Test Items:

Category	Test Item	Specimen Type	Sample Volume	Reaction Time	Measuring Range
Diabetes	HbA1c	WB	5μL	15min	3.0-14.0%
Inflammation	CRP	S/P/WB	5μL	3min	0.5-200μg/mL
	PCT	S/P/WB	100μL	10min	0.1-50ng/mL
	SAA	S/P/WB	5μL	15min	2.0-300μg/mL
Cardiac	CK-MB	S/P/WB	100μL	10min	2.0-80ng/mL
	cTnI	S/P/WB	100μL	10min	0.05-40ng/mL
	Myo	S/P/WB	100μL	10min	20-500ng/mL
	NT-proBNP	S/P/WB	100μL	15min	50-25000pg/mL
	D-Dimer	P/WB	100μL	10min	0.1-10μg/mL
	H-FABP	S/P/WB	100μL	15min	1-120ng/mL
Hormone	T3	S/P/WB	100μL	15min	0.5-10nmol/L
	T4	S/P/WB	100μL	10min	10-350nmol/L
	TSH	S/P/WB	100μL	15min	0.1-60μIU/mL
	25-OH-VD	S/P	100μL	10min	5-70ng/mL
	β-HCG	S/P/WB	50μL	15min	2-20000mIU/mL
	LH	S/P/WB	100μL	15min	5-200mIU/mL
	FSH	S/P/WB	100μL	10min	1-150mIU/mL
	GH	S/P/WB	100μL	10min	0.05-100ng/mL
	PRL	S/P/WB	100μL	10min	1-100ng/mL
	AMH	S/P/WB	100μL	10min	0.1-50ng/mL
Gastric Function	PGI	S/P/WB	100μL	10min	10-60ng/mL
	PGII	S/P/WB	100μL	10min	5-100ng/mL
	G-17	S/P/WB	100μL	10min	5-300ng/mL
Renal Function	NGAL	S/P/WB/Urine	100μL	10min	50-5000ng/mL
	mAlb	Urine	100μL	5min	10-200mg/L
	β2-MG	S/P/WB	10μL	10min	0.5-20mg/L
	Cys-C	S/P/WB	10μL	5min	0.5-10ng/L
Tumor	PSA	S/P/WB	100μL	10min	0.1-100ng/mL

New items are available soon!

LS-1100

Dry Fluorescence Immunoassay Analyzer (Portable)

Accurate, Anytime and Anywhere

Digitally signed by Poiata Vitalie
Date: 2023.05.29 16:50:13 EEST
Reason: MoldSign Signature
Location: Moldova

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CE IVD

Lansion Biotechnology Co., Ltd.

LS-1100 Dry Fluorescence Immunoassay Analyzer (Portable)

Analyzer Introduction:

LS-1100 uses the advanced method of Time-resolved Fluorescence Immunoassay (TRFIA), for the in-vitro quantitative detection of bio-markers for Diabetes Mellitus, Inflammation, Cardiovascular Diseases, Hormone, Gastric Diseases, Renal Diseases, Tumor, etc.

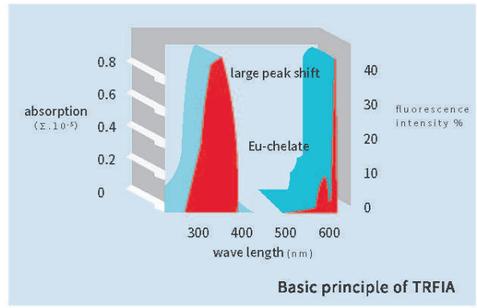
Application: Laboratory, ER, Cardiology, ICU, Respiratory, Pediatrics, etc.

Features:

Quantitative, Rapid and High Sensitive
Reliable Result (QC system, QR code calibration)

Method	Time-resolved Fluorescence Immunoassay (TRFIA)
Specimen	Serum/Plasma/Whole Blood/Urine
Weight	1.3kg
Dimensions	225mm×152mm×105mm (L×W×H)
Screen	7 inch touch screen
Data Storage	⩾5000
Printer	Built-in thermal printer
Battery	Built-in lithium battery (super standby time)
Communication	RS232(LIS/HIS), RJ45, USB, WIFI, Bluetooth

Time-resolved Fluorescence Immunoassay (TRFIA) Method:



Basic principle of TRFIA

TRFIA is super-sensitive detection technique characterized by specific fluorescence of rare earth ions. It is not only highly sensitive, but also overcomes the instability of enzyme marker and is the best choice for immunological detection. The high fluorescence intensity and long life of labeled ionic chelates are beneficial to eliminate the influence of fluorescent substances in samples and environment on the test results.

Easy Operation:

QR Code Calibration

Information Input

Sample Dispense

Automatic Detection

Result Output

PSA Test Kit User Manual

(Dry Fluorescence Immunoassay)

[PRODUCT NAME]

PSA Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

1 test/kit
5 tests/kit
25 tests/kit
50 tests/kit
100 tests/kit

[INTENDED USE]

PSA Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro quantitative measurement of PSA (Prostate Specific Antigen) in human serum and plasma. This test is used as an important indicator for monitoring the change of the condition of prostate cancer and observation of the curative effect.

