



# PT Etana Biotechnologies Indonesia

Jakarta, September 2022

PT Etana Biotechnologies Indonesia is engaged in manufacturing and sales of biopharmaceutical products. PT Etana already built a PIC/S compliance state-of-the-art biopharmaceutical facility in Jakarta and develop strong collaboration with leaders of biopharmaceutical industries



PTEBI Manufacturing Facility

## Finished product:

- Erythropoietin
- Bevacizumab
- Covid-19 Vaccine
- Covid-19 Drugs



## VISION

To become ASEAN most valuable biopharmaceutical company with extensive Biopharmaceutical's portfolio

## DIVISION

- Oncology Division (MAB, Chemicals)
- Anti Infectious (Vaccine, Drugs)
- Others

## MISSION

Providing high quality, affordable and innovative biopharmaceutical for ASEAN and Muslim countries

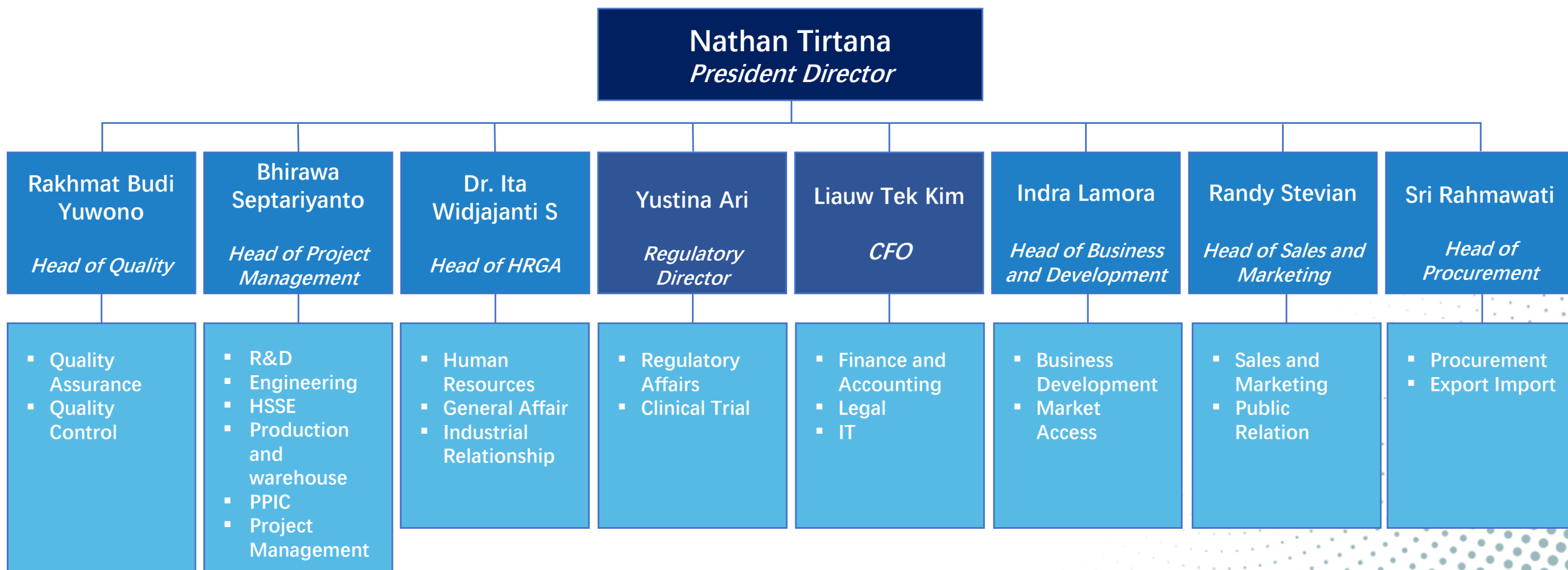
# Etana means “Strength in Purpose”

