

Test-Reagent for 5-Hydroxyindoleacetic Acid (Qualitative Colorimetric Method)

5-羥吲哚乙酸測定試劑盒(化學顯色法)

WUHAN CHENKANG SCIENCE TECHNOLOGY CO.,LTD



(基本信息)

(Basic Information)

生產商: 武漢市農康科技有限責任公司

Manufacturer: WUHAN CHENKANG SCIENCE TECHNOLOGY CO.LTD.

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海外一級總代理: ANCO RESOURCES PTE LIMITED

Overseas First-Level Sole Agent Name: ANCO RESOURCES PTE LIMITED

海外一級總代理通訊地址: 香港新界葵芳興芳路223號新都會廣場2座20樓2006室

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***特別留意及免責聲明:** 本產品僅作為初步篩檢工具, 用於檢測尿液中人體內氨基酸代謝異常, 基於生產商 - 農康科技所提供的臨床數據顯示, 其中某些癌症, 如腸癌、胃癌、乳腺癌、食道癌、肝癌、婦科及其他腫瘤的陽性檢出率敏感度較高。唯其結果不能作為癌症診斷的唯一依據, 須結合臨床症狀、影像學檢查(如CT、MRI)及病理切片等醫學手段由專業醫生綜合評估。本產品屬於輔助性檢測工具, 檢驗結果不構成醫療診斷, 使用者不應基於結果自行決定治療方案或終止現有治療。

***Special Attention and Disclaimer:** This product is only intended as a preliminary screening tool for detecting abnormal amino acid metabolism in human urine. According to clinical data provided by the manufacture - Wuhan Chenkang Science Technology Co. Ltd., this test demonstrates relatively high sensitivity in detecting certain cancers, such as Colorectal Cancer, Gastric Cancer, Breast Cancer, Esophageal Cancer, Liver Cancer, Gynecological and other Tumors. However, the results cannot serve as the sole basis for cancer diagnosis. They must be evaluated comprehensively by medical professionals in conjunction with clinical symptoms, imaging examinations (e.g., CT, MRI), pathological biopsies,

and other diagnostic methods. This product is an auxiliary testing tool, and its results do not constitute a medical diagnosis. Users should not make treatment decisions or discontinue existing treatments based solely on the test results.

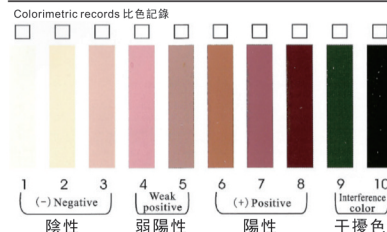
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- 5.Ioannis ILIAS, A clinical overview of pheochromocytomas/ paragangliomas and carcinoid tumors, Nuel Med Biol. 2008 August; 35 (Suppl1) S27-534.

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- 2.Li Yuqing, Liu Hongchun, Geng Jie. The Significance of Urinary 5-Hydroxyindoleacetic Acid in Screening for Gastrointestinal Lesions [J]. Chinese Journal of Gerontology, 2019, 39(10): 2380-2382.
- 3.Hernandez R, A prospective clinical trial evaluating urinary 5-hydroxyindoleacetic acid levels in the diagnosis of acute appendicitis, Am J Emerg Med. 2008 Mar; 26(3):282-6
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Standard Colorimetric Plate (標準比色板)



使用說明書Instruction Manual

產品名稱：5-羥吲哚乙酸測定試劑盒（化學顯色法）
Generic Name: Test-Reagent for 5-Hydroxyindoleacetic Acid
(Qualitative Colorimetric Method)

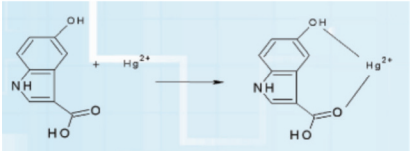
包裝規格：0.5毫升x 1支
Packaging Specifications: 0.5ml x 1 bottle

(預期用途)

本試劑用於定性檢測人體晨尿中的5-羥吲哚乙酸。5-羥吲哚乙酸是細胞異常活動引起人體應激反應導致氨基酸異常代謝的產物之一，消化系統由幽門螺旋桿菌感染引起的胃潰瘍、胃炎、乳腺系統炎症、嗜路細胞瘤、急性闌尾炎、酒精過敏體質酒後都會引起的人體應激反應，這些應激反應導致體內的氨基酸代謝異常，使得晨尿中5-羥吲哚乙酸的含量遠遠超過正常人。本試劑通過與5-羥吲哚乙酸發生特徵顯色反應，即可判定被測試者體內是否有相關的異常代謝，臨床上主要用於細胞異常活動引起的應激反應及各類炎症疾病的輔助診斷，本產品不用於腫瘤的輔助診斷。

