Immunofluorescence POCT Solution

Multi-Channel Analyzer & Reagents for IVD Manufacturers and Distributors

Guangdong Wesail Biotech Co., Ltd.

◎ Analyzer Features
WS-Mi6000

Rapid

180 T/H, result in 2~8 min for single parameter or 15 min for multi-parameters

Precision

±0.1°C precise temperature control improving test repeatability

Accurate

CV ≤2% between channels, CV ≤5% between analyzers

Display-Friendly

High resolution 11.1" large touch screen provides operational stability and quick response

Compact

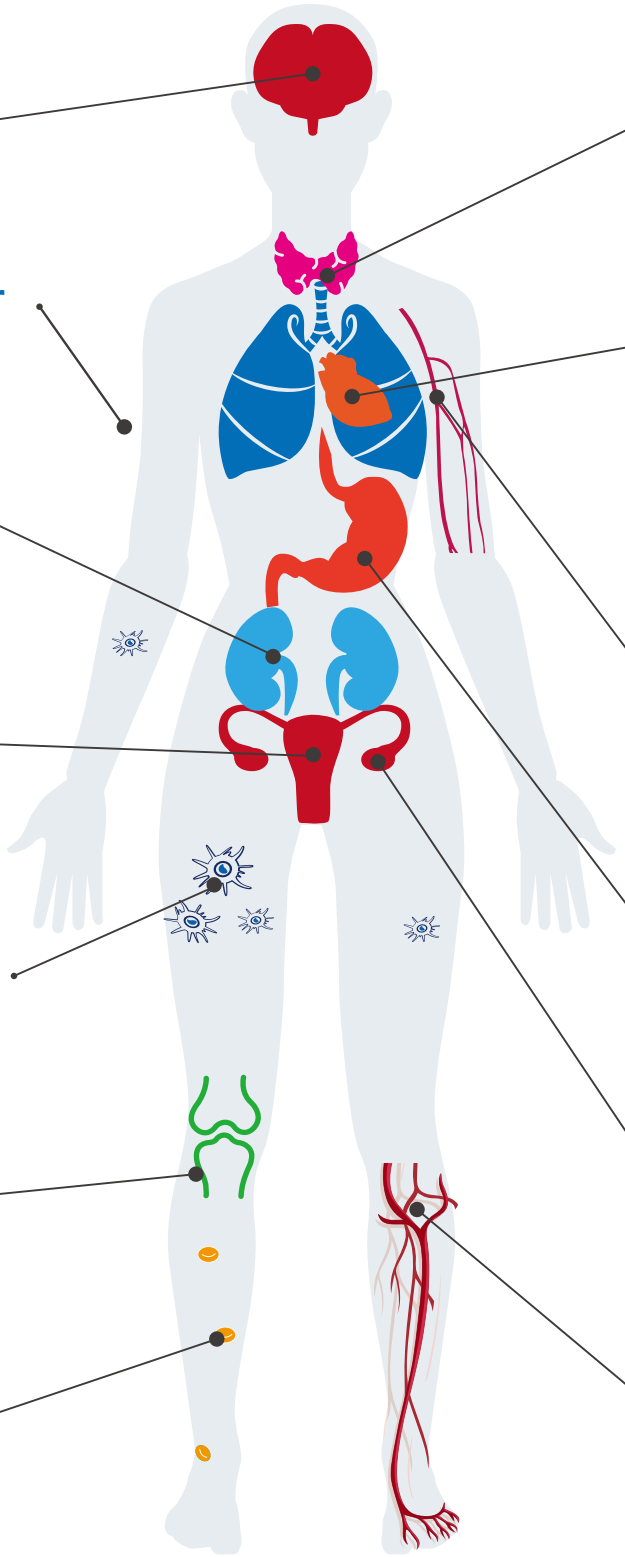
All-in-one analyzer with incubator, barcode reader and thermal printer, no extra step required from cartridge insert to result

◎ Specification - Multi-Channel

Test Speed	180 T/H
Dimension	395.5 × 223.5 × 193 (L x W x H) mm
Weight	≈ 6.4 kg
Display	11-inch Touchscreen
LIS System	Uni or Bi-directional
Data Processor	Intelligence
Sampling	Manual
Barcode Reader	Built-in (external available)
Parameters Import	Barcode
Printer	Built-in Thermal
Incubator	Built-in
Clot and Bubble Detection	No
Auto-dilution	No

Test Menu

Up to 32 tests available with expected expansion to 50 tests



Brain
S100β

Tumor Marker
CEA
AFP
PSA
fPSA ↑

Renal Injury
MAU
NGAL ↑
β2-MG ↑
Cys-C ↑

Pregnancy
β-hCG
FSH
LH
P ↑
PRL ↑
E2 ↑
T ↑
PIGF ↑
sFlt-1 ↑

Inflammation
hs-CRP+CRP
SAA
IL-6
PCT ↑
mPCT ↑

Bone Metabolism
Osteocalcin
25-OH VD

Anemia
Ferritin
Folate ↑
Vitamin B12 ↑

Thyroid
TSH
T4
T3
fT4 ↑
fT3 ↑

Cardiac Marker
hs-cTnI
CK-MB
H-FABP
Myoglobin
cTnI/CK-MB/Myo
ST2
Lp-PLA2
NT-proBNP
BNP