**Our Purpose: Serve patients by providing high quality, affordable and innovative biopharmaceutical products**

**Our Values: 3C ETANA**

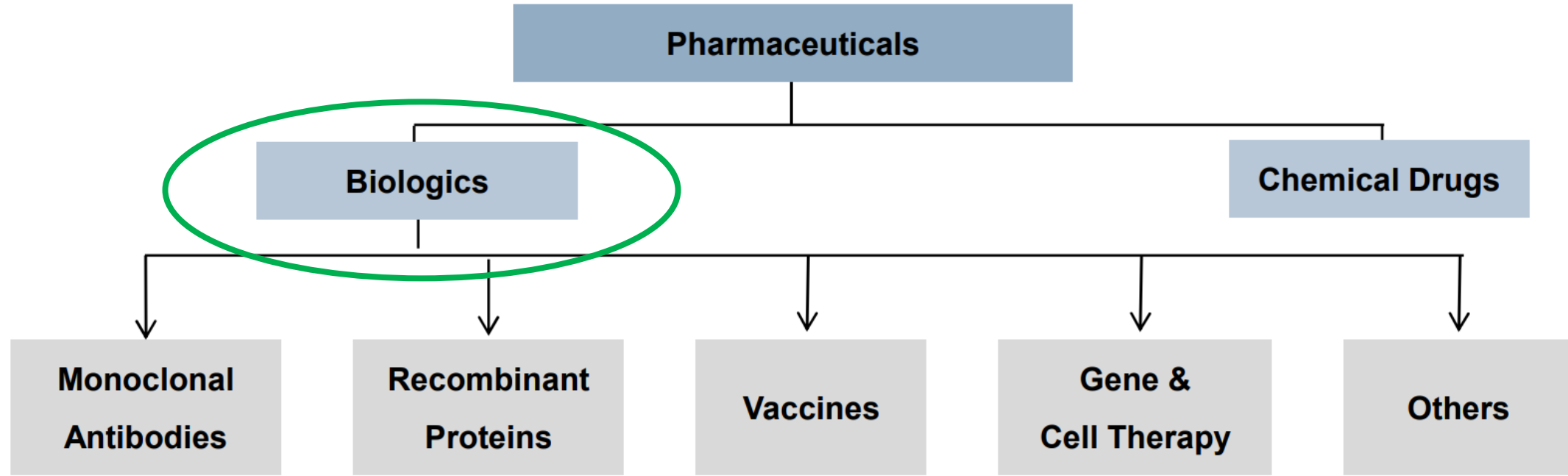
- › **Commit**
- › **Care**
- › **Collaborate**
- › **Empower and Excel**
- › **Trust**
- › **Agile**
- › **Nurture**
- › **Acknowledge**

# 2022 Etana Organizational Structure





# Market Segmentation



**Definition:** The FDA is defining Biologics as a products that includes a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources - human, animal, or microorganism - and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available.

# Core Competence: Ready to use Manufacturing System, one of the largest GMP factory in Indonesia

## GMP Compliance

- PIC/S guideline
- BPOM guideline

## Future Expansions

- Additional PFS / Vial filling line
- Upstream API manufacturing

## Strategic Location

- Jakarta Industrial Estate Pulogadung (JIEP), East Jakarta



## Highlights

Build ing	Description	Size
A	Warehouse	1,000 m <sup>2</sup>
B	Production	3,600 m <sup>2</sup>
C	Animal House (new)	476 m <sup>2</sup>
D	Central Utility (new)	600 m <sup>2</sup>
E	QC, QA, and R&D	795 m <sup>2</sup>
TOTAL		6,471 m <sup>2</sup>

## Facility Capabilities

- Level 1 Fill Finish and Packaging
- Level 2 Fermentation and Purification
- Annual Capacity PFS 100 million doses
- Annual Capacity Vial 120 million doses
- Technology Support from Top Tier Biotech Companies worldwide

