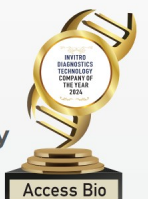




Access Bio emerged as a
Invitro Diagnostics Technology
Company of the Year 2024



Awarded By
Life Sciences
Review



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 well-being for all people.

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RAPID DIAGNOSTIC TESTS

- **CareSuperb™ Platform**
 - COVID-19 Home Test
 - COVID-19/Flu A&B Combo Home Test
 - COVID-19/Flu A&B/RSV Combo Test
- **COVID-19 Antigen Home Test**
- **COVID-19 Antigen**
- **G6PD**
- **Malaria**
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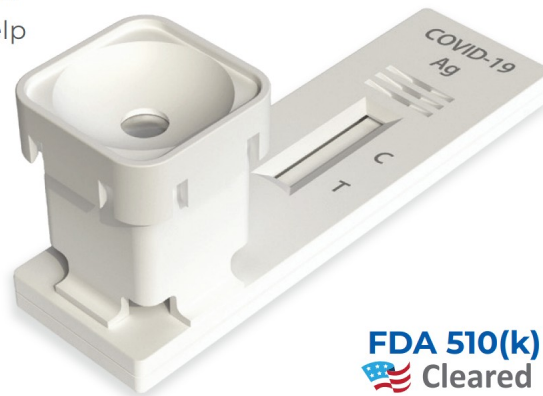


Setting a **New Platform** in Rapid Diagnostics

The CareSuperb™ platform is a user-friendly next-generation technology designed to deliver results with improved sensitivity.

CareSuperb™ COVID-19 Antigen Home Test

The CareSuperb™ COVID-19 Antigen Home Test is a rapid, easy-to-use lateral flow assay for the qualitative detection of the SARS-CoV-2 nucleocapsid protein antigens using an anterior nasal swab sample. Results are visually read within minutes to help identify active COVID-19 infection.



■ Clinical Performance

97.2% PPA
98.8% NPA

FDA 510(k)
Cleared

- ✓ Fast and Easy Self-Test with Overall Accuracy of 98.5%
- ✓ Test Results in 15 Minutes
- ✓ No Special Equipment or Training Required

Product Specifications

Test Type	Qualitative Lateral Flow Assay
Specimen Type	Anterior Nasal Swab
Intended Use	Over-the-counter for Self-testing
Kit Package	1 test, 2 tests, 20 tests / kit
Results	15 min
Storage Condition	2 – 30°C

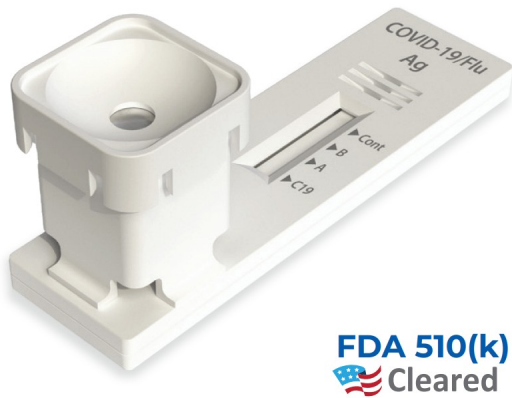
Manufactured by ACCESS BIO, INC.

Setting a **New Platform** in Rapid Diagnostics

CareSuperb™

COVID-19 / Flu A & B Antigen Combo Home Test

The CareSuperb™ COVID-19/Flu A&B Antigen Combo Home Test is a rapid, visually interpreted lateral flow assay that simultaneously detects the nucleocapsid protein antigens of SARS-CoV-2, and nucleoprotein antigens of Influenza A and Influenza B from a single anterior nasal swab sample. This convenient test helps differentiate between common respiratory viruses.



Product Specifications

Test Type	Qualitative Lateral Flow Assay
Intended Use	Over-the-counter
Kit Package	1 test, 2 tests, 20 tests / kit
Results	10 min
Storage Condition	2 – 30°C

Manufactured by ACCESS BIO, INC.

