

# PT. MITRA BAHAGIA CITRA MEDIKA

Jl. Raya Kalirungkut 27 Blok C No. 63 SURABAYA

EAST JAVA----INDONESIA

Phone : 62.31.8782078 ; 62.31.8782079

E-mail : [medika\\_mandiri@yahoo.com](mailto:medika_mandiri@yahoo.com)

Nomor : 0057/SPH-MBCM/I/22  
Lampiran : 1 (satu) bendel  
Perihal : Surat Penawaran Harga

Surabaya, 21 Januari 2022

Kepada Yth.

**DIREKTUR**

**RUMAH SAKIT MATA UNDAAN**

**Jl. Undaan Kulon No. 19, Peneleh**

**Kota Surabaya**

Dengan hormat,

Bersama ini kami PT. Mitra Bahagia Citra Medika Surabaya, distributor resmi alat – alat kesehatan untuk wilayah Indonesia, bermaksud mengajukan penawaran harga untuk Rapid Test Antigen, dengan perincian barang dan harga seperti yang tersebut di bawah ini :

No.	Nama Barang	Merk/Asal Negara	Harga Satuan	Disc.	Harga Satuan Setelah Diskon
1.	FLOWFLEX SARS-CoV-2 Antigen Rapid Kemasan : 25 Test/Box	ACON/China	Rp 30.000,-/Test	15%	Rp 25.500,-/Test

**Keterangan :**

- Harga : Belum termasuk +PPN 11%.
- Kondisi barang : 100 % baru dan dapat berfungsi dengan baik.

**Bersama ini kami lampirkan :**

- Spesifikasi teknis
- Brosur Barang
- AKL/Ijin Edar dari Depkes
- LoA/Surat Penunjukkan

Demikian penawaran harga dari kami, dengan harapan mendapatkan pesanan dari Bapak/Ibu. Atas perhatian serta kerjasamanya kami sampaikan banyak terima kasih.

Hormat Kami,

PT. Mitra Bahagia Citra Medika

**PT. MITRA BAHAGIA CITRA MEDIKA**

**Drs. Harijanto Tanudjaja**

Direktur

# PT. MITRA BAHAGIA CITRA MEDIKA

Jl. Raya Kalirungkut 27 Blok C No. 63 SURABAYA

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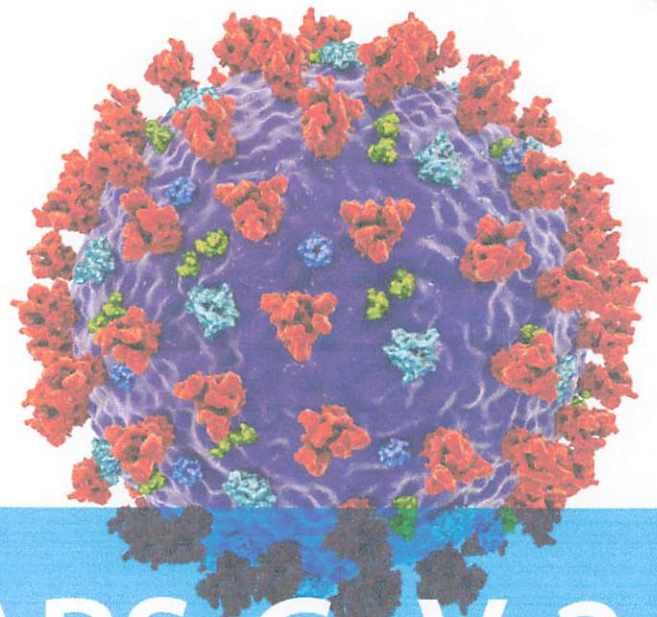
Phone : 62.31.8782078 ; 62.31.8782079

E-mail : [medika\\_mandiri@yahoo.com](mailto:medika_mandiri@yahoo.com)

