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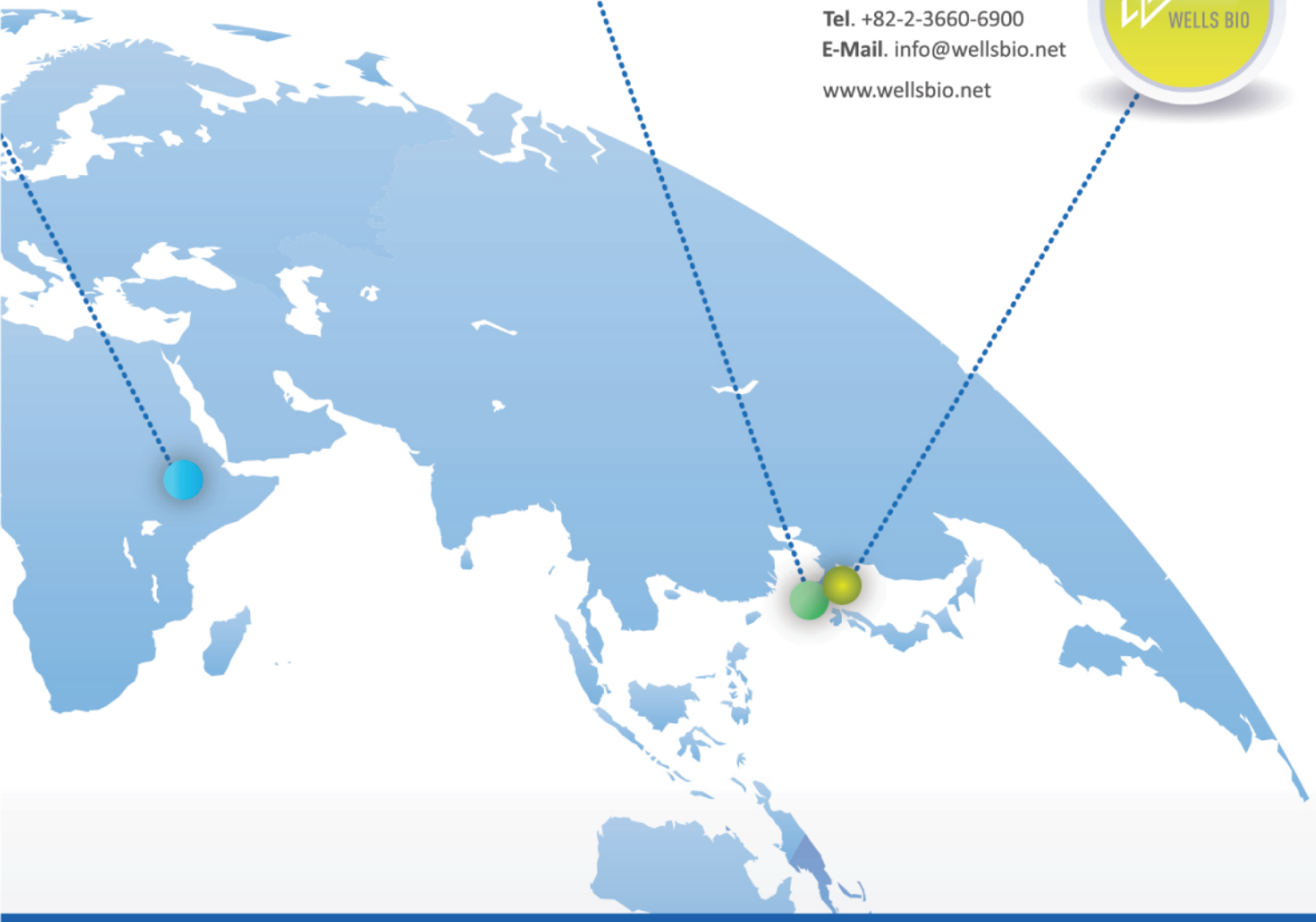


ACCESS to Life, BIO for Hope

Life is precious regardless of nationality, race or religion. Access Bio saves lives and instills hope through advanced in vitro technology for the early diagnosis of diseases. Access Bio will serve as a bridge connecting science and life to promote health and wellbeing for all people.

CONTENTS

RAPID DIAGNOSTIC TESTS

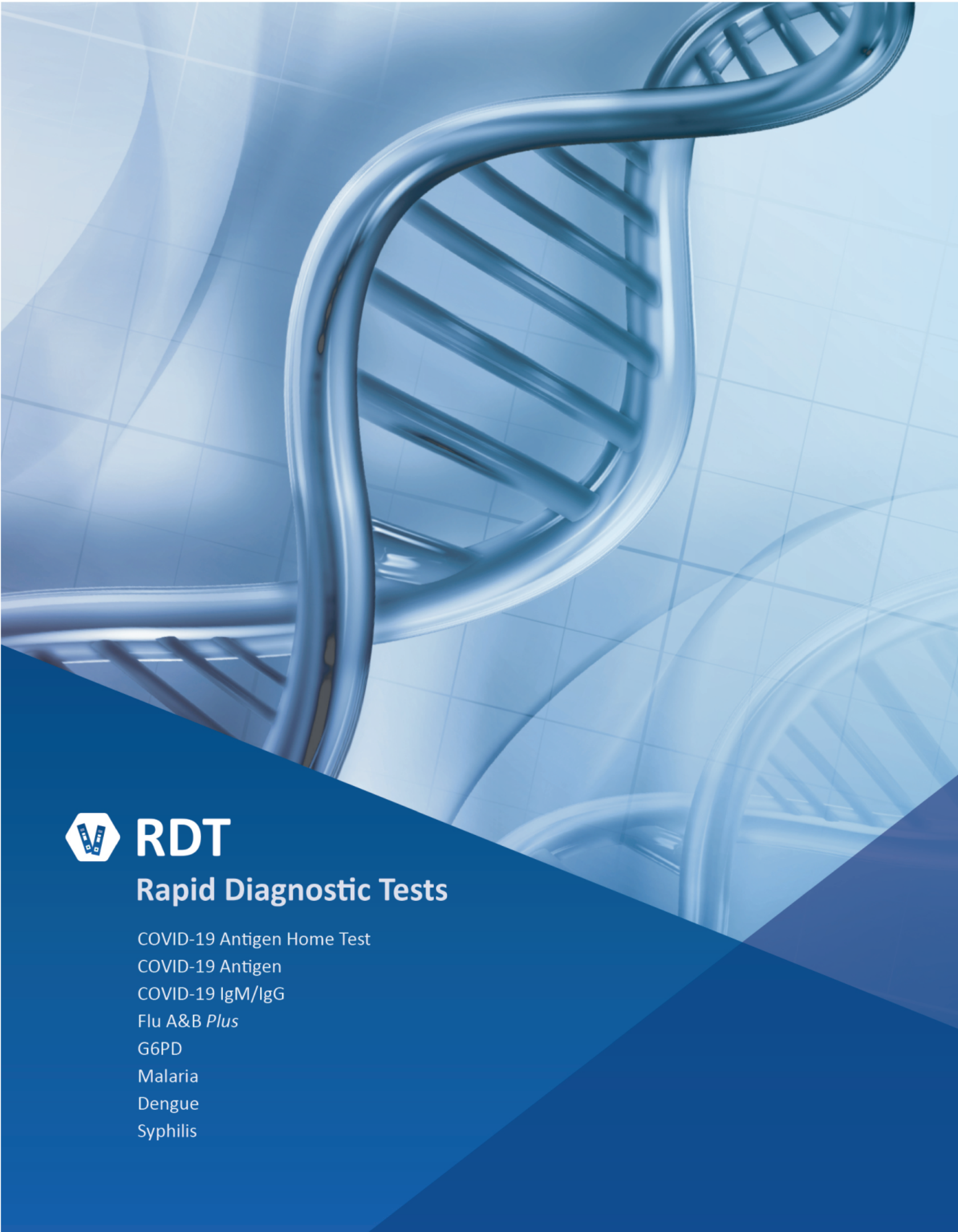
RDTs are suitable for preliminary or emergency medical screening.

ANALYZERS

Designed to measure different chemicals and other characteristics in a number of biological samples.

MOLECULAR DIAGNOSTICS

Used to analyse biological markers in the genome and proteome.



RDT

Rapid Diagnostic Tests

COVID-19 Antigen Home Test
COVID-19 Antigen
COVID-19 IgM/IgG
Flu A&B *Plus*
G6PD
Malaria
Dengue
Syphilis

Rapid Test for Detection of Antigen of SARS-CoV-2

CareStart™ COVID-19 Antigen Home Test

US FDA
Emergency
Use Authorized

The *CareStart*™ COVID-19 Antigen Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigens from SARS-CoV-2.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older or adult collected anterior nasal (nares) swab samples from individuals aged 2 years or older.