[TEST PRINCIPLE]

PSA Test Kit (Dry Fluorescence Immunoassay) uses the principle of antigen-antibody reaction. The testing sample will migrate forward due to capillary action, then the PSA of the sample will combine with antibody which is attached to fluorescence microspheres. This marked complex is attached to the detection area of immobilized antibody and the other fluorescence microspheres are attached to the control area.

When the test strip is inserted into the analyzer, the analyzer automatically scans two ribbons and detected the fluorescence intensity of the composite emission from the testing area and the control area. The ratio of the two fluorescence values was used to calculate the content of the detected substances.

[MAIN COMPONENTS]

1. PSA test strip in a sealed pouch with desiccant.....25 tests
2. QR code card for calibration.....1 piece
3. User Manual.....1 piece
4. Quantitative suction and dropping tube (Optional).

Note: Do not mix or interchange different batches of kit.

[STORAGE AND VALIDITY]

Store the test kit at 4°C-30°C, with a valid period of 18 months.

Test strip should be used within 30 minutes once the foil pouch is opened.

[APPLICABLE DEVICES]

1. FIC-S100 Dry Fluorescence Immunoassay Analyzer
2. LS-1000 Dry Fluorescence Immunoassay Analyzer
3. LS-2000 Dry Fluorescence Immunoassay Analyzer
4. LS-1100 Dry Fluorescence Immunoassay Analyzer
5. LS-2100 Dry Fluorescence Immunoassay Analyzer
6. LS-4000 Hand-Held Dry Fluorescence Immunoassay Analyzer
7. LS-7000 Microfluidic and Dry Fluorescence Immunoassay Analyzer

[SAMPLE REQUIREMENT]

1. Used for human **serum and plasma**. Other bodily fluids and samples may not get the accurate result.
2. Plasma can be anticoagulant with heparin and sodium citrate under aseptic conditions.
3. At room temperature, the test should be performed within 4 hours after the sample collection.
4. Serum or plasma sample can be stored at 2°C-8°C for 3 days at most. If more than 3 days, it should be stored at -20°C. It is suggested to use fresh sample to test. Stale blood sample may not get accurate result.
5. The sample before testing should be recovered to room temperature (15°C-30°C).
6. **Sample Volume: 100μL**

[TEST PROCEDURE]

1. Collect samples according to user manual.
2. Before the test, the sample and test strip should be recovered to room temperature (15°C-30°C).

For LS-1100

3. Perform QR code calibration when necessary. (Details refer to LS-1100 User Manual)
4. On the main interface of LS-1100, press "Test" icon to enter testing interface. Input patient information, sample information, doctor information when necessary. (Details refer to LS-1100 User Manual)
5. Remove test strip from sealed pouch and put it on a clean table, horizontally placed.
6. Using pipette to drop 100μL sample into the sample port in the test strip.
7. **Reaction Time: 10 minutes**

For panel inside: Insert the test strip into the analyzer immediately after sample dispensing. Then click "Test".

For panel outside: After reaction time 10 minutes is elapsed, insert the test strip into the analyzer and then click "Test".

8. The result will be shown on the screen and printed automatically.

Notes: It is required to perform QR code calibration when starting to use one new batch of kit.

[EXPECTED VALUE]

Cut-Off Value: 10.0ng/mL

The cut-off value for PSA was determined by testing samples from 500 apparently healthy individuals. The 97.5th percentile of the concentration for PSA is 10.0ng/mL. According to different statistics method, the probability that value of a normal person below 10.0ng/mL is 97.5%.

It is recommended that each laboratory establish its own reference range for the population it serves.

[INTERPRETATION OF RESULT]

1. If the test result of the sample is more than 100ng/mL, the analyzer displays ">100ng/mL", and if the result is less than 0.1ng/mL, the analyzer displays "<0.1ng/mL". Specific data can be exported through related software as needed.

2. When the sample concentration exceeds the detection limit, the maximum dilution ratio is 3 times when the sample is diluted with calf serum or negative sample.

[LIMITATION]

1. This kit is only for the serum and plasma test.
2. The test result of this kit are only one of the diagnostic aids for the clinicians.
3. The result of the test should be evaluated in the context of all the clinical and laboratory data available. In those instances where the laboratory results do not agree with the clinical evaluation, additional tests should be performed accordingly.

[PRODUCT PERFORMANCE]

1. Measuring Range: 0.1-100ng/mL.
2. Lower Detection Limit: ≤0.1ng/mL.
3. Accuracy: Verify with comparison experiments, the relative deviation ≤15%, the correlation coefficient r≥0.990.
4. Within-Run Precision: ≤15%.
5. Between-Run Precision: ≤15%.
6. Hook Test: No hook effect with high concentration sample. Hook test was conducted with reference material exceeding the upper limit of linear range, and the detection result was greater than the upper limit of detection.