Thrombosis
D-Dimer

Stomach
PG I
PG II

Fertility
AMH
InhB ↑

Diabetes
HbA1c
C Peptide ↑
Insulin ↑

↑ Upcoming

◎ Feature Reagent Performances

Category	Product	Sample volume	Reaction time	Sample	Package	Detection range
Cardiac Marker	hs-cTnI	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.020 ng/mL-100.000 ng/mL
	CK-MB	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.200 ng/mL-300.000 ng/mL
	Myoglobin	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	7.80 ng/mL-2000.00 ng/mL
	cTnI/CK-MB/Myo	75 μL	12 mins	S/P/W	20 or 50 Tests/Kit	cTnI 0.200 ng/mL-80.000 ng/mL CK-MB: 2.000 ng/mL-150.000 ng/mL Myo: 10.00 ng/mL-500.00 ng/mL
	H-FABP	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.60 ng/mL-512.00 ng/mL
	ST2	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	2.0 ng/mL-1000.0 ng/mL
	Lp-PLA2	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	7.50 ng/mL-1200.00 ng/mL
	NT-proBNP	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	30 pg/mL-45000 pg/mL
	BNP	60 μL	8 mins	P/W	20 or 50 Tests/Kit	10.0 pg/mL-6000.0 pg/mL
Thrombosis	D-Dimer	60 μL	8 mins	P/W	20 or 50 Tests/Kit	0.150 mg/L FEU-35.000 mg/L FEU
Inflammation	hs-CRP+CRP	5 μL	2 mins	S/P/W	20 or 50 Tests/Kit	0.50 mg/L-350.00 mg/L
	SAA	5 μL	2 mins	S/P/W	20 or 50 Tests/Kit	0.50 mg/L-1000.00 mg/L
	IL-6	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	2.0 pg/mL-5000.0 pg/mL
	PCT	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.020 ng/mL-200.000 ng/mL
	mPCT	30 μL	5 mins	S/P/W	20 or 50 Tests/Kit	0.020 ng/mL-200.000 ng/mL
Diabetes	HbA1c	5 μL	5 mins	W	20 or 50 Tests/Kit	3.8 %-18.5 %
Thyroid	TSH	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.010 μIU/mL-100.000 μIU/mL
	T4	60 μL	5 mins	S/P/W	24 or 48 Tests/Kit	5.00 nmol/L-320.00 nmol/L
	T3	60 μL	5 mins	S/P/W	24 or 48 Tests/Kit	0.20 nmol/L-10.00 nmol/L
Pregnancy	β-hCG	5 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.10 mIU/mL-10000.00 mIU/mL
	FSH	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.15 mIU/mL-200.00 mIU/mL
	LH	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.50 mIU/mL-200.00 mIU/mL
Fertility	AMH	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.050 ng/mL-23.000 ng/mL

◎ Feature Reagent Performances

Category	Product	Sample volume	Reaction time	Sample	Package	Detection range
Stomach	PGI	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	1.00 ng/mL-200.00 ng/mL
	PGII	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.40 ng/mL-100.00 ng/mL
Tumor Marker	CEA	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.20 ng/mL-1200.00 ng/mL
	AFP	60 μL	8 mins	S/P/W	24 or 48 Tests/Kit	0.60 ng/mL-1210.00 ng/mL
	PSA	60 μL	8 mins	S/P/W	24 or 48 Tests/Kit	0.014 ng/mL-150.000 ng/mL
Renal Injury	MAU	60 μL	2 mins	Urine	20 or 50 Tests/Kit	5.00 mg/L-500.00 mg/L
Bone Metabolism	Osteocalcin	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.50 ng/mL-300.00 ng/mL
	25-OH VD	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	3.00 ng/mL-120.00 ng/mL (7.50 nmol/L-300.00 nmol/L)
Anemia	Ferritin	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.5 ng/mL-2000.0 ng/mL

Guangdong Wesail Biotech Co., Ltd.

Address : No.1 Taoyuan RD, Songshan Lake Science and Technology Industrial Park, Songshan Lake, Dongguan, Guangdong, China

Website : http://en.wesailbio.com

E-mail : customer@wesailbio.com

Phone/Fax : 400-900-1339

Version : WS-SPOC-EN-20230719

Linker

Facebook

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen via:
medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20214579

Bijlagen
-

Uw aanvraag
5 juli 2021

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 8 juli 2021
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 5 juli 2021 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Guangdong Wesail Biotech Co., Ltd. met Europees gemachtigde Lotus NL B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

Glycated Hemoglobin A1c Test Kit (Immunofluorescence)
Pepsinogen □ Test Kit (Immunofluorescence)
Pepsinogen □ Test Kit (Immunofluorescence)
C Peptide Test Kit (Immunofluorescence)
Insulin Test Kit (Immunofluorescence)
Nucleic Acid Extraction Kit
(geen merknaam) (NL-CA002-2021-61009)
High Sensitivity Cardiac Troponin I Test Kit(Immunofluorescence)
N-terminal pro-Brain Natriuretic Peptide Test Kit(Immunofluorescence)
Heart Type Fatty Acid Binding Protein Test Kit(Immunofluorescence)
Handheld Immunofluorescence Analyzer
Incubator
(geen merknaam) (NL-CA002-2021-61006)
Microalbuminuria Test Kit(Immunofluorescence)
Thyroid Stimulating Hormone Test Kit(Immunofluorescence)
Osteocalcin Test Kit(Immunofluorescence)
Ferritin Test Kit(Immunofluorescence)
Central Nerve Specific Protein 100 β Test Kit(Immunofluorescence)
(geen merknaam) (NL-CA002-2021-61010)
Myoglobin Test Kit(Immunofluorescence)
D-Dimer Test Kit(Immunofluorescence)
Soluble Growth Stimulation Expressed Gene 2 Protein Test Kit(Immunofluorescence)
cTnI/CK-MB/Myo Test Kit(Immunofluorescence)
Myeloperoxidase Test Kit(Immunofluorescence)
(geen merknaam) (NL-CA002-2021-61007)