- This test is authorized for individuals with symptoms of COVID-19 within the first 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

- For use under Emergency Use Authorization (EUA) only
- For *in vitro* diagnostic use only

Home Test for SARS-CoV-2 Antigen Detection (Ages 2 and Up)

- Fast and easy to self-test anywhere
- Easy to use with mobile application providing step-by-step instructions
- Test results obtained in 10 minutes
- Identify individual's current infection status to COVID-19
- No special equipment or training required
- Health Canada authorized for use under Interim Order

Manufacturer: ***ACCESS BIO, INC.***

CareStart™ COVID-19 Antigen

The *CareStart*™ COVID-19 Antigen test is a lateral flow chromatographic immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal or anterior nasal swab samples collected by a healthcare provider from individuals who are suspected of COVID-19 within the first 5 days of symptom onset when tested at least twice over three days with at least 48 hours between tests and from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests.

US FDA
Emergency
Use Authorized

- For use under Emergency Use Authorization (EUA) only
- For *in vitro* diagnostic use only
- For professional use only / For prescription use only

- Fast and easy to use in Point-of-Care setting
- CE-marked
- Use for anterior nasal or nasopharyngeal swab specimen
- Test results obtained in 10 minutes
- No special equipment or training required
- Identify individual's current infection status to COVID-19
- Clinical Performance (Nasal Swab) 87.18% PPA and 100.00% NPA

Manufacturer: ***ACCESS BIO, INC.***

Rapid Diagnostic Test for Detection of COVID-19 IgM/IgG

CareStart™ COVID-19 IgM/IgG

Rapid Serology Testing Tool for COVID-19

The *CareStart*™ COVID-19 IgM/IgG test is a lateral flow immunochromatographic assay for the detection and differentiation of SARS-CoV-2 IgM/IgG antibodies in human blood specimens in a single test in 10 minutes.

US FDA
Emergency
Use Authorized

- For use under Emergency Use Authorization (EUA) only
- For *in vitro* diagnostic use only
- For professional use only / For prescription use only

Control Available

Features

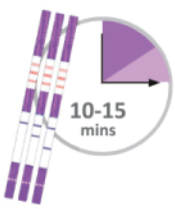
- Fast and easy to use in Point-of-Care setting
- CE-marked
- Detect and differentiate IgM/IgG antibody specific to SARS-CoV-2
- Require a small sample volume (10uL of whole blood, serum or plasma)
- Test results obtained in 10 minutes
- No special equipment or training required

Manufacturer: ***ACCESS BIO, INC.***

CareStart™ Flu A&B Plus+

Reliable detection of all influenza A&B strains

Influenza is a highly contagious viral infection of the nose, throat, and lungs that occurs most often in the late fall, winter, and early spring. Since other viruses infecting respiratory track have similar symptoms, it is critical to properly diagnose influenza viral infection before any treatment. The *CareStart*™ Flu A&B Plus is an in vitro rapid immunochromatographic assay for the qualitative detection of influenza virus type A and B nucleoprotein antigens directly from nasopharyngeal swab specimens of symptomatic patients.



* *Related products :*
Influenza A & B *(Dipstick)*

Technical Specifications

Test Type	**Qualitative Rapid Diagnostic Test**
Specimen	**Nasopharyngeal swab**
Specimen Volume	**80 µl**
Result Time	**10-15 min.**
Storage Cond.	**1-30°C**

Manufacturer: ***ACCESS BIO, INC.*** *Not for sale in* ***USA***

CareStart™ **G6PD** RDT

Recommended by the WHO during the Malaria Policy Advisory Meeting

G6PD deficiency is an X-linked recessive genetic disorder, resulting in no or low G6PD activity. G6PD deficienct patients are vulnerable to the spontaneous destruction of red blood cells when exposed to high oxidative stress.
High oxidative stress may result from consumption of primaquine (antimalarial), aspirin, Fava beans, and menthol.
There is no cure for the condition but the G6PD deficiency can be manageable.

Control Available

Technical Specifications

Test Type	**Qualitative Rapid Diagnostic Test**
Specimen Type	**Whole Blood**
Specimen Volume	**2µl**
Result Time	**10 min.**
Storage Cond.	**4-30°C**

Manufacturer: ***ACCESS BIO, INC.*** *Not for sale in* ***USA***

CareStart™ **Malaria** RDT

The best Malaria RDT on the market

Malaria is one of three major infectious diseases in the world and nearly half of the world's population is at risk of malaria infection. As more malaria parasites are becoming resistant to anti-malarial drugs, WHO recommends prescribing anti-malarial drugs to diagnosed patients only.

Portfolio of CareStart™ ***Malaria*** *RDTs*

Combo RDT	***CareStart™*** **Malaria Pf/PAN**	***CareStart™*** **Malaria Pf/Pv**	***CareStart™*** **Malaria Pf/VOM**	***CareStart™*** **Malaria**
	(HRP2/pLDH) Ag Combo RDT	(HRP2/pLDH) Ag Combo RDT	(HRP2/pLDH) Ag Combo RDT	Screen RDT
Pf Exclusive RDT	***CareStart™*** **Malaria Pf**	***CareStart™*** **Malaria Pf**	***CareStart™*** **Malaria Pf**	***CareStart™*** **Malaria Pf**
	(HRP2) Ag RDT	(pLDH) Ag RDT	(HRP2/pLDH) Ag RDT	(HRP2/pLDH) Ag Combo 3-Line RDT
PAN Malaria RDT	***CareStart™*** **Malaria PAN**			
	(pLDH) Ag RDT			

** All Malaria Products are available in* ***Single Kit - all components included in one pack.***

Technical Specifications

Test Type	**Qualitative Rapid Diagnostic Test**
Specimen Type	**Whole Blood**
Specimen Volume	**5µl**

Result Time	**20 min.**
Storage Cond. Varies on Prod.	**1-40°C or 4-30°C**

Manufacturer: ***ACCESS BIO, INC.*** *Not for sale in* ***USA***

CareStart™ **Dengue** RDT

Total diagnostic solution for all clinical stages of dengue infection

Dengue fever is the primary disease of tropical and subtropical regions. Degue virus is transmitted by mosquitoes and 2.5 billion people, two fifths of the world's population, are now at risk of Dengue infection according to WHO research.

* *Also, available in* careUS™ brand

Dengue RDTs Series:

CareStart™	*CareStart™*	*CareStart™*
Dengue Combo ***NS1 & IgM/IgG***	*Dengue* ***NS1***	*Dengue* ***IgM/IgG***

Technical Specifications

Test Type	**Qualitative Rapid Diagnostic Test**
Specimen Type	**Whole blood/Serum/Plasma**
Specimen Volume	**NS1 Ag: 80 µl/60 µl/60 µl** **IgM/IgG: 20 µl/10 µl/10µl**

Result Time	**15-20 min.**
Storage Cond.	**1-30°C**

Manufacturer: ***ACCESS BIO, INC.*** *Not for sale in* ***USA***

careUS™ Syphilis

Accurately identify and diagnose Syphilis to prevent long-term effects

Syphilis is a curable STD if detected early. Long-term effects may cause paralysis, blindness, dementia and death if left untreated.

Technical Specifications

Test Type	**Qualitative Rapid Diagnostic Test**
Package	**25 or 50 tests/box**
Specimen Type	**Whole blood/Serum/Plasma**
Specimen Volume	**20 µL/10 µL/10 µL**
Result Time	**15 - 20 min**
Storage Cond.	**1 - 30°C**
Shelf life	**24 months**

Manufacturer: ***WELLS BIO, INC.*** *Not for sale in* ***USA***

Analyzers

Analyer 100

A1C Cartridge

S1 Analyzer

G6PD Biosensor

careSURE™ Analyzer 100

Fully automated HbA1c POC analyzer

careSURE™ Analyzer 100 calculates the mean serum glucose values for the past 2-3 months by measuring HbA1c (Hemoglobin A1c) in blood. Making it possible to gain effective glucose control thanks to its accurate data compared to conventional measuring systems. This one-step measuring method overcomes the disadvantages of complicated hospital equipment.