CareSuperb™

COVID-19 / Flu A & B / RSV Antigen Combo Test



The CareSuperb™ COVID-19/Flu A&B/RSV Antigen Combo Test is a rapid, visually read lateral flow assay designed to simultaneously detect the nucleocapsid protein antigens of SARS-CoV-2, and nucleoprotein antigens of Influenza A, Influenza B and Respiratory Syncytial Virus (RSV) using an anterior nasal swab. This comprehensive test aids in distinguishing between multiple respiratory infections.

Product Specifications

Test Type	Qualitative Lateral Flow Assay
Result	Visually Read
Storage Condition	2 – 30°C

Manufactured by ACCESS BIO, INC.

Rapid Test for Detection of Antigen Home Test

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.

- 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 Self-Test anywhere
- ✓ Easy to use with mobile application providing step-by-step instructions
- ✓ Test results obtained in 10 minutes
- ✓ Identifies the individual's current COVID-19 infection status
- ✓ No special equipment or training required

Manufactured by ACCESS BIO, INC.

The CareStart™ COVID-19 Antigen test is a lateral flow chromatographic immunoassay intended for the qualitative detection of nucleocapsid protein antigens from nasopharyngeal or anterior nasal swab sample collected by healthcare providers.

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 with anterior nasal or nasopharyngeal swab specimen
- ✓ Test results obtained in 10 minutes
- ✓ No special equipment or training required
- ✓ Identifies the individual's current COVID-19 infection status
- ✓ Clinical Performance (Anterior Nasal Swab) 87.18% PPA and 100.00% NPA

Manufactured by ACCESS BIO, INC.

G6PD deficiency is an X-linked recessive genetic disorder, resulting in no or low G6PD activity. G6PD deficient 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.



CE

Technical Specifications

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

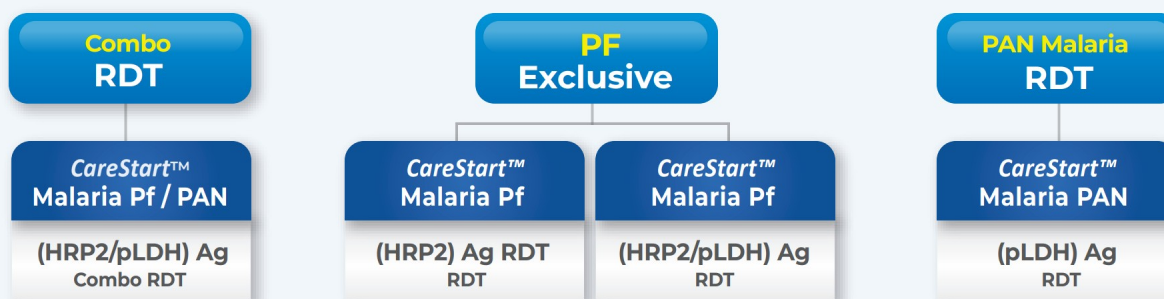
Manufactured by ACCESS BIO, INC. Not for sale in the USA

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 antimalarial drugs, the WHO recommends prescribing anti-malarials only to diagnosed patients.



Portfolio of CareStart™ Malarid RDTs



Technical Specifications

Test Type	Qualitative Rapid Diagnostic Test	Result Time	20 min
Specimen Type	Whole Blood	Storage Cond. Varies on Prod.	1-40°C
Specimen Volume	5µl		

Manufactured by ACCESS BIO, INC. Not for sale in the USA

Total diagnostic solution for all clinical stages of dengue infection

Dengue fever is the primary disease of tropical and subtropical regions. Dengue virus 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.