## SPESIFIKASI RAPID TEST COVID ANTIGEN ACON

No.	Nama Barang	Merk	Spesifikasi
1	Flowflex SARS-CoV-2 Antigen Rapid Test	ACON	Untuk mendeteksi keberadaan antigen virus yang menunjukkan adanya infeksi virus SARS-CoV-2 atau COVID-19 Sampel yang digunakan adalah Nasal Swab Relative Sensitivity : 97.1 % (83.8%-99.9%) Relative Specificity : 99.6 % (97.7%-99.9%) Accuracy : 99.3 % (97.5%-99.9%) Confidence Intervals : 95 % Waktu pembacaan hasil 15 menit Suhu penyimpanan 2 - 30°C Contents : - 25 test Cassettes - 1 Positive Control Swab - 2 Extraction Buffers - 25 Extraction Tubes - 1 Negative Control Swab - Package Insert

**Flowflex**<sup>TM</sup>



# SARS-CoV-2 Antigen Rapid Test

A rapid, highly reliable and affordable kit, providing an aid in early diagnosis of individuals who are suspected of COVID-19 by their healthcare provider.

The King of Rapid Test with **25** Years Experience.



Fast



Reliable



Easy to Use



User friendly

**ACON**<sup>®</sup>

ACON Biotech (Hangzhou) Co., Ltd.

# Flowflex SARS-CoV-2 Antigen Rapid Test

The Flowflex SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms.

- Nasal swab specimens
- Fast results within 15~20 minutes
- Excellent performance compared to molecular methods
- Room temperature storage

## Clinic Performance

The performance of Flowflex SARS-CoV-2 Antigen Rapid Test was established with 307 nasal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19. The performance of the Flowflex SARS-CoV-2 Antigen Rapid Test was compared to RT-PCR method.

Clinical Performance for SARS-CoV-2 Antigen Rapid Test

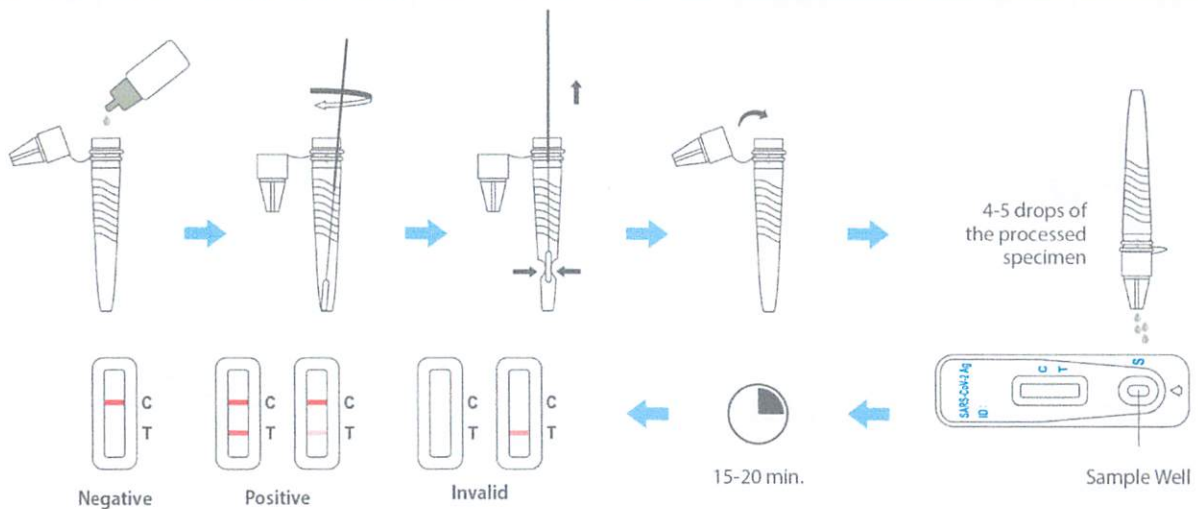
Method	Results	RT-PCR		Total
		Negative	Positive	
SARS-CoV-2 Antigen Rapid Test	Negative	269	4	273
	Positive	1	33	34
Total		270	37	307
PPA: 89.2% (74.7%-96.3%)*		NPA: 99.6% (97.7%-99.9%)*		OPA: 98.4% (96.1%-99.4%)*

PPA- Positive Percent Agreement; NPA - Negative Percent Agreement; OPA - Overall Percent Agreement, \*95% Confidence Intervals