1 All-in-one cartridge

Integrated **sampling device** with all **necessary reagents**

2 One step measuring and fast result

Result in **3 minutes** with **3 µL whole blood**

3 User-friendly data display

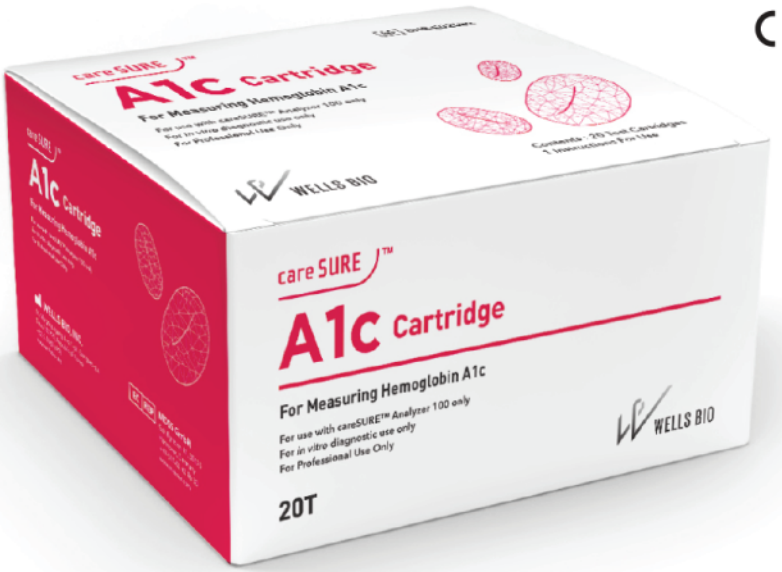
HbA1c and eAG results in one test, Selection of units (% or mmol/mol)

Technical Specifications

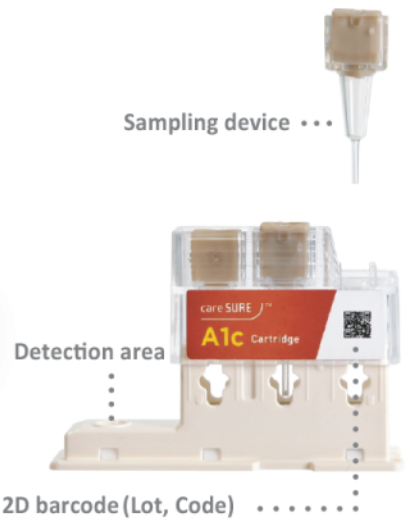
Test Type	**Quantitative HbA1c test**
Specimen Type	**Venous blood / Capillary blood**
Specimen Volume	**3 µL**
Result Time	**3 min**
Storage Cond.	**Analyzer 100 : -10 - 60°C, Cartridge : 2 - 8°C**
Shelf life	**Cartridge : 12 months**

Manufacturer: ***WELLS BIO, INC.*** *Not for sale in* ***USA***

careSURE™ A1c Cartridge



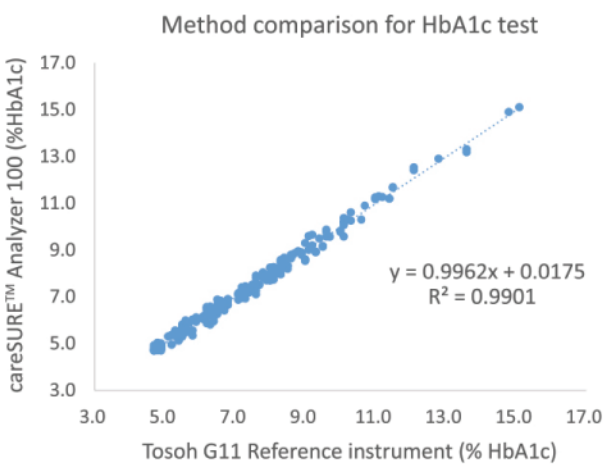
CE



Performance

Accuracy

Method comparison. careSURE™ Analyzer 100
vs. a laboratory HPLC method (Tosoh G11)
Using 48 venous blood samples.



Repeatability

Within 5% precision,
Number of replicates, N = 100
CV = Coefficient of Variation

Sample	Replicate	HbA1c %	CV (%)
Sample #1	20	5.3	1.9%
Sample #2	20	6.3	2.1%
Sample #3	20	8.0	1.8%
Sample #4	20	9.4	2.0%
Sample #5	20	10.4	1.6%

Manufacturer: ***WELLS BIO, INC.*** *Not for sale in* ***USA***

careSTART™ S1 Analyzer

Increase workflow efficiency with rapid and reliable results

The careSTART™ S1 Analyzer is intended for the quantitative measurement of total glucose-6-phosphate dehydrogenase(G6PD) enzyme activity, hemoglobin(Hb) concentration to evaluate G6PD/Hb Ratio, and total bilirubin(T-BIL) concentration from the capillary or venous blood specimen by using electrochemical and optical method.

Technical Specifications

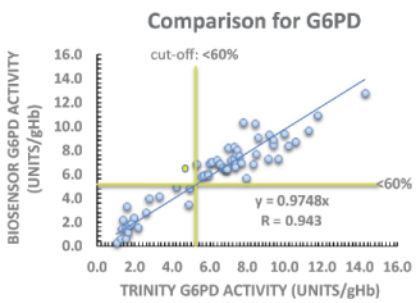
Test method	G6PD : Electrochemical Hemoglobin / Bilirubin : Photochemical
Display	4" TFT-LCD (with Touch Screen)
Battery	Li-Polymer Battery (3,000mAh)
Interface	2D Barcode & Bluetooth & Wi-Fi & micro USB
Shelf life	G6PD Strip : 24 months Hb Strip : 18 months T-BIL Strip : 12 months

Manufacturer: ***WELLS BIO, INC.*** *Not for sale in* ***USA***

G6PD Performance

G6PD Correlation Analysis: Haiti Study
Only one outlier from the results of comparison study between Trinity and careStart™ G6PD with 60% cut-off

- N=61 children
- Specimen : Venous Blood
- Correlation : 0.943



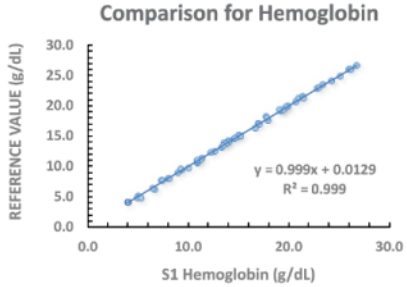
Hemoglobin Performance

ACCURACY : The results from clinical studies comparing the careSTART™ S1 Hb strip test strip to the Hemocue Hb 301 microcuvette are summarized below.

careSTART™ S1 Hb vs. HemoCue® Hb 301.
- N = 60 Samples

Repression analysis for hemoglobin concentration			
Linear regression	R^2	N	Range [g/dL]
Y=0.999x+0.0129	0.999	60	4.0 ~ 26.8 g/dL

System accuracy for hemoglobin concentration	
Within ±5%	Within ±10%
58/60 (96.7%)	60/60 (100%)

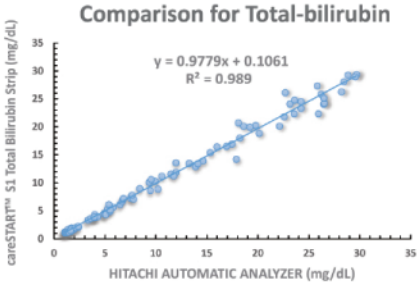


Total-Bilirubin Performance

ACCURACY : The results from clinical studies comparing the careSTART™ S1 Total Bilirubin Strip to 7020 Hitachi Automatic Analyzer are summarized below.

careSTART™ S1 Total Bilirubin vs 7020 Hitachi Automatic Analyzer
- N = 100 Samples
- Specimen : Venous Blood

Repression analysis for Total-bilirubin concentration			
Linear regression	R^2	N	Range [mg/dL]
Y= 0.9779x + 0.1061	0.989	100	1.03~29.56



careSTART™ G6PD Biosensor

World's first G6PD quantitative test in 4 minutes.

Awareness of G6PD deficiency has grown significantly in the healthcare community. Along with the use of the antimalarial drug primaquine and every-day life, health care individuals are looking to educate more about the health conditions of G6PD deficiency. Using the handheld G6PD Biosensor, individuals are able to obtain a quantitative value for their G6PD enzyme levels in under 4 minutes.

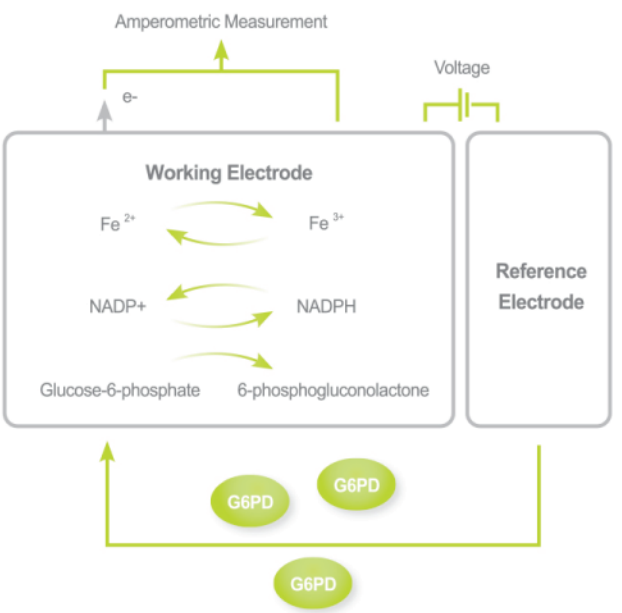
Technical Specifications

Test Type	Quantitative G6PD test
Specimen	Venous blood / Capillary blood
Specimen Volume	7 µL
Result Time	4 min
Storage Cond.	Analyzer temperature: 10 - 40°C Strip : 2 - 40°C
Shelf life	24 months

