


  
**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
<b>NORMAL</b>	-	NO IMMEDIATE RISK	0
<b>PRE-SIL</b>	+	EARLY MILD RISK	1

<b>CIN1+</b>	-	MILD TO MODERATE RISK	2
<b>CIN2+</b>	-	MODERATE TO SEVERE RISK	3
<b>CIN3+</b>	-	SEVERE RISK	4
<b>INTERPRETATION</b>	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/

## REFERENCE

1. Tae-Jung Kim, Ahwon Lee, Sung-Jong Lee<sup>1</sup>, Won-Chul Lee<sup>2</sup>, Yeong-Jin Choi, Kyo-Young Lee, Chang Suk Kang. Prognostic Significance of Amplification of the c-MYC Gene in Surgically Treated Stage IB-IIB Cervical Cancer. Received: September 29, 2011, Accepted: November 7, 2011, The Korean Journal of Pathology 2011; 45: 596-603.
2. Cornelia O. Ndifon; Ghaith Al-Eydi., Atypical Squamous Cells of Undetermined Significance. StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Last Update: April 24, 2023.
3. Iris Babion, Lise M.A. De Strooper, Roosmarijn Luttmers, Maaike C.G. Bleeker, Chris J.L.M. Meijer, Daniëlle A.M. Heideman, Saskia M. Wilting, and Renske D.M. Steenbergen. Complementarity between miRNA expression analysis and DNA methylation analysis in hrHPV-positive cervical scrapes for the detection of cervical disease. EPIGENETICS 2019, VOL. 14, NO. 6, 558–567
4. TIAN LI, LIANGDAN TANG, DUHONG BIAN, YING JIA, XIN HUANG and XINHUA ZHANG, Detection of hTERC and c-MYC genes in cervical epithelial exfoliated cells for cervical cancer screening. Received December 19, 2013; Accepted February 28, 2014, INTERNATIONAL JOURNAL OF MOLECULAR MEDICINE 33: 1289-1297, 2014
5. Qing Li<sup>1,2</sup>, Yongfeng Tang<sup>2</sup>, Xue Cheng<sup>2</sup>, Jie Ji<sup>2</sup>, Jingmin Zhang<sup>2</sup>, Xiaojun Zhou<sup>1</sup>, EGFR protein expression and gene amplification in squamous intraepithelial lesions and squamous cell carcinomas of the cervix. Received November 21, 2013; Accepted January 3, 2014; Epub January 15, 2014; Published February 1, 2014 Int J Clin Exp Pathol 2014;7(2):733-741.
6. T. Soonthornthum<sup>1</sup>, H. Arias-Pulido<sup>1</sup>, N. Joste<sup>2</sup>, L. Lomo<sup>2</sup>, C. Muller<sup>3</sup>, T. Rutledge<sup>3</sup> & C. Verschraegen<sup>1\*</sup>. Epidermal growth factor receptor as a biomarker for cervical cancer. Received 30 July 2010; revised 5 November 2010; accepted 5 November 2010, Annals of Oncology 22: 2166–2178, 2011, Published online 16 February 2011

7. Alfonso Dueñas-González\*<sup>1</sup>, Marcela Lizano<sup>1</sup>, Myrna Candelaria<sup>2</sup>, Lucely Cetina<sup>2</sup>, Claudia Arce<sup>2</sup> and Eduardo Cervera<sup>2</sup>, Epigenetics of cervical cancer. An overview and therapeutic perspectives. Published: 25 October 2005, Molecular Cancer 2005
8. Lisanne Verhoef<sup>1,2</sup>, Maaike C. G. Bleeker<sup>1,2</sup>, Nicole Polman<sup>1,2</sup>, Renske D. M. Steenbergen<sup>1,2</sup>, Renée M. F. Ebisch<sup>3</sup>, Willem J. G. Melchers<sup>4</sup>, Ruud L. M. Bekkers<sup>5,6</sup>, Anco C. Molijn<sup>7</sup>, Wim G. Quint<sup>7</sup>, Folkert van Kemenade<sup>8</sup>, Chris J. L. M. Meijer<sup>1,2</sup>, Johannes Berkhof<sup>9</sup> and Daniëlle A. M. Heideman<sup>1,2</sup>. Evaluation of DNA methylation biomarkers ASCL1 and LHX8 on HPV-positive self-collected samples from primary HPV-based screening. Received: 29 August 2022 Revised: 4 April 2023 Accepted: 12 April 2023, Published online: 26 April 2023, Molecular Diagnostics, British Journal of Cancer.
9. Bernardo Vega Crespo<sup>1\*</sup>, Vivian Alejandra Neira<sup>1,2</sup>, José Ortiz S<sup>1</sup>, Ruth Maldonado-Rengel<sup>3,4</sup>, Diana López<sup>2</sup>, Andrea Gómez<sup>1</sup>, María José Vicuña<sup>1</sup>, Jorge Mejía<sup>1</sup>, Ina Benoy<sup>5</sup>, Tesifón Parrón Carreño<sup>6</sup> and Veronique Verhoeven<sup>7</sup>, Evaluation of Urine and Vaginal Self-Sampling versus Clinician-Based