Test Menu

	Test Item	Sample Type	Sample Volume	Reaction Time	Measuring Range	Qualification
Diabetes	HbA1c	WB	10μL	10 mins	4 %-14 %	CE, NMPA, NGSP
	Insulin	WB/S/P	100 μl	10 mins	1-300 μU/mL	CE, NMPA*
Vitamin	25-OH Vit-D	S/P	100 μL	10 mins	5-100 ng/mL	CE, NMPA
Thyroid function	T3	WB/S/P	100 μL	10 mins	0.6-10 nmol/L	CE, NMPA
	T4	WB/S/P	100 μL	10 mins	20-320 nmol/L	CE, NMPA
	TSH	WB/S/P	100 μL	10 mins	0.1-100 mIU/L	CE, NMPA
	FT3	WB/S/P	100 μL	10 mins	0.4-50 pmol/L	CE, NMPA
	FT4	WB/S/P	100 μL	10 mins	1-100 pmol/L	CE, NMPA
Fertility	β-HCG	WB/S/P	100 μL	10 mins	2-100000 IU/L	CE, NMPA
	LH	WB/S/P	100 μL	10 mins	1-100 mIU/mL	CE, NMPA
	FSH	WB/S/P	100 μL	10 mins	1-100 mIU/mL	CE, NMPA
	PROG	WB/S/P	100 μL	10 mins	1.4-60 ng/mL	CE, NMPA
	TESTO	WB/S/P	100 μL	10 mins	0.2-15 ng/mL	CE, NMPA
	PRL	WB/S/P	100 μL	10 mins	1-200 ng/mL	CE, NMPA
	AMH	WB/S/P	100 μL	10 mins	0.1-16 ng/mL	CE, NMPA*
	E2	WB/S/P	100 μL	10 mins	9-3000 pg/mL	CE, NMPA
Hormone	Cortisol	WB/S/P	100 μL	10 mins	45-1000 nmol/L	CE, NMPA
Cardiac markers	CK-MB	WB/S/P	100 μL	10 mins	0.3-100 ng/mL	CE, NMPA
	NT-proBNP	WB/S/P	100 μL	10 mins	18-35000 pg/mL	CE, NMPA
	cTnI	WB/S/P	100 μL	10 mins	0.04-50 ng/mL	CE, NMPA
	Myo	WB/S/P	100 μL	10 mins	2-400 ng/mL	CE, NMPA
	hs-CRP	WB/S/P	10 μL	3 mins	0.5-200 mg/L	CE, NMPA
	BNP*	WB/P	100 μL	10 mins	5-5000 pg/mL	CE*, NMPA
	cTnT*	WB/S/P	100 μL	10 mins	0.03-10 ng/mL	CE, NMPA
	ST2*	WB/S/P	100 μL	10 mins	3.1-200 ng/mL	CE*, NMPA
	S100β*	WB/S/P	100 μL	10 mins	0.05-10 ng/mL	CE*, NMPA
	LP-PLA2*	WB/S/P	100 μL	10 mins	20-1000 ng/mL	CE*, NMPA
Coagulation	D-Dimer	WB/P	100 μL	10 mins	0.2-10 mg/L	CE, NMPA
Inflammation	CRP	WB/S/P	10 μL	3 mins	0.5-150 mg/L	CE, NMPA
	PCT	WB/S/P	100 μL	10 mins	0.05-100 ng/mL	CE, NMPA
	IL-6	WB/S/P	100 μL	10 mins	3-4000 pg/mL	CE, NMPA
	Total IgE	WB/S/P	100 μL	10 mins	0.75-2000 IU/mL	CE, NMPA*
	SAA/W-CRP*	WB/S/P	100 μL	5 mins	SAA:5.0-200 mg/L; W-CRP:0.5-150 mg/L	CE*, NMPA
	SAA*	WB/S/P	100 μL	5 mins	5.0-200 mg/L	CE, NMPA*
Tumor markers	AFP	WB/S/P	100 μL	10 mins	10-300 ng/mL	CE, NMPA*
	CEA	WB/S/P	100 μL	10 mins	2.5-400 ng/mL	CE, NMPA*
	PSA	WB/S/P	100 μL	10 mins	0.5-100 ng/mL	CE*, NMPA*
	fPSA	WB/S/P	100 μL	10 mins	0.2-30 ng/mL	CE*, NMPA*
	CA125	WB/S/P	100 μL	10 mins	2-2500 U/mL	CE, NMPA*
	CA19-9	WB/S/P	100 μL	10 mins	0.6-1000 U/mL	CE, NMPA*
	CA15-3	WB/S/P	100 μL	10 mins	5-300 U/mL	CE, NMPA*

