



CERVICAL PRECANCER DNA TEST

子宮頸癌變前兆篩檢
非侵入性核酸檢測(報告範本)

Patient:	Hospital:
Age: 60 歲	Treating Physician:
Gender: Female	Specimen ID:
Order Received: 2024/5/	Sampling Date: 2024/5/

Lab Requisition #: CP#
Specimen Type: Exosome DNA
Date Reported:
Clinical Indication:

RESULTS

HPV INFECTION (HPV 感染)

INTEGRATED GENOME 整合基因組	HPV		
	LOW RISK 低風險	HIGH RISK 高風險	
TYPE 病毒類型	6	16	18
VIRAL LOAD 病毒載量	-	++	-
INTERPRETATION	MODERATE VIRAL LOAD OF HPV16 INFECTION 檢出中度 HPV16 病毒感染載量		

VIRAL LOAD 病毒載量分級: - : Not detectable (沒有檢測到病毒); + : Low viral load (病毒載量低); ++: Moderate viral load (中等病毒載量); +++: High viral load (病毒載量高)

It's estimated that over 70% of women under 39 contract HPV at some stage in their lives. Approximately half of HPV infections involve specific high-risk types, notably HPV 16 and HPV 18, which account for about 70% of all cervical cancer cases. However, not all HPV 16 or 18 infections lead to cancer. Most HPV infections resolve spontaneously within two years. While HPV poses a significant risk factor for cervical cancer, it's not the sole factor responsible for malignant transformation.

據估計，超過 70% 的 39 歲以下女性在生命的某個階段感染了 HPV。大約一半的 HPV 感染涉及特定的高危類型，特別是 HPV 16 和 HPV 18，它們約佔所有子宮頸癌病例的 70%。然而，並非所有 HPV 16 或 18 感染都會導致癌症。大多數 HPV 感染在兩年內自發消退。雖然 HPV 是子宮頸癌的重要危險因素，但它並不是導致惡性轉化的唯一因素。

PRECANCER STAGE 子宮頸癌前分期

CLINICAL STAGE 臨床階段	SCORE	RISK 風險程度	MOLECULAR PRECANCER STAGE 分子癌前分期
NORMAL	-	NO IMMEDIATE RISK	0
PRE-SIL	+	EARLY MILD RISK	1

CIN1+	-	MILD TO MODERATE RISK	2
CIN2+	-	MODERATE TO SEVERE RISK	3
CIN3+	-	SEVERE RISK	4
INTERPRETATION	MOLECULAR PRECANCER STAGE 1 EARLY MILD RISK FOR PRENEOPLASIA LESION 分子癌前病變 1 期: “早期輕度” 癌前病變風險		

PRECANCER STAGE 子宮頸癌前分期說明如下:

Normal: The cervical cells appear healthy and without any signs of abnormal growth or changes.

Pre-SIL (Squamous Intraepithelial Lesion): Early abnormal changes in the cervical cells are observed, indicating potential precursor stages of cervical cancer.

CIN1+ (Cervical Intraepithelial Neoplasia 1+): Mild to moderate abnormal changes are present in the cervical cells, indicating the presence of precancerous lesions.

CIN2+ (Cervical Intraepithelial Neoplasia 2+): Moderate to severe abnormal changes are evident in the cervical cells, suggesting a higher likelihood of progression to cervical cancer.

CIN3+ (Cervical Intraepithelial Neoplasia 3+): Severe abnormal changes are observed in the cervical cells, indicating a high-grade precancerous condition that may progress to invasive cervical cancer if left untreated.

正常：子宮頸細胞看起來很健康，沒有任何異常生長或變化的跡象。

Pre-SIL（鱗狀上皮內病變）：觀察到子宮頸細胞的早期異常變化，表明子宮頸癌的潛在前兆階段。

CIN1+（宮頸上皮內瘤變 1+）：子宮頸細胞中存在輕度至中度異常變化，表明存在癌前病變。

CIN2+（宮頸上皮內瘤變 2+）：子宮頸細胞中明顯出現中度至重度異常變化，表明進展為子宮頸癌的可能性更高。

CIN3+（宮頸上皮內瘤變 3+）：在子宮頸細胞中觀察到嚴重的異常變化，表明存在高度癌前病變狀況，如果不及時治療，可能會發展為浸潤性子宮頸癌。

RECOMMENDATION

CERVICAL EXAM FOR EVERY 6 -12 MONTHS

每 6 -12 個月定期進行一次子宮頸檢查

PRINCIPLE

The UROPRO CERVICAL PRECANCER DNA TEST is a comprehensive analysis designed to assess the risk of cervical cancer. By examining a range of biomarkers, it provides valuable insights into the progression of cervical cancer and the presence of HPV infection, including its integration into the host genome. The test results are presented as a staging index, highlighting the key molecular stages associated with the development of cervical cancer. This detailed analysis offers a nuanced understanding of an individual's cervical cancer risk, empowering healthcare providers to tailor appropriate interventions and treatments accordingly.

UROPRO 子宮頸癌前 DNA 測試是一項綜合分析，旨在評估子宮頸癌的風險。通過檢查一系列生物標誌物，它為子宮頸癌的進展和 HPV 感染的存在(包括其整合到宿主基因組中) 提供了有價值的見解。測試結果以分期指數的形式呈現，突顯出與子宮頸癌發展相關的關鍵分子階段。這種詳細的分析提供了對個人子宮頸癌風險細緻入微的瞭解，使醫療保健提供者能夠相應地定製適當的干預措施和治療方法。

PERFORMANCE CHARACTERISTICS

Performance is based on a population-based study with women aged between 10 to 70 years old.

UROPRO TEST		VALIDATED SAMPLES		TOTAL
		POSITIVE	NEGATIVE	
STAGING INDEX	0 +1	0	245	245
	2	4	22	26
	3	18	9	27
	4	78	0	78
TOTAL		100	276	376

Sensitivity: >99.9%

靈敏度

Specificity: 88.8%

特異性

COMMENTS

The UROPRO CERVICAL PRECANCER DNA TEST is a finger exosome DNA cancer test and is intended to be a first-line screening test for cervical cancer. Under optimal condition, the sensitivity is greater than 99.9% based on a population-based study with clinically validated patients. The specificity of the test is 88.8%.

UROPRO 子宮頸癌前 DNA 檢測是一種手指外泌體 DNA 檢測，旨在作為子宮頸癌的一線篩查檢測。在最佳條件下，根據對臨床驗證患者的人群研究，靈敏度大於 99.9%。該試驗的特異性為 88.8%。

* The **UROPRO CERVICAL PRECANCER DNA TEST** is intended to be an ancillary test and should be used in conjunction with other clinical diagnostic procedures for any medical decisions. Like other laboratory tests, the **UROPRO CERVICAL PRECANCER DNA TEST** must be ordered by an authorized healthcare provider.

* UROPRO 子宮頸癌前 DNA 檢測旨在作為輔助檢測，應與其他臨床診斷程序結合使用，以做出任何醫療決定。與其他實驗室檢查一樣，UROPRO 子宮頸癌前 DNA 測試必須由授權的醫療保健提供者訂購。

Deviations from the “Sample Collection Procedure” recommended for the **UROPRO CERVICAL PRECANCER DNA TEST may compromise its overall accuracy.

**偏離 UROPRO 子宮頸癌前 DNA 檢測所規範的“採樣操作步驟”可能會影響其整體準確性。

Sign: **BING LING, MD**

Date: **2024/5/**

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