Dengue RDT Series:

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

Technical Specifications

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

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

Manufactured by **ACCESS BIO, INC.** Not for sale in the **USA**



ANALYZERS

- S1 Analyzer
- G6PD Biosensor



ANALYZERS

careSTART™

S1 Analyzer

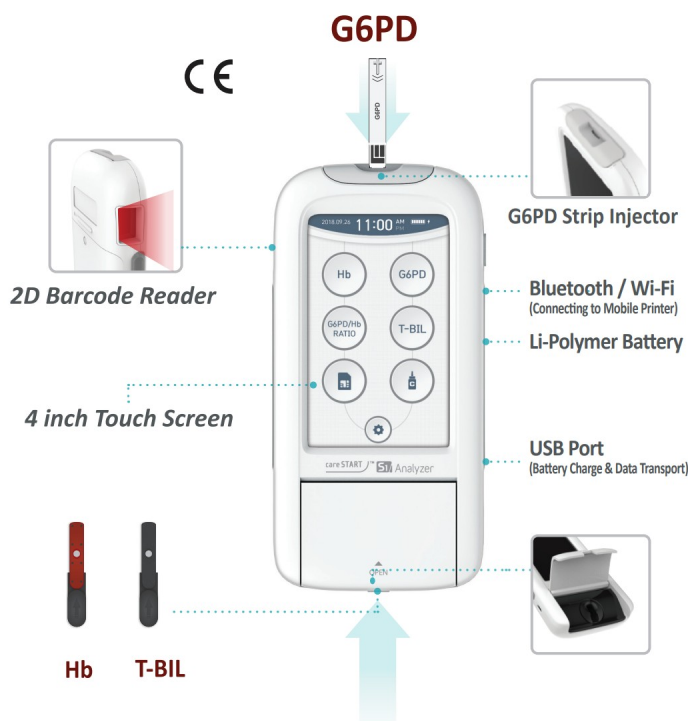
Increase workflow efficiency with rapid and reliable results

The careSTART™ 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 (3,000 mAh)
Interface	2D Barcode & Bluetooth & Wifi & micro USB
Shelf life	G6PD Strip : 24 months Hb Strip : 18 months T-BIL Strip : 12 months

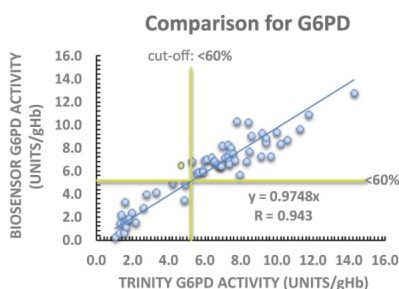
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G6PD Performance

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



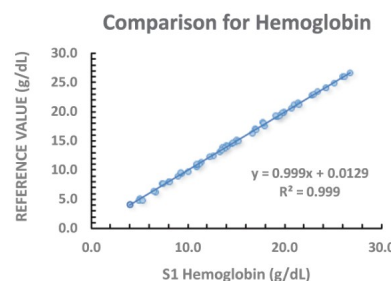
Hemoglobin Performance

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

Regression 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%)

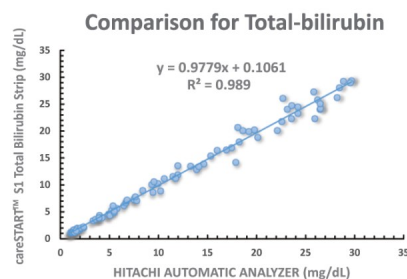


Total-Bilirubin Performance

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

Regression 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



World's first G6PD quantitative test in 4 minutes.

Awareness of G6PD deficiency has grown significantly in the healthcare community. Health care individuals are looking to educate more about the health conditions of G6PD deficiency for struggles caused by the deficiency in everyday life and appropriate use of the antimalarial drugs. Using the handheld G6PD Biosensor, individuals are able to obtain a quantitative value for their G6PD enzyme levels under 4 minutes.