Test Menu

	Test Item	Sample Type	Sample Volume	Reaction Time	Measuring Range	Qualification
Anemia	FER	WB/S/P	100 μL	10 mins	5-1500 ng/mL	CE, NMPA
	VB12*	WB/S/P	100uL	10 mins	100-2000 pg/mL	CE, NMPA*
	Folate*	S/P	100uL	10 mins	1-25 ng/mL	CE, NMPA*
Renal function	NGAL*	Urine	20 μL	10 mins	10-1500 ng/mL	CE, NMPA*
	β2-MG*	S/P/Urine	100 μL	10 mins	0.1-15 mg/L	CE, NMPA*
	MALB	Urine	100 μL	10 mins	5-500 mg/L	CE, NMPA*
	Cys-C*	Urine	20 μL	10 mins	0.1-10 mg/L	CE, NMPA*
Tropical infectious disease	Dengue NS 1	WB/S/P	100 μL	10 mins	Qualitative	CE, NMPA*
	Malaria Pf/Pv*	WB	100uL	10 mins	Qualitative	CE, NMPA*
Gastric	PG I/PG II*	WB/S/P	100 μL	10 mins	PG I: 10-160 ng/mL; PG II: 6.25-100 ng/mL	CE*, NMPA*
	H.P. Ag	Feces	/	10 mins	/	CE, NMPA*
Rheumatoid	Anti-CCP	WB/S/P	10 μL	10 mins	8-500 U/mL	CE, NMPA*
	RF	WB/S/P	10 μL	10 mins	10-650 IU/mL	CE, NMPA*
	ASO	WB/S/P	10 μL	10 mins	20-1000 IU/mL	CE, NMPA*

*Ongoing

Fingerstick Blood Reagents

	Test Item	Sample Type	Sample Volume	Reaction Time	Measuring Range	Qualification
Diabetes	HbA1c	WB/Fingerstick blood	10 μL	10 mins	4 % - 14 %	CE
Inflammation	CRP	WB/S/P/Fingerstick blood	10 μL	3 mins	0.5 - 150 mg/L	CE
Vitamin	25-OH Vit-D	WB/S/P/Fingerstick blood	10 μL	10 mins	5 - 100 ng/mL	CE
Anemia	FER	WB/S/P/Fingerstick blood	10 μL	10 mins	5 - 1500 ng/mL	CE
Hormone	Cortisol	WB/S/P/Fingerstick blood	20 μL	10 mins	45-1000 nmol/L	CE
Allergy	Total IgE	WB/S/P/Fingerstick blood	10 μL	10 mins	0.75-2000 IU/mL	CE

*Under development: PCT, TSH, FSH, β-HCG, cTnI, CK-MB, D-Dimer, HP-Ab

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FA 50

Quantitative Immunoassay Analyzer

EXCEEDINQUALITYANDMORE

Fluorescence Immunoassay System

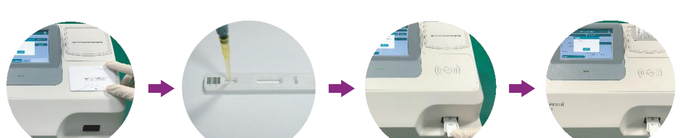
Main Advantages of FA Platform

- CE, U.S.FDA , NGSP certified
- Accurate results based on TRFIA methodology
- Consistent sample volume (10/100 μL), easy to operate
- Self-developed analyzer and reagents for wide applications

Incubator (optional)

Provides better temperature control for incubation >

Test procedure



Magnetic card calibration | Pipette sample | Insert cassette | Result

Analyzer

Time-Resolved Fluorescence Immunoassay

Longer fluorescence lifetime
Larger strokes shift
Higher fluorescence specificity

Intelligent Software

Internal timer for batch tests
Internal temperature monitor
>11 languages available
2 test modes: standard & fast mode

Easy Operation

1 step easy calibration by reading card

Maintenance-free

Non-liquid system, zero maintenance

Powerful Functionality

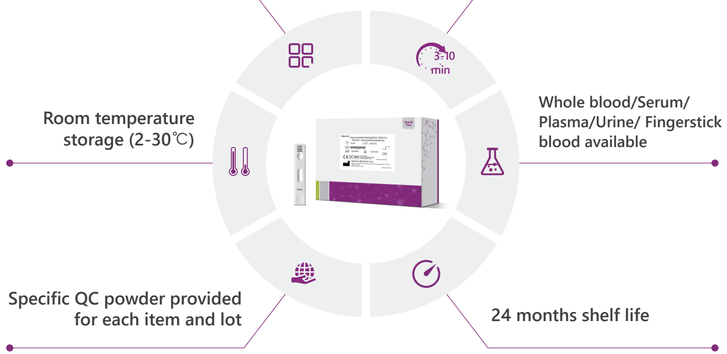
2 USB ports, Ethernet, LIS connection
5-inch LCD touch screen on Linux system
L-J graph available
Built-in or external printer