Manufacturer: ***WELLS BIO, INC.*** *Not for sale in* ***USA***

Technology

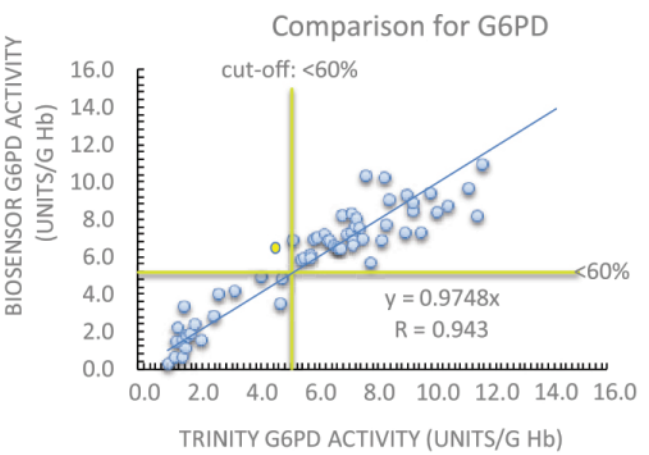
Enzyme activity detection through
Electrochemical sensing technology



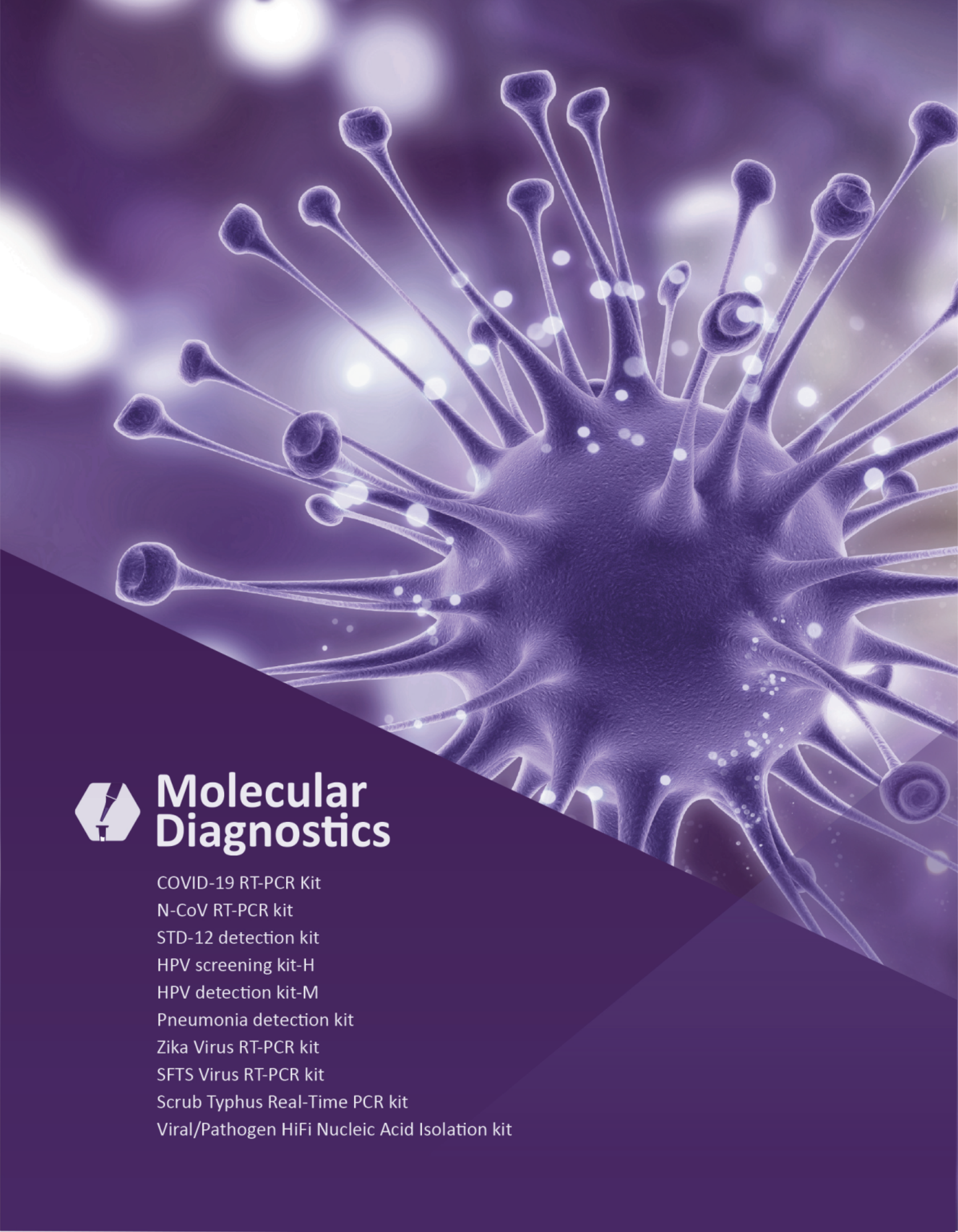
Performance

G6PD Correlation Analysis: Haiti Study

Only one sample's discordant between Trinity and *careStart*™ G6PD with 60% cut-off



- N=61 children
- Specimen : Venous Blood
- Correlation : 0.943



Molecular Diagnostics

COVID-19 RT-PCR Kit
N-CoV RT-PCR kit
STD-12 detection kit
HPV screening kit-H
HPV detection kit-M
Pneumonia detection kit
Zika Virus RT-PCR kit
SFTS Virus RT-PCR kit
Scrub Typhus Real-Time PCR kit
Viral/Pathogen HiFi Nucleic Acid Isolation kit

CareStart™ COVID-19 RT-PCR Kit

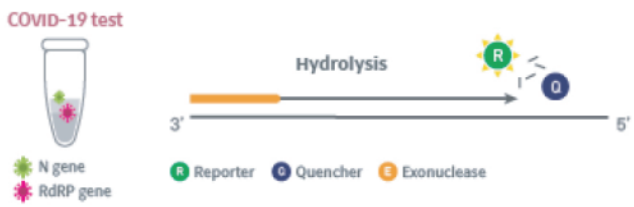
Sensitive and Reliable Molecular Diagnostic Test for COVID-19

The *CareStart*™ MDx RT-PCR is a real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal and oropharyngeal swab specimens from individuals suspected of COVID-19 by their healthcare provider.

US FDA Emergency Use Authorized CE

Features

- One Step Real-Time Reverse Transcription PCR Technology
- Preventing contamination using the UDG (Uracil-DNA Glycosylase System)
- Endogenous control included for sample extraction and amplification efficiency verification
- Reaction time within 83 min (Improving laboratory efficiency)



The reverse transcription (RT) and qPCR step are both conducted in the same reaction well. As the specific sequence is amplified, the taqman probe hybridized to the target is dissociated to generate fluorescence.

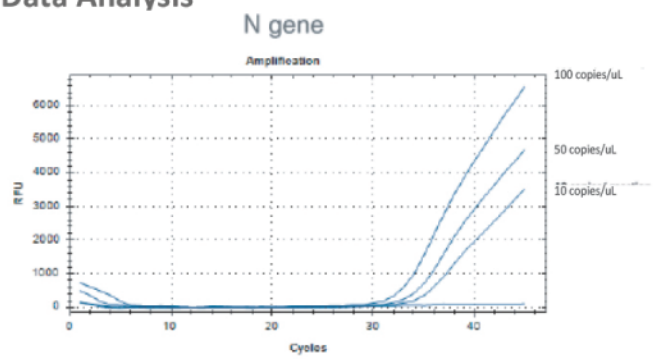
Detection Target

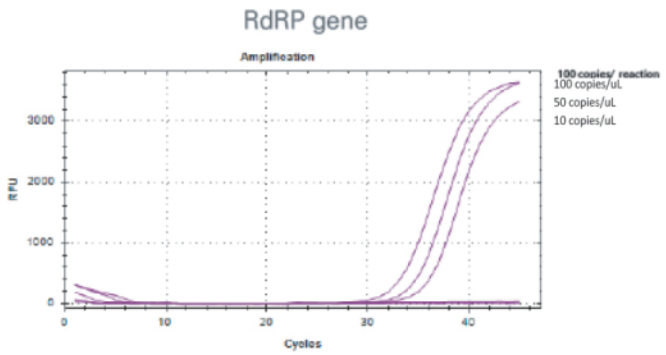
- N gene (SARS-CoV-2)
- RdRP gene (SARS-CoV-2)

Specimen Type

- Nasopharyngeal swab
- Oropharyngeal swab
- Sputum

Data Analysis





Applicable Instrument

- CFX96™ Dx system
- Applied Biosystems 7500 Real-Time PCR system
- Applied Biosystems QuantStudio 5 Dx Real-Time PCR Instrument

Fluorescent Reporter

Dye	Target
FAM	N gene
Cy5/Quasar	RdRP gene

Ordering Information

Cat. No.	MCGM-10072
Package Unit	100 tests/kit
Kit Component	4 X 1 step RT-PCR Mix SARS-COv-2 primer / probe Mix MS2 Phage Control External Positive Control External Negative Control Instructions for Use
Storage	Below -20°C
Shelf-life	12 months

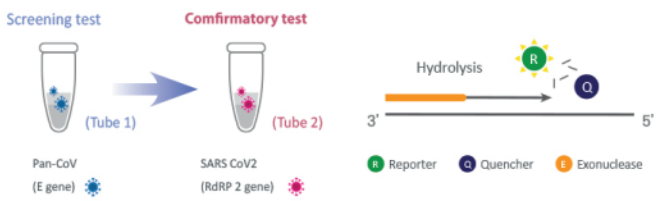
Manufacturer: ***ACCESS BIO, INC.***

careGENE™ N-CoV RT-PCR kit

careGENE™ N-CoV RT-PCR kit is anin vitrodiagnostic medical device for qualitative detection of coronavirus disease (COVID-19) from RNA extracted from human Nasopharyngeal swab, Oropharyngeal swab and sputum using real-time RT-PCR (Reverse transcription-Polymerase Chain Reaction).

