neuromuscular and neuropsychiatric disorders.

Hypermagnesemia is found in acute and chronic renal failure, magnesium excess, and magnesium release from the intracellular space.

The method described here is based on the reaction of magnesium with xylidyl blue in alkaline solution containing EGTA to mask the calcium in the sample.

Urine magnesium levels are determined in magnesium depletion tests.

Principle

This kit uses xylidyl blue method to determine the content of magnesium. In the alkaline solution, magnesium in the serum combine with xylidyl blue dye to generate a purple complex. The absorbance of this complex at 505 nm is directly proportional to the concentration of magnesium in the sample.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R	Sodium Hydroxide	77 mmol/L
	Xylidyl Blue	0.14 mmol/L
	Polyvinylpyrrolidone	0.03 mmol/L
Calibrator (Optional)	Magnesium Chloride	Refer to the label for marked value

The components in different batches are non-interchangeable.

The measurement system can be traceable to enterprise standard.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum or plasma is suitable for samples, which are stable for 1 week at 2 - 8 ℃ and for 1 month at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.800, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. It is recommended that medical institutions purchase the kit containing calibrator when using the kit for the first time.
7. The same sample tested with reagents from different manufacturers may lead to different measured values.
8. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/100
Main Wavelength	505 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	8 min
Reaction Direction	+		

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2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water/Saline (μL)	3	/	/
Reagent (μL)	300	300	300
Mix well, incubate at 37 ℃ for 8 min, and measure absorbance *A*.			

3. Calibration

Use Zybio matched calibrator, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of magnesium (Mg) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

0.8~1.0 mmol/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of Mg^{2+} in the sample exceeds 2.0 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is < 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Bilirubin	280 μmol/L
Ca^{2+}	3 mmol/L
K^{+}	8 mmol/L
Na^{+}	180 mmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.800.
2. Analytical sensitivity: at the test concentration of 1.00 mmol/L, the reagent absorbance change (ΔA) ≥ 0.05.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 4%, between-run relative range ≤ 6%.
5. Linear Range:

[0.20, 2.0] mmol/L, the correlation coefficient (*r*) ≥ 0.990.

[0.20, 0.80) mmol/L, the absolute deviation ≤ 0.08 mmol/L;

[0.80, 2.0] mmol/L, the relative deviation ≤ 10%.

6. Calibrator accuracy: relative deviation ≤ 10%.
7. Calibrator homogeneity: within-vial *CV* ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Ehrhardt V, Paschen K, Vogt W, et al. Magnesium-Bestimmung im Serum und Urin mit einer verbesserten Xylidyl-Blau-Methode[C]. Workshop Kaiserslautern, 1989.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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Current Version: 02 Date of Issue: May, 2022

CE IVD

zybio

Instructions for Use of Total Bilirubin (TBIL) Kit (Vanadate Oxidation Method)

Package Specification

REF	Reagent	Systems
01.09.00.21.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.00.21.EC.03	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of total bilirubin concentration in human samples (serum or plasma). Clinically, it is mainly used as one of the evaluation indicators for bilirubin metabolism diseases.

Summary

Measurement of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder blockage.

Bilirubin is formed in the reticuloendothelial system during the degradation of aged erythrocytes. The heme portion from hemoglobin and from other heme-containing proteins is removed, metabolized to bilirubin, and transported as a complex with serum albumin to the liver. In the liver, bilirubin is conjugated with glucuronic acid for solubilization and subsequent transport through the bile duct and elimination via the digestive tract.

Diseases or conditions which, through hemolytic processes, produce bilirubin faster than the liver can metabolize it, cause the levels of unconjugated (indirect) bilirubin to increase in the circulation. Liver immaturity and several other diseases in which the bilirubin conjugation mechanism is impaired cause similar elevations of circulating unconjugated bilirubin. Bile duct obstruction or damage to hepatocellular structure causes increases in the levels of both conjugated (direct) and unconjugated (indirect) bilirubin in the circulation.

Principle

The total bilirubin in the sample is oxidized to biliverdin, which causes a decrease in absorbance at 450 nm.

1. Bilirubin $\xrightarrow{\text{Vanadate}}$ Biliverdin

The concentration of total bilirubin in the sample shall be calculated by measuring the absorbance change at 450 nm and comparing with that in calibrator treated in the same manner.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Citric Acid buffer	100 mmol/L
	Surfactant 1	0.2% (v/v)
R2	Citrate Buffer	18.36 mmol/L
	Sodium Metavanadate	6.56 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum or plasma (heparin anticoagulation) is suitable for samples, which are stable for 3 days at 2 - 8 ℃. Samples should be protected from direct light.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.050, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/35
Main Wavelength	450 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	546 nm	**Reaction Time**	10 min
Reaction Direction	-		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	10
Calibrator (μL)	/	10	/
Purified Water (μL)	10	/	/
Reagent 1 (μL)	280	280	280
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	70	70	70
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

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4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of total bilirubin (TBIL) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

3.4~20.5 μmol/L (0.2~1.2mg/dL)

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of TBIL in the sample exceeds 500 μmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Hemoglobin	5 g/L
Chyle	0.30%

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.050.