Technical Specifications

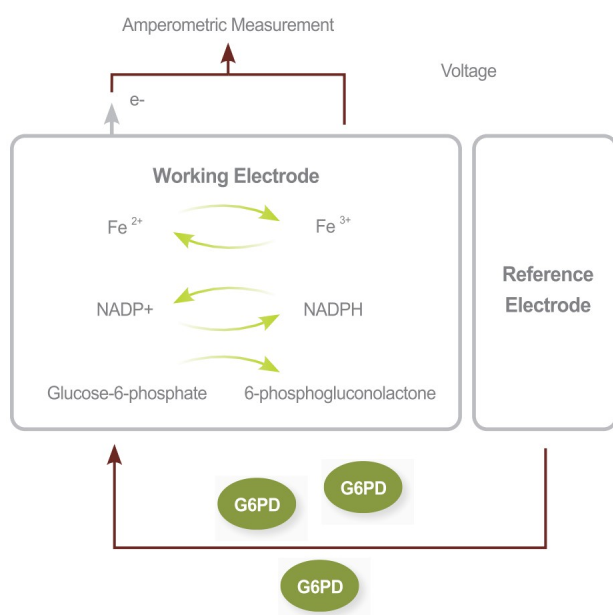
Test Type	Qualitative G6PD Test
Specimen	Venous blood / Capillary blood
Specimen Volume	7µl
Result Time	4 min
Storage Cond.	Analyzer temperature 10-40°C Strip : 2-40°C
Shelf Life	24 months

Manufactured by **WELLS BIO, INC.** Not for sale in the **USA**



Technology

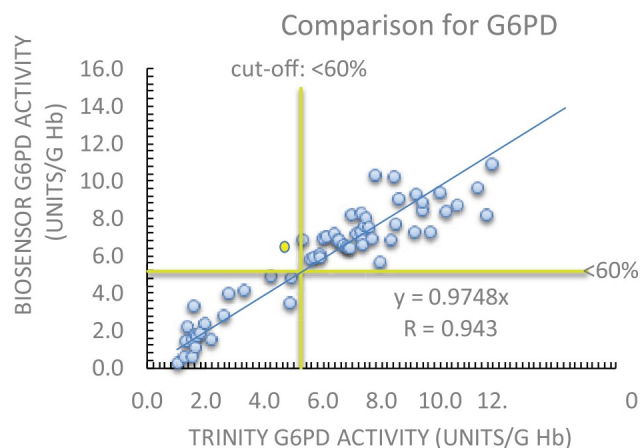
Enzyme activity detection through
Electrochemical sensing technology



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

- **STD-12** Detection Kit
- **HPV** Screening Kit-**H**
- **HPV** Screening Kit-**M**
- **Pneumonia** Detection Kit
- **Zika Virus** RT-PCR Kit
- **SFTS Virus** RT-PCR Kit
- **Scrub Typhus** Real-time PCR Kit
- **COVID-19** RT-PCR
- **Viral/Pathogen** Isolation Kit



care GENE™

STD-12 detection kit

Sexually transmitted diseases (STDs) constitute an epidemic of tremendous magnitude, with an estimated 18.9 million persons acquiring a new STD each year. Reported disease rates underestimate the true burden of infection because the majority of STDs are asymptomatic and because of underreporting. STDs have far-reaching public health consequences for the sexual and reproductive health of individual persons, as well as for the longterm health and health care costs of the community.

Technical Specifications

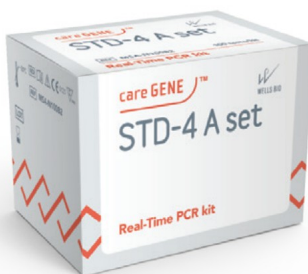
Test Type	Molecular Diagnostics
Package	100 tests/kit
Specimen	Vaginal swab, urine
Specimen Volume	DNA extract 5 µL
Result Time	1h 50 min
Storage Cond.	Below -20°C
Shelf life	12 months
Detection Target	Mycoplasma hominis, Mycoplasma genitalium, Neisseria gonorrhea, Trichomonas vaginalis, Ureaplasma urealyticum, Chlamydia trachomatis, Gardnerella vaginalis, Treponema pallidum, Herpes Simplex Virus 1, Herpes Simplex Virus 2, Ureaplasma parvum, Candida albicans

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STD-12 detection kit



STD-4 A set
(NG/CT/UU/MG)



STD-4 B set
(TP/UP/MH/TV)



STD-4 C set
(CA/GV/HSV1/HSV2)