Procalcitonin Test Kit (Immunofluorescence)
Creatine Kinase Isoenzyme-MB Test Kit (Immunofluorescence)
C-Reactive Protein Test Kit (Immunofluorescence)
Human Serum Amyloid A Test Kit (Immunofluorescence)
Interleukin-6 Test Kit (Immunofluorescence)
(geen merknaam) (NL-CA002-2021-61008)
β-human Chorionic Gonadotropin Test Kit (Immunofluorescence)
Luteinizing Hormone Test Kit (Immunofluorescence)
Anti-Mullerian Hormone Test Kit (Immunofluorescence)
Follicle Stimulating Hormone Test Kit (Immunofluorescence)
(geen merknaam) (NL-CA002-2021-61011)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten ontleend worden, ze dienen alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

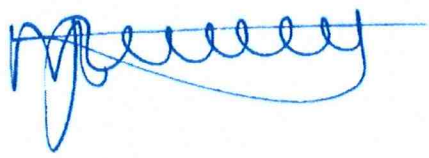
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Guangdong Wesail Biotech Co., Ltd. de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat de in-vitro diagnostica voldoen aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit).

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 108683 0001 Rev. 01

Holder of Certificate: **Guangdong Wesail Biotech Co., Ltd.**
2F, Building 1, 5 Hualian Street
Songshan Lake Science and Technology Industrial Park
Songshan Lake
523808 Dongguan, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents for Immunochemistry.**
Design and Development, Production, Distribution and Servicing of In Vitro Diagnostic Instruments for Immunochemistry.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 108683 0001 Rev. 01

Report No.: GZ2355001 / GZ2355001_CN

Valid from: 2023-10-13
Valid until: 2026-10-12

Date, 2023-09-19

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 108683 0001 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Guangdong Wesail Biotech Co., Ltd.
2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production of In Vitro Diagnostic Reagents for Immunochemistry.
Distribution of In Vitro Diagnostic Reagents and Instruments for Immunochemistry.

Guangdong Wesail Biotech Co., Ltd.
Room 201, Building 10, 19 Alishan RD, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Servicing of In Vitro Diagnostic Instruments for Immunochemistry.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

EC Declaration of Conformity

according to the Directive 98/79/EC
(applicable to IVD Devices of NOT Annex Ⅱ and NOT self-test)

Manufacturer	Guangdong Wesail Biotech Co., Ltd. 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China
European Representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Product/s	High Sensitivity Cardiac Troponin I Test Kit (Immunofluorescence) REF No.: BA0010 Model: 20 tests/kit
Basic UDI-DI	697384100A00103K
UDI-DI	6973841000857
Intended Use	This kit applies to the quantitative determination of cardiac troponin I (cTnI) in human serum, plasma and whole blood in vitro, and is mainly used for the auxiliary diagnosis of acute myocardial infarction in clinic.
GMDN Code	54010
EMDN Code	W0102160703
Classification	Others/General
Conformity Assessment Route	Annex Ⅲ, except point 6, of Directive

Applicable Standards			
	EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 15223-1:2016
	EN 13612:2002	EN ISO 23640:2015	EN 13641:2002
	EN 13975:2003	EN ISO 17511:2003	EN ISO 14971:2012
	ISO 14971:2019	EN ISO 13485:2016	ISO 15198:2004

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Signed this Day/ 30th of Month/ June of Year/ 2021, Place (Dongguan), China

Signature (on behalf of the manufacturer)

Name of authorized signatory: **Dong Yu**

Position held in the company: **General Manager**

Company Seal/Stamp:

EC Declaration of Conformity

according to the Directive 98/79/EC

(applicable to IVD Devices of NOT Annex Ⅱ and NOT self-test)

Manufacturer	Guangdong Wesail Biotech Co., Ltd. 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China
European Representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Product/s	D-Dimer Test Kit (Immunofluorescence) Model:20 tests/kit, 50 tests/kit
Classification	Others/General
Conformity Assessment Route	Annex Ⅲ, except point 6, of Directive (Module A)

Applicable Standards

EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 15223-1:2016
EN 13612:2002	EN ISO 23640:2015	EN 13641:2002
EN 13975:2003	EN ISO 17511:2003	EN ISO 14971:2012
ISO 14971:2019	EN ISO 13485:2016	ISO 15198:2004

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Signed this Day/ 30th of Month/ June of Year/ 2021, Place (Dongguan), China

Signature (on behalf of the manufacturer) Dong Yu

Name of authorized signatory: Dong Yu

Position held in the company: General Manager

Company Seal/Stamp:

EC Declaration of Conformity

according to the Directive 98/79/EC

(applicable to IVD Devices of NOT Annex Ⅱ and NOT self-test)

