Providing Unique Whole Solutions to SARS-CoV-2

With SARS-CoV-2 IgG/IgM Rapid Test
SARS-CoV-2 IgG and IgM EIA Test Kits
NES-32 Nucleic Acid Extration System
Viral Nucleic Acid Isolation Kit (Spin Column)
960 Real-Time PCR System
SARS-CoV-2 RT PCR Test Kit

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

ACON®

Introduction

For more than 25 years, *ACON* Labs has led the way in making high quality diagnostic and medical devices more affordable to people all around the world. In fact, the *ACON* Labs name is well known in over 150 countries.

Headquartered in San Diego, California, the US office is the center of strategic management, administration, business development, innovative research and development. Our state of the art manufacturing facility is ISO 13485:2016 certified, FDA registered, and has been inspected by US FDA.

Our current product lines include **Diabetes Care, Clinical Chemistry (Urinalysis and Point of Care Tests), Rapid Test, Immunoassay (EIA/ELISA and Allergen Test) and Molecular Diagnostics.** As a global enterprise, we also have distributors all around the world who contribute to our products development, international sales and technical support.

Disclaimer: Some products in this brochure may not be available in all countries. Please consult with your local *ACON* Labs sales representative for details.

ACON History

1995 — ***ACON* was founded**
Founded in Bethlehem, PA, USA, ACON operated in a 27,000 sq. ft. manufacturing facility.

1999 — **Moved to San Diego, CA, USA**

2001 — **Became a large manufacturer**
ACON increased our manufacturing facility to 150,000 sq. ft. with more than 1,500 employees

2006 — **Launched new product lines**
ACON sold the LF (lateral flow) rapid diagnostic business in the US, Europe, Canada, Israel, Japan, Australia, and New Zealand. We launched and started to focus on new product lines including Diabetes Care, Clinical Chemistry, and Immunoassay.

2009 — **Expanded product lines**
ACON sold the LF rapid diagnostic business in Asia, the Middle East, Africa and Latin America. We continued to expand our business in Diabetes Care, Clinical Chemistry, and Immunoassay.

2015 — **Moved to a much larger facility for manufacture, R&D and business development**
Our new facility of 70,000 sq. m (750,000 sq. ft.) includes state-of-the-art manufacturing equipment to supply the growing demand of the global diagnostic market.

2018 — **Centralised and Point of Care Solutions**
The Centralised and Point of Care Solutions were launched to offer a better solution, and the business expanded globally.

Future — **Looking forward**
We hope to develop more products to meet the IVD and Medical Diagnostic market needs by expanding diagnostic and healthcare services.

Serology Testing

SARS-CoV-2 IgG/IgM Rapid Test

A rapid test for the qualitative detection of IgM and IgG antibodies to the SARS-CoV-2 in serum, plasma, venous whole blood, or capillary fingertip blood. *