Application

Laboratory | Clinics | Ambulance | ER | ICU&CCU

CCU | Outpatient Departments | Endocrinology Department | Infection Control Center

Reagent



Overall Product Solution

FA20

Handheld Dry Fluorescence Immunoassay Analyzer

FA50

Quantitative Immunoassay Analyzer

FA30

Quantitative Immunoassay Analyzer

FA50 Specification V2.4-20240604

Item		Descriptions
General	Principle	Immunofluorescent, quantitative, TRFIA (Time-resolved fluorescence immunoassay)
	Parameters	HbA1c, CK-MB, cTnI, Myo, hs-CRP, PCT, NT-proBNP, CK-MB/Myo/cTnI, D-Dimer, T3, T4, TSH, FT3, FT4, β-HCG, PRL, LH, FSH, PROG, AMH, TESTO, PCT, CRP, 25-OH-VitD, FER, AFP, CEA, PSA,
	Light source	LED light 365 ± 10nm (＞1000 h continuous working)
	Calibration	Magnetic card auto calibration
	LIS	Support LIS
	Language	Chinese, English, Persian, German,Spanish, Portuguese,French, Italian, Russian, Ukrainian,Bahasa Indonesia and
Test	Incubation time	3-10min
	Measurement time	15sec
	Sample volume	100 μL
	Test mode	Standard and Fast mode
Specifications	Input	5.0-inch touch screen,
	Output	Internal thermal printer, support auto print, manual print
	Display	5.0-inch touch screen
	Printer paper	57×35mm
	Interface	Network port, 2 USB
	Result storage	50,000 results
	Dimension	300mm (length) x270mm (width) x160mm (height)
	Net weight	4KG
Others	Transportation and storage	-10℃ to +55℃, relative humidity ≤93% (packaged)
	Work temperature	10-30°C
	Power requirement	100~240 AC, 50/60Hz
	Power	≤50VA
	Relative humidity	≤70%
	Atmospheric pressure	70.0kPa-106.0kPa

Instructions for Cardiac Troponin T (cTnT) Test Kit (Immunofluorescence)

1. PRODUCT NAME

Generic name: Cardiac Troponin T (cTnT) Test Kit (Immunofluorescence)

Trade name: cTnT

2. PACKAGE

Specification 1: 25T/kit REF: 52026234

Specification 2: 50T/kit REF: 52027135

Quality Control (optional):

Level 1: 0.5mL × 1 REF: 52105149

Level 2: 0.5mL × 1 REF: 52105150

Level 3: 0.5mL × 1 REF: 52105151

3. INTENDED USE & INDICATION

For in vitro quantitative determination of cTnT level in human serum, plasma or whole blood. It is mainly used in clinical auxiliary diagnosis of myocardial infarction.

For professional use only.

4. TEST PRINCIPLE

When the test sample is added to the sample port on the test card, cTnT in the sample combines with mouse anti-cTnT monoclonal antibody which is coupled to fluorescent particles to form fluorescent particles - antibody - antigen complexes. This immune complex reaches the test area (T) along the nitrocellulose membrane and combines with the pre-coated mouse anti-cTnT monoclonal antibody, its fluorescence intensity is directly proportional to the cTnT level in the sample, the remaining antibody coupled with fluorescent particles reaches the quality control area (C) and binestopre-coated rabbit IgG. If the sample does not contain cTnT, the test area (T) will not appear fluorescence.

5. MAIN COMPONENTS & ADDITIONAL REQUIRED EQUIPMENT

The test kit consists of test card, magcard, sample diluent, quality control (optional) and the instruction.

(1) The test card consists of card shell and test strip. The test strip contains sample pad, glass fiber, nitrocellulose membrane, absorbent paper and PVC plate.

(2) Magcard: load calibration curve information for this batch of reagents.

(3) Sample diluent: the main ingredient is phosphate buffered saline (PBS). See label for sample diluent volume.

(4) Quality control (optional): Self-prepared lyophilized powders, mainly consist of cTnT recombinant antigen and PBS. All are free of human-derived substances and have batch specificity. Please find target values in the target value list.

(5) Equipment: applicable to FA20/FA30/FA50/FA120 Quantitative Immunoassay Analyzer manufactured by Genrui Biotech Inc.

Note: Components of kits from different batches should not be used interchangeably.

6. ACCESSORIES REQUIRED BUT NOT PROVIDED

(1) Pipettes and pipette tips: 100 μL

(2) Timer

7. SPECIAL STORAGE & TRANSPORT CONDITIONS

(1) The test kit should be stored at 2-30℃, and the shelf life of test cards and sample diluent is 24 months when sealed. After the test card and sample diluent are opened, the shelf life is 1 hour at 18-30℃ and 40%-65% humidity. When the humidity is > 65%, it should be used right after opened.