Manufacturer	Guangdong Wesail Biotech Co., Ltd. 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China
European Representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Product/s	cTnI/CK-MB/Myo Test Kit (Immunofluorescence) Model:20 tests/kit, 50 tests/kit
Classification	Others/General
Conformity Assessment Route	Annex Ⅲ, except point 6, of Directive (Module A)

Applicable Standards

EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 15223-1:2016
EN 13612:2002	EN ISO 23640:2015	EN 13641:2002
EN 13975:2003	EN ISO 17511:2003	EN ISO 14971:2012
ISO 14971:2019	EN ISO 13485:2016	ISO 15198:2004

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Signed this Day/ 30th of Month/ June of Year/ 2021, Place (Dongguan), China

Signature (on behalf of the manufacturer) Dong Yu

Name of authorized signatory: Dong Yu

Position held in the company: General Manager

Company Seal/Stamp:

EC Declaration of Conformity

according to the Directive 98/79/EC

(applicable to IVD Devices of NOT Annex Ⅱ and NOT self-test)

Manufacturer	Guangdong Wesail Biotech Co., Ltd. 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China
European Representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Product/s	β-human Chorionic Gonadotropin Test Kit (Immunofluorescence) Model:20 tests/kit, 50 tests/kit
Classification	Others/General
Conformity Assessment Route	Annex Ⅲ, except point 6, of Directive (Module A)

Applicable Standards		
EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 15223-1:2016
EN 13612:2002	EN ISO 23640:2015	EN 13641:2002
EN 13975:2003	EN ISO 17511:2003	EN ISO 14971:2012
ISO 14971:2019	EN ISO 13485:2016	ISO 15198:2004

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Signed this Day/ 30th of Month/ June of Year/ 2021, Place (Dongguan), China

Signature (on behalf of the manufacturer) Dong Yu

Name of authorized signatory: **Dong Yu**

Position held in the company: **General Manager**

Company Seal/Stamp:

EU DECLARATION OF CONFORMITY

According to Art. 17 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Manufacturer:	Guangdong Wesail Biotech Co., Ltd. 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China
Trademark:	WESAIL
SRN:	CN-MF-000008828
European Representative:	MedPath GmbH Mies-van-der-Rohe-Strasse 8 80807 Munich, Germany
SRN:	DE-AR-000000087
Product or trade name:	Immunofluorescence Analyzer
Product Model:	WS-Mi6000
Basic UDI-DI :	697384100B600055
Intended Use:	The Immunofluorescence Analyzer should be used along with WESAIL reagents for qualitative or quantitative detection and analysis of human samples to be tested.
Classification acc. to IVDR Ax. VIII:	Class A, rule 5
Applied Standard & Common Specification:	EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 18113-1:2011, EN ISO 18113-3:2011, EN 13612:2002, EN ISO 15223-1:2021, EN ISO 23640:2015, EN 62366-1:2015, EN IEC 61010-2-081:2020, EN 61010-1:2010+A1:2019, EN IEC 61010-2-010:2020, IEC 61010-2-101:2018, EN IEC 61326-1:2021, EN IEC 61326-2-6:2021
Conformity assessment procedure:	Article 17 + Ax. II + Ax. III

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). All supporting documentations are retained under the premises of the manufacturer.

Signed this Day/ 28th of Month/ August of Year/ 2023, Place Dongguan , China

Signature (on behalf of the manufacturer) Dong Yu

Name of authorized signatory: Dong Yu

Position held in the company: General Manager

Company Seal/Stamp:

16354

D-Dimer Test Kit (Immunofluorescence)

(For *In Vitro* Diagnostic Use Only)

[Product Name] D-Dimer Test Kit (Immunofluorescence)

[Package Specification & REF ID]

20 tests/kit (BA0140), 50 tests/kit (BA0141)

[Intended Use]

This kit applies to the quantitative determination of D-Dimer in human plasma and whole blood in vitro, and the results cannot be used for the auxiliary diagnosis and exclusion diagnosis of venous thrombosis.

Fibrinmonomer in blood is cross-linked by activated factor XIII, and then hydrolyzed by activated plasmin to produce specific degradation products called fibrin degradation products (FDP). D-Dimer is the simplest fibrin degradation product, and an increase in its concentration reflects an intravascular hypercoagulable state and secondary hyperfibrinolysis in the body1. Therefore, the concentration of D-Dimer is of great significance in the diagnosis, assessment of therapeutic efficacy, and prognostic evaluation of thrombotic diseases. Due to its high sensitivity and negative predictive value, clinically a negative D-Dimer has been widely used as an important basis for excluding pulmonary embolism (PE) and deep venous thrombosis (DVT).

[Principle]

The kit is based on the principle of the lateral flow fluorescence immunoassay utilizing an immuno-sandwich format. When the sample is added to the sample port, the sample first passes through the sample pad, and then D-Dimer in the sample specifically binds to the fluorescent-conjugated D-Dimer monoclonal antibody on the conjugate pad to form a fluorescent complex. When the fluorescence complex flows to the test band, it will bind to the D-Dimer monoclonal antibody pre-coated on the nitrocellulose membrane and will be fixed on the test band. The antigen content in the complex is proportional to the fluorescence intensity of the test band. When the free fluorescence complex reaches the control band, the complex will specifically bind to the goat IgG pre-coated on the control band and therefore will be fixed on it. The immunofluorescence analyzer converts the received fluorescence signal value into electrical signal value, and automatically converts the concentration of D-Dimer in the sample (mg/L FEU) by substituting the T/C value (T/C peak area) into the preset calibration curve.