[PRECAUTIONS]

1. Only used for in vitro diagnostics.
2. Do not use the kit beyond the expiration date.
3. After the test strip is removed from the sealed pouch, it should be tested as soon as possible to avoid excessive time in the air, resulting in dampness.
4. Do not reuse the test strip.
5. The damaged test strip or package cannot be used.
6. Do not mix the components of different kits.

[REFERENCES]

1. Brooks DE, Devine DV, Harris PC, et al. RAMP(TM): A rapid, quantitative whole blood immunochromatographic platform for point-of-care testing. Clin Chem. 1999, 45: 1676-1678.
2. Jung K, Elgeti U, Lein M, er al. Ratio of free or Complexed Prostate-specific Antigen to Total PSA: Which Ratio Improves Differentiation between Bengin Prostatic Hyperplasic and Prostate Cancer? Clin Chem. 2000, 46(1): 55-62.
3. Allard WJ, Zhou Z,Yueng KK. Novel immunoassay for the measurement of complexed prostate-specific antigen in serum. Clin, Chem. 1998, 44(6): 1216-1223.

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Revision Date: May 24, 2019

Version Number: 0.1

Production date and expiration see the label.

FSH Test Kit User Manual

(Dry Fluorescence Immunoassay)

[NAME]

FSH Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

1 test/kit
5 tests/kit
20 tests/kit
25 tests/kit
50 tests/kit
100 tests/kit

[INTENDED USE]

FSH Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro quantitative measurement of FSH (Follicle stimulating hormone) in serum. Clinically, it can be used to monitor hypothalamic-pituitary-ovary function, and can also be used as an auxiliary indicator for diseases such as amenorrhea, infertility and polycystic ovary syndrome.

[PRINCIPLE]

FSH Test Kit (Dry Fluorescence Immunoassay) uses the principle of antigen-antibody reaction. The testing sample will migrate forward due to capillary action, then the FSH of the sample will combine with antibody which is attached to fluorescence microspheres. This marked complex is attached to the detection area of immobilized antibody and the other fluorescence microspheres are attached to the control area. When the test strip is inserted into the analyzer, the analyzer automatically scans two ribbons and detected the fluorescence intensity of the composite emission from the testing area and the control area. The ratio of the two fluorescence values was used to calculate the content of the detected substances.

[MAIN COMPONENTS]

1. FSH test strip in a sealed pouch with desiccant.....25 tests
2. QR code card for calibration.....1 piece
3. User Manual.....1 piece
4. Quantitative suction and dropping tube (Optional).

Note: Do not mix or interchange different batches of kit.

[STORAGE AND VALIDITY]

Store the test kit at 4°C-30°C, with a valid period of 18 months.
Test strip should be used within 30 minutes once the foil pouch is opened.

[APPLICABLE DEVICES]

1. LS-1000 Dry Fluorescence Immunoassay Analyzer
2. LS-2000 Dry Fluorescence Immunoassay Analyzer
3. LS-1100 Dry Fluorescence Immunoassay Analyzer
4. LS-2100 Dry Fluorescence Immunoassay Analyzer
5. LS-4000 Hand-Held Dry Fluorescence Immunoassay Analyzer
7. LS-7100 Microfluidic and Dry Fluorescence Immunoassay Analyzer

[SAMPLE REQUIREMENT]

1. Used for human **serum**. Other bodily fluids and samples may not get the accurate result.
2. At room temperature(15°C-30°C), the test should be performed within 4 hours after the sample collection.
3. Serum sample can be stored at 2°C-8°C for 3 days at most. If more than 3 days, it should be stored at -20°C. It is suggested to use fresh sample to test. Stale blood sample may not get accurate result.
4. The sample before testing should be recovered to room temperature (15°C-30°C).
5. Frozen samples should be completely melted, rewarmed and mixed completely before use. Avoid repeated freeze-thaw. It is suggested freeze-thaw of sample should not more than 1 time.
6. **Sample Volume: 100μL**

[TEST PROCEDURE]

1. Collect samples according to user manual.
2. Before the test, the sample and test strip should be recovered to room temperature (15°C-30°C).

For LS-1100

3. Perform QR code calibration when necessary. (Details refer to LS-1100 User Manual)
4. On the main interface of LS-1100, press "Test" icon to enter testing interface. Input patient information, sample information, doctor information when necessary. (Details refer to LS-1100 User Manual)
5. Remove test strip from sealed pouch and put it on a clean table, horizontally placed.
6. Using pipette to drop 100μL sample into the sample port in the test strip.
7. **Reaction Time: 10 minutes**

For panel inside: Insert the test strip into the analyzer immediately after sample dispensing. Then click "Test".
For panel outside: After reaction time 10 minutes is elapsed, insert the test strip into the analyzer and then click "Test".
8. The result will be shown on the screen and printed automatically.

Notes: It is required to perform QR code calibration when starting to use one new batch of kit.