Features

- One Step Real-Time Reverse Transcription PCR Technology
- Preventing contamination using the UDG (Uracil-DNA Glycosylase System)
- Endogenous control included for sample extraction and amplification efficiency verification
- Reaction time within 83 min (Improving laboratory efficiency)



- The reverse transcription (RT) and qPCR step are both conducted in the same reaction well. As the specific sequence is amplified, the taqman probe hybridized to the target is dissociated to generate fluorescence.

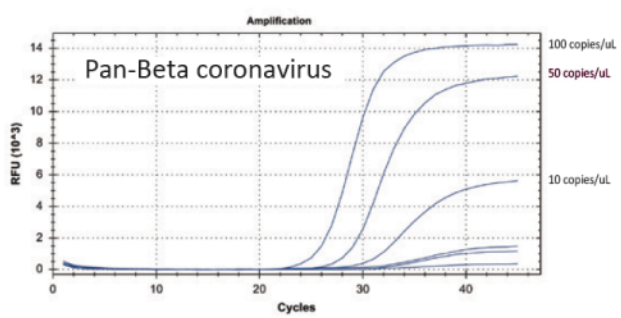
Detection Target

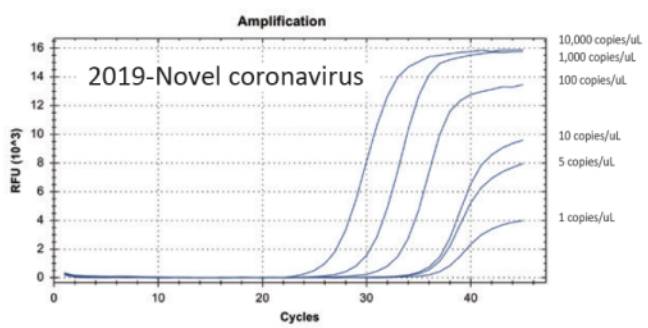
- E gene (SARS-CoV-2)
- RdRP gene (SARS-CoV-2)

Specimen Type

- Nasopharyngeal swab
- Oropharyngeal swab
- Sputum

Data Analysis





Applicable Instrument

- CFX96™ Dx system
- Applied Biosystems 7500 Real-Time PCR system
- Applied Biosystems QuantStudio 5 Dx Real-Time PCR Instrument

Fluorescent Reporter

Detection target	Reporter (Pan-CoV set)
Pan-CoV (E gene)	FAM
Internal Control	ROX

Detection target	Reporter (N-CoV set)
N-CoV (RdRP)	FAM
Internal Control	ROX

Ordering Information

Cat. No.	MNC-N10082
Package Unit	100 tests/kit
Kit Component	4 X 1 step RT-PCR Mix Pan-CoV primer/probe mix N-CoV primer/probe mix Nuclease free water Positive control, IFU
Storage	Below -20 °C
Shelf-life	12 months

Manufacturer: ***WELLS BIO, INC.*** *Not for sale in* ***USA***

care GENE™ STD-12 detection kit

70 to 80% of Sexually transmitted diseases (STD) are asymptomatic even though they are infected. If not treated properly, women may cause vaginitis, cervical cancer, and urethritis, which can cause serious complications such as abortion, premature birth, and infertility. The STD tests with conventional end point PCR are used but have the complexity of the test and risk of cross-contamination concerns. Therefore, we adopted real-time PCR method, with has already been validated by several products, improves the accuracy and usability of the test.

CE marked | KMFDS approved

Features

- Demonstrates no cross-reactivity, ensuring that positive results are clinically meaningful
- Preventing contamination using the Uracil-DNA Glycosylase(UDG) System
- Endogenous control included for sample extraction and amplification efficiency verification
- Short turn around time, less than 110 minutes reaction time

Detection Target

- Mycoplasma hominis (MH)
- Mycoplasma genitalium (MG)
- Neisseria gonorrhea(NG)
- Trichomonas vaginalis (TV)
- Ureaplasma urealyticum (UU)
- Chlamydia trachomatis (CT)
- Gardnerella vaginalis (GV)
- Treponema pallidum (TP)
- Herpes Simplex Virus 1 (HSV1)
- Herpes Simplex Virus 2 (HSV2)
- Ureaplasma parvum (UP)
- Candida albicans (CA)

Specimen Type

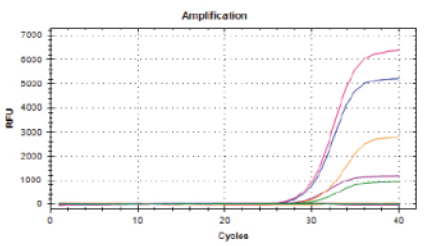
- Vaginal swab
- Urine

Applicable Instrument

- CFX96™ Dx system

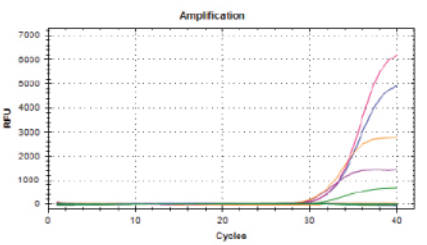
Data Analysis

Positive Set A example



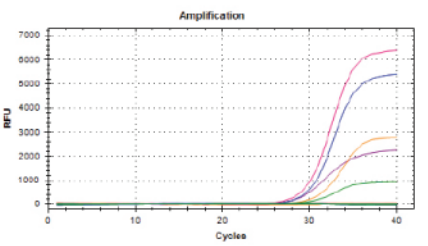
Reporter	Set A
FAM	NG
HEX	CT
Cy5	UU
Quasar 705	MG
ROX	IC

Positive Set B example



Reporter	Set B
FAM	TP
HEX	UP
Cy5	MH
Quasar 705	TV
ROX	IC

Positive Set C example



Reporter	Set C
FAM	CA
HEX	GV
Cy5	HSV1
Quasar 705	HSV2
ROX	IC

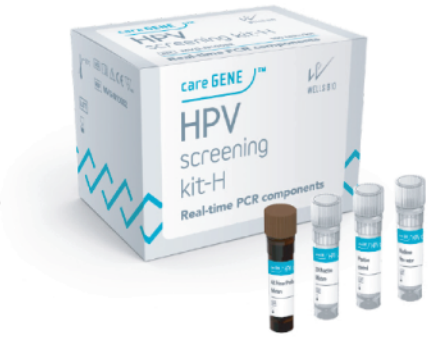
Ordering Information

Product	STD-12	STD-4 A set (NG, CT, UU, MG)	STD-4 B set (TP, UP, MH, TV)	STD-4 C set (CA, GV,HSV1 & 2)
Cat. No.	MST-N10082	MSA-N10082	MSB-N10082	MSC-N10082
Package Unit	100 tests/kit			
Kit Component	2X Reaction Mixture A set Primer/Probe mix B set Primer/Probe mix C set Primer/Probe mix Positive Control A Positive Control B Positive Control C Nuclease free water Instructions for Use	2X Reaction Mixture A set Primer/Probe mix Positive Control A Nuclease free water Instructions for Use	2X Reaction Mixture B set Primer/Probe mix Positive Control B Nuclease free water Instructions for Use	2X Reaction Mixture C set Primer/Probe mix Positive Control C Nuclease free water Instructions for Use
Storage	Below -20°C			
Shelf-life	12 month			

Manufacturer: ***WELLS BIO, INC.*** *Not for sale in* ***USA***

careGENE MT HPV screening kit-H

HPV is an etiologic agent for one of the most common sexually transmitted diseases. More than 100 viral types of HPV have been identified. Over 30 types of the HPV are associated with sexually transmitted infections and certain high-risk HPV can cause cancers of the cervix, vagina, vulva, penis and anus. Because 40% of HPV infections are mixed infection, the accurate identification of high-risk HPV genotypes, especially HPV 16 or HPV 18 in mixed infection, is important for assessing the risk of progression to a cervical cancer.