[Components]

The kit consists of the Reagent and Control (optional).

Reagent:

Composition	Main ingredients/information	20 tests/kit		50 tests/kit	
		BA0140		BA0141	
		Quantity	Specification	Quantity	Specification
Test Cassette	Nitrocellulose membrane (D-Dimer monoclonal antibody, goat IgG), conjugate pad (fluorescent conjugated D-Dimer monoclonal antibody), sample pad, absorbent pad	20	Individual package	50	Individual package
Certificate of conformity/ calibrate card	Product information (item name, item code, batch number, production date, expiration date), calibration curve	1 copy	----	1 copy	----
Product insert	/	1 copy	----	1 copy	----

The components in different batch of Reagent kits are not interchangeable.

Control (optional):

Composition	Main ingredients	Specification 1	Specification 2	Specification 3
		BD0141	BD0142	BD0143
Control Level 1	D-Dimer antigen, BSA, phosphate buffer	1×0.25 mL/bottle (reconstitution volume)	2×0.25 mL/bottle (reconstitution volume)	3×0.25 mL/bottle (reconstitution volume)
Control Level 2	D-Dimer antigen, BSA, phosphate buffer			
Target Value Card	/	1 copy	1 copy	1 copy

The components in different batch of Control kits are not interchangeable. The target range is batch-specific, please refer to the target value information on the Target Value Card for details.

[Storage and Stability]

The Reagent kit should be store at room temperature (2-30°C or 35.6-86°F) in a dry shady place. Avoid direct sunlight. 18 months of shelf life (production date to expiration date).
The test cassette should be used within half an hour as long as the aluminum foil bag is opened, and used immediately when the room temperature exceeds 25°C or in an environment with high humidity.
The kit can be transported for 30 days at the temperature of -20 °C to 45 °C.
The Control should be sealed and stored at a temperature of 2°C to 8°C, and the validity period is 18 months.
After reconstitution, the Control should be stored in the shady place at a temperature of 2°C to 8°C and has a shelf life of 24 hours.
Production batch number, production date and expiration date are shown on the packing label.

[Applicable Instrument]

Immunofluorescence analyzers: WS-Si1000, WS-Si1300, WS-Si1500 and WS-Mi6000 produced by Guangdong Wesail Biotech Co., Ltd.

[Sample Requirements]

1. Applicable to the following sample:
   Fresh venous citrated plasma or whole blood samples, fasting blood collection is unnecessary.
2. Precautions during sample collection:

2.1 The sample shall be protected against hemolysis and free of fibrin and other impurities;
2.2 White blood cells or platelets should be avoided when collecting plasma samples.
2.3 Before testing, the plasma samples should be centrifuged at room temperature (15°C~25°C) for 10 minutes at 1,300g~2,000g (generally 3,500~4,000rpm), which can be configured according to the Instructions for Use of the centrifuge.

3. Storage and preparation of samples:

3.1 The whole blood sample at room temperature should be used within 4 hours and, if it cannot be tested within 4 hours, it should be timely transferred for storage at 2°C~8°C. The samples that are not detected within 24 hours should be discarded and the blood has to be drawn again.

Sample type	Storage condition	Storage time
Plasma/Serum	≤-20 °C	30 days
Plasma/Serum	2～8 °C	24 hours
Plasma/Serum	15～30°C	8 hours
Whole Blood	15～30°C	4 hours

3.2 The sample can only be frozen and thawed once after thawing.

[Test Procedure]

Before the test, you are required to thoroughly read the relevant operating instructions for this reagent and the immuno-fluorescence analyzers.

Model of Analyzer	Steps	Details	Notes
WS-Si1000; WS-Si1300	Preparation	1.1 Power on the analyzer and incubator, allow them to preheat and perform self-checking respectively. 1.2 After the self-check of the analyzer is completed, insert the calibrate card into the corresponding scanning area of the analyzer, click the QR code icon to identify and import the item information. 1.3 Set the incubator to 8 minutes, 18.5°C.	The samples and kits must be restored to room temperature before testing
	Sample addition	2.1 Pipette 60 μL sample into the sample port of the cassette, insert the cassette into the incubator immediately, and the incubator will count down for 8 minutes.	Avoid sample overflow the sample port
	Detection	3.1 The incubator will automatically alarm at the last 10 seconds of incubation. Pull out the cassette immediately and insert it into the analyzer which will automatically recognize the QR code information on the cassette and display it in the test interface. After confirming the information is correct, select sample type and click “Test”, and the analyzer will automatically scan the cassette. 3.2 The analyzer will convert the scanned signal value through the preset calibration curve, and display the test results in the test interface. 3.3 Click “Print” to print results.	It has to be inserted into the analyzer for detection immediately after incubation
WS-Si1500; WS-Mi6000	Preparation	1.1 Power on the analyzer, allow it to preheat and perform self-checking. 1.2 After the self-check of the analyzer is completed, put the calibrate card in the corresponding scanning area, click "import" and the analyzer will identify and import the QR code information. 1.3 Insert the cassette, the analyzer will automatically identify the item information, and then eject the cassette, exposing the sample port. Select sample type in the test interface.	The samples and kits must be restored to room temperature before testing
	Sample addition	2.1 Pipette 60 μL sample to the sample port, then immediately insert the cassette into the analyzer, and the incubation time will automatically count down.	Avoid sample overflow the sample port
	Detection	3.1 After incubation, automatic detection is performed. The analyzer will convert the scanned signal value through the preset calibration curve, and display the test results in the test interface. 3.2 Click “Print” to print results.	/

[Quality Control Procedure]

Periodic quality control shall be carried out to ensure the effectiveness and accuracy of test results.
The analyzer’s optical parts and moving parts are validated by the quality control card.
Periodic validation is performed on the validity and accuracy of reagent test results by using the D-Dimer Control from Guangdong Wesail Biotech Co., Ltd.
The kit does not contain the D-Dimer Control and the quality control card, if necessary, please contact the manufacturer.