[EXPECTED VALUE]

The following reference interval was obtained after statistical analysis of the confidence interval for the tests of the content of FSH in serum samples of healthy people:

	Stage	Range (mIU/mL)
Mature male		1.25-13.50
Mature female	Follicular phase	2.45-15.55
	Ovulation	5.35-24.80
	Luteal phase	1.65-10.25
	Menopause	24.60-135.75

It is recommended that each laboratory establish its own reference range for the population it serves.

[INTERPRETATION OF RESULT]

1. If the test result of the sample is more than 200mIU/mL, the analyzer displays "> 200mIU/mL", and if the result is less than 0.6mIU/mL, the analyzer displays "< 0.6mIU/mL". Specific data can be exported through related software as needed.
2. When the sample concentration exceeds the detection limit, the maximum dilution ratio is 3 times when the sample is diluted with diluent.

[LIMITATION OF THE PROCEDURE]

1. This test kit is only for the serum test.
2. The test result of this kit are only one of the diagnostic aids for the clinicians.
3. Samples containing interfering substances may affect the test results, and the maximum allowable concentrations are: cholesterol 3mg/ml, bilirubin 2mg/ml, and triglyceride 10mg/ml.

[PRODUCT PERFORMANCE]

1. Measuring Range: 1mIU/mL-200mIU/mL.
2. Lower Detection Limit: ≤0.6mIU/mL.
3. Accuracy: Verify with comparison experiments, the relative deviation ≤15%, the correlation coefficient r≥0.990.
4. Within-Run Precision: ≤15%.
5. Between-Run Precision: ≤15%.

[PRECAUTIONS]

1. This kit is for *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. After the test strip is removed from the sealed pouch, it should be tested as soon as possible to avoid excessive time in the air, resulting in dampness.
4. Do not reuse the test strip.
5. The damaged test strip or package cannot be used.
6. Do not mix components from different kit Lots.

[REFERENCES]

1. Yang Yue. Clinical significance of measuring six sex hormones in woman[J]. Chinese journal of clinicians, 2003, 31(4): 50-51.
2. Johnson MR, Carter G, Grint C, et al. Relationship between ovarian steroids, gonadotropin and relaxin during the menstrual cycle. Acta Endocrinol, 1983, 129(2): 121-125.
3. Carr BR. Disorders of the ovary and female reproductive tract. In Williams Textbook of Endocrinology, 8th edition. Edited by Wilson JD and Foster DW. Philadelphia, PA: WB Saunders Co, 1992, 733-798.
4. Hall JE. Polycystic ovarian disease as a neuroendocrine disorder of the female reproductive axis. In Endocrinology and metabolism Clinics of North America, Neuroendocrinology Ⅱ. Edited by Veldhuis JD. Philadelphia, PA: WB Saunders Co, 1993, 75-92.

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Revision Date: Aug 07, 2020
Version Number: 0.0
Production date and expiration see the label.

LH Test Kit User Manual

(Dry Fluorescence Immunoassay)

[NAME]

LH Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

1 test/kit
5 tests/kit
20 tests/kit
25 tests/kit
50 tests/kit
100 tests/kit

[INTENDED USE]

LH Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro quantitative measurement of luteinizing hormone in serum.
Clinically, it is mainly used to test whether a woman ovulates, screen the causes of infertility or early abortion, and also can be used as the auxiliary diagnosis of premature ovarian failure.

[PRINCIPLE]

LH Test Kit (Dry Fluorescence Immunoassay) uses the principle of antigen-antibody reaction. The testing sample will migrate forward due to capillary action, then the LH of the sample will combine with antibody which is attached to fluorescence microspheres. This marked complex is attached to the detection area of immobilized antibody and the other fluorescence microspheres are attached to the control area.
When the test strip is inserted into the analyzer, the analyzer automatically scans two ribbons and detected the fluorescence intensity of the composite emission from the testing area and the control area. The ratio of the two fluorescence values was used to calculate the content of the detected substances.

[MAIN COMPONENTS]

1. LH test strip in a sealed pouch with desiccant.....25 tests
2. QR code card for calibration.....1 piece
3. User Manual.....1 piece
4. Quantitative suction and dropping tube (Optional).

Note: Do not mix or interchange different batches of kit.

[STORAGE AND VALIDITY]

Store the test kit at 4°C-30°C, with a valid period of 18 months.
Test strip should be used within 30 minutes once the foil pouch is opened.

[APPLICABLE DEVICES]

1. LS-1000 Dry Fluorescence Immunoassay Analyzer
2. LS-2000 Dry Fluorescence Immunoassay Analyzer
3. LS-1100 Dry Fluorescence Immunoassay Analyzer
4. LS-2100 Dry Fluorescence Immunoassay Analyzer
5. LS-4000 Hand-Held Dry Fluorescence Immunoassay Analyzer
6. LS-7100 Microfluidic and Dry Fluorescence Immunoassay Analyzer

[SAMPLE REQUIREMENT]

1. Used for human **serum**. Other bodily fluids and samples may not get the accurate result.
2. At room temperature(15°C-30°C), the test should be performed within 4 hours after the sample collection.
3. Serum sample can be stored at 2°C-8°C for 3 days at most. If more than 3 days, it should be stored at -20°C. It is suggested to use fresh sample to test. Stale blood sample may not get accurate result.
4. The sample before testing should be recovered to room temperature (15°C-30°C).
5. Frozen samples should be completely melted, rewarmed and mixed completely before use. Avoid repeated freeze-thaw. It is suggested freeze-thaw of sample should not more than 1 time.
6. **Sample Volume: 100μL**

[TEST PROCEDURE]

1. Collect samples according to user manual.
2. Before the test, the sample and test strip should be recovered to room temperature (15°C-30°C).