# Core Competency: Establish strong BD capability through Cooperation with Strong investors and Pharmaceutical Companies

## INVESTOR



## PARTNER



# Bevacizumab

## Gold standard treatment for various cancer



### Indication:

**Bevacizumab** is indicated for the treatment of various cancers, such as:

1. Metastatic Colorectal Cancer
2. Advanced, metastatic or recurrent non-squamous Non-Small Cell Lung Cancer (NSCLC)
3. Glioblastoma, Peritoneal, Merkel Cell Carcinoma
4. Renal Cell Carcinoma, Ovarian Cancer, Cervical Cancer

### Eminence:

**Bevacizumab** is a drug available for a variety of solid tumors.

**Bevacizumab** has changed the treatment paradigm and is becoming the standard of care in the treatment of • advanced cancer.



## Product Information

**InaRNAVac** is a mRNA-based vaccine encoding the receptor-binding domain (RBD of spike glycoprotein (S protein) of SARS-CoV-2 to prevent COVID-19 caused by the infection of SARS-CoV-2 in adults 18 years of age and above. Packaging Pre-filled syringe, 1x0.5 mL single human dose, 1 dose per package.



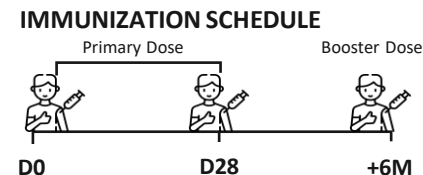
The "New Coronavirus mRNA Vaccine" (ARCoV) developed by **Abogen**, the **Military Medical Research Institute of the Chinese Academy of Military Sciences**, and **Walvax**<sup>[1]</sup>



**Stable at 2<sup>o</sup>-8<sup>o</sup> C** for as long as 12 months, easy storage and distribution, administrable without freeze-thaw procedure

THE  
**1<sup>st</sup>**

Halal mRNA vaccine in the world and locally produced mRNA vaccine



Halal Certificate Number  
ID00410000248600522



### Clinical Trial

### Made in, and Made for Indonesia

### Aimed for future vaccine security and self-reliance



Non-clinical research  
published in *Cell*



Phase I clinical research  
published in  
*The Lancet Microbe*



Heterologous boosting  
research published  
in *Cell*



**The 1<sup>st</sup> Halal mRNA Vaccine Certified by  
LPPOM-MUI**

Indonesian Supreme Court issued a decision (31 P/HUM/2022) that requires the Government to use only Halal vaccines for the public – **15<sup>th</sup> June 2022**



Local production complies with Domestic Content Level (TKDN) policy implementation emphasized by the president of Indonesia



Indonesia through PT Etana Biotechnology already has the capability for mRNA technology



Ensuring sufficient supply for mass vaccination

#### References

- <sup>[1]</sup> ZHAO H, WANG T-C, LI X-F, et al. Long-term stability and protection efficacy of the RBD-targeting COVID-19 mRNA vaccine in nonhuman primates [J]. Signal Transduction and Targeted Therapy, 2021, 6(1): 438.  
<sup>[2]</sup> ZHANG N-N, LI X-F, DENG Y-Q, et al. A Thermostable mRNA Vaccine against COVID-19 [J]. Cell, 2020, 182(5): 1271-83.e16

# Erythropoietin Alfa



Renogen is the 1<sup>st</sup> Erythropoietin Alfa in Indonesia conduct the clinical trial compared to innovator: with equal efficacy and safety.

Publication in Acta Medica Indonesia  
Vol. 51 No. 3 July 2019

## Indication

Patients with anemia caused by renal insufficiency, including patients with hemodialysis and non-hemodialysis due to chronic renal failure.

Patients with anemia caused by non-myeloid malignancy applied chemotherapy, other than those with anemia caused by other factors in the treatment of cancer patients (e.g., iron or folate deficiency, hemolysis or intestinal tract bleeding).

