Linkor Signature

Reagents Kits

by immunEC

Instructions for use

Prior to any tests, please read this Instructions for Use.
Strictly follow the instructions, or there is no guarantee that reliable results will be generated.

Notes :

- For in vitro diagnostic use only.
- For professional use only.
- Reagents are designed for single use only, do not reuse it.
- Do not use the reagents when expired, it could lead to incorrect test results.
- Components of the reagents from different lots cannot be interchanged or use.
- Do not touch sample and test area of the reagent card to prevent contamination of the reagent block.
- After the test card is taken out, please use it immediately. Do not take it with wet or dirty hands.
- Do not use the test card when it is wet, dirty or deformed, or when the test area of the sample area is scratched or damaged.
- Serum/plasma/whole blood samples shall be collected by proper medical techniques.
- It is recommended to collect fasting blood in the morning (except for emergency cases).
- The collection site shall be free from inflammation or edema.
- Avoid collecting blood from the earlobe unless specifically required.
- Used test cards may carry blood containing pathogenic components. To ensure the safety of use and avoid environmental pollution, do not contact the residual blood sample on the discarded test strip with any part of the body. All samples, used test strips and other potentially infectious materials should be disposed of in accordance with national or local regulations.
- Professionals are responsible for reviewing test results.
- Results below the detection range are shown as "<" a value.
- Results beyond the detection range are shown as ">" a value.
- If the test results are inconsistent or even contrary to the clinical situation, the reasons should be analyzed and found.
- The test results are for clinical reference and shall not serve as the sole basis for diagnosis and treatment. The clinical diagnosis and treatment of patients should be comprehensively considered based on their symptoms/signs, medical history, other laboratory tests and treatment response.

Interpretation of symbols:

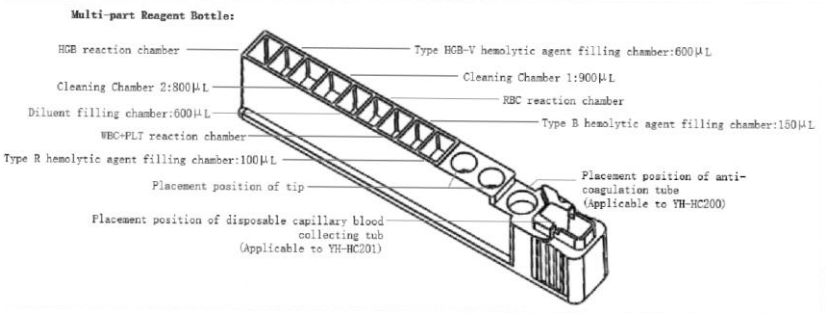
	Sufficient for tests		Use -by date
	Consult instructions for use		Storage temperature
	In vitro Diagnostics		Do not reuse
	Batch number		CE Marking
	Keep away from sunshine		Keep away from moisture
	Manufacturer		Authorized Representative in European Community
	Warning		Do not use if package is damaged and consult instructions for use

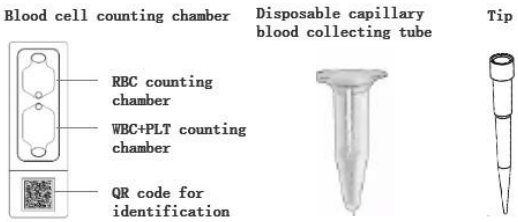
Name of Registrant/Manufacturer: HUNAN EHOME HEALTH TECHNOLOGY COMPANY LIMITED
Domicile of Registrant : Room 103 and 104, No.13 Building, Country Garden Wisdom Garden, Xueshi Street, Yuelu District, Changsha, Hunan,P. R. China
Medical Device Registration Certificate No.:XCXB 20210472
Production Registration Certificate No.:XCSXSCB 20210146

1.CBC Analysis Reagent Kit

Name : Kit for Sample Processing for Hematology Analysis
Specification : 20 tests /box

Kit composition :
- 1 x NFC Card, with lot information and standard curve information
- 20 x Multi-Part Reagent Bottle
- 20 x Blood Cell Counting Plate
- 20 x white blood collection tubes with anticoagulant: ETDA
- -40 x Tips





