

**CÔNG TY CỔ PHẦN
Y SINH THIỆN ĐỨC**

**CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh phúc**

Số: 19.26/CV-TĐ

V/v: Cam kết sản phẩm dùng 1 lần

Hà Nội, ngày 04 tháng 03 năm 2026

Kính gửi: Sở y tế Hà Nội

Công ty Cổ phần Y sinh Thiện Đức xin được gửi lời chào trân trọng tới Quý Sở.

Theo quy định tại khoản 4 Điều 26 Nghị định 98/2021/NĐ-CP ngày 08/11/2021 về Quản lý thiết bị y tế:

“Điều 26. Hồ sơ công bố tiêu chuẩn áp dụng

Hồ sơ công bố tiêu chuẩn áp dụng đối với trang thiết bị y tế thuộc loại A, B bao gồm:

4. Giấy xác nhận đủ điều kiện bảo hành do chủ sở hữu thiết bị y tế cấp, trừ trường hợp thiết bị y tế sử dụng một lần theo quy định của chủ sở hữu thiết bị y tế hoặc có tài liệu chứng minh không có chế độ bảo hành.”



Mặt hàng “Que thử xét nghiệm định tính 14 thông số nước tiểu” của chúng tôi thuộc thiết bị y tế loại B và được chủ sở hữu Qingdao Hightop Biotech Co., Ltd. xác định là sản phẩm dùng 1 lần. Trên tài liệu nhãn gốc và hướng dẫn sử dụng gốc của mặt hàng này cũng thể hiện thông tin sản phẩm dùng 1 lần và không được tái sử dụng. Chúng tôi xin đính kèm công văn này nhãn gốc và hướng dẫn sử dụng gốc thể hiện thông tin trên.

Vì vậy, chúng tôi xin không cung cấp giấy xác nhận đủ điều kiện bảo hành cho mặt hàng “Que thử xét nghiệm định tính 14 thông số nước tiểu”.

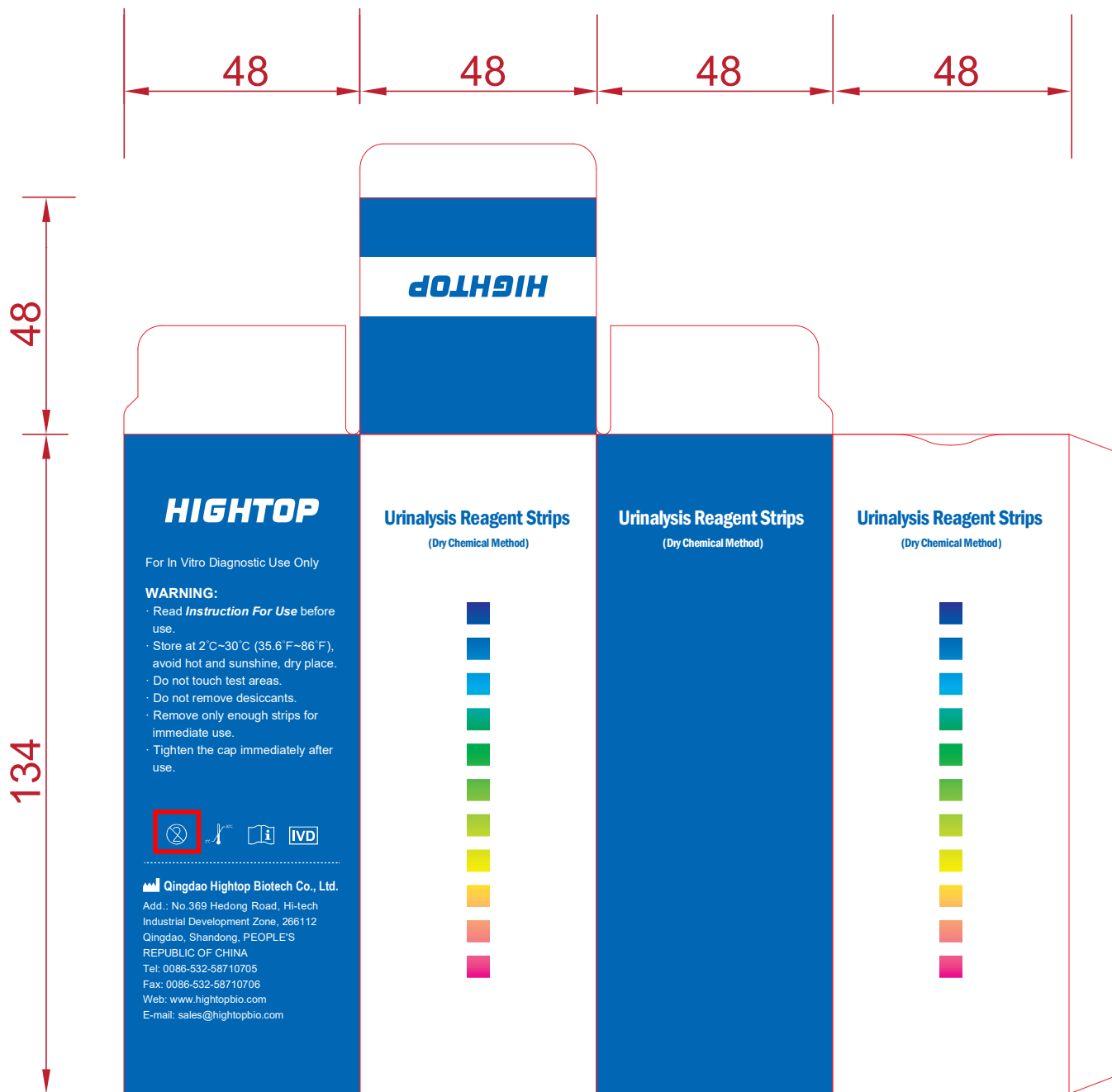
Chúng tôi xin cam kết và chịu hoàn toàn trách nhiệm những nội dung nêu trên.