## Presentation/Packing

Injection (pre-filled syringe, sterile, clear, colourless, buffered parenteral solution)  
2,000 IU/mL, 3,000 IU/mL, 4,000 IU/mL

# Product Profile of PCV-13

13-valent Pneumococcal Polysaccharide Conjugate Vaccine: Prevention of invasive diseases caused by 13 serotypes of *Streptococcus pneumoniae* for infants and children 6 weeks through 5 years of age

- Launched on 31 December 2019 in China
- The **Second PCV13** in the World
- Expected to submit PQ application in 2022

<b>Serotypes</b>	■ 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F
<b>Presentation</b>	■ single-dose vial/pre-filled syringe, 0.5mL/dose
<b>Carrier Protein</b>	■ tetanus toxoid
<b>Storage</b>	■ 2°C to 8°C
<b>Shelf Life</b>	■ 24 months
<b>Schedule</b>	■ 2-6 months: 3 primary doses + 1 booster dose 7-11 months: 2 primary doses + 1 booster dose 12-23 months: 2 doses ≥ 24 months: 1 dose



# Product Profile of HPV-2

Recombinant Bivalent Human Papillomavirus Vaccine (Types 16/18) (*Pichia pastoris*) : For the prevention of cervical cancers and precancerous lesions caused by human papillomavirus types 16/18

- Strict quality standards applied, with a total of 1920 quality control points in the production process, and 5 more quality control points compared with European Pharmacopoeia standards
- Good safety and immunogenicity demonstrated by the first multi-center phase III HPV vaccine clinical trial with the largest sample size ever conducted in China

<b>Composition</b>	40 µg HPV 16L1, 20 µg HPV 18L1 and 225 µg aluminum phosphate
<b>Indicated Population</b>	Females 9 to 30 years of age
<b>Presentation/ Formulation</b>	Single-dose vial (0.5 mL) and single-dose pre-filled syringe (0.5 mL) in liquid suspension formulation
<b>Shelf-life &amp; Storage</b>	36 months, storage at 2-8°C and protection from light
<b>Schedule</b>	3-dose regimen: 0, 2, 6 months 2-dose regimen*: 0, 6 months for age 9-14





# Halal Assurance System

## PT Etana Biotechnologies Indonesia

mRNA Covid-19 Vaccine

REPUBLIC INDONESIA  
(REPUBLIC OF INDONESIA)  
جمهورية إندونيسيا

SERTIFIKAT HALAL  
(HALAL CERTIFICATE)

شهادة الحلال

Nomor Sertifikat / Certificate Number: ID00410000248600522  
رقم الشهادة

Berdasarkan keputusan penetapan halal produk Majelis Ulama Indonesia nomor :  
Based on the decree to stipulating halal products of the Indonesian Council of Ulama :  
استنادا على قرار مجلس العلماء الإندونيسي عن تحديد الحلال للمنتجات :  
LPPOM-00140147470622 Tanggal 15 Juni 2022

Jenis Produk / Type of Product: Produk biologi / نوع المنتج  
Nama Produk / Name of Product: -Terlampir / As Attached- / اسم المنتج  
Nama Pelaku Usaha / Name of Company: YUXI WALVAX BIOTECHNOLOGY CO., LTD. / اسم الشركة  
Alamat Pelaku Usaha / Company's Address: NO.83 SOUTH DONGFENG ROAD, HIGH & NEW TECHNOLOGY INDUSTRIES DEVELOPMENT ZONE, YUXI, YUNNAN, 653100, P.R. CHINA / عنوان الشركة

Diterbitkan di Jakarta pada / Issued in Jakarta on: 16 Juni 2022 / أصدرت الشهادة بجاكرتا في  
Berlaku sampai dengan / Valid until: 16 Juni 2026 / سارية المفعول حتى

telah memenuhi ketentuan perundang-undangan  
Has complied with the provision of laws and regulations  
قد استوفت أحكام التشريع

KEPALA  
BADAN PENYELENGGARA JAMINAN PRODUK HALAL  
HEAD OF HALAL PRODUCT ASSURANCE BODY

رئيس وكالة ضمان المنتجات الحلال



Muhammad Aqil Irham

Dokumen ini telah dibebastugaskan secara elektronik menggunakan sertifikat elektronik yang diterbitkan oleh Badan Sertifikasi Elektronik, BSEI