## Materials Provided

- Test Cassettes
- Package Insert
- Extraction Buffer
- Extraction Tubes
- Negative Control Swab
- Positive Control Swab

## Test Procedure and Interpretation



## Ordering Information

Product Name	Catalog No.	Format	Specimen	Package
Flowflex SARS-CoV-2 Antigen Rapid Test	L031-11825	Cassette	Nasal swabs	25 Tests/Kit



aconlabs.com

ACON Biotech (Hangzhou) Co., Ltd.  
 No.210 Zhenzhong Road, West Lake District,  
 Hangzhou, P.R.China, 310030  
 Tel: +86-571-8777 5737  
 Fax: +86-571-8777 5781  
 Email: information@aconlab.com.cn



**KEMENTERIAN KESEHATAN REPUBLIK INDONESIA  
DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN**

Jalan H.R. Rasuna Said Blok X-5 Kavling 4 - 9 Jakarta 12950  
Telepon : (021) 5201590 Pesawat 2029, 8011  
Faksimile : (021) 52964838 Kotak Pos : 203



Berdasarkan Peraturan Menteri Kesehatan R.I Nomor 62 Tahun 2017 Tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik In Vitro Dan Perbekalan Kesehatan Rumah Tangga dengan ini diberikan persetujuan untuk diedarkan dengan :

**NOMOR IZIN EDAR**

**ALAT KESEHATAN**

**KEMENKES RI AKL 20303026620**

Nama Dagang / Merek : **FLOWFLEX™ SARS-CoV-2 Antigen Rapid Test**  
Kelompok / Kelas Resiko : Diagnostik *In Vitro* / B  
Kategori Produk : Peralatan Imunologi dan Mikrobiologi  
Sub Kategori : Pereaksi Serologi  
Jenis Produk : Respiratory viral panel multiplex nucleic acid assay  
Tipe / Ukuran : Ref. No.L031-118M5, L031-118P5 dan L031-11825  
Kemasan : Dus, isi 1 tes, 5 tes dan 25 tes  
Nama Produsen / Pabrikasi : ACON BIOTECH (HANGZHOU) CO., LTD., China  
Nama Pendaftar : PT. MITRA BAHAGIA CITRA MEDIKA, Jawa Timur  
Atas dasar lisensi dari : -

**Ketentuan**


1. Persetujuan izin edar berlaku sampai dengan 09 Juni 2025.
2. Wajib menyampaikan laporan berkala dan laporan jika ada kejadian yang tidak diinginkan akibat penggunaan Alat Kesehatan tersebut di atas sesuai ketentuan berlaku.
3. Izin edar ini merupakan persetujuan perpanjangan, perubahan legal manufacture dan penambahan isi kemasan dari Nomor Izin Edar Alat Kesehatan KEMENKES RI AKL 20303026620 tanggal 4 November 2020. Dengan demikian izin edar sebelumnya dinyatakan tidak berlaku.
4. Apabila dikemudian hari ada pihak lain yang berhak atas merek dan/atau keagenan produk tersebut, pendaftar bersedia mengembalikan izin edar.
5. Penandaan dan informasi produk yang terlampir merupakan bagian yang tidak terpisahkan dari persetujuan izin edar ini.
6. Apabila di kemudian hari terdapat kekeliruan, maka persetujuan izin edar ini akan ditinjau kembali.

Jakarta, 27 Oktober 2021



**Catatan:**

- UU ITE No 11 Tahun 2007 Pasal 5 ayat 1
- Informasi Elektronik dan/atau Dokumen Elektronik dan/atau hasil cetaknya merupakan alat bukti hukum yang sah.
- Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan BSR.E.