(2) The unopened QC is stable for 24 months (see the label for specific date) at -25℃ to 8℃, the reconstituted QC is stable for 6 days at -20℃ or 6 days at 2-8℃ in the shade, and can be freeze-thawed once.

(3) Transport: The test kit is at 2-30℃, the QC is at -25℃-8℃.

8. SAMPLE REQUIREMENTS

(1) The optimal sample is fresh non-hemolyzed serum, plasma or whole blood. It is recommended to use sample from venous blood, as results of other body fluids and samples may not be accurate.

(2) Serum/plasma: After sample is collected, serum should be separated as soon as possible to avoid hemolysis. The test with serum or plasma sample should be completed within 24 hours at room temperature. The sample is stable for 7 days if stored at 2-8℃ and is stable for 1 month if frozen below -18℃.

(3) Whole blood: It should be used immediately after collection. If it cannot be tested within 24 hours, it should be refrigerated at 2-8℃ for no more than 3 days. Samples should not be frozen.

(4) The samples should be brought to room temperature before determination. The frozen samples should be completely thawed, rewarmed and mixed well before use. Do not freeze and thaw repeatedly.

(5) Human serum is preferred for determination, and EDTA is recommended as an anticoagulant for plasma and whole blood testing.

9. TEST METHOD

Carefully read the instruction before using the test kit and strictly follow the instruction to ensure reliable results. Bring all reagents to room temperature (18-30℃) before use.

(1) Calibration procedure: Place magcard of the corresponding item to the magnetic card reader area, when the magcard is read successfully, check whether the magcard and the test card are of the same batch. (Note: reagents are precalibrated and specific calibration curve parameters for each batch of reagents have been stored in the magcard.)

(2) Quality control procedure: It is recommended to refer to the instrument manual and use the Genrui quality control to verify whether the target value of the test quality control is under control during the measurement procedure after calibration. The quality controls should be used as follows.

a）Bring the quality control to room temperature (18-30°C) before use.

b）Carefully open the bottle cap to avoid spraying of the contents.

c）Add 0.5 mL of purified water.

d）Put on the bottle cap and leave it at room temperature for 15 minutes, gently shake the bottle to fully dissolve the dry powder.

e）After the dry powder is fully dissolved, repeat the operation for the sampling.

If the measured values of quality controls are within the given range of target values, the determination of clinical samples and data analysis can be continued; otherwise, the causes should be identified before test.

(3) Sampling:

Add 0.1mL of serum, plasma or whole blood into the container with sample diluent, mix thoroughly (pipette 10 times or mix manually 15 times). Take 0.1mL of diluted sample, and drop it vertically to the sample well on the test card directly and start timing.

(4) Testing:

There are two test modes for Genrui FIA System, Standard Test mode and Fast Test mode.

a) For Standard Test mode: Insert it into the analyzer's test card slot (the sample well end towards the inside) after adding sample mixture to the sample well. Press "STD Mode" to start testing.

b) For Fast Test mode: Set the timer and count down right after adding sample mixture into the sample well and leave it at room temperature for 10 minutes. Insert it into the analyzer's test card slot (the sample well end towards the inside). Press "Fast Mode" to start testing.

(5) Then instantly the instrument will detect and print out the results.

Note: For detailed instructions on how to operate the instrument, please refer to the manual of Quantitative Immunoassay Analyzer.

10. REFERENCE RANGE

Reference range: <0.1 ng/mL

Note: Due to geographical, ethnic, gender and age differences, it is recommended that each laboratory establishes its own reference range.

11. EXPLANATION FOR TEST RESULTS

(1) When the control area (C) appear fluorescent strips, the analyzer will automatically detect the fluorescence and analyze the test card, and then provide quantitative results.

(2) When no fluorescent strips appear in the control area (C), the analyzer cannot detect the fluorescence and alarm will be activated automatically, indicating that the operation is incorrect or the test card is damaged. In this case, carefully read the instructions again and re-test with a new test card, if the problem still exists, immediately stop using products of this batch and contact your supplier.

(3) When the measured value of the sample is higher than 10 ng/mL, the instrument shows > 10 ng/mL, and when the measured value of the sample is less than 0.02 ng/mL, the instrument shows < 0.02 ng/mL.

(4) This test kit does not produce Hook Effect within 100 ng/mL.

12. DETECTION LIMIT

(1) This test kit is for in vitro diagnostic use only.

(2) Diagnosis and treatment can not solely base on this test result, please take into account the clinical history and other laboratory test results. Each laboratory is recommended to establish its own reference range based on its patient population.

13. INTERFERING SUBSTANCE

(1) When hemoglobin is < 2.0 g/dL, triglyceride < 5000 mg/dL, cholesterol < 1000 mg/dL, bilirubin < 66 mg/dL, rheumatoid factor (RF) < 1000 IU/mL, total protein < 500 g/L and HAMA < 1000 ng/mL in the sample, there shall be no interference on the test value of reagent.