[Reference Range]

1. Considering the differences in geography, race, gender and age, laboratories are recommended to establish their own reference intervals according to their own conditions.
2. The D-Dimer Test Kit (Immunofluorescence) from Guangdong Wesail Biotech Co., Ltd. was used to test 346 apparently healthy people, and the reference interval of normal population was confirmed in the range of 0 mg/L FEU to 0.550 mg/L FEU.

Cases	Gender		Age (years)	Reference interval (mg/L FEU)
	Male	Female		
346	168	178	18-78	0-0.550

[Interpretation of Test Results]

1. The detection range of samples is 0.150 mg/L FEU～35.000 mg/L FEU. For the samples exceeding the upper detection limit the results are reported "＞35.000 mg/L FEU", or less than the lower detection limit the results are reported "＜0.150 mg/L FEU".
2. When the test kit expires, the immunofluorescence analyzer will directly report “kit failure”.
3. When the control band exceeds the acceptable value set in the analyzer or the test cassette expires, the immunofluorescence analyzer will report “invalid detection”.
4. D-Dimer is an important diagnostic indicator of secondary fibrinolysis and a specific molecular marker of ongoing thrombus formation in the body. The reported values of D-Dimer cannot be converted between the two forms, DDU and FEU.
5. D-Dimer-negative patients (false negatives) may still have a small thrombus or distal venous thrombosis in a very small number of cases. The reasons for this are: ① the thrombus size is very small, and it is located in a distal site; ② false-positive results due to radiological or ultrasound examinations; ③ a long time interval between clinical presentation and specimen collection; ④ decreased fibrinolytic activity.
6. The test results of the kit are for clinical reference only and cannot be taken alone as the basis for diagnosis or exclusion of cases. For the purpose of diagnosis, the test results should be used in combination with clinical examination, medical history and other examination results.

[Limitations of Test Method]

1. The following may lead to false positive results: influence of cross reaction of similar antibody components in blood (such as high concentration of heterophile antibody or rheumatoid factor); some non-specific components in blood having similar epitopes which can be captured by the fluorescent conjugated antibodies.
2. The following may lead to false negative results: antigenic determinants blocked by some unknown components fail to bind with antibodies; unstable D-Dimer antigens that gradually degenerate with time and temperature are not recognized by the antibody. Effective test results require a good test cassette and the proper sample storage environment.
3. Other factors may also lead to errors in D-Dimer test result, including technical reasons, operational errors and other factors related to the sample. For the abnormal results caused by such factors, it is required to repeat the detection and avoid non-standard use process.
4. It is not recommended to dilute the sample for detection when the sample concentration is greater than 35.000 mg/L FEU.
5. Interferent:

5.1 Endogenous substances:

This product employs the lateral flow fluorescence immunoassay method to detect and quantify D-Dimer in the sample at the corresponding position of the test cassette. However, the presence of high levels of endogenous substances in the sample may affect the chromatography of the sample on the cellulose nitrate membrane or the normal reaction of the antigen-antibody, which may lead to erroneous test results. According to the research results, when the concentration of interfering substances in the sample is within the following range, the deviation of the detection results is within ±15.0%.

No.	Substances	Concentration
1	Triglycerides	≤15 mg/mL
2	Cholesterol	≤400 mg/dL
3	Bilirubin	≤40 mg/L
4	Hemoglobin	≤6 mg/mL
5	Rheumatoid factor	≤200 IU/mL
6	Creatinine	≤30 mg/dL
7	Albumin	≤60 g/L

8	Immunoglobulin	≤50 g/L
9	Urea	≤5 mg/mL
10	Uric acid	≤20 mg/mL

5.2 Drugs:

According to the research results, when the sample drug concentration is in the following range, the deviation of the detection results is within ±15.0%.

No.	Substances	Concentration
1	Acetaminophen	20 mg/dL
2	Acetylsalicylic acid	60 mg/dL
3	Amikacin	15 mg/dL
4	Ampicillin	5.3 mg/dL
5	Ascorbic Acid (Vitamin C)	5.0 mg/dL
6	Caffeine	6.0 mg/dL
7	Chloramphenicol	5.0 mg/dL
8	Cimetidine	2.0 mg/dL
9	Diazepam	0.5 mg/dL
10	Erythromycin	6.0 mg/dL
11	Gentamicin	12 mg/dL
12	Ibuprofen	50 mg/dL
13	Lidocaine	1.2 mg/dL
14	Warfarin	11 mg/dL
15	Propranolol	0.5 mg/dL

[Product Performance Index]

1. The limit of detection shall not be greater than 0.015 mg/L FEU.
2. Accuracy: When tested with the enterprise reference, the relative deviation between the test result and the calibration concentration shall not exceed ±15.0%.
3. Linearity: Within the range of [0.150, 35.000] mg/L FEU, the correlation coefficient (r) of linear regression shall not be less than 0.9900.
4. Repeatability: The intra-batch coefficient of variation (CV) shall not be greater than 10.0% when tested with the enterprise reference.
5. Inter-batch variation: The inter-batch coefficient of variation (CV) shall not be greater than 15.0% when tested with the enterprise reference.
6. When the sample concentration is up to 500.000 mg/L FEU, no high-dose hook effect is observed.