浙江外办  
国家：印度尼西亚  
  
20006816-3 E S C

# 公 证 书

中华人民共和国浙江省杭州市国立公证处

## Letter of Appointment

9<sup>th</sup> Sep 2020

To Whom It May Concern,

We

**Acon Biotech (Hangzhou). Co., Ltd**  
 #210 Zhenzhong Road, West Lake Science and Technology Park  
 Hangzhou, China, 310023

Which is the certified and allied manufacturing company of

**ACON Laboratories, Inc.,**  
 5850 Oberlin Drive, #340, San Diego, CA92121, U.S.A

Certify that:

**PT Mitra Bahagia Citra Medika,**  
 Jl. Raya Kalirungkut 27 Blok C-63  
 SURABAYA  
 Tel: 62-31-8782078-9  
 Fax: 62-31-8782178

is herein as the **Exclusive Distributor** by and on behalf of **ACON**, to submit to MOH for product registration, distribute, supply and provide the after-sale service of ACON **"Promotor®"** brand of 960 Real-time PCR system and **"Promotor®"** brand of SARS-CoV-2 RT-PCR Test Kit, **"Flowflex"** brand of SARS-CoV-2 antigen rapid test in **Indonesia**.

This agreement takes effective immediately and is valid until 9<sup>th</sup> Sep, 2025, where after it is automatically prolonged for period of one full calendar year, unless cancelled in writing sixty (60) days in advance notice by either party.

This Letter of Authorization will be only used for registration, tender bid submission and distribution purpose and should not be used for any other business or non-business purpose.

Should you require any further clarifications, please do not hesitate to contact us.

Sincerely yours,

  
 William Cheng

International sales director

ACON Biotech (Hangzhou) Co., Ltd.

### Appendix A

Items	Catalog	Product Name	HS Code number
1	P131-1591	"Promotor®" SARS-CoV-2 RT-PCR Test Kit	N/A
2	P111-2011	"Promotor®" 960 Real-time PCR Instrument	N/A
3	L031-11825	"Flowflex" SARS-CoV-2 antigen rapid test	N/A

# 公 证 书

(2020)浙杭证字第 25734 号

申请人：艾康生物技术（杭州）有限公司，住所：浙江省杭州市西湖区振中路 210 号。

法定代表人：蒋萍，女，一九七三年五月十二日出生，公民身份号码：330103197305121325。

委托代理人：程平华，男，一九八四年一月二十一日出生，公民身份号码：362334198401215310

公证事项：签名、印鉴

兹证明艾康生物技术（杭州）有限公司的委托代理人程平华于二〇二〇年九月二十五日来到我处，在本公证员的面前确认，前面英文本的授权函上艾康生物技术（杭州）有限公司的印鉴及程平华的签名均系其本人所为。

中华人民共和国浙江省杭州市国立公证处

公证员

梁洁

二〇二〇年九月十七日



IV55246417



NOTARIAL CERTIFICATE

(Translation)

(2020)ZHZ. Zi, No.25734

Applicant: Acon Biotech (Hangzhou) Co., Ltd, Domicile: No. 210  
Zhenzhong Road, Xihu District, Hangzhou City, Zhejiang Province.

Legal Representative: Jiang Ping, female, was born on May 12, 1973,  
ID Card No. 330103197305121325 .

Authorized Representative: Cheng Pinghua , male, was born on  
January 21, 1984, ID Card No. 362334198401215310.

Notarial Item: Signature and Seal

This is to certify that Cheng Pinghua, the authorized representative  
of Acon Biotech (Hangzhou) Co., Ltd came to my office on September  
25, 2020, and confirmed in the presence of me, the notary, that the seal of  
Acon Biotech (Hangzhou) Co., Ltd and the signature of Cheng Pinghua  
affixed on the Letter of Appointment attached hereto was stamped and  
signed by himself.

Notary: Liang Jie(Signature)

Hangzhou National Notary Public Office

Zhejiang Province (Seal)

The People's Republic of China

September 27, 2020

I V55246418



认字第20006816-3号

兹证明前面文书上公证处的印章和公证员梁洁的签名(印章)属实。



中华人民共和国外交部(330)  
2020年10月12日 杭州

Handwritten signature



00513898

KONSULAT JENDERAL REPUBLIK INDONESIA  
CONSULATE GENERAL OF THE REPUBLIC OF INDONESIA  
(SHANGHAI)

No. 1174/PK.07.03/10/20/04  
Dilihat untuk pengesahan tanda tangan:  
Seen for legalization the signature of

FAO HANGZHOU

Shanghai, 13 Oktober 2020  
Konsulat Jenderal RI tidak bertanggung jawab atas isi dokumen

Atn. Konsul Jenderal  
For The Consul General



Handwritten signature