14. PRODUCT PERFORMANCE INDICATORS

(1) Analysis sensitivity: ≤ 0.02 ng/ mL

(2) Linearity range: 0.02-10 ng/ mL (Linear correlation coefficient: r ≥ 0.9900)

(3) Precision: intra-batch precision: CV ≤ 15%; inter-batch precision of the kit CV ≤ 15%

(4) Accuracy: -15% ≤ Bias% ≤ +15%

(5) Specificity: the interference test: -15%≤Bias% ≤+15%

(6) QC precision: CV ≤ 15%

(7) Expected results of QC: the test results shall be within the target range

15. PRECAUTIONS

(1) Once opened, use the test cards as soon as possible, which may be exposed to moisture in the air. Do not reuse the test cards.

(2) Components in test kit of different batches cannot be used interchangeably.

(3) For substances containing sources of infection or suspected of containing sources of infection, there should have proper biosafety assurance procedures. Pay attention to the following notes:

-- Wear gloves when handling sample or disinfecting the reagent.

-- Disinfect spilled sample or reagent with disinfectant.

-- Disinfect or handle potential contamination sources of all samples or reagents in accordance with local regulations.

16. EXPLANATION OF GRAPHIC SYMBOL

	Consult instructions for use		Temperature limit
LOT	Batch code		Use-by date
IVD	*In vitro* diagnostic medical device	CE	CE Marking
	Date of manufacture		Volume
	Manufacturer		Keep away from sunlight
Σ	Contains sufficient for < n>tests		Keep dry
EC REP	Authorized representative in the European community	REF	Catalogue number

17. Reference

1.Katus H , Borgya A , Hallermayer K , et al. Specific antibodies to troponin T, their production and use in a reagent for the determination of myocardial necrosis: US, US6376206 B1[P]. 2002.

2. Katus H A , Remppis A , Looser S , et al. Enzyme linked immuno assay of cardiac troponin T for the detection of acute myocardial infarction in patients[J]. Journal of Molecular & Cellular Cardiology, 1989, 21(12):1349-1353.

3.Katus H A , Scheffold T , Remppis A , et al. Proteins of the Troponin Complex[J]. Laboratory Medicine, 1992, 23(5):311-317.

18. METROLOGICAL TRACEABILITY

The kit is traceable to the Elecsys Troponin T hs assay, produced by Roche Diagnostic GmbH.

19. Help Information

If you need help, please contact after sales department.

20. INSTRUMENTS & APPLICATIONS

Genrui's Immunofluorescence products are designed to work in automated lab, which are compatible with the FA20/FA30/FA50/FA120 Quantitative Immunoassay Analyzer. There may or may not be an application developed for your particular instrument, please visit the instrument section of our website.

21. MANUFACTURER

Genrui Biotech Inc.

Address: 4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China.

Web: www.genrui-bio.com

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Carrer de Tapioles, 33, 2-1,
08004, Barcelona, Spain
E-mail : rep@themedunion.com

Genrui

Declaration of Conformity

Certificate No.: EU2024011

Manufacturer:

Genrui Biotech Inc.

4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China.

Tel: +86 755 26835560 Fax: +86 755 26678789

Product Name:

See attachment

Model:

See attachment

Classification:

Others device, not in annex II and not for self-testing, not for performance evaluation.

Conformity Assessment Route:

IVDD 98/79/EC Annex III (excludes section 6)

We here with declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices.

General Applicable Directive:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Standards Applied:

EN ISO 13485:2016	EN 13612:2002	EN ISO 14971:2012	EN ISO 18113-1:2011
EN 62304:2006	EN 61326-2-6:2013	EN 61010-2-101:2002	EN 61326-1:2013
EN 62366:2008	EN ISO 15223-1:2016	EN 61010-1:2010	EN ISO 18113-3:2011

CE

Place, Date of Issue: Shenzhen, January. 14th, 2022

Position Held in Company Management Representative

Signature:Li Yiping

Genrui

Declaration of Conformity

Certificate No.: EU2024011

Attachment :

Product Name:
Quantitative Immunoassay Analyzer

Model:
FA50

Including reagents as following:

No.	Kit name	Quality Control name
1	D-Dimer test kit (Immunofluorescence)	D-Dimer Quality Control
2	Glycosylated Hemoglobin (HbAlc) Test Kit (Immunofluorescence)	Glycosylated Hemoglobin (HbAlc) Quality Control
3	β-Human Chorionic Gonadotropin (β-HCG) Test Kit(Immunofluorescence)	β-Human Chorionic Gonadotropin (β-HCG) Quality Control
4	High Sensitive C-Reactive Protein(hs-CRP) Test Kit(Immunofluorescence)	High Sensitive C-Reactive Protein (hs-CRP) Quality Control
5	cTnI/CK-MB/Myo (Cardiac panel) Test Kit (Immunofluorescence)	cTnI/CK-MB/Myo (Cardiac panel) Quality Control
6	N-terminal Pro-brain Natriuretic Peptide (NT-proBNP) Test Kit(Immunofluorescence)	N-terminal Pro-brain Natriuretic Peptide (NT-proBNP) Quality Control
7	Myoglobin (Myo) Test Kit (Immunofluorescence)	Myoglobin (Myo) Quality Control
8	Procalcitonin (PCT) Test Kit (Immunofluorescence)	Procalcitonin (PCT) Quality Control
9	Cardiac Troponin I (cTnI) Test Kit (Immunofluorescence)	Cardiac Troponin I (cTnI) Quality Control
10	CK-MB(CK-MB) Test Kit (Immunofluorescence)	CK-MB (CK-MB) Quality Control
11	Interleukin 6 (IL-6) Test Kit	Interleukin 6 (IL-6) Quality Control

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Declaration of Conformity

Certificate No.: EU2024011

	(Immunofluorescence)	
12	C-Reactive Protein (CRP) Test Kit (Immunofluorescence)	C-Reactive Protein (CRP) Quality Control
13	Triiodothyronine (T3) Test Kit (Immunofluorescence)	Triiodothyronine (T3) Quality Control
14	Thyroxine (T4) Test Kit (Immunofluorescence)	Thyroxine (T4) Quality Control
15	Free Triiodothyronine (FT3) Test Kit (Immunofluorescence)	Free Triiodothyronine (FT3) Quality Control
16	Free Thyroxine (FT4) Test Kit (Immunofluorescence)	Free Thyroxine (FT4) Quality Control
17	Alpha Fetoprotein (AFP) Test Kit (Immunofluorescence)	Alpha Fetoprotein (AFP) Quality Control
18	Carcinoembryonic Antigen (CEA) Test Kit (Immunofluorescence)	Carcinoembryonic Antigen (CEA) Quality Control
19	Thyroid Stimulating Hormone (TSH) Test Kit (Immunofluorescence)	Thyroid Stimulating Hormone (TSH) Quality Control
20	CA19-9 Test Kit (Immunofluorescence)	CA19-9 Quality Control
21	CA125 Test Kit (Immunofluorescence)	CA125 Quality Control
22	Dengue NS1 Antigen Test Kit (Immunofluorescence)	Dengue NS1 Antigen Quality Control
23	Malaria Pf/Pv Antigen Test Kit (Immunofluorescence)	Malaria Pf/Pv Antigen Quality Control
24	Serum Amyloid A (SAA) Test Kit (Immunofluorescence)	Serum Amyloid A (SAA) Quality Control
25	Tuberculosis IgG (TB-IgG) Test Kit (Immunofluorescence)	Tuberculosis IgG (TB-IgG) Quality Control
26	Tuberculosis IgM (TB-IgM) Test Kit (Immunofluorescence)	Tuberculosis IgM (TB-IgM) Quality Control
27	Ferritin (FER) Test Kit (Immunofluorescence)	Ferritin (FER) Quality Control
28	Follicle Stimulating Hormone (FSH) Test Kit (Immunofluorescence)	Follicle Stimulating Hormone (FSH) Quality Control
29	Luteinizing Hormone (LH)Test Kit (Immunofluorescence)	Luteinizing Hormone (LH) Quality Control

Genrui

Declaration of Conformity

Certificate No.: EU2024011

30	Prolactin (PRL) Test Kit (Immunofluorescence)	Prolactin (PRL) Quality Control
31	Anti-Müllerian Hormone (AMH) Test Kit (Immunofluorescence)	Anti-Müllerian Hormone (AMH) Quality Control
32	Progesterone (Prog) Test Kit (Immunofluorescence)	Progesterone (Prog) Quality Control
33	Testosterone (Testo) Test Kit (Immunofluorescence)	Testosterone (Testo) Quality Control
34	25-OH Vitamin D (25-OH Vit-D) Test Kit (Immunofluorescence)	25-OH Vitamin D (25-OH Vit-D) Quality Control
35	Prostate Specific Antigen (PSA) Test Kit (Immunofluorescence)	Prostate Specific Antigen (PSA) Quality Control
36	Free Prostate Specific Antigen (f-PSA) Test Kit (Immunofluorescence)	Free Prostate Specific Antigen (f-PSA) Quality Control
37	Cystatin C (Cys-C) Test Kit (Immunofluorescence)	Cystatin C (Cys-C) Quality Control
38	Cardiac Troponin T (cTnT) Test Kit (Immunofluorescence)	Cardiac Troponin T (cTnT) Quality Control
39	CA15-3 Test Kit (Immunofluorescence)	CA15-3 Quality Control
40	Microalbumin (MALB) Test Kit (Immunofluorescence)	Microalbumin (MALB) Quality Control
41	Neutrophil Gelatinase-Associated Lipocalin (NGAL) Test Kit (Immunofluorescence)	Neutrophil Gelatinase-Associated Lipocalin (NGAL) Quality Control
42	β2-Microglobulin (β2-MG) Test Kit (Immunofluorescence)	β 2-Microglobulin (β 2-MG) Quality Control
43	Cortisol Test Kit (Immunofluorescence)	Cortisol Quality Control
44	Total Immunoglobulin E (Total IgE) Test Kit (Immunofluorescence)	Total Immunoglobulin E (Total IgE) Quality Control
45	Estradiol (E2) Test Kit (Immunofluorescence)	Estradiol (E2) Quality Control
46	Vitamin B12 (VB12) Test Kit (Immunofluorescence)	Vitamin B12 (VB12) Quality Control
47	Folate Test Kit (Immunofluorescence)	Folate Quality Control