[Precautions]

1. This product is used for in vitro testing only.
2. Do not test the samples with high fat chyle, jaundice, severe hemolysis and high rheumatoid factor.
3. Product performance cannot be guaranteed when other sample types, or sample collection and processing methods are used.
4. Do not use the test kit with damaged package, unclear mark or beyond expiry date.
5. Please operate in strict accordance with the instructions, and the test cannot be stopped halfway once the test starts. The test that is stopped halfway cannot be resumed. If retesting is required, a new test cassette must be used for retesting.
6. Retesting is required for an invalid result.
7. A corresponding calibrate card is provided for each batch of cassettes and must be updated in time.
8. Test cassettes, which are disposable, should be handled as biological products after use according to relevant regulations.
9. The desiccant in the aluminum foil bag cannot be taken internally.
10. Biosafety warning: clinical samples, test wastes, disposable articles and other materials exposed in the test shall be handled as potential infectious substances, and corresponding preventive measures shall be taken.

11. The test results cannot serve as the absolute basis for diagnosis, and should be interpreted by the doctors according to clinical characteristics and other test results.
12. Due to methodology or antibody specificity, testing the same sample with kits from different manufacturers may produce different test results. Therefore, direct comparison should not be conducted among different kits.

[References]

1. Expert Consensus on the Emergency Clinical Application of "D-Dimer Test". Chinese Journal of Emergency Medicine, 2013, 22(8): 827-836.

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SYMBOL	DESCRIPTION
	Manufacturer
EC REP	Authorized representative in the European Community
IVD	*In Vitro* Diagnostic Medical Device
LOT	Batch Code
	Use-by date
30°C 2°C	Temperature Limitation
CE	CE Mark
REF	Catalogue number
	Biological risks
	Do not re-use
Σ	Contains Sufficient for <n> Tests
	Date of manufacture
	Keep Away From Sunlight
i	Consult instructions for use
	Keep Dry

Establishment of the Measuring Interval for D-Dimer

Evaluation Method

The measuring interval was established using three batches of D-Dimer reagent kits on the WS-Si1000 Fluorescence Immunoassay Analyzer. Based on the expected linear range, the measuring range was extended to over 130% of the anticipated upper limit, and concentration points were set accordingly. Samples were precisely prepared by diluting high-concentration clinical samples with simulated clinical sample diluent at defined ratios.
Each sample was tested in triplicate. The mean value, coefficient of variation (CV), linear correlation coefficient (r), absolute bias, and relative bias were calculated.

Evaluation Criteria

Linear Range Requirements

The linear range of the D-Dimer reagent kit shall meet the following criteria:

- The linear correlation coefficient (r) should be ≥0.99;
- For the relative bias section (≤ 5.000 mg/L FEU), the relative bias shall be ≤ 15%;
- For the absolute bias section (> 5.000 mg/L FEU), the absolute bias shall not exceed 0.500 mg/L FEU;
- Within the linear range, CV shall be ≤ 10%.

Measuring Range Requirements

The measuring range of the D-Dimer reagent kit shall meet the following criteria:

- For concentrations above the linear range, relative bias shall be ≤ 20%;
- For concentrations below the linear range, absolute bias shall not exceed 0.010 mg/L FEU;
- CV shall be ≤ 15%.

Measuring Interval Study

Three batches of D-Dimer reagent kits were evaluated using the fluorescence immunoassay analyzer to establish the measuring interval.
Clinical samples at concentrations of: 14 mg/L FEU, 32 mg/L FEU, 72 mg/L FEU, 258 mg/L FEU, 1002 mg/L FEU, 3976 mg/L FEU, 7942 mg/L FEU, 31739 mg/L FEU, 39672 mg/L FEU, 44695 mg/L FEU, 47604 mg/L FEU, and 52892 mg/L FEU were prepared by mixing a high-value sample (52892 mg/L FEU) with a low-value sample (10 mg/L FEU) at specific ratios.
Each sample was measured three times. The mean value, linear correlation coefficient (r), absolute bias, and relative bias were calculated. The linear range and measuring range of the D-Dimer reagent kit were determined according to the above acceptance criteria.
Results are shown in Tables 1–3.

Table 1 Results of Measurement Interval Establishment-1

	Lot Number: AA0142004001								
No.	Potency	Test 1	Test 2	Test 3	AV	SD	CV	Absolute	Relative