	Intended Use	Composition
Hemolytic agent for CBC analysis	- Damage red blood cells, - Dissolve hemoglobin, - Maintain the morphology of the cells to be analyzed prior to the CBC analysis, Differential cell count is conducted following the staining of white blood cells, or differential cell count and quantitative hemoglobin test are conducted directly.	- Buffer solution (NaCl), - Sodium chloride, - Surface active agent (Triton X-100), - Fixing agent (glutaraldehyde), - Preservative (proclin300), - Hydrochloric acid. Type B packing volume : 150μL Type R packing volume : 100μL Type HGB-V packing volume : 600μL
Diluent for CBC analysis	Dilute the whole blood sample to be tested. Clinically, the sample is diluted to prepare a cell suspension prior to the CBC analysis.	- Buffer solution (NaCl), - Sodium chloride, - Fixing agent (glutaraldehyde), - Preservative (proclin300). Packing volume : 600μL
Blood Cell Counting Plate	Count the formed elements in blood samples. Total and differential cell count and the hemoglobin content is calculated based on the principle of colorimetry.	- Glass, - Polycarbonate (PC), - PET double-sided adhesive tape.
Capillary Blood Collection Tube	Collect and store human capillary blood, which is then diluted to a specified concentration with a diluent.	

Please take necessary preventive measures (such as wearing masks, gloves, and lab coats) during operation. In the event that any liquid or test sample from the multi-part reagent bottle accidentally comes into contact with skin, eyes or other surfaces of human body, they must be rinsed with clear water. If such liquid or test sample is ingested accidentally, medical treatment is required.

Product Performance Indicator :

Type of test	Precision	Accuracy	Linearity	Counting criteria
WBC	CV ≤ 6%	± 15.0 %	R ≥ 0,990	≤ 0.5×10^9/L
RBC	CV ≤ 3%	± 6.0 %	R ≥ 0,990	≤0.05×10^{12}/L
PLT	CV ≤ 10%	± 20.0 %	R ≥ 0,990	≤ 10×10^9/L
HGB	CV ≤ 2.5%	± 6.0 %	R ≥ 0,990	≤ 2g/L

Storage Conditions and Expiration Date :

The product should be stored at 5°C-30°C, protected from light.
Shelf life: 2 years.
Production & Expiration date: see the product label.
Do not use the reagents when expired.
If the product has been stored at low temperatures, bring it to room temperature before use.
Care should be taken during transportation to avoid compression, puncture by sharp objects, and moisture.

2. Vitamin D Reagent Kit

Name : 25.OH-VD Rapid Quantitative Test
Specification : 20 tests /box

Kit composition :
- 1 x NFC Card, with lot information and standard curve information
- 20 x Vit. D Test Card
- 20 x Vit. D Diluent Vial

Intended Use :
The product is used to detect the content of 25-OH-VD in human serum/plasma/whole blood.
There are 3 forms of vitamin D in the human body, vitamin D3 (cholecalciferol), vitamin D2 (ergocalciferol), and vitamin D converted into 25-hydroxyvitamin D (25-OH-VD) in the liver through hydroxylation, which is the main form. The level of 25-OH-VD in serum can reflect the level of vitamin D in the body.

Composition :
1. Test card : The solid phase carrier is nitrocellulose membrane coated with 25-OH-VD mouse monoclonal antibody, coating concentration: (0. 1-3) mg/mL; fluorescent microspheres labeled with 25-OH-VD sheep monoclonal antibody, labeling concentration: (0.01-0.5) mg/mL.
2. Sample diluent: 0.9% sodium chloride (200μL/pc, Cartridge: 10.0mL/vial, 15.0mL/vial).

Test Principle :
This product uses a sandwich method and conducts testing in the form of solid-phase immunochromatography. The sample to be tested spreads upward from sample adding end under the capillary forces. As it passes through the conjugate pad, the 25-OH-VD antigens in the sample bind with markers to form into complexes of labeled antibody and antigen. Those complexes spread along with the sample to the nitrocellulose membrane, and are captured in the area (test line) coated by 25-OH-VD antibody antibody, forming the immune complexes of labeled antibody, antigen and coated antibody. The markers continue migrating along the membrane and the reaction occurs when moving to the control line(C line). The fluorescence intensity at each test line is directly proportional to the concentrations of 25-OH-VD. Based on the fluorescence intensity, the concentrations of 25-OH-VD can be quantitatively determined.

Test Method :
Unpack reagent kit and place at room temperature (18℃-28℃) for at least 30min to equilibrate.

Interpretation of Test Result :
Due to differences in geography, ethnicity, gender and age, it is recommended that each laboratory establish its own reference interval.
- For samples with concentration values below the blank limit (1.0ng/mL), the results are reported at <1.0ng/mL; for samples with concentration values exceeding 120.0ng/mL, to obtain a more accurate value, dilute the sample with normal saline and retest it, with the maximum dilution ratio of 1:4.
- For sample with test results close to the reference interval that are considered questionable, it is recommended to retest and monitor it dynamically.
- Due to the methodological differences or variations in immunospecificity, testing the same sample with reagents from different manufacturers may deliver different results. Therefore, test results from different reagents shall not be directly compared to avoid incorrect clinical interpretation. Laboratories are advised to indicate the reagent characteristics in their test reports.