CE marked | KMFDS approved

Features

- Demonstrates no cross-reactivity, ensuring that positive results are clinically meaningful
- Preventing contamination using the Uracil-DNA Glycosylase(UDG) System
- Endogenous control included for sample extraction and amplification efficiency verification
- Short turn around time, less than 105 minutes reaction time

Detection Target

- High-risk HPV Genotyping : HPV 16, HPV 18
- High-risk HPV Screening : HPV 31, HPV 33, HPV 35, HPV 39, HPV 45, HPV 51, HPV 52, HPV 56, HPV 58, HPV 59, HPV 66, HPV 68

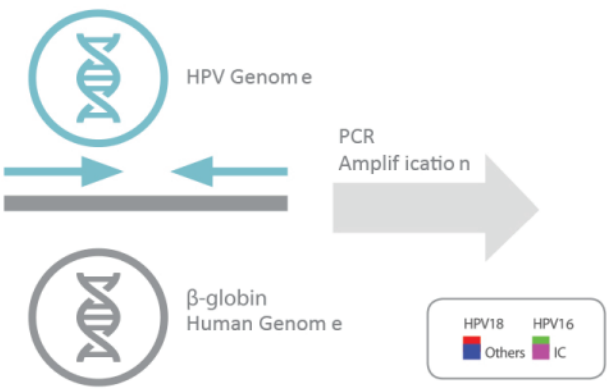
Specimen Type

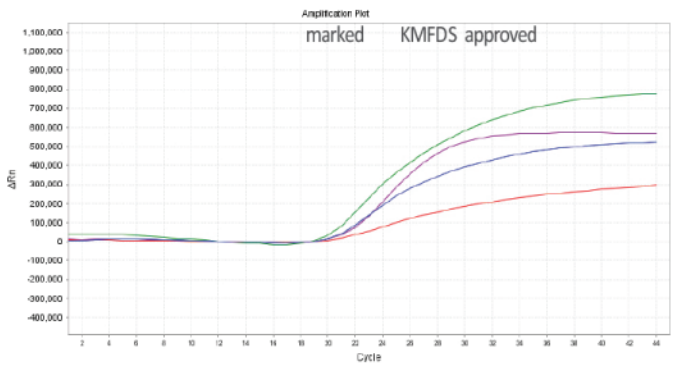
- Crude cervical scraping specimen (Liquid based cytology)

Applicable Instrument

- Applied Biosystems 7500 Real-Time PCR system

Data Analysis





Fluorescent Reporter

Dye	HPV genotype
FAM	HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68
VIC	HPV 16
Cy5	HPV 18
ROX	IC (β-globin)

Ordering Information

Cat. No.	MVG-N10082
Package Unit	100 tests/kit
Kit Component	2X Reaction Mixture 4X Primer/Probe Mixture Positive control Nuclease free water Instructions for Use
Storage	Below -20°C
Shelf-life	12 months

Manufacturer: ***WELLS BIO, INC.*** *Not for sale in* ***USA***

careGENE™ HPV detection kit-M

The careGENE™ HPV detection kit-M is designed to detect 25 types of human papillomavirus types (HPV). In conjunction with qPCR, it can genotype 4 high-risk HPVs (16, 18, 31, and 59) and 3 low-risk HPVs (6, 53, and 61). It can collectively detect 10 other high-risk HPVs (HPV 33, 35, 39, 45, 51, 52, 56, 58, 66, and 68), and 8 other low-risk HPVs (HPV 11, 40, 43, 44, 54, 70, 73, and 81) from crude cervical scraping (Liquid based Cytology). This kit was developed based on TaqMan probe qPCR technology, utilizing polymerase chain reaction (PCR) for the amplification of specific target sequences and target specific probes for the detection of amplified HPV DNA.

CE

Features

- Demonstrates no cross-reactivity, ensuring that positive results are clinically meaningful
- Preventing contamination using the Uracil-DNA Glycosylase(UDG) System
- Endogenous control included for sample extraction and amplification efficiency verification

Detection Target

- HPV Genotyping
  - High-risk HPV 16/18/31/59
  - Low-risk HPV 6/53/61
- HPV Screening
  - High-risk HPV 33/35/39/45/51/52/56/58/66/68
  - Low-risk HPV 11/40/43/44/54/70/73/81

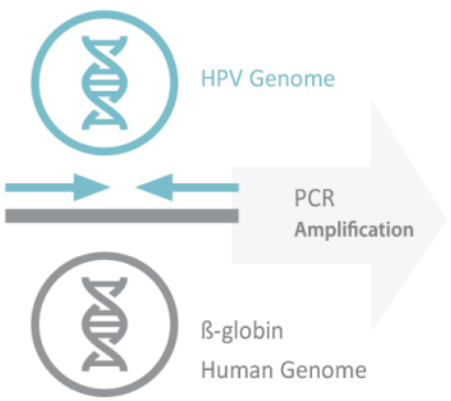
Specimen Type

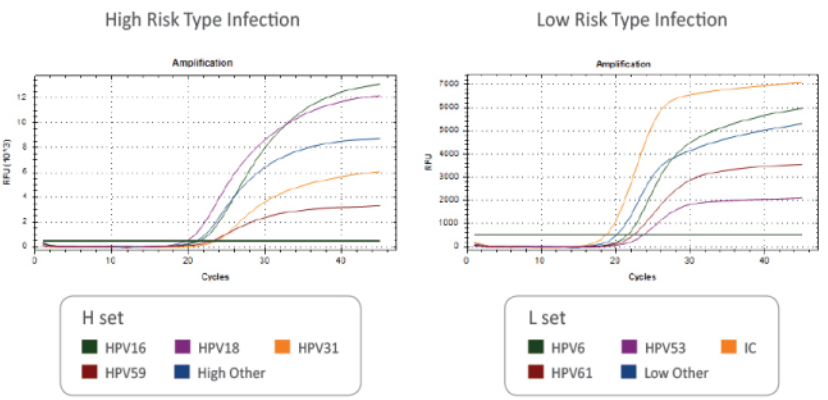
- Crude cervical scraping specimen (Liquid based cytology)

Applicable Instrument

- CFX96™ Dx system

Data Analysis





Fluorescent Reporter

Dye	HPV genotype
FAM	High-risk HPV 33, 35, 39, 45, 51, 52, 56, 58, 66, 68 Low-risk HPV 11, 40, 43, 44, 54, 70, 73, 81
HEX	High-risk HPV 16 / Low-risk HPV 6
Cy5	High-risk HPV 18 / Low-risk HPV 53
QUASAR705	High-risk HPV 59 / Low-risk HPV 61
ROX	High-risk HPV 31 / Internal Control

Ordering Information

Cat. No.	MVI-N10082
Package Unit	100 tests/kit
Kit Component	2X Reaction Mixture Mix H, Mix L Positive control 1 & 2 Nuclease free water Instructions for Use
Storage	Below -20°C
Shelf-life	12 months

Manufacturer: ***WELLS BIO, INC.*** *Not for sale in* ***USA***

care GENE™ Pneumonia detection kit

CE marked

Pneumonia has a mortality rate of 12 to 14% despite antibiotic treatment and is one of the most common causes of death among infectious disease. In particular, the elderly has a higher mortality rate, and the prevalence of pneumonia and the resulting mortality rate are on the rise due to the rapid increase in the elderly population. It can help treat macrolide antimicrobial resistance by detecting the exact causative bacteria of pneumonia in respiratory samples of people with respiratory infections and revealing genetic mutations in mycoplasma pneumonia.