N/REF: PS/RPS/2722/2024

O F I C I O

Comunicación: RPS/2722/2024
Nº AEMPS: 24-04072
Fecha: 27/09/2024
Asunto: **Anotación de la comunicación en el Registro de Responsables de la puesta en el mercado de Productos Sanitarios**

Medunion S.L.
CALLE TAPIOLES, 33, 2- 1,
08004 - Barcelona
BARCELONA
Cataluña

Con fecha **27/09/2024** ha sido **registrada** en la aplicación de Registro de Responsables de la puesta de mercado de Productos Sanitarios (RPS) de la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) la comunicación presentada por **Medunion S.L.**, con la siguiente información:

1. Número de identificación asignado en el registro

RPS/2722/2024

2. Responsable de la puesta en el mercado de los productos sanitarios

Empresa **Medunion S.L.**
CALLE TAPIOLES, 33, 2- 1,
08004 - Barcelona (BARCELONA)
Cataluña

En calidad de **Representante**

3. Legislación que declara cumplir:

DIV - Directiva 98/79/EC.

4. Página(s) adicional(es) de productos sanitarios incluidos en esta comunicación.

REGISTRO DE RESPONSABLES DE LA PUESTA EN EL MERCADO DE PRODUCTOS SANITARIOS
DEPARTAMENTO DE PRODUCTOS SANITARIOS

Nota.- Esta notificación no tiene el carácter de una autorización sanitaria de comercialización, ni entraña un juicio sobre la conformidad del producto con la legislación vigente.Únicamente avala el cumplimiento del Registro de Responsables según el artículo 9 del RD 1662/2000 por el que se regulan los Productos Sanitarios para Diagnóstico in vitro.

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ANEXO: PRODUCTOS SANITARIOS COMUNICADOS POR EL RESPONSABLE

Nombre comercial Tipo de producto	**Fecha de introducción en el mercado** Finalidad
1 - KT-3D Hematology Control (Impedance method) PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/10/2024 Es aplicable al control de calidad de WBC, RBC, HGB, MCV, HCT y PLT de los analizadores hematológicos automáticos de Genrui Biotech Inc. para monitorear y evaluar la precisión de los resultados de detección.

Fabricante	**Pais**
Genrui Biotech Inc.	REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

Nombre comercial Tipo de producto	**Fecha de introducción en el mercado** Finalidad
2 - KT-5D Hematology Control (Optical method) PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/10/2024 Es aplicable al control de calidad de WBC, RBC, HGB, MCV, HCT y PLT de los analizadores hematológicos automáticos de Genrui Biotech Inc. para monitorear y evaluar la precisión de los resultados de detección.

Fabricante	**Pais**
Genrui Biotech Inc.	REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

Nombre comercial Tipo de producto	**Fecha de introducción en el mercado** Finalidad
3 - KT-CAL Hematology Calibrator (Optical method) PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/10/2024 La calibración de los parámetros WBC, RBC, HGB, MCV, HCT y PLT para los analizadores hematológicos automáticos de Genrui Biotech Inc. establece la trazabilidad econométrica de los resultados de las mediciones del analizador de células sanguíneas.

Fabricante	**Pais**
Genrui Biotech Inc.	REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

Nombre comercial Tipo de producto	**Fecha de introducción en el mercado** Finalidad
4 - Cortisol Test Kit (Immunofluorescence) PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/10/2024 El inmunoensayo se utiliza para la determinación cuantitativa in vitro de cortisol en suero, plasma, sangre total y sangre capilar humanos. La determinación de cortisol se utiliza para el reconocimiento y tratamiento de trastornos funcionales de la glándula suprarrenal. Solo para uso profesional.