Limitations of Test Method :
- Rheumatoid factor (RF), antinuclear antibody (ANA), and antineutrophil cytoplasmic antibody (ANCA) in the sample may interfere with the test result, which should be comprehensively evaluated in combination with the patient's medical history, clinical examination and other data.
- Severely hemolyzed, lipemic or turbid samples may lead to inaccurate test results and shall be avoided.

Sample Requirements :

- Anticoagulant: plasma, whole blood or peripheral blood samples treated with EDTA-K2, EDTA-K3, lithium heparin, sodium heparin or sodium citrate do not significantly affect test results.
- Interfering substance: 400 μmol/L bilirubin, 15g/L hemoglobin or 15mg/mL triglycerides make no interference for test results.
- Cross-reaction: 100ng/mL 1,25 (OH) 2D2, 100ng/mL 1,25 (OH) 2D3 structural analogs have no significant effect on the detection results.
- The sample diluent is a colorless and clear solution, iIt shall not be mixed with other reagents to prevent cross-contamination.

Product Performance Indicator :

Type of test	Precision	Accuracy	Linearity	Sensitivity
Repeatability (intra-dosing CV)	CV ≤ 10%	±15%	R ≥ 0.990 for the concentration of 5.0 to 120 ng/mL	≤ 5.0 ng/mL.
Intermediate accuracy (CV between tests)	CV ≤ 15%			
Crochet Effect : A sample of 25-OH-Vit D with a concentration < 1000 ng/mL did not have a Hook effect.				

Storage Condition and shelf life :

It shall be stored at 2℃-30℃,

Shelf life: 2 years.

Production & Expiration date: see the product label.

Do not use the reagents when expired.

After opening the aluminum foil bag of test card, **the valid period is 1h to prevent moisture exposure.**

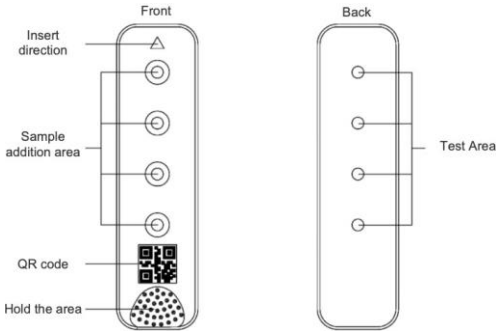
3. Combo Glucose/Lipids Reagent Kit

Name : GLU/HDL-C/TC/TG Combo test kit
Specification : 20 tests /box

Kit composition :
- 1 x NFC Card, with lot information and standard curve information
- 20 x Glu/HDL-C/LDL-C/TC/TG Combo test kit :
- 20 x blue blood collection tubes with anticoagulant: Lithium heparin
- 20 x Tips

Intended use :
This assay kit is suitable for in vitro quantitative detection of glucose (GLU), HDL-cholesterol (HDL-C), LDL-cholesterol (LDL-C), total cholesterol (TC) and triglyceride (TG) in human whole blood or serum plasma samples. Blood glucose testing serves as a key indicator for monitoring blood sugar levels. Elevated glucose concentrations may signal diabetes or impaired glucose tolerance. HDL-cholesterol, LDL-cholesterol total cholesterol and triglycerides are primary lipid profile indicators. High lipid levels often indicate lipid metabolism disorders such as hypercholesterolemia or hypertriglyceridemia, which correlate with increased risks of coronary heart disease, atherosclerosis, and other cardiovascular conditions. Controlling these lipid levels can significantly reduce cardiovascular event risks. Current clinical and laboratory methods for glucose detection include the glucose oxidase method and glucose dehydrogenase method. Total cholesterol analysis primarily uses the oxidase method and COD-PAP (Catalase-Dehydrogenase-Pathogenic Antigen) method. Triglyceride testing employs colorimetric, endpoint, and oxidase techniques, while HDL-C measurement mainly utilizes precipitation assays.