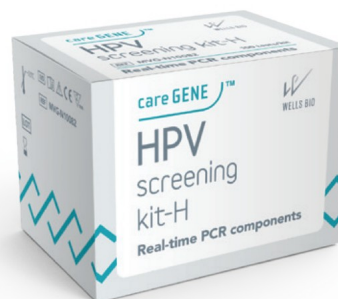
Designed to detect 14 types of High-Risk Human Papillomavirus group

- Human Papillomavirus (HPV) is a major cause of cervical cancer, the second-most common type of cancer among women worldwide. Women aged over 30 are highly recommended to get routine screening to minimize risk of cervical cancer.
- In conjunction with real time PCR, it can differentiate HPV-16, HPV-18, and the other high-risk HPV genotype.

Technical Specifications

Test Type	Molecular Diagnostics
Package	100 tests/kit
Specimen	Crude cervical scraping specimen (liquid based cytology)
Specimen Volume	DNA extract 5 µL
Result Time	103 min
Storage Cond.	below -20°C
Shelf life	12 months

Manufactured by **WELLS BIO, INC.** Not for sale in the **USA**



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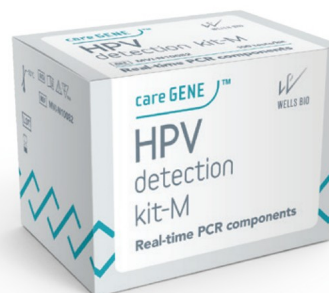
Designed to detect 25 types of High/Low-Risk Human Papillomavirus group

- 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).

Technical Specifications

Test Type	Molecular Diagnostics
Package	100 tests/kit
Specimen	Crude cervical scraping specimen (liquid based cytology)
Specimen Volume	DNA extract 5 µL
Result Time	103 min
Storage Cond.	below -20°C
Shelf life	12 months

Manufactured by **WELLS BIO, INC.** Not for sale in the **USA**



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Highly Efficient Detection for Total 12 Target Pathogens

- An in vitro diagnostic Real-Time PCR reagent that can detect 12 types of pneumonia-causing bacteria and mutant genes that show macrolide resistance, which is the most common among pneumonia antibacterial agents.

Technical Specifications

Test Type	Molecular Diagnostics
Package	100 tests/kit
Specimen	Nasopharyngeal swab, sputum
Specimen Volume	DNA extract 5 µL
Result Time	110 min
Storage Cond.	below -20°C
Shelf life	12 months

Manufactured by **WELLS BIO, INC.** Not for sale in the **USA**



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One-step Real Time RT-PCR kit

- Zika virus belongs to Flaviviridae, 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. The outbreak of Zika fever began in April 2015 in Brazil, and subsequently other countries in South America, Central America and the Caribbean. Zika has been known as an etiologic agent for microcephaly.

Technical Specifications

Test Type	Molecular Diagnostics
Package	96 tests/kit
Specimen	Serum, urine
Specimen Volume	RNA extract 5 µL
Result Time	90 min
Storage Cond.	below -20°C
Shelf life	12 months

Manufactured by **WELLS BIO, INC.** Not for sale in the **USA**

WHO EUL

CE



Identify SFTS Virus infections to provide effective treatment

- Severe fever with thrombocytopenia syndrome (SFTS) is a tick-borne infectious disease caused by the SFTS virus. The main symptoms of SFTS include fever, vomiting, diarrhea, thrombocytopenia, and leukopenia. In severe cases, the death rate is 6~30% due to neurological symptoms, bleeding symptoms and multiple organ damage.

Technical Specifications

Test Type	Molecular Diagnostics
Package	100 tests/kit
Specimen	Whole blood
Specimen Volume	RNA extract 5 µL
Result Time	125 min
Storage Cond.	below -20°C
Shelf life	12 months

Manufactured by **WELLS BIO, INC.** Not for sale in the **USA**



CE

Identify Orientia tsutsugamushi infections to provide effective treatment

- Scrub typhus is a disease caused by a bacteria called Orientia tsutsugamushi. The most common symptoms of scrub typhus include fever, headache, body aches, and sometimes rash. Without appropriate treatment, the case fatality rate of scrub typhus can reach 30% or even higher.