Features

- Highly Efficient Detection for Total 12 Target Pathogens
- Three-Tubes Multiplex Real-Time PCR Reaction within 110 minutes
- Excellent Performance in LoD. ≥ 25 copies/uL

Detection Target

- Mycoplasma pneumonia (MP)
- M. pneumonia Mutation (MP-)
- Chlamydia pneumonia (CP)
- Legionella pneumophila (LP)
- Streptococcus pneumonia (SP)
- Staphylococcus aureus (SA)
- Haemophilus influenza (HI)
- Klebsiella pneumonia (KP)
- Pseudomonas aeruginosa (PA)
- Moraxella catarrhalis (MC)
- Bordetella pertussis (BP)
- Bordetella parapertussis (BPP)

Specimen Type

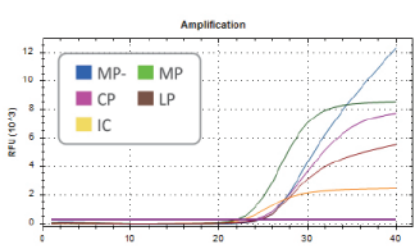
- Sputum
- Nasopharyngeal Swab

Applicable Instrument

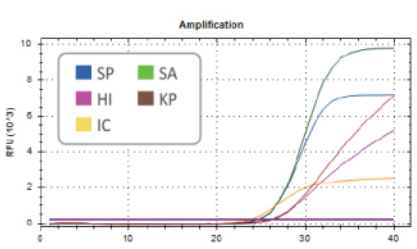
- CFX96™ Dx system

Data Analysis

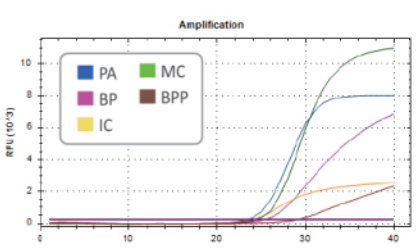
Positive PPM-1 example



Positive PPM-2 example



Positive PPM-3 example



Fluorescent Reporter

Dye	Mix-1 Tube	Mix-2 Tube	Mix-3 Tube
FAM	MP-	SP	PA
HEX	MP	SA	MC
Cy5	CP	HI	BP
QUASAR705	LP	KP	BPP
ROX	IC	IC	IC

Manufacturer: ***WELLS BIO, INC.*** *Not for sale in* ***USA***

Ordering Information

Cat. No.	MPN-N10082
Package Unit	100 tests/kit
Kit Component	2 X Reaction Mixture 4 X Primer/Probe Mix -1 4 X Primer/Probe Mix -2 4 X Primer/Probe Mix -3 PC 1, PC 2, PC 3 Nuclease free water Instructions for Use
Storage	Below -20°C
Shelf-life	12 months

careGENE™ Zika Virus RT-PCR kit

Zika virus belongs to Flaviviridae and has a novel single-stranded, positive-sense RNA. Zika virus is believed to be transmitted to humans by infected Aedes spp. mosquitoes. Studies indicated that Zika virus has been endemic in Africa and Southeast Asia. In 2007, an epidemic of Zika virus infection in humans occurred in Yap, Federated States of Micronesia, in the Pacific region. During 2007–2013, a few cases of Zika virus infected travelers returning from Africa or Southeast Asia were reported. The outbreak of Zika fever began in April 2015 in Brazil, and subsequently spread to other countries in South America, Central America and the Caribbean.

CE marked

Features

- Short turn around time included pre-treatment within 3 hours
- Increased specificity through dual target detection
- Excellent analytical accuracy : Zika virus RNA in serum and urine specimens (patient-matched specimen)
- Master mix format enables reduced hands-on time
- Reduced contamination by single tube supplied

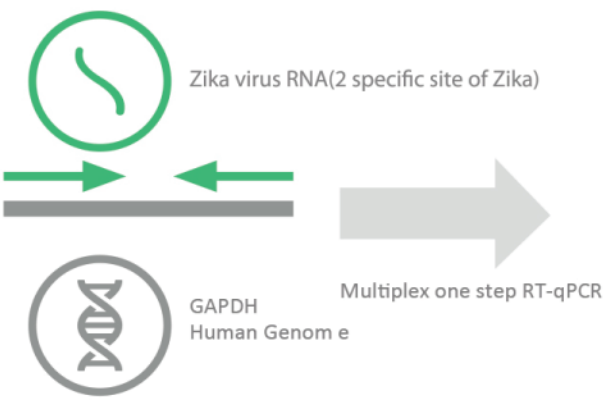
Detection Target

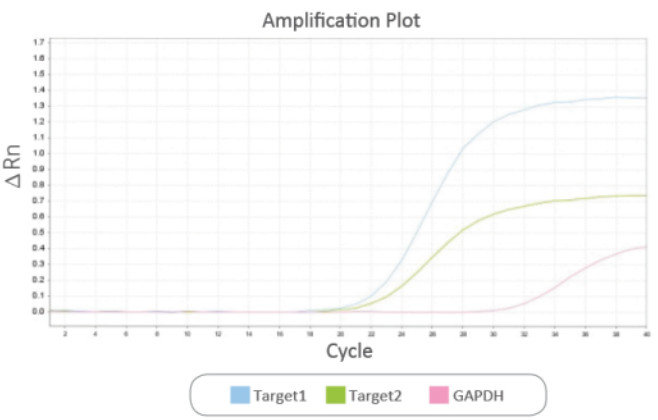
- Zika virus RNA target 1
- Zika virus RNA target 2

Specimen Type

- Serum specimen
- Urine specimen

Data Analysis





Applicable Instrument

- CFX96™ Dx system
- Applied Biosystems 7500 Real-Time PCR system

Fluorescent Reporter

Dye	Detection Target
FAM	Zika virus RNA target 1
Cy5/Alexa647	Zika virus RNA target 2
VIC/HEX	Internal Control

Ordering Information

Cat. No.	MZK-N09682
Package Unit	96 tests/kit
Kit Component	4X 1 Step RT-PCR Mix Zika primer/probe Mix Nuclease free water Instructions for Use
Storage	Below -20℃
Shelf-life	12 months

Manufacturer: ***WELLS BIO, INC.*** *Not for sale in* ***USA***

careGENE™

SFTS Virus RT-PCR kit

KMFDS approved

Severe fever with thrombocytopenia syndrome (SFTS) is firstly reported in China in 2011. It is an emerging infectious disease in China, Japan and South Korea. It is caused by novel bunyavirus, called SFTS virus. The vector of SFTS is Haemaphysalis longicornis tick and domesticated animals may serve as intermediate hosts. The clinical manifestations of SFTS are fever, vomiting, diarrhea, thrombo cytopenia and leukopenia. In severe cases, multiple organ failure, disseminated intravascular coagulopathy, and central nervous systems manifestation are present. The case-fatality rate is 6-30%. There is no effective antiviral therapy and supportive care is the main treatment.

Features

•TaqMan Probe Technology for high sensitivity and specificity
- Short turnaround time within 100 min reaction time
- Excellent Performance in L.o.D. ≥ 25 copies/uL

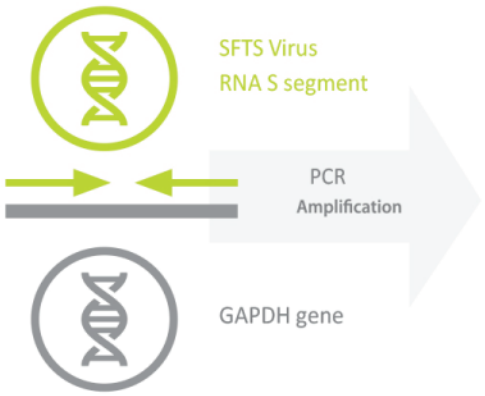
Detection Target

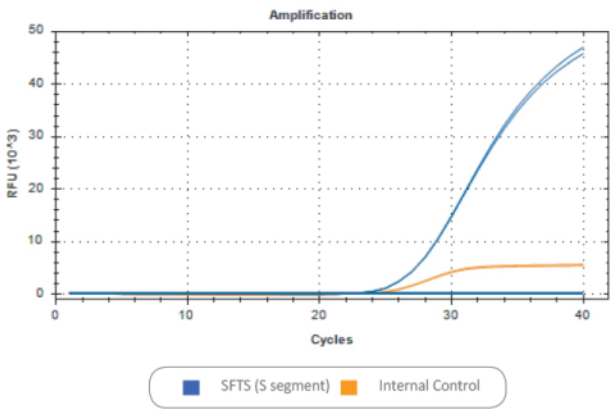
- SFTS Virus RNA S segment

Specimen Type

- Human whole blood

Data Analysis





Applicable Instrument

- CFX96™ Dx system

Fluorescent Reporter

Dye	Detection Target
FAM	SFTSV RNA S segment
ROX	Internal Control

Manufacturer: ***WELLS BIO, INC.*** *Not for sale in* ***USA***

Ordering Information

Cat. No.	MSF-N10082
Package Unit	100 tests/kit
Kit Component	4X Reaction Mixture SFTS Primer/ Probe Mix Positive Control Nuclease free water Instruction for use
Storage	Below -20°C
Shelf-life	12 months

care GENE™ Scrub Typhus Real-time PCR kit

Scrub typhus is an acute febrile disease that occurs when bitten by larvae of hairy mites infected by O. tsutsugamushi bacteria, and the incidence is high mainly in Asia, but tends to increase due to increased overseas travel and influx of workers. Scrub typhus generally occurs in autumn, and can be clinically diagnosed by showing characteristic findings such as eschar and rash along with outdoor activity. However, in fact, Scrub typhus often does not have a rash or eschar. Although it responds well to antibiotic treatment, delayed diagnosis can lead to serious complications such as interstitial pneumonia, acute renal failure, meningitis, and gastrointestinal bleeding, and later multiple organ failure and death. Since it is often difficult to diagnose Scrub typhus only with clinical symptoms, a product with proven accuracy and usability that can be diagnosed with real-time polymerase testing is need.