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ANEXO: PRODUCTOS SANITARIOS COMUNICADOS POR EL RESPONSABLE

Nombre comercial Tipo de producto	**Fecha de introducción en el mercado** Finalidad
5 - Estradiol (E2) Test Kit (Immunofluorescence) PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/10/2024 El inmunoensayo se utiliza para la determinación cuantitativa in vitro de E2 en suero, plasma y sangre entera humanos. Se utiliza principalmente para ayudar en el diagnóstico de enfermedades ováricas. Solo para uso profesional.

Fabricante	**Pais**
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6 - Folate Test Kit (Immunofluorescence) PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/10/2024 El inmunoensayo se utiliza para la determinación cuantitativa in vitro de folato en suero y plasma humanos. La determinación de folato se utiliza para el reconocimiento y tratamiento de la anemia megaloblástica. Solo para uso profesional.

Fabricante	**Pais**
Genrui Biotech Inc.	REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

7 - Total Immunoglobulin E (Total IgE) Test Kit (Immunofluorescence) PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/10/2024 Inmunoensayo para la determinación cuantitativa in vitro de IgE en suero, plasma, sangre total y sangre capilar humanos. La determinación de IgE se utiliza para el diagnóstico de enfermedades alérgicas. Solo para uso profesional.

Fabricante	**Pais**
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8 - Vitamin B12 (VB12) Test Kit (Immunofluorescence) PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/10/2024 El inmunoensayo se utiliza para la determinación cuantitativa in vitro de vitamina B12 en suero, plasma y sangre total humanos. La determinación de vitamina B12 se utiliza para el reconocimiento y tratamiento de la anemia megaloblástica. Solo para uso profesional.

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Nombre comercial Tipo de producto	**Fecha de introducción en el mercado** Finalidad

Fabricante	**Pais**
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9 - CA15-3 Test Kit (Immunofluorescence)

PARA DIAGNÓSTICO "IN VITRO"
Autocertificación

30/10/2024
Para la determinación cuantitativa in vitro del nivel de CA15-3 en suero, plasma y sangre total humanos. Se utiliza principalmente en el diagnóstico clínico auxiliar del cáncer de mama.
Solo para uso profesional.

Fabricante	**Pais**
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10 - Cardiac Troponin T (cTnT) Test Kit (Immunofluorescence)

PARA DIAGNÓSTICO "IN VITRO"
Autocertificación

30/10/2024
Para la determinación cuantitativa in vitro del nivel de cTnT en suero, plasma o sangre
total humana. Se utiliza principalmente en el diagnóstico clínico auxiliar del infarto de miocardio. Solo para uso profesional.

Fabricante	**Pais**
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11 - Cystatin C (Cys-C) Test Kit (Immunofluorescence)

PARA DIAGNÓSTICO "IN VITRO"
Autocertificación

30/10/2024
Para la determinación cuantitativa in vitro del nivel de Cys-C en suero, plasma u orina humana. La determinación de Cys-C se utiliza para el reconocimiento y tratamiento de trastornos funcionales del riñón. Solo para uso profesional.

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ANEXO: PRODUCTOS SANITARIOS COMUNICADOS POR EL RESPONSABLE

Nombre comercial Tipo de producto	**Fecha de introducción en el mercado** Finalidad
12 - Microalbumin (MALB) Test Kit (Immunofluorescence) PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/10/2024 Para la determinación cuantitativa in vitro de MALB en orina. La determinación de MALB se utiliza para la detección y el tratamiento de pacientes con riesgo de enfermedad renal. Solo para uso profesional.

Fabricante	**Pais**
Genrui Biotech Inc.	REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

Nombre comercial Tipo de producto	**Fecha de introducción en el mercado** Finalidad
13 - Neutrophil Gelatinase-Associated Lipocalin (NGAL) Test Kit (Immunofluorescence) PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/10/2024 Para la determinación cuantitativa in vitro del nivel de NGAL en orina humana. La determinación de NGAL se utiliza para el reconocimiento y tratamiento de trastornos funcionales del riñón. Solo para uso profesional.

Fabricante	**Pais**
Genrui Biotech Inc.	REPÚBLICA POPULAR CHINA / PEOPLE'S REPUBLIC OF CHINA

Nombre comercial Tipo de producto	**Fecha de introducción en el mercado** Finalidad
14 - Beta 2-Microglobulin (Beta 2-MG) Test Kit (Immunofluorescence) PARA DIAGNÓSTICO "IN VITRO" Autocertificación	30/10/2024 Para la determinación cuantitativa in vitro de Beta 2-MG en suero, plasma u orina humanos. La determinación de Beta 2-MG se utiliza para el reconocimiento y tratamiento de trastornos funcionales del riñón. Solo para uso profesional.

Fabricante	**Pais**
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