For LS-1100

3. Perform QR code calibration when necessary. (Details refer to LS-1100 User Manual)
4. On the main interface of LS-1100, press “Test” icon to enter testing interface. Input patient information, sample information, doctor information when necessary. (Details refer to LS-1100 User Manual)
5. Remove test strip from sealed pouch and put it on a clean table, horizontally placed.
6. Using pipette to drop 100μL sample into the sample port in the test strip.
7. **Reaction Time: 10 minutes**

For panel inside: Insert the test strip into the analyzer immediately after sample dispensing. Then click “Test”.
For panel outside: After reaction time 10 minutes is elapsed, insert the test strip into the analyzer and then click “Test”.
8. The result will be shown on the screen and printed automatically.

Notes: It is required to perform QR code calibration when starting to use one new batch of kit.

[EXPECTED VALUE]

The following reference interval was obtained after statistical analysis of the confidence interval for the tests of the content of LH in serum samples of healthy people:

	Stage	Range(mIU/mL)
Mature male		1.50-9.25
Mature female	Follicular phase	1.25-11.80
	Ovulation	13.15-94.75
	Luteal phase	1.05-14.50
	Menopause	7.70-64.20

It is recommended that each laboratory establish its own reference range for the population it serves.

[INTERPRETATION OF RESULT]

1. If the test result of the sample is more than 200mIU/mL, the analyzer displays "> 200mIU/mL", and if the result is less than 1mIU/mL, the analyzer displays "< 1mIU/mL". Specific data can be exported through related software as needed.
2. When the sample concentration exceeds the detection limit, the maximum dilution ratio is 3 times when the sample is diluted with diluent.

[LIMITATION OF THE PROCEDURE]

1. This test kit is only for the serum test.
2. The test result of this kit are only one of the diagnostic aids for the clinicians.
3. Samples containing interfering substances may affect the test results, and the maximum allowable concentrations are: cholesterol 3mg/ml, bilirubin 2mg/ml, and triglyceride 10mg/ml.

[PRODUCT PERFORMANCE]

1. Measuring Range: 1.02-200mIU/mL.
2. Lower Detection Limit: ≤1 mIU/mL.
3. Accuracy: Verify with comparison experiments, the relative deviation ≤15%, the correlation coefficient r≥0.990.
4. Within-Run Precision: ≤15%.
5. Between-Run Precision: ≤15%.

[PRECAUTIONS]

1. This kit is for *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. After the test strip is removed from the sealed pouch, it should be tested as soon as possible to avoid excessive time in the air, resulting in dampness.
4. Do not reuse the test strip.
5. The damaged test strip or package cannot be used.
6. Do not mix components from different kit Lots.

[REFERENCES]

1. Yang Yue. Clinical significance of measuring six sex hormones in women[J]. Chinese Journal of Clinicians, 2003, 31(4): 50-51.

2. Scott MG, Ladenson JH, Green ED, Gast MJ. Hormonal evaluation of female infertility and reproductive disorders. Clin. Chem. 1989, 35: 620–630.

3. Huerta R, Malacara JM, Fajardo ME, Nava LE, Bocanegra A, Sanchez J. High-Frequency FSH and LH Pulses in Obese Menopausal Women. Endocrine, 1997, 7(3): 281-286.

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Revision Date: Aug 07, 2020
Version Number: 0.0
Production date and expiration see the label.

PRL Test Kit User Manual

(Dry Fluorescence Immunoassay)

[NAME]

PRL Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

1 test/kit
5 tests/kit
20 tests/kit
25 tests/kit
50 tests/kit
100 tests/kit

[INTENDED USE]

PRL Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro quantitative measurement of PRL (prolactin) in serum.
Clinically, it is mainly used to evaluate the endocrine function of pituitary gland.

[PRINCIPLE]

PRL Test Kit (Dry Fluorescence Immunoassay) uses the principle of antigen-antibody reaction. The testing sample will migrate forward due to capillary action, then the PRL of the sample will combine with antibody which is attached to fluorescence microspheres. This marked complex is attached to the detection area of immobilized antibody and the other fluorescence microspheres are attached to the control area.
When the test strip is inserted into the analyzer, the analyzer automatically scans two ribbons and detected the fluorescence intensity of the composite emission from the testing area and the control area. The ratio of the two fluorescence values was used to calculate the content of the detected substances.

[MAIN COMPONENTS]

1. PRL test strip in a sealed pouch with desiccant.....25 tests
2. Sample diluent.....25 pieces
3. QR code card for calibration.....1 piece
4. User Manual.....1 piece
5. Quantitative suction and dropping tube (Optional).