KMFDS approved

Features

- TaqMan Probe Technology for high sensitivity and specificity
- Short turnaround time within 80 min reaction time
- Excellent Performance in L.o.D. ≥ 5 copies/uL

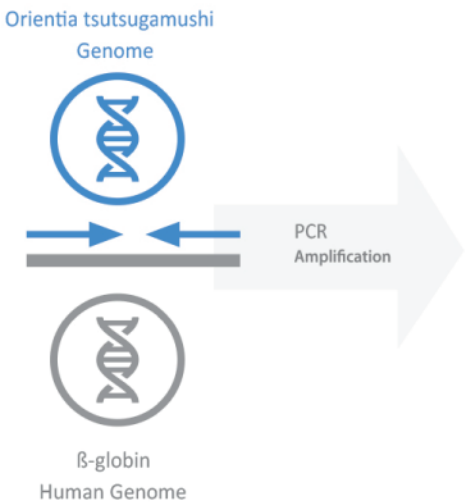
Detection Target

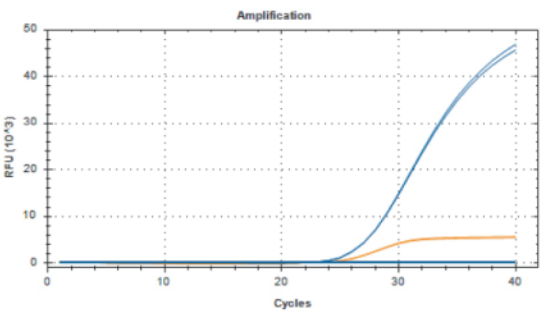
- Orientia tsutsugamushi gene (16s rRNA)

Specimen Type

- Human whole blood

Data Analysis





infection

Applicable Instrument

- CFX96™ Dx system

Fluorescent Reporter

Dye	Detection Target
FAM	Scrub Typhus
ROX	Internal Control

Ordering Information

Cat. No.	MTH-N10082
Package Unit	100 tests/kit
Kit Component	2 X Reaction Mixture 4 X Primer/ Probe mix Positive Control Nuclease free water Instruction for use
Storage	Below -20°C
Shelf-life	12 months

Manufacturer: ***WELLS BIO, INC.*** *Not for sale in* ***USA***

careGENE™ Viral/Pathogen HiFi Nucleic Acid Isolation kit

Due to the magnetic separation technology being applied to careGENE™ Viral/Pathogen HiFi Nucleic Acid Isolation kit, it can collect, transport and mix magnetic particles by using permanent magnetic rods with disposable tip combs. The extraction process is as follows. Magnetic rods (covered with disposable tip combs) moves up and down in the sample plate (S plate) to collect magnetic particles which are bound to nucleic acids. And next, the magnetic rods transfer magnetic particles to the next plates (W1, W2 and W3) sequentially for washing. Finally, the magnetic rods transfer the particles to the Elution plate (E plate), the particles and eluting solution are all mixed up, then the nucleic acids can be separated and purified by mixing and isolating the magnetic particles in the E plate. As a result, the target nucleic acids are separated and purified from human specimens

Features

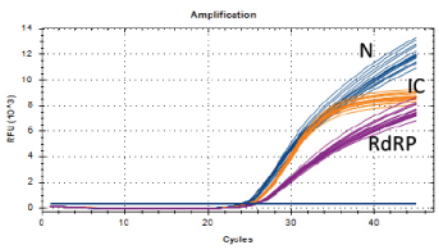
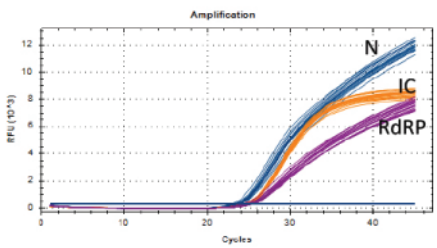
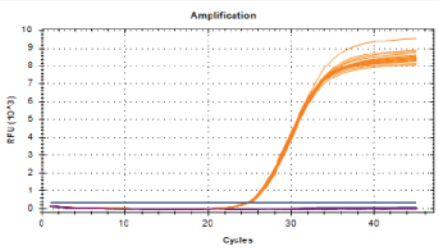
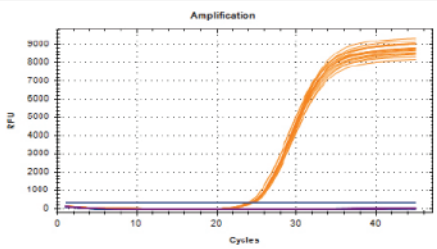
- Easy to use with automated extraction platform
- 35 min processing time to extract 96 samples
- Coefficient of Variation < 3%, Standard Deviation < 0.3
- Minimize contamination by fully automated process

Specimen Type

- Nasopharyngeal swab
- Nasal swab
- Virginal swab
- Serum
- Urine

CE marked | KMFDS approved
USA FDA listed

Comparison with a competitor

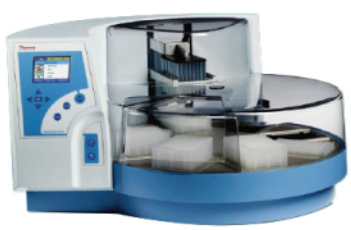
	Thermo Fisher Scientific. (KingFisher Flex)	Competitor T
Positive control		
Negative control		

	Thermo Fisher Scientific. (KingFisher Flex)						Competitor T					
	Positive control			Negative control			Positive control			Negative control		
	FAM	ROX	Cy5	FAM	ROX	Cy5	FAM	ROX	Cy5	FAM	ROX	Cy5
AVERAGE	23.99	24.71	25.47	-	24.51	-	23.48	24.49	25.05	-	24.11	-
STDEV	0.16	0.14	0.17	-	0.13	-	0.24	0.13	0.29	-	0.2	-

Ordering Information

Instrumentation	KingFisher Flex (Thermo Fisher Scientific)
Cat. No.	MVP-N09683
Package Unit	96 tests/kit
Kit Component	Tip comb/plate set, S plate, W1/2/3 plate, E plate, Instruction for use
Storage	15~30°C
Shelf-life	12 months

KingFisher Flex
(Thermo Fisher Scientific.)



Manufacturer: ***WELLS BIO, INC.*** *Not for sale in* ***USA***

Order Information

Rapid Diagnostic Tests

Product	Product Name	Package
COVID-19	*CareStart*™ COVID-19 Antigen Home Test	2 tests/box
	CareStart™ COVID-19 Antigen Test	20 tests/box
	CareStart™ COVID-19 IgM/IgG RDT	25 tests/box
Influenza A & B	*CareStart*™ Flu A&B Plus	20 tests/box
G6PD Deficiency	*CareStart*™ G6PD RDT	25 tests/box
	careUS™ G6PD RDT Control	15 vials/box (50µl per vial)
Malaria	*CareStart*™ Malaria RDT	25 tests/box
Dengue	*CareStart*™ Dengue NS1	25 tests/box
	CareStart™ Dengue IgM/IgG	25 tests/box
	CareStart™ Dengue NS1 & IgM/IgG Combo	25 tests/box
STD	careUS™ Syphilis	25 tests/box

Analyzers

Product	Product Name	Package
HbA1c	careSURE™ Analyzer 100	1 each/box
	careSURE™ A1c Cartridge	20 tests/box
G6PD/Hb/T-BIL	careSTART™ S1 Analyzer	1 each/box
	careSTART™ S1 G6PD Strip	25 strips/box
	careSTART™ S1 Hb Strip	25 strips/box
	careSTART™ Total-Bilirubin Strip	25 strips/box
G6PD	careSTART™ G6PD Biosensor Analyzer	1 each/box
	careSTART™ G6PD Biosensor Strip	25 strips/box
	careSTART™ G6PD Biosensor Control Level I	10 bottles/box (50µl per bottle)
	careSTART™ G6PD Biosensor Control Level II	10 bottles/box (50µl per bottle)

Molecular Tests

Product	Product Name	Package
COVID-19	*CareStart™* COVID-19 RT-PCR kit	100 tests/kit
	careGENE™ N-CoV RT-PCR kit	50 or 100 tests/kit
STD	careGENE™ STD-12 detection kit	100 or 1000 tests/kit
	careGENE™ STD-4 A set	100 tests/kit
	careGENE™ STD-4 B set	100 tests/kit
	careGENE™ STD-4 C set	100 tests/kit
HPV	careGENE™ HPV screening kit-H	100 tests/kit
	careGENE™ HPV screening kit-M	100 tests/kit
Pneumonia	careGENE™ Pneumonia detection kit	100 tests/kit
Zika	careGENE™ Zika Virus RT-PCR kit	96 tests/kit
SFTS	careGENE™ SFTS Virus RT-PCR kit	100 tests/kit
Scrub Typhus	careGENE™ Scrub Typhus Real-time PCR kit	100 tests/kit
Nucleic Acid Isolation	careGENE™ Viral/Pathogen HiFi Nucleic Acid Isolation kit	96 tests/kit

AccessBio

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