Kính thư,

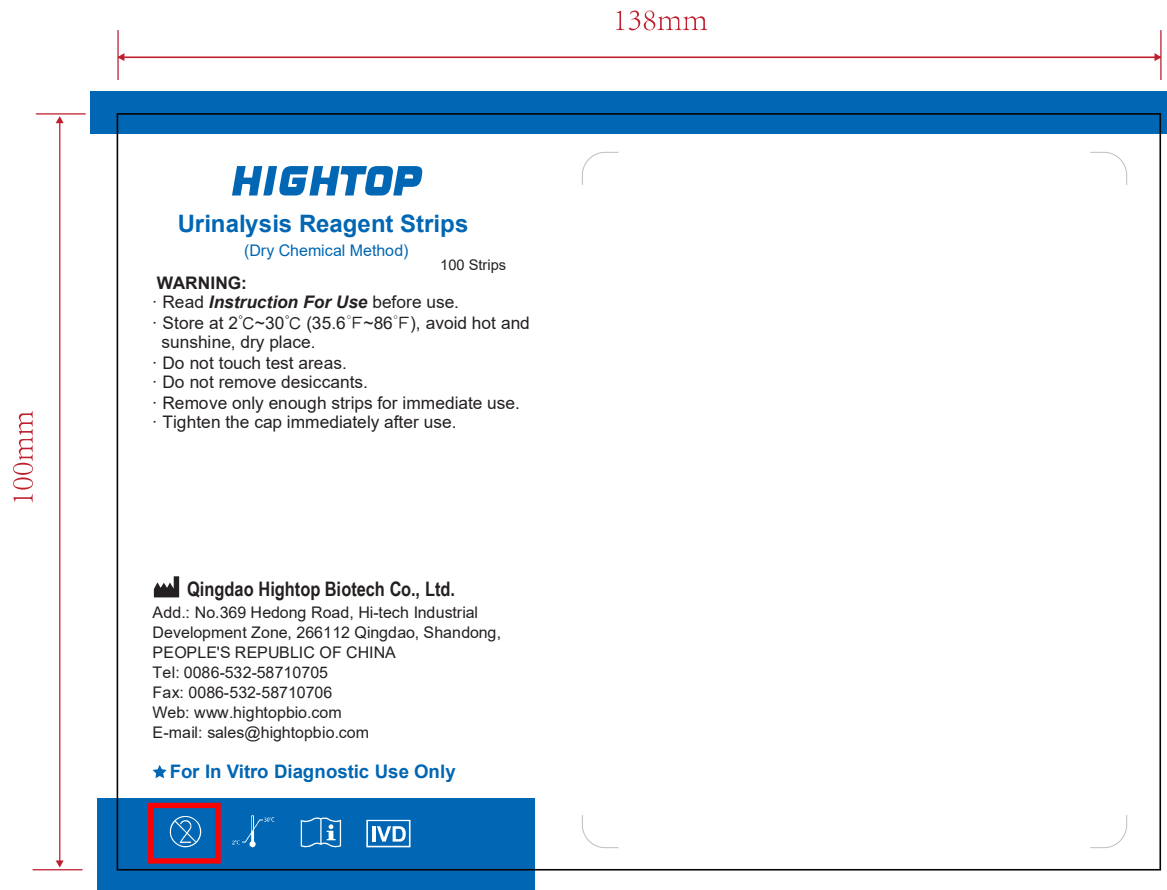
Dẫn chứng từ nhà sản xuất ký hiệu sản phẩm sử dụng 1 lần:

- 1) Ký hiệu  được thể hiện trên nhãn gốc nhà sản xuất
- 2) Giải thích ký hiệu  là ký hiệu cho sản phẩm chỉ sử dụng 1 lần được thể hiện trên Hướng dẫn sử dụng gốc từ nhà sản xuất đính kèm

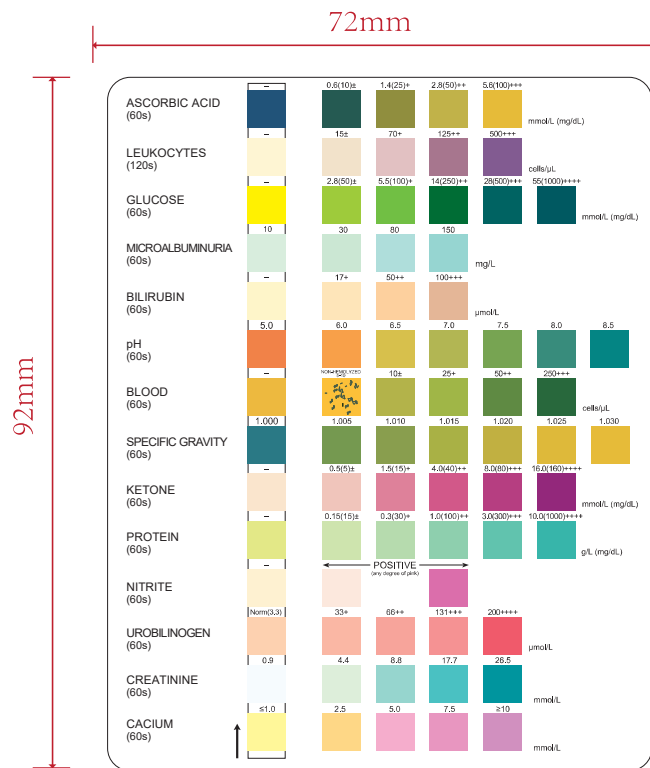
1. Nhãn gốc của nhà sản xuất



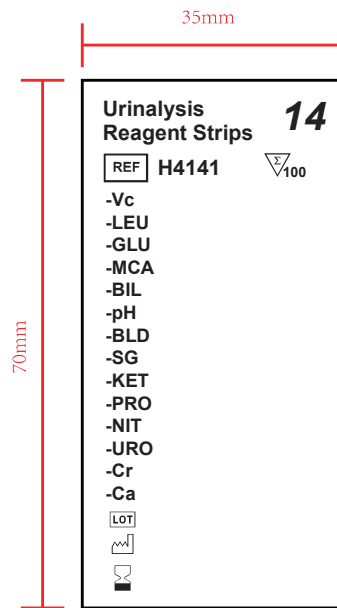
Packing Box



Canister label



Color chart



Box Label

2. Hướng dẫn sử dụng gốc

URINALYSIS REAGENT STRIPS (DRY CHEMICAL METHOD)

PACKAGING

100 Strips/canister;
Urinalysis control (optional)
Urinalysis control A: 1 mL×1, 3 mL×1, 10 mL×1; Urinalysis control B: 1 mL×1, 3 mL×1, 10 mL×1.

INTENDED USE

Depending on the product being used, Urinalysis Reagent Strips (URS) provide tests for Ascorbic Acid (Vc), Leukocytes (LEU), Glucose (GLU), Microalbuminuria (MCA), Bilirubin (BIL), pH, Blood (BLD), Specific Gravity (SG), Ketone (KET), Protein (PRO), Nitrite (NIT), Urobilinogen (URO), Creatinine (Cr) and Calcium (Ca) in human urine qualitatively.

Test results may provide information regarding the status of carbohydrate metabolism kidney and liver function, acid-base balance and bacteriuria. Please refer to the outside box and bottle label for the specific test parameters of the product you are using.

TEST PRINCIPLE

Urinalysis Reagent Strips (URS) are firm plastic strips to which several different reagent areas are affixed. Each reagent area is affixed with different chemistry substances, which reacts with relevant material in the urine samples separately, then color changed according to the proportion of each component in the urine.