(Intended Use)

This reagent is used for the qualitative detection of 5-hydroxyindoleacetic acid in human morning urine. 5-hydroxyindoleacetic acid is one of the byproducts of abnormal amino acid metabolism caused by the body's stress response due to abnormal cellular activity. Conditions such as gastric ulcers and gastritis caused by Helicobacter pylori infection in the digestive system, inflammation in the mammary system, pheochromocytoma, acute appendicitis, and alcohol allergy reactions can all trigger the body's stress response. These stress responses lead to abnormal amino acid metabolism, resulting in levels of 5-hydroxyindoleacetic acid in morning urine far exceeding those in normal individuals. This reagent works by producing a characteristic color reaction with 5-hydroxyindoleacetic acid, allowing the determination of whether the tested individual has related abnormal metabolism. Clinically, it is primarily used as an auxiliary diagnostic tool for stress responses caused by abnormal cellular activity and various inflammatory diseases, but this product is not meant for assisting in tumor diagnosis.



(檢驗原理)

本試劑通過汞鹽與5-羥吲哚乙酸發生特徵顯色反應，根據顏色的不同即可判定被測試者體內是否有相關的異常代謝。

(Testing Principle)

This reagent undergoes a characteristic color reaction with mercuric salt and 5-hydroxyindoleacetic acid. Based on the resulting color, it can determine whether the tested individual has related abnormal metabolism.

(主要成分)

分析純級發煙硝酸、6N硫酸、硝酸亞汞、硫酸汞、苯酚、去離子水。

(Main Ingredients)

Fuming Nitric Acid - Analytical Grade, 6N Sulfuric Acid, Mercurous Nitrate, Mercuric Sulfate, Naphthol, Deionized Water.

(儲存條件及有效期限)

應在乾燥、通風、避免陽光直射及熱源的室內保存，儲存溫度範圍為5°C至40°C。在此條件下，有效期限為三(3)年，生產日期、失效日期及有效期限詳見包裝上標識。

(Storage Instructions and Shelf Life)

This reagent should be stored in a dry, well-ventilated room, avoiding direct sunlight and heat sources, within the temperature range of 5°C to 40°C. Under these conditions, the shelf life is three (3) years, the production date, expiration date, and shelf life are indicated on the package label.

(樣本要求)

檢測者收集晨尿樣本，測試前一天切勿飲酒，勿服用各類藥物，少食高蛋白、高氨基酸的食品及保健品。

(Sample Requirement)

The user should collect a morning urine sample, on the day before testing, no alcohol consumption, refrain from taking any medications, and minimize intake of high-protein, high-amino-acid foods and supplements.

(測試流程)

用塑膠杯盛取晨尿，然後戴上手套，用開瓶器打開安瓿瓶（按壓打開），並將其置於底座上。用滴管吸取3毫升晨尿，加入裝有0.5毫升試劑的安瓿中，充分搖勻，靜置3-5分鐘。將沉澱物的顏色與標準比色板進行比較以判定結果。（請參閱標準比色板上的參考值/範圍）將所有使用過的材料放入密封處置袋中，然後根據當地環境法規進行處置。

(Test Procedure)

Collect morning urine in a plastic cup, then put on gloves and use the opener to open the ampoule (press to open), placing it on the base. Use a dropper to extract 3 mL of urine and add it to the ampoule containing 0.5 mL reagent. Mix thoroughly by shaking and let it stand for 3-5 minutes. Compare the precipitate color with the standard colorimetric plate for result interpretation (refer to Reference Values/ Range on the plate).

Put all used materials into the sealed disposal bag, then dispose it according to local environmental regulations.

(陽性判斷值)

參考標準比色板。

(Positive Judgment Value)

Refer to the standard colorimetric plate.

(測試結果的解釋)

檢測結果如為陰性，表明此人5-羥吲哚乙酸代謝正常；檢驗結果如為陽性，應在三日內排除各種干擾（勿飲酒，勿服各類藥物，少飲水，少食高蛋白、高氨基酸的食品及保健品），再進行複查。如仍為陽性，則應到相關專科醫院做詳細檢查。

(Interpretation of Test Result)

A negative test result indicates normal 5-hydroxyindoleacetic acid metabolism in the individual; While a positive result requires the elimination of various interfering factors (including no alcohol consumption, refrain from taking any medications, minimize intake of water, minimize intake of high-protein, high-amino-acid foods and supplements) within three days before retesting, and if the result remains positive, the individual should undergo comprehensive examination at a relevant specialized hospital.