2. Analytical sensitivity: at the test concentration of 30 μmol/L, the reagent absorbance change (ΔA) > 0.003.

3. Accuracy: relative deviation ≤ 10%.

4. Precision: within-run CV ≤ 4%, between-run relative range ≤ 10%.

5. Linear Range:

[3, 500] μmol/L, the correlation coefficient (r) ≥ 0.990.

[3, 20] μmol/L, the absolute deviation ≤ 2 μmol/L;

(20, 500] μmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Doumas B, Cheung P, Perry B. Candidate reference method for determination of total bilirubin in serum: development and validation[J]. Clin Chem, 1985, 31:1779-1789.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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EC REP Lotus NL B.V.
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Current Version: 02 Date of Issue: May, 2022

Instructions for Use of Triglyceride (TG) Kit (Single) (Enzymatic Method)

Package Specification

REF	Reagent
01.09.02.01.EC.01	R 30 mL × 6
01.09.02.01.EC.02	R 60 mL × 2

Intended Use

In vitro test for the quantitative determination of triglyceride in human samples (serum). Clinically, it is mainly used as an aid to diagnosis of hypertriglyceridemia.

Summary

Triglycerides are esters of the trihydric alcohol glycerol with 3 long-chain fatty acids. They are partly synthesized in the liver and partly ingested in food. The determination of triglycerides is utilized in the diagnosis and treatment of patients having diabetes mellitus, nephrosis, liver obstruction, lipid metabolism disorders and numerous other endocrine diseases. The enzymatic triglycerides assay as described by Eggstein and Kreutz still required saponification with potassium hydroxide. Numerous attempts were subsequently made to replace alkaline saponification by enzymatic hydrolysis with lipase. Bucolo and David tested a lipase/protease mixture; Wahlefeld used an esterase from the liver in combination with a particularly effective lipase from Rhizopus arrhizus for hydrolysis. This method is based on the work by Wahlefeld using a lipoprotein lipase from microorganisms for the rapid and complete hydrolysis of triglycerides to glycerol followed by oxidation to dihydroxyacetone phosphate and hydrogen peroxide. The hydrogen peroxide produced then reacts with 4-aminophenazone and 4-chlorophenol under the catalytic action of peroxidase to form a red dyestuff (Trinder endpoint reaction). The color intensity of the red dyestuff formed is directly proportional to the triglyceride concentration and can be measured photometrically.

Principle

$$TG + H_2O \xrightarrow{\text{Lipase}} \text{Glycerol} + \text{Fatty Acid}$$

$$\text{Glycerol} + ATP \xrightarrow{\text{Glycerol Kinase}} \text{Glycerin-3-Phosphoric Acid} + ADP$$

$$\text{Glycerin-3-Phosphoric Acid} + O_2 \xrightarrow{\text{GPO}} \text{Dihydroxyacetone Phosphate} + H_2O_2$$

$$H_2O_2 + \text{4-AAP} + \text{Phenol} \xrightarrow{\text{Peroxidase}} \text{Quinonimine} + H_2O$$

The TG content in the sample could be calculated by comparing the absorbance change measured at 505 nm with calibrator treated in the same way.

Reagents Components and Concentration

Composition: R

R	Lipoprotein Lipase	2.5 KU/L
	Peroxidase	1.2 KU/L
	GPO	7.5 KU/L
	Glycerol Kinase	5.0 KU/L
	ATP	50 mmol/L
	4-AAP	0.5 mmol/L
	Phenol	2 mmol/L
	MOPS Buffer	80 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The reagents could be stable for 2 weeks at 2 - 8 ℃ in transportation.
4. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400, Zybio EXC200/220 Chemistry Analyzer. Other models shall be used after verification.

Specimen Information

1. Non-hemolyzed serum is suitable for samples.
2. The serum is stable for 3 days at 2 - 8 ℃ and for 30 days at -20 ℃.
3. Repeated freezing and thawing should be avoided.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or blank absorbance > 0.200, the reagent is invalid and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. **Parameters**

Method	End-Point Method	**Sample / Reagent**	1/100
Main Wavelength	505 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. **Operation**

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent (μL)	300	300	300
Mix well, incubate at 37 ℃ for 10 min, and measure absorbance *A*			

3. **Calibration**

Use Zybio clinical chemistry multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. **Quality Control**

Indoor quality control is recommended. Values obtained should fall within the

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limited range. If there is a failure of any of controls, the laboratory should take appropriate corrective measures.