MAIN COMPONENT

Parameter	Reagent Component
Vc	0.5% w/w 2,6-dichlorophenol sodium salt
LEU	0.4% w/w indoxyl ester derivative; 0.3% w/w diazonium salt
GLU	3.5% w/w glucose oxidase; 0.5% w/w peroxidase
MCA	2.2% w/w phenolsulfonphthalein dye
BIL	0.5% w/w 2,4-dichloroaniline diazonium salt
pH	0.3% w/w methyl red; 4% w/w bromothymol blue
BLD	4% w/w 3,3', 5,5'-tetramethylbenzidine; 6.7% w/w cumene hydroperoxide
SG	2.7% w/w bromothymol blue
KET	6.5% w/w sodium nitroferricyanide
PRO	0.3% w/w tetrabromophenol blue
NIT	2.5% w/w N-1- naphthyl ethylenediamine hydrochloride; 4.5% w/w p-aminophenylarsinic acid
URO	1.5% w/w p-diethylaminobenzaldehyde
Cr	0.3% w/w sulfate; 0.3% w/w benzidine
Ca	0.5% w/w methylthymol blue; 0.3% w/w 8-hydroxyquinoline
Urinalysis control A	0.002% w/w N - 1 - naphthyl-ethylenediamine dihydrochloride; 3.5% w/w sodium chloride; 0.075% w/w lithium acetoacetate; 0.0028% w/w protease K; 0.0028% w/w trypsin; 0.045% w/w ascorbic acid; 0.05% w/w calcium chloride; 0.006% w/w bovine serum albumin.
Urinalysis control B	0.0015% w/w human hemoglobin; 0.2% w/w bovine serum albumin; 0.75% w/w glucose; 0.01% w/w sodium nitrite; 0.015% w/w 5-Methoxy-2-methylindole; 0.07% w/w cetyltrimethylammonium bromide; 0.18% w/w creatinine

STORAGE CONDITION AND VALIDITY PERIOD

Storage of strips: Store at 2°C~30°C, avoid hot and sunshine, dry place. The validity period is 24 months. Unused strips that remain in the original container are stable with 3 months after it is opened at temperature of 15°C~30°C and humidity of less than 50%.

Storage of urinalysis control: The urinalysis control is lyophilized powder, refrigerated at 2°C~8°C , and the validity period is 24 months; After re-dissolution, refrigerated and stored at 2°C~8°C for 7 days.

APPLICABLE INSTRUMENTS

This product is suitable for the urine analyzer of Qingdao Hightop Biotech Co., Ltd. Instrument model: HT-115A/B; HT-114A/B; HT-113A/B; HT-112A/B; HT-111A/B; HT-1420A; HTUS-2400.

SPECIMEN COLLECTION AND PREPARATION

The samples should be fresh, no preservative, no centrifuged urine sample. The urine samples should be thoroughly mixed before the test. The use of fresh morning urine is recommended. If immediate testing is not possible, the sample should be stored in the refrigerator for no more than 4 hours, but not frozen, and then balance to room temperature before used in the test.

TEST PROCEDURE

1. After taking out the strips, cover the caps, then completely submerge the strip into the urine sample, take it out after 1 to 2 seconds. Blot the lengthwise edge of the strip on an absorbent paper towel to further remove excess urine, waiting for the set time stated on the label and then get the results by comparing the color with the color map, or put it on the objective table of urine analyzer and test according to the operation instruction.

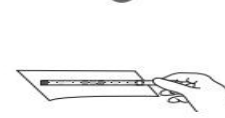
1~2 seconds



2



3



1~2 minutes



2. The urinalysis control is lyophilized powder and needs to be dissolved before use. Open the vial carefully, avoiding any loss of the material and reconstitute with the specific volume of deionized water indicated on the bottle label. Replace the rubber stopper, close the vial and leave to stand for 30 minutes before use. Ensure that all traces of dry material are dissolved by swirling gently. The re-dissolved quality control sample should be stored at 2°C~8°C. The values of urinalysis control, please refer to the Urinalysis Control Operation Instruction.

SPECIFIC PERFORMANCE CHARACTERISTICS

Parameter	Unit	Reference Range	Limit of Detection	Testing Range	Semi-quantitative Value	Read Time(s)
Vc	mmol/L	0	0.6	0~5.6	--~3+	60
LEU	cells/μl	0	15	0~500	--~3+	120
GLU	mmol/L	0	2.8	0~55	--~4+	60
MCA	mg/L	<30	10	10~150	—	60
BIL	μmol/L	<17	17	0~100	--~3+	60
pH	—	5.0-8.0	—	5.0~8.5	—	60
BLD	cells/μl	<10	10	0~250	--~3+	60
SG	—	1.010-1.025	—	1.000~1.030	—	60
KET	mmol/L	0	0.5	0~16	--~4+	60
PRO	g/L	<0.15	0.15	0~10	--~4+	60
NIT	μmol/L	Neg.	18	Neg.~Pos.	--~+	60
URO	μmol/L	<33	33	3.3~200	--~4+	60
Cr	mmol/L	0.9-17.7	0.9	0.9~26.5	—	60
Ca	mmol/L	2.5-7.5	1.0	1.0~10.0	—	60

1. **Accuracy:** The test results are not more than one order of gradient with the corresponding reference values, and the opposite result is not allowed. Positive reference solution must not score a negative result, negative reference solution cannot score a positive result.