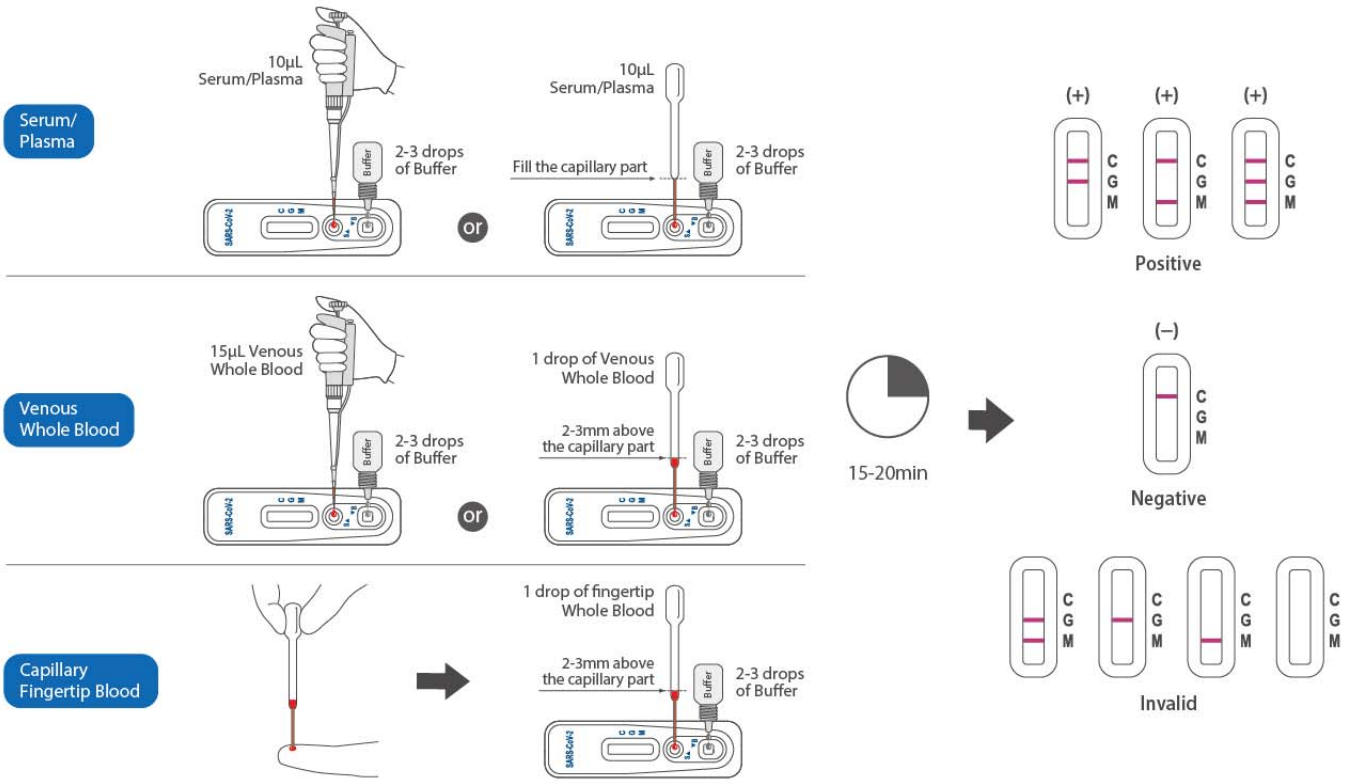
Key Features and Performance

Features	Descriptions
Detection	IgM and IgG antibodies to SARS-CoV-2
Specimen	Serum, Plasma, Venous Whole Blood, Capillary Fingertip Blood
Sensitivity	99.1%(95%CI: 95.1%-100%)
Specificity	98.3%(95%CI: 96.2%-99.5%)
Accuracy	98.5%(95%CI: 96.9%-99.5%)
Test Time	15-20 minutes
Shelf life	12 months
Storage Temperature	2-30°C

Materials Provided

- Test cassettes
- Disposable specimen applicator
- Buffer
- Package insert

Test Procedure and Interpretation



Ordering Information

Product Name	Catalog No.	Format	Specimen	Package
ACON SARS-CoV-2 IgG/IgM Rapid Test	L031-11711 √	Cassette	Serum, Plasma, Whole blood	25 Tests/Kit

√ CE marked

* SARS-CoV-2 IgG/IgM Rapid Test provides an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Results from the SARS-CoV-2 IgG/IgM Rapid Test should not be used as the sole basis for diagnosis.

Serology Testing

SARS-CoV-2 IgG EIA Test Kit
SARS-CoV-2 IgM EIA Test Kit

The SARS-CoV-2 IgG and IgM EIA Test Kits are two qualitative enzyme immunoassay for the detection of IgG or IgM antibodies to SARS-CoV-2 in human serum or plasma.*

High Quality
- High sensitivity and specificity
- High reproducibility
- Consistent and reliable performance at competitive pricing

Simple and Easy to Use
- Total incubation time as short as 70 minutes
- Simplified procedure designed for added convenience
- Color-coded and numbered reagents for easy handing
- Ready to use reagents shorten initial preparation

Convenient
- All necessary reagents provided
- Breakaway 8-well strips in 96 microwell plate in resealable foil pouch
- Can be performed on automated sample processors
- Shelf life up to 12 months

Key Features and Performance

Feature	SARS-CoV-2 IgG EIA Test Kit	SARS-CoV-2 IgM EIA Test Kit
Detection	IgG antibodies to SARS-CoV-2	IgM antibodies to SARS-CoV-2
Type of Test	Qualitative	Qualitative
Specimen Type	Serum/Plasma	Serum/Plasma
Specimen Volume	5 µl	5 µl
Total Incubation Time	70 min (30/30/10)	70 min (30/30/10)
Sensitivity	95.2%	90.5%
Specificity	98.0%	99.5%
Overall Agreement	97.8%	98.1%
Within-Run Precision CV(%)	<7%	<8%
Between-Run Precision CV(%)	<8%	<8%
Shelf Life	12 months	12 months

Ordering Information

Product Name	Catalogue	Specimen	Package
SARS-CoV-2 IgG EIA Test Kit	I231-1321	Serum/Plasma	96/480 Tests/Kit
SARS-CoV-2 IgM EIA Test Kit	I231-1331	Serum/Plasma	96/480 Tests/Kit

* The SARS-CoV-2 IgG and IgM EIA Test Kits are only intended for assisting detection of suspected cases with nucleic acid negative, or combining with nucleic acid detection in the diagnosis of suspected cases. Results from SARS-CoV-2 IgG and IgM testing should not be used as the sole basis to diagnosis or exclude SARS-CoV-2 infection.