Composition :
- Glucose assay zone: Glucose oxidase 2~3 U, horseradish peroxidase 4~5 U
- HDL assay zone: Dextran sulfate 0.05~0.15mg cholesterol esterase 3.5U~4.5U, horseradish peroxidase (4~5 U), cholesterol oxidase 1.5U~2.5U.
- Total cholesterol assay zone: Cholesterol esterase 3.5U~4.5U, horseradish peroxidase 4~5 U, cholesterol oxidase 1.5U~2.5U;
- Triglyceride assay zone: Lipase 4~5 U, horseradish peroxidase 4~5 U, glycerokinase 2~3 U, phosphoglycerate oxidase 1.8U~2.5U.



Test principle :
The sample to be tested will automatically and evenly spread to the reaction area when added to the sample area of the test strip. In the reaction area, the reaction substance and chromogenic agent on the detection test strip react with the substance to be tested in the sample, showing the color change. The Analyzer determines the color change in the reaction area of the detection test strip at 630nm wavelength, which is used as the calculation basis for the concentration of the detection substance. After the calculation of the internal processor of the instrument, the test results will be displayed in the form of units with clinical significance.

The specific reaction principle is as follows:

Glucose: D-glucose + glucose oxidase → D-gluconic acid + H_2O_2
H_2O_2 + 4-AAP + MAOS → quinone imine

HDL-cholesterol: Precipitant + non-HDL → insoluble precipitate
HDL-cholesterol ester + cholesterol esterase → cholesterol + free fatty acids
Cholesterol + cholesterol oxidase → 4-cholestenone + H_2O_2
H_2O_2 + 4-AAP + MAOS → quinone imine

Total cholesterol: Cholesterol esters + cholesterol esterase → cholesterol + free fatty acids
Cholesterol + cholesterol oxidase → 4-cholestenone + H_2O_2
H_2O_2 + 4-AAP + MAOS → quinone imine

Triglycerides: Triglyceride + lipase → glycerol + free fatty acids
Glycerol + glycerol kinase +ATP→ Glycerol 3-phosphate +ADP
3-Glycerol phosphate + glycerol phosphate oxidase → dihydroxyacetone phosphate + H_2O_2 H_2O_2+4-AAP+MAOS→ quinone imine

Interpretation of Test Result :
Sample volume and reaction time: For the glucose/total cholesterol/triglyceride test in the reagent kit, each contains 15 μL of reagent with a reaction time of 180 seconds.
For the HDL-cholesterol test, each contains 18 μL of reagent with a reaction time of 180 seconds.

Blood sugar, blood lipid and uric acid will fluctuate after eating and at different times after meals.
It is recommended to fast for 8 hours before testing.

Due to regional and individual differences, the levels of glucose, LDL-cholesterol, HDL-cholesterol, total cholesterol and triglycerides measured may vary. Therefore, it is recommended that each laboratory should establish its own reference range for its characteristic population.

Limitations of the test method :
- The appropriate red blood cell pressure ratio is 30% - 45%. Samples beyond this range can affect results.
- When the concentration of interferon bilirubin is not greater than 342 μmol/L, ascorbic acid concentration is not greater than 100mg/L, hemoglobin concentration is not greater than 4.0 g /L and creatinine is not greater than 442 μmol/L, the test results will not be affected.

Product performance indicators :

Type of test	Precision		Accuracy	Linear Range	Linearity	Sensitivity
	Repeatability (intra-assay CV)	**Intermediate accuracy** (Inter-tests CV)				
Glucose	CV ≤ 12%	CV ≤ 8%	± 15.0 %	2.0~15 mmol/L	R ≥ 0,9750	1 mmol
HDL - Chol.	≤ 0.15mmol/L for C [0.25-0.76mmol/L] CV ≤ 8% for C [0.76-2,5 mmol/L]	CV ≤ 15%	≤ 0.16mmol/L for C [0.25-0.76 mmol/L] ≤ ±15% for C [0.76-2,5 mmol/L]	0.25~2.5 mmol/L		0,13 mmol
LDL - Chol.	CV ≤ 10%	CV ≤ 15%				0,20 mmol
Total Chol.	CV ≤ 12%	CV ≤ 15%	± 15.0 %	2.59~12.93mmol/L		1.3 mmol
Triglycerides	≤ 0.15mmol/L for C [0.51-1.33 mmol/L] CV ≤ 8% for C [1.33-7,34 mmol/L]	CV ≤ 15%	≤ 0.2mmol/L for C [0.51-1.33 mmol/L] ≤ ±15% for C [1.33-7,34 mmol/L]	0.51~7.34mmol/L		0.25 mmol

Storage Condition and Shelf life:

It shall be stored at 2℃-30℃,
Shelf life: 1 year.
Production & Expiration date: see the product label.
Do not use the reagents when expired.
After opening the aluminum foil bag of test card, **the valid period is 1h.**