2. **Repeatability:** The consistency of the test results was not less than 90% in the same batch of test paper.

3. **Batch difference:** Test the same specimen with different batches strips repeatedly, and the difference between the detection results should be no more than one order of magnitude.

INTERPRETATION OF RESULT

1. **Vc:** If the ascorbic acid test is positive, it should be retested after 24 hours with non-ingestion of foods or drugs containing ascorbic acid. Ascorbic acid can inhibit the reaction of NIT, LEU, URO, GLU and BLD, and produce false negative result. It may cause false positive result when other strong reducing agent existing in the urine.

2. **LEU:** High concentration of glucose, high specific gravity, high level of albumin, high concentration of formaldehyde or presence of blood may cause decreased test results. False positive results may occasionally be due to contamination of the specimen by vaginal discharge.

3. **GLU:** This test is specific for glucose; no substances excreted in urine other than glucose is known to give a positive result. When Ascorbic Acid more than 1.4 mmol/L in urine will result in false negative. Reactivity may be influenced by urine SG and temperature.

4. **MCA:** This area is more sensitive to albumin than to other proteins. High specific gravity urine, alkaline urine, disinfectant including quaternary ammonium compound or chloride-containing skin disinfectants can cause false positive results.

5. **BIL:** In normal conditions, the most sensitive method cannot detect the bilirubin in normal urine. The presence of a small amount of bilirubin in the urine is sufficient to indicate its abnormality and requires further examination. Some metabolites of drugs (e.g. pyridine, b-indole acid) can cause false positive reactions under acid condition. No less than 1.4 mmol/L of ascorbic acid can cause false negative results.

6. **pH:** The pH test area permits quantitative differentiation of pH values to one unit within the range of 5.0~8.5 pH reading is not affected by variation in the urinary buffer concentration.

7. **BLD:** This test is extremely sensitive to hemoglobin, and can complement each other with microscopic examination. But if the test area changes green, it means that the red blood cells in urine has burst. Usually, testing result with women urine in menstrual period is positive. Elevated specific gravity or protein in urine may reduce the sensitivity of the test. Certain oxidative pollutants such as hypochlorite can result in false positive result. Peroxidase in microorganisms associated with urinary tract infection can result in false positive result. Less than 1.4 mmol/L of ascorbic acid will not affect the detecting result.

8. **SG:** High concentration alkaline urine can result in low detection results, and urine containing protein (1.0-7.5g/L) can result in high detection results.

9. **KET:** Positive results (trace or less) may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites. Some high SG and low pH urine may give false positive result. Phenosulfonphthalein may cause false positive result.

10. **PRO:** False positive results may be found in strongly basic urine.

11. **NIT:** This test is specific for nitrite and will not react with substances normally excreted in the urine. It may show false negative result when the concentration of ascorbic acid is greater than 1.4 mmol/L in the urine.

12. **URO:** A high concentration of p-aminobenzoic acid in urine may cause atypical color reaction. Formaldehyde in the urine may lead to false negative. Some dark substances, such as azo pigments and riboflavin, can cover the color changes on the filter paper. The negative results of this test do not confirm that there is no urinogen in the sample.

13. **Cr:** In the urine, such antibiotics as pyruvate, acetic acid and penicillin G, cephalothiphene and cefoxitin, can cause some higher results.

14. **Ca:** The test results of calcium may be interfered by other metal-ions. It may cause false positive result when lots of magnesium in the urine.

As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single test result or method.











WARNINGS AND PRECAUTIONS

1. Do not touch test areas of Urinalysis Reagent Strips so as to avoid pollution.

2. Checking the batch number before use. Please do not use it if expired or the color obviously changed in the test areas.

3. All samples and test strips after use should be collected and disused after centralized sterilization.

INSTRUCTIONS OF SYMBOL

	Consult instruction for use		Keep dry
	Store between		Batch number
	For single use		In vitro diagnostic medical device
	Manufacturer		Date of manufacture
	Expire date		Contains sufficient for <n> tests

MANUFACTURER

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