(檢測方法的局限性)

本試劑僅用於定性檢測人晨尿中的5-羥吲哚乙酸，陽性檢測結果僅供臨床參考，不作為臨床診治的唯一依據，需結合其他實驗室檢測進行判斷；建議檢測結果結合其他臨床診斷綜合進行考慮；受方法學及產品原材料所限，本產品檢測結果與其他同類試劑的檢測結果不具有可比性。

(Limitation of Test Method)

This reagent is intended solely for qualitative detection of 5-hydroxyindoleacetic acid in human morning urine, a positive result should be used for clinical reference only and must not serve as the sole basis for clinical diagnosis or treatment, it requires correlation with other laboratory tests for proper determination; It is recommended that the test results be considered in combination with other clinical diagnoses; Due to limitations of methodology and raw materials of this product, the test results obtained with this product should not be compared with the result from other similar reagents.

(產品性能指標)

本產品所有性能指標（包括準確性、特異性、重複性和靈敏度）均通過實驗室嚴格驗證，證明在指定條件下具有穩定的檢測性能，符合醫療檢測標準，確保檢測結果可靠。

- 準確性：對濃度10mg/mL的酪氨酸標準溶液進行檢測，重複測定5次，均應呈陽性。
- 特異性：對工尿樣進行檢測，重複測定5次，均應為陰性。
- 重複性：對濃度為10mg/mL的酪氨酸標準溶液進行檢測，重複測定10次，均應呈陽性，顯色一致。
- 靈敏度：對濃度為1mg/mL的酪氨酸標準溶液進行檢測，重複測定3次，均應呈陽性或弱陽性。

(Product Performance Indicators)

All performance indicators (including accuracy, specificity, repeatability, and sensitivity) of this product have been rigorously laboratory verified, demonstrating stable detection performance under specified conditions while meeting medical testing standards for reliable results.

- Accuracy: When testing a 10 mg/mL tyrosine standard solution, all 5 repeated measurements must yield positive results.
- Specificity: When testing artificial urine samples, all 5 repeated measurements must yield negative results.
- Repeatability: When testing a 10 mg/mL tyrosine standard solution, all 10 repeated measurements must yield consistent positive results with uniform coloration.
- Sensitivity: When testing a 1 mg/mL tyrosine standard solution, all 3 repeated measurements must yield positive or weak positive results.

(注意事項)

- 本試劑具有強腐蝕性，使用時應特別注意。如果灑到皮膚或衣物上，請立即用肥皂和水清洗。若不慎灑入眼睛，請立即用清水徹底沖洗，並在必要時就醫。
- 若沉澱物呈綠色或灰綠色，則是由黃疸干擾所致。應在黃疸消失後再檢測。
- 胃炎、胃潰瘍患者伴有幽門螺旋桿菌感染的病人，用本試劑檢測呈陽性者，應注意有早期胃病變的可能。如未發現病變部位，應在殺滅幽門螺旋桿菌後，定期用本試劑監測，並密切注意胃病的發展狀況。
- 疾病重症患者在各種治療過程中，或營養嚴重消耗的情況下（尤其是晚期病人），因失去應激反應能力，不容易出現陽性結果。
- 本試劑中含有的汞鹽是以穩定的絡合物狀態存在，因此試驗結束後的廢液以填埋方式處理即可。

(Warnings)

- This reagent is strongly corrosive and should be handled with special care. If it splashes on skin or clothing, wash immediately with soap and water. If it accidentally splashes into the eyes, rinse thoroughly with water and seek medical attention if necessary.
- If the sediment appears greenish or grey-green, this could be due to interference from jaundice. It is recommended to repeat the test after the jaundice has resolved.
- For patients with gastritis or gastric ulcers accompanied by Helicobacter pylori infection who test positive with this reagent, the possibility of early gastric lesions should be considered. If no specific lesion sites are identified, regular monitoring with this reagent should be implemented after Helicobacter pylori eradication therapy, with close observation for any progression of gastric pathology.
- In critically ill patients undergoing various treatment regimens or experiencing severe nutritional depletion (particularly in advanced-stage cases), the diminished capacity for stress responses may significantly reduce the likelihood of obtaining positive test results with this reagent.
- The mercury salts contained in this reagent exist in a stable complex compound form, therefore the waste liquid generated after testing may be safely disposed of through landfill treatment without significant environmental risk.