Note: Do not mix or interchange different batches of kit.

[STORAGE AND VALIDITY]

Store the test kit at 4°C-30°C, with a valid period of 18 months.
Test strip should be used within 30 minutes once the foil pouch is opened.

[APPLICABLE DEVICES]

1. LS-1000 Dry Fluorescence Immunoassay Analyzer
2. LS-2000 Dry Fluorescence Immunoassay Analyzer
3. LS-1100 Dry Fluorescence Immunoassay Analyzer
4. LS-2100 Dry Fluorescence Immunoassay Analyzer
5. LS-4000 Hand-Held Dry Fluorescence Immunoassay Analyzer
6. LS-7100 Microfluidic and Dry Fluorescence Immunoassay Analyzer

[SAMPLE REQUIREMENT]

1. Used for human **serum**. Other bodily fluids and samples may not get the accurate result.
2. At room temperature(15°C-30°C), the test should be performed within 4 hours after the sample collection.
3. Serum sample can be stored at 2°C-8°C for 3 days at most. If more than 3 days, it should be stored at -20°C. It is suggested to use fresh sample to test. Stale blood sample may not get accurate result.
4. The sample before testing should be recovered to room temperature (15°C-30°C).
5. Frozen samples should be completely melted, rewarmed and mixed completely before use. Avoid repeated freeze-thaw. It is suggested freeze-thaw of sample should not more than 1 time.
6. **Sample Volume: 100μL**

[TEST PROCEDURE]

1. Collect samples according to user manual.
2. Before the test, the sample and test strip should be recovered to room temperature (15°C-30°C).

For LS-1100

3. Perform QR code calibration when necessary. (Details refer to LS-1100 User Manual)
4. On the main interface of LS-1100, press "Test" icon to enter testing interface. Input patient information, sample information, doctor information when necessary. (Details refer to LS-1100 User Manual)
5. Remove test strip from sealed pouch and put it on a clean table, horizontally placed.
6. Using pipette to deliver 100μL of sample into one tube of sample diluent. Mix gently and thoroughly. And then drop 100μL of mixed fluid into the sample port in the test strip.
7. **Reaction Time: 10 minutes**

For panel inside: Insert the test strip into the analyzer immediately after sample dispensing. Then click "Test".
For panel outside: After reaction time 10 minutes is elapsed, insert the test strip into the analyzer and then click "Test".
8. The result will be shown on the screen and printed automatically.

Notes: It is required to perform QR code calibration when starting to use one new batch of kit.

[EXPECTED VALUE]

The following reference interval was obtained after statistical analysis of the confidence interval for the tests of the content of PRL in serum samples of healthy people:

Mature male：86.30-425.72μIU/mL
Mature female：72.55-600.4μIU/mL

Note: It is recommended that each laboratory establish its own reference range for the population it serves due to the difference of geographic, ethnic and age.

[INTERPRETATION OF RESULT]

1. If the test result of the sample is more than 4000μIU/mL, the analyzer displays "> 4000μIU/mL", and if the result is less than 20μIU/mL, the analyzer displays "<20μIU/mL". Specific data can be exported through

related software as needed.

2. When the sample concentration exceeds the detection limit, the maximum dilution ratio is 3 times when the sample is diluted with diluent.

[LIMITATION OF THE PROCEDURE]

1. This test kit is only for the serum test.
2. The test result of this kit is only one of the diagnostic aids for the clinicians.
3. Samples containing interfering substances may affect the test results, and the maximum allowable concentrations are: cholesterol 3mg/ml, bilirubin 2mg/ml, and triglyceride 10mg/ml.

[PRODUCT PERFORMANCE]

1. Measuring Range: 25-4000μIU/mL.
2. Lower Detection Limit: ≤20μIU/mL.
3. Accuracy: Verify with comparison experiments, the relative deviation ≤15%, the correlation coefficient r≥0.990.
4. Within-Run Precision: ≤15%.
5. Between-Run Precision: ≤15%.

[PRECAUTIONS]

1. This kit is for *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. After the test strip is removed from the sealed pouch, it should be tested as soon as possible to avoid excessive time in the air, resulting in dampness.
4. Do not reuse the test strip.
5. The damaged test strip or package cannot be used.
6. Do not mix components from different kit Lots.

[REFERENCES]

1. Yang Yue. Clinical significance of measuring six sex hormones in women[J]. Chinese Journal of Clinicians, 2003, 31(4): 50-51.
2. Scott MG, Ladenson JH, Green ED, Gast MJ. Hormonal evaluation of female infertility and reproductive disorders. Clin Chem. 1989, 35: 620–630.
3. Huerta R, Malacara JM, Fajardo ME, Nava LE, Bocanegra A, Sanchez J. High-Frequency FSH and PRL Pulses in Obese Menopausal Women. Endocrine, 1997, 7 (3): 281-286.
4. Pincus SM, Veldhuis JD, Mulligan H, Iranmanish A, Evans WS. Effects of age on the irregularity of PRL and FSH serum concentrations in women and men. Am J Physiol 273 (Endocrinol Metab 36), 1997, E989-E995.