Technical Specifications

Test Type	Molecular Diagnostics
Package	100 tests/kit
Specimen	Whole blood
Specimen Volume	DNA extract 5 µL
Result Time	85 min
Storage Cond.	below -20°C
Shelf life	12 months

Manufactured by **WELLS BIO, INC.** Not for sale in the **USA**



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Identify COVID-19 infections to provide effective treatment

- Detect two gene regions and simultaneously detect N gene as well as RdRP gene of SARS-CoV-2.

Technical Specifications

Test Type	Molecular Diagnostics
Package	50 or 100 tests/kit
Specimen	Nasopharyngeal swab, oropharyngeal swab, sputum
Specimen Volume	RNA extract 10 µL
Result Time	83 min
Storage Cond.	below -20°C
Shelf life	12 months

Manufactured by **WELLS BIO, INC.** Not for sale in the **USA**



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Rapid, Reliable, and Affordable Nucleic Acid Extraction with CareGeneX™

- CareGeneX™ Isolation Kit is a magnetic bead-based nucleic acid extraction kit specifically designed for use with the KingFisher Flex instrument. This high-throughput platform offers fast and efficient extraction of RNA and DNA from human samples for gene amplification testing

Features

- High-throughput platform with high rate, purity, and yield extraction
- Easy to use with automated extraction platform
- Fast process extracts 96 samples in 28 minutes
- High precision: Coefficient of variation (CV) <3%, Standard Deviation (STDEV) <0.3
- Highly pure viral RNA extraction from various clinical samples
- Minimizes contamination with fully automated process
- Less viscous compared to competitors, making dilution easier
- Tip comb, wash, sample, and elution plates available
- Custom packaging available



CareGeneX™ Isolation Kit

Technical Specifications


Instrumentation	KingFisher Flex (Thermo Fisher Scientific)
Technology	Magnetic separation technology
Specimen type	Blood, serum, sputum, tissue
Specimen Volume	200 µL
Reaction time	28 min / 96 samples
Storage Cond.	15 -30°C
Shelf life	12 months


Manufactured by **WELLS BIO, INC.**



Compatible instrument: KingFisher Flex

Order Information

 Rapid Diagnostic Tests	Product	Product Name	Package
	COVID-19/Flu/RSV	CareSuperb™ COVID-19 Antigen Test	1 or 2 or 20 tests/kit
		CareSuperb™ COVID-19/Flu A&B Antigen Test	1 or 2 or 20 tests/kit
		CareSuperb™ COVID-19/Flu A&B/RSV Antigen Test	Under Development
		CareStart™ COVID-19 Antigen Home Test	2 tests/kit
		CareStart™ COVID-19 Antigen Test	20 tests/kit
	G6PD Deficiency	CareStart™ G6PD RDT	25 tests/kit
	Malaria	CareStart™ Malaria RDT	25 tests/kit
	Dengue	CareStart™ Dengue NS1	25 tests/kit
		CareStart™ Dengue NS1 & IgM/IgG Combo	25 tests/kit

 Analyzers	Product	Product Name	Package
	G6PD/Hb/T-BIL	careSTART™ S1 Analyzer	1 each/kit
		careSTART™ S1 G6PD Strip	25 strips/kit
		careSTART™ S1 Hb Strip	25 strips/kit
		careSTART™ Total-Bilirubin Strip	25 strips/kit
	G6PD	careSTART™ G6PD Biosensor Analyzer	1 each/kit
		careSTART™ G6PD Biosensor Strip	25 strips/kit
		careSTART™ G6PD Biosensor Control Level I	10 bottles/kit (50µl per bottle)
		careSTART™ G6PD Biosensor Control Level II	10 bottles/kit (50µl per bottle)



Molecular Tests

Product	Product Name	Package
STD	careGENE™ STD-12 detection kit	100 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
COVID-19	careGENE™ COVID-19 RT-PCR kit	50 or 100 tests/kit
Nucleic Acid Isolation	careGeneX™ Viral/Pathogen Kitsolation kit	96 tests/kit



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