5. Calculation

TG (mmol/L) = (*A* Sample / *A* Calibrator) × C Calibrator

Reference Intervals

≤ 2.30 mmol/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration exceeds 10.00 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional shall be responsible for the review of the test result, which may be affected by the subject's age, gender, or weight. The measured values within the critical range should be re-determined and confirmed, if it is obviously beyond the reference range or if it is still beyond the reference range after confirmation, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations-Interference

The deviation of test results caused by interferents is within ± 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
VC	500 mg/L
Hemoglobin	5 g/L
Bilirubin	342 μmol/L

Performance Characteristics

1. The reagent blank absorbance: ≤ 0.200.
2. Analytical sensitivity: at the test concentration of 1.0 mmol/L, the reagent absorbance change $\Delta A > 0.03$.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 8%.
5. Linear Range:

[0.50, 10.00] mmol/L, the correlation coefficient (r) ≥ 0.990.

[0.50, 2.00) mmol/L, the absolute deviation ≤ 0.20 mmol/L;

[2.00, 10.00] mmol/L, the relative deviation ≤ 10%.

References

[1] Peter T. Triglyceride-rich lipoproteins as a causal factor for cardiovascular disease[J]. Vascular Health & Risk Management, 2016, 12:171-183.

[2] Shen Mengyuan, Niu Xiaohan, Wang Lixin. Application of blood lipid monitoring in diagnosis of cardiovascular and cerebrovascular diseases. China Journal of Laboratory Medicine, 2018, 41 (11): 893.

[3] Giovanni B, Harold D. Quantitative Determination of Serum Triglycerides by the Use of Enzymes[J]. Clinical Chemistry, 1973(5):476-482.

[4] Trinder, P. Determination of Glucose in Blood Using Glucose Oxidase with an Alternative Oxygen Acceptor[J]. Ann.clin.biochem, 1969, 6(1):24-27.

Label Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture

Manufacturer Information

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CE IVD

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Instructions for Use of Uric Acid (UA) Kit (Uricase Method)

Package Specification

REF	Reagent	Systems
01.09.01.07.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.01.07.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of uric acid concentration in human samples (serum or plasma). Clinically, it is mainly used as an aid to diagnosis of hyperuricemia.

Summary

Uric acid is the final product of purine metabolism in the human organism. Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

The oxidation of uric acid provides the basis for two approaches to the quantitative determination of this purine metabolite. One approach is the reduction of phosphotungstic acid in an alkaline solution to tungsten blue, which is measured photometrically. The method is, however, subject to interferences from drugs and reducing substances other than uric acid.

A second approach, described by Praetorius and Poulson, utilizes the enzyme uricase to oxidize uric acid; this method eliminates the interferences intrinsic to chemical oxidation. Uricase can be employed in methods that involve the UV measurement of the consumption of uric acid or in combination with other enzymes to provide a colorimetric assay.

Another method is the colorimetric method developed by Town et al. The sample is initially incubated with a reagent mixture containing ascorbate oxidase and a clearing system. In this test system it is important that any ascorbic acid present in the sample is eliminated in the preliminary reaction; this precludes any ascorbic acid interference with the subsequent POD indicator reaction. Upon addition of the starter reagent, oxidation of uric acid by uricase begins.

Principle

1. Uric acid + O_2 + H_2O $\xrightarrow{\text{Uricase}}$ Allantoin + CO_2 + H_2O_2

2. H_2O_2 + 4-AAP + TOOS $\xrightarrow{\text{Peroxidase}}$ Quinoneimine + H_2O

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Sodium 3-(N-ethyl-3-methylanilino)-2-hydroxypropanesulfonate (TOOS)	1.11 mmol/L
	Ascorbate Oxidase	10 kU/L
R2	Trometamol (Tris) buffer	200 mmol/L
	Uricase	1.5 kU/L
	Peroxidase	5 kU/L
	4-Aminoantipyrine (4-AAP)	4 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum or plasma (heparin or EDTA anticoagulation) is suitable for samples, which are stable for 3 days at 2 - 8 ℃ and for 30 days at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.200, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. **Parameters**

Method	End-Point Method	**Sample/Reagent**	1/50
Main Wavelength	546 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. **Operation**

Addition	**Blank**	**Calibration**	**Detection**
Sample (μL)	/	/	5
Calibrator (μL)	/	5	/
Purified Water (μL)	5	/	/
Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	50	50	50
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

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3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of uric acid (UA) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

Male: 202~416 μmol/L

Female: 140~380 μmol/L

This reference interval is determined based on 95% distribution interval obtained from 210 healthy males and 210 healthy females specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of UA in the sample exceeds 1190 μmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Hemoglobin	5 g/L
Chyle	0.30%
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.200.