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Revision Date: Aug 07, 2020
Version Number: 0.0
Production date and expiration see the label.

cTnI /CK-MB/Myo Test Kit User Manual

(Dry Fluorescence Immunoassay)

[PRODUCT NAME]

cTnI /CK-MB/Myo Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

1 test/kit
5 tests/kit
25 tests/kit
50 tests/kit
100 tests/kit

[INTENDED USE]

cTnI /CK-MB/Myo Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro quantitative measurement of cTnI /CK-MB/Myo (Cardiac Troponin I/ Creatine Kinase Isozyme/Myoglobin) in human serum .
cTnI is used as an aid in the diagnosis of myocardial injury such as Acute Myocardial Infarction (AMI),Unstable Angina, Acute Myocarditis and Acute Coronary Syndrome (ACS).
CK-MB is an important indicator for the diagnosis of acute myocardial infarction (AMI), which is secreted into the blood in large quantities during the attack.CK-MB began to rise 3-6h when AMI symptoms occur, and reached the peak value after 12-24h. If there were no complications, the level of CK-MB in the blood would be restored to the normal level after 3d; if there were complications, the level of CK-MB in the blood would remain high and not decrease. If AMI occurs again, the CK-MB that has declined will rise again. CK-MB measurement can also be used as a non-invasive evaluation index for myocardial reperfusion after thrombolytic therapy.
Myo can be used as the most sensitive index in the early diagnosis of acute myocardial infarction (AMI).

[TEST PRINCIPLE]

cTnI/CK-MB/Myo Kit (Dry Fluorescence Immunoassay) uses the principle of antigen-antibody reaction. The testing sample will migrate forward due to capillary action, then the sample will combine with antibody which is attached to fluorescence micro-spheres. This marked complex is attached to the detection area of immobilized antibody and the other fluorescence micro-spheres are attached to the control area. When the test strip is inserted into the analyzer, the analyzer automatically scans ribbons and detected the fluorescence intensity of the composite emission from the testing area and the control area. The ratio of the two fluorescence values was used to calculate the content of the detected substances.

[MAIN COMPONENTS]

1. cTnI/CK-MB/Myo test strip in a sealed pouch with desiccant.....25 tests
2. QR code card for calibration.....1 piece
3. User Manual.....1 piece
4. Quantitative suction and dropping tube (Optional).

Note: Do not mix or interchange different batches of kit.

[STORAGE AND VALIDITY]

Store the test kit at 4°C-30°C, with a valid period of 18 months.
Test strip should be used within 60 minutes once the foil pouch is opened.

[APPLICABLE DEVICES]

1. LS-1000 Dry Fluorescence Immunoassay Analyzer
2. LS-2000 Dry Fluorescence Immunoassay Analyzer
3. LS-1100 Dry Fluorescence Immunoassay Analyzer
4. LS-2100 Dry Fluorescence Immunoassay Analyzer
5. LS-4000 Hand-Held Dry Fluorescence Immunoassay Analyzer
6. LS-7000 Dry Fluorescence Immunoassay Analyzer
7. LS-7100 Microfluidic and Dry Fluorescence Immunoassay Analyzer
8. LS-3000 Automatic Fluorescence Immunoassay Analyzer
9. LS-3100 Automatic Fluorescence Immunoassay Analyzer

[SAMPLE REQUIREMENT]

1. Used for human **serum** . Other bodily fluids and samples may not get the accurate result.
2. At room temperature(15°C-30°C), the test should be performed within 4 hours after the sample collection.
3. Serum sample can be stored at 2°C-8°C for 24 hours, can be stored at -20°C for 6 months. It is suggested to use fresh sample to test. Microbial contamination samples can not be used.
4. Frozen samples should be completely melted, rewarmed and mixed completely before use. Avoid repeated freeze-thaw. It is suggested freeze - thaw of sample should not more than 1 time.
5. **Sample Volume: 100μL**

[TEST PROCEDURE]

1. Collect samples according to user manual.
Before the test, the sample and test strip should be recovered to room temperature (15°C-30°C).

For LS-1100:

1. Perform QR code calibration when necessary. (Details refer to LS-1100 User Manual)
2. On the main interface of LS-1100, press "Test" icon to enter testing interface. Input patient information, sample information, doctor information when necessary. (Details refer to LS-1100 User Manual)
3. Remove test strip from sealed pouch and put it on a clean table, horizontally placed.
4. Using pipette to drop 100μL sample into the sample port in the test strip.
5. **Reaction Time: 10 minutes**
   For panel inside: Insert the test strip into the analyzer immediately after sample dispensing. Then click "Test".
   For panel outside: After reaction time 10 minutes is elapsed, insert the test strip into the analyzer and then click "Test".
6. The result will be shown on the screen and printed automatically.
   Notes: It is required to perform QR code calibration when starting to use one new batch of kit.