	(mg/L FEU)							Deviation	Deviation
1	0.012	0.005	0.010	0.013	0.009	0.004	43.3%	0.003	-
2	0.024	0.026	0.023	0.023	0.024	0.002	7.2%	0.000	-
3	0.048	0.046	0.052	0.050	0.049	0.003	6.2%	0.001	-
4	0.121	0.127	0.111	0.111	0.116	0.009	7.9%	0.005	-
5	0.303	0.345	0.334	0.306	0.328	0.020	6.1%	0.025	-
6	0.757	0.721	0.655	0.713	0.696	0.036	5.2%	0.061	-
7	1.893	2.058	2.064	1.866	1.996	0.113	5.6%	0.103	-
8	4.732	4.668	5.198	5.417	5.094	0.385	7.6%	0.362	-
9	11.830	12.418	11.743	11.894	12.018	0.354	2.9%	-	1.59%
10	23.661	22.581	23.454	26.286	24.107	1.937	8.0%	-	1.89%
11	31.548	29.922	31.958	35.382	32.421	2.759	8.5%	-	2.77%
12	35.053	32.428	38.824	33.640	34.964	3.397	9.7%	-	2.60%
13	38.948	43.155	34.084	41.719	39.653	4.876	12.3%	-	10.30%
14	43.276	47.929	44.526	37.262	43.239	5.449	12.6%	-	0.08%
15	48.084	44.31	42.70	57.12	48.044	7.905	16.5%	-	0.08%
Correlation coefficient (0.025-35.000)			0.9998						
Correlation coefficient (0.025-43.000)			0.9999						

Table 2 Results of Measurement Interval Establishment-2

	Lot Number: AA0142004002								
No.	Potency (mg/L FEU)	Test 1	Test 2	Test 3	AV	SD	CV	Absolute Deviation	Relative Deviation
1	0.012	0.013	0.008	0.010	0.010	0.003	24.4%	0.002	-
2	0.024	0.024	0.020	0.022	0.022	0.002	9.1%	0.002	-
3	0.048	0.050	0.043	0.048	0.047	0.004	7.7%	0.001	-
4	0.121	0.138	0.128	0.123	0.130	0.008	5.9%	0.009	-
5	0.303	0.303	0.343	0.335	0.327	0.021	6.5%	0.024	-
6	0.757	0.831	0.869	0.839	0.846	0.020	2.4%	0.089	-
7	1.893	1.924	1.755	1.899	1.859	0.091	4.9%	0.034	-
8	4.732	4.355	4.611	4.800	4.589	0.223	4.9%	0.144	-
9	11.830	11.435	12.327	11.437	11.733	0.514	4.4%	-	0.82%
10	23.661	24.147	25.555	22.407	24.036	1.577	6.6%	-	1.59%
11	31.548	32.370	28.005	31.663	30.679	2.343	7.6%	-	2.75%
12	35.053	38.633	32.144	36.331	35.703	3.290	9.2%	-	2.60%
13	38.948	33.165	37.425	44.188	38.259	5.559	14.5%	-	10.30%
14	43.276	37.597	46.081	48.695	44.124	5.802	13.1%	-	1.96%
15	48.084	42.19	41.28	54.98	46.151	7.663	16.6%	-	4.02%

Correlation coefficient (0.025-35.000)	0.9996
Correlation coefficient (0.025-43.000)	0.9996

Table 3 Results of Measurement Interval Establishment-3

	Lot Number: AA0142004003								
No.	Potency (mg/L FEU)	Test 1	Test 2	Test 3	AV	SD	CV	Absolute Deviation	Relative Deviation
1	0.012	0.013	0.009	0.010	0.011	0.002	19.5%	0.001	
2	0.024	0.021	0.024	0.023	0.023	0.002	6.7%	0.002	
3	0.048	0.048	0.048	0.046	0.047	0.001	2.4%	0.001	
4	0.121	0.136	0.120	0.135	0.130	0.009	6.9%	0.009	
5	0.303	0.320	0.284	0.297	0.300	0.018	6.1%	0.003	
6	0.757	0.702	0.728	0.743	0.724	0.021	2.9%	0.033	
7	1.893	1.917	2.134	1.896	1.982	0.132	6.6%	0.089	
8	4.732	4.544	5.237	4.952	4.911	0.348	7.1%	0.179	
9	11.830	11.802	12.089	10.902	11.598	0.619	5.3%		1.97%
10	23.661	22.288	23.654	26.912	24.285	2.376	9.8%		2.64%
11	31.548	29.797	27.552	28.586	28.645	1.124	3.9%		9.20%
12	35.053	35.299	37.786	34.132	35.739	1.866	5.2%		2.60%
13	38.948	43.565	35.036	44.579	41.060	5.242	12.8%		10.30%
14	43.276	48.773	40.183	49.150	46.035	5.072	11.0%		6.38%
15	48.084	55.25	44.66	41.07	46.994	7.375	15.7%		2.27%
Correlation coefficient (0.025-35.000)			0.9977						
Correlation coefficient (0.025-43.000)			0.9976						

Conclusion

Based on the establishment study conducted using the WS-Si1000 Fluorescence Immunoassay Analyzer for batches AA0142004001, AA0142004002, and AA0142004003, the following measuring intervals were determined:

Linear range: 0.025 mg/L FEU - 35.000 mg/L FEU

Measuring range: 0.025 mg/L FEU - 43.000 mg/L FEU

广东唯实生物技术有限公司

Guangdong Wesail Biotech Co., Ltd. (WESAIL)

Training Certificate

Its hereby certified that

Sergiu Sorocovici
From "GBG-MLD"SRL, has successfully completed all technical training course of Immunofluorescence analyzer Model WS-Mi6000, WS-Si1000 and WS-i60 including installation, Use, Service, Scientific and Technical Support, and is qualified to offer technical support for above mentioned products.

FOR & ON BEHALF OF

广东唯实生物技术有限公司

Guangdong Wesail Biotech Co., Ltd. (WESAIL)

国际营销总监/日期： Vincent NONG

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