2. Analytical sensitivity: at the test concentration of 360 μmol/L, the reagent absorbance change (ΔA) ≥ 0.03.

3. Accuracy: relative deviation ≤ 10%.

4. Precision: within-run CV ≤ 4%, between-run relative range ≤ 6%.

5. Linear Range:

[100, 1190] μmol/L, the correlation coefficient (r) ≥ 0.990.

[100, 300] μmol/L, the absolute deviation ≤ 30 μmol/L;

(300, 1190] μmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Young D. Effects of drugs on clinical laboratory tests[J]. Ann Clin Biochem, 1997, 34:579-581.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

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CE IVD

Instructions for Use of Urea (UREA) Kit (Urease-GLDH Method)

Package Specification

REF	Reagent	Systems
01.09.01.06.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.01.06.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of urea concentration in human samples (serum or plasma). Clinically, it is mainly used as one of the evaluation indicators of renal function.

Summary

Urea is the major end product of protein nitrogen metabolism. It is synthesized by the urea cycle in the liver from ammonia which is produced by amino acid deamination. Urea is excreted mostly by the kidneys but minimal amounts are also excreted in sweat and degraded in the intestines by bacterial action. Determination of blood urea nitrogen is the most widely used screening test for renal function. When used in conjunction with serum creatinine determinations it can aid in the differential diagnosis of the three types of azotemia: prerenal, renal and postrenal. Elevations in blood urea nitrogen concentration are seen in inadequate renal perfusion, shock, diminished blood volume (prerenal causes), chronic nephritis, nephrosclerosis, tubular necrosis, glomerular nephritis (renal causes) and urinary tract obstruction (postrenal causes). Transient elevations may also be seen during periods of high protein intake. Unpredictable levels occur with liver diseases.

Principle

1. $Urea + H_2O \xrightarrow{Urease} 2NH_3 + CO_2$

2. $NH_3 + \alpha\text{-Ketoglutaric Acid} + NADH + H^+ \xrightarrow{GLDH} Glutamic\ Acid + NAD^+ + H_2O$

Oxidation of NADH to NAD^+ causes a decrease in absorbance at 340 nm, which is directly proportional to the Urea concentration in the sample.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Trometamol (Tris) buffer	100 mmol/L
	Nicotinamide adenine dinucleotide (NADH)	0.3 mmol/L
R2	α-Ketoglutaric Acid	10 mmol/L
	Urease	6.0 kU/L
	Glutamate dehydrogenase (GLDH)	2.0 kU/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum or plasma (heparin or EDTA anticoagulation) is suitable for samples, which are stable for 3 days at 2 - 8 ℃ and for 30 days at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance < 1.000, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	Rate Method	Sample/Reagent	1/100
Main Wavelength	340 nm	Reaction Temperature	37 ℃
Sub Wavelength	405 nm	Reaction Time	10 min
Reaction Direction	-		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent 1 (μL)	240	240	240
Mix well, incubate at 37 ℃ for 5 min			
Reagent 2 (μL)	60	60	60
Mix well, after 1 min, measure the absorbance change within 2 min, and calculate the absorbance change rate ΔA/ min.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

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4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of urea (UREA) in the sample can be calculated on the working curve based on its absorbance change rate.

Reference Intervals

1.7~8.3 mmol/L (10~50 mg/dL)

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of UREA in the sample exceeds 40.0 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Hemoglobin	5 g/L
Chyle	0.30%
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≥ 1.000; the reagent blank absorbance change rate (ΔA/min) ≤ 0.04.

2. Analytical sensitivity: at the test concentration of 7.5 mmol/L, the reagent absorbance change rate (ΔA/min) ≥ 0.008.

3. Accuracy: relative deviation ≤ 10%.

4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 6%.

5. Linear Range:

[0.5, 40.0] mmol/L, the correlation coefficient (*r*) ≥ 0.990.

[0.5, 5.0] mmol/L, the absolute deviation ≤ 0.5 mmol/L;

(5.0, 40.0] mmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Ai H, Chen K. Diagnostic Value of Blood Urea Nitrogen and Serum Creatinine in the Diagnosis of Early Diabetic Nephropathy[J]. Journal of Practical Medical Techniques, 2008, 15:431-433.

Symbol Interpretation

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