Molecular Diagnostics

NES-32 Nucleic Acid Extration System

Promotor®

Efficient and easy to operate nucleic acid extraction system (Magnetic Beads).

- Get extracted product within 40 minutes.
- Maximum 32 specimen processed at a time.
- Ready-to-use extraction plate provided.
- High purity and good CV performance.
- Low loss rate of magnetic beads.
- UV sterilization and disposable consumables eliminate contamination.

CE

Viral Nucleic Acid Isolation Kit (Spin Column)

Use a simple, rapid protocol to generate high-quality templates for a broad range of downstream applications.

- Fast procedures and easy to use.
- Isolation and purification of high-quality viral DNA/RNA.
- High efficient recovery yield.
- Pure DNA/RNA ready for downstream applications.
- No phenol-chloroform extraction.

DNA/RNA

RNA

CE

Ordering Information

Product Name	Catalog No.	Type	Specimen	Kit Size
NES-32 Nucleic Acid Extraction System	P111-1011√	Magnetic Separation Analyzer	Serum, Plasma, Whole blood, Swabs or Feces	1 Unit/Kit
Nucleic Acid extraction kit	P121-1301√	Magnetic Beads	Serum, Plasma or Swabs	32 Tests/Kit
Nucleic Acid (RNA) Extraction Kit	P121-1121√	Magnetic Beads	Serum, Plasma, Swabs or Feces	32 Tests/Kit
Nucleic Acid (RNA) Extraction Kit (ready-to-use)	P121-1221√	Magnetic Beads	Serum, Plasma, Swabs or Feces	32 Tests/Kit
Viral DNA/RNA Isolation Kit	P121-1291√	Spin Column	Serum, Plasma or Swabs	32/50 Tests/Kit
Viral Nucleic Acid Isolation Kit	P121-1051√	Spin Column	Serum, Plasma or Swabs	32 Tests/Kit

√ CE marked

Molecular Diagnostics

960 Real-Time PCR System

Promotor®

Key Features and Performance

Features	Descriptions
Thermal Cycling System	Peltier-based, 96-well block
Max Block Ramp Rate	5°C/s
Max Block Cooling Rate	3.5°C/s
Temperature Accuracy	≤±0.1°C
Temperature Uniformity (at 55°C)	≤±0.1°C
Channel	4 channels
Compatible Dyes	Chanel 1: FAM, SYBR Green; Chanel 2: VIC, HEX, JOE, TET Chanel 3: ROX, Texas Red; Chanel 4: CY5
Supported Volumes	20-100 µL
Optical System	Long life LED and PMT
Multiplex analysis	Up to 4 targets per well

SARS-CoV-2 RT PCR Test Kit

- Single-well, triple target assay covering high conserved regions within N, E and ORF1ab gene for high specificity.
- Full-process controls with negative, positive and internal controls.
- Qualitative detection of nucleic acids from SARS-CoV-2. *

Key Features and Performance

Features	Descriptions
Technology	Real-Time reverse transcription polymerase chain reaction (rRT-PCR)
Target Region	N, E, ORF1ab
Specimen Type	Oropharyngeal swab, nasopharyngeal swab and deep cough sputum
Internal Control	Yes
Minimum Sample Volume	200 µL
Test Duration	90 minutes
Limit of Detection	500 copies/mL
Precision of In-batch and batch (CV)	<5%
Positive Percent Agreement	97.46% (95%CI: 92.75%-99.47%)
Negative Percent Agreement	98.26% (95%CI: 94.99%-99.64%)
Accuracy	97.93% (95%CI: 95.56%-99.24%)
Storage Temperature	-20±5°C
Package Size	32 Tests/Kit

Ordering Information

Product Name	Catalog No.	Components	
SARS-CoV-2 RT-PCR Test Kit	P131-1591	SARS-CoV-2 PCR Reaction Mix Positive Control	Enzyme Mix Negative Control
960 Real-Time PCR System	P111-2011	960 Real-Time PCR Instrument Power Socket 8 strip tubes	User Manual and Software Manual Software disk

* Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status.

ACON®

***ACON* Laboratories, Inc.**
5850 Oberlin Drive, #340, San Diego, CA 92121 USA
Tel: 1-858-875-8000
Fax: 1-858-200-0729
Email: info@aconlabs.com

PN 2200028701- Date 6/20