[EXPECTED VALUE]

Reference Range:

cTnI ≤0.5ng/mL

CK-MB ≤5ng/mL

Myo ≤70ng/mL

cTnI/CK-MB/Myo concentration is determined using samples obtained from 180 apparently healthy individuals.

It is recommended that each laboratory establish its own reference range for the population it serves.

[INTERPRETATION OF RESULT]

1. If the test result of cTnI is more than 40ng/mL, the analyzer displays ">40ng/mL", and if the result is less than 0.1ng/mL, the analyzer displays "<0.1ng/mL". If the test result of CK-MB is more than 80ng/mL, the analyzer displays ">80ng/mL", and if the result is less than 2ng/mL, the analyzer displays "<2ng/mL". If the test result of Myo is more than 500ng/mL, the analyzer displays ">500ng/mL", and if the result is less than 20ng/mL, the analyzer displays "<20ng/mL". Specific data can be exported through related software as needed(Optional) .
2. When the sample concentration exceeds the detection limit, the maximum dilution ratio is 3 times when the sample is diluted with calf serum or negative sample.

[LIMITATION]

1. The test result of this kit are only one of the diagnostic aids for the clinicians.
2. Samples containing interfering substances may affect the test results, and the maximum allowable concentrations are: hemoglobin 3mg/mL, bilirubin 2mg/mL, and triglyceride 10mg/mL.

[PRODUCT PERFORMANCE]

1. Measuring Range: cTnI: 0.1ng/mL～40ng/mL
   CK-MB: 2ng/mL～80ng/mL
   Myo: 20ng/mL～500ng/mL
2. Accuracy: Verify with comparison experiments, the relative deviation ≤15%, the correlation coefficient r≥0.990.
3. Within-Run Precision: ≤15%.
4. Between-Run Precision: ≤15%.

[PRECAUTIONS]

1. Only used for in vitro diagnostics.
2. Do not use the kit beyond the expiration date.
3. After the test strip is removed from the sealed pouch, it should be tested as soon as possible to avoid excessive time in the air, resulting in dampness.
4. Do not reuse the test strip.
5. The damaged test strip or package cannot be used.
6. Do not mix the components of different kits.

[REFERENCES]

1. Yang Zhenhua, Pan Bozhong, Xu Juntang. Chinese Medical Association Test Document: Guidelines for the Application of Markers of Myocardial Injury. Chinese Journal of Laboratory Medicine,2002,25(3):185-189.
2. Jin Caining ,Xu Guobin,Zhu Lihua,etc. Determination of Human Myocardial TnI and its application in clinical diagnosis. Journal of Clinical Laboratory,2002,20(2):118-120.
3. Department of Medical Administration, Ministry of Health. National Clinical Laboratory Operating Procedures. Southeast University Press, 2015 4th edition.

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Email: peter@lotusnl.com

Revision Date: August 20, 2020

Version Number: 0.0

Production date and expiration see the label.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- LS-1100 Dry Fluorescence Immunoassay Analyzer

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- LS-2100 Dry Fluorescence Immunoassay Analyzer

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
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European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- LS-4000 Dry Fluorescence Immunoassay Analyzer (Handheld)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
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European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- cTnI Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
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European Representative: Lotus NL B.V.

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Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- CK-MB Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
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In Vitro Diagnostic Directive:

- Myo Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

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Position held in the company: CTO
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Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- NT-proBNP Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
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Position held in the company: CTO
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In Vitro Diagnostic Directive:

- D-Dimer Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
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Place: Nanjing,China

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Position held in the company: CTO
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European Representative: Lotus NL B.V.

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Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- CRP Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

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We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:
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European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- PCT Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
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Signed on:

Place: Nanjing,China

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European Representative: Lotus NL B.V.

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Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- PCT/CRP Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
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EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2021
Seal/Stamp:

Lansion Biotechnology Co., Ltd.

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DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
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European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- SAA Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
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European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- SAA/CRP Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- TT3 Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- TT4 Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- TSH Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 09.02.2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- AMH Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:

Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- 25-OH-VD Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:

Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- HbA1c Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:

Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- β -HCG Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:

Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- LH Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 04.02.2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

320115093554

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- FSH Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 04.02.2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

320115093554

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- PRL Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 09.02.2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- 25-OH-VD3 Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: General Manager
Date: 25/03/2021
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- BNP Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on: 25/03/2021

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: General Manager
Date: 25/03/2021
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- H-FABP Test Kit(Dry Fluorescence Immunoassay)

Category:Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on: 25/03/2021

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: General Manager
Date: 25/03/2021
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- IL-6 Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on: 25/03/2021

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: General Manager
Date: 25/03/2021
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- hs-cTnI Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on: 08/05/2021

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: General Manager
Date: 08/05/2021
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- Ferritin Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: General Manager
Date: 08/05/2021
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- PGI/PGII Test Kit(Dry Fluorescence Immunoassay)

Category:Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: General Manager
Date: 08/05/2021
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- PCT/IL-6 Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here 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.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: General Manager
Date: 12/08/2021
Seal/Stamp:
Lansion Biotechnology Co., Ltd.