لَمَجْلِسُ الْفَتْوَى الْإِسْلَامِيِّ  
LEMBAGA PENGKAJIAN PANGAN OBAT-OBATAN DAN KOSMETIKA  
MAJELIS ULAMA INDONESIA (LPPOM-MUI)  
THE ASSESSMENT INSTITUTE FOR FOODS, DRUGS, AND COSMETICS  
THE INDOONESIAN COUNCIL OF ULAMA (LPPOM-MUI)



HALAL ASSURANCE SYSTEM STATUS

保证哈拉系统的状态

NO. HS1A24933/112021/ETN

بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

Berdasarkan pemeriksaan dokumen dan audit implementasi Sistem Jaminan Halal, Lembaga Pengkajian Pangan, Obat - obatan dan Kosmetika - Majelis Ulama Indonesia (LPPOM-MUI) menyatakan bahwa :  
Based on the on-desk appraisal and implementation audit of Halal Assurance System, The Assessment Institute for Foods, Drugs and Cosmetics - The Indonesian Council of Ulama (LPPOM-MUI) states that :  
按照审查文件和审计哈拉保证系统，LPPOM-MUI 宣布：

Nama Perusahaan / (公司名称) : PT Etana Biotechnologies Indonesia  
Name of Company  
Alamat Perusahaan/Pabrik / (公司地址) : PT CKO Otto Pharmaceutical Kawasan Industri Delta Silicon 3/ Jl. Kapuk Timur Blok F23-17, Lippo Cikarang, Bekasi, Jawa Barat, Indonesia  
Address  
dinilai telah menerapkan Sistem Jaminan Halal / has been implementing Halal Assurance System  
已贯彻执行哈拉保证系统

dengan kategori/with category/ 评分 :  
SANGAT BAIK / EXCELLENT

Jakarta, 12 NOVEMBER 2021  
Direktur Eksekutif,  
Executive Director,  
LP-POM  
Ir. Hj. Muti Arintawati, M.Si.

Berlaku sampai dengan / Valid until / 有效期: 11 NOVEMBER 2025  
Lembar ini bukan merupakan Sertifikat SJH/This is not HAS Certificate

REPUBLIC INDONESIA  
(REPUBLIC OF INDONESIA)  
جمهورية إندونيسيا

LAMPIRAN SERTIFIKAT HALAL  
(THE ATTACHMENT OF HALAL CERTIFICATE)

مرافقة لشهادة الحلال

Nomor Sertifikat / Certificate Number: ID00410000248600522  
رقم الشهادة

Nama Pelaku Usaha / Name of Company: YUXI WALVAX BIOTECHNOLOGY CO., LTD. / اسم الشركة  
Jenis Produk / Type of Product: Produk biologi / نوع المنتج  
Alamat Pabrik / Factory's Address: YUXI WALVAX BIOTECHNOLOGY CO., LTD. NO.83 SOUTH DONGFENG ROAD, HIGH & NEW TECHNOLOGY INDUSTRIES DEVELOPMENT ZONE YUXI 653100 YUNNAN / عنوان المصنع

Daftar Produk / Product Name

No	Nama Produk / Product Name
1	SARS-CoV-2 mRNA Vaccine (AWceorna)

Hal: 1 / Total Produk: 1

Diterbitkan di Jakarta pada / Issued in Jakarta on: 16 Juni 2022 / أصدرت الشهادة بجاكرتا في  
Berlaku sampai dengan / Valid until: 16 Juni 2026 / سارية المفعول حتى

KEPALA  
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Muhammad Aqil Irham

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# Thank You



PT Etana Biotechnologies  
Indonesia



Jl. Rawa Gelam V Blok L, Kav.11 – 13  
Kawasan Industri Pulogadung,  
Jakarta Timur  
Indonesia 13930



<https://www.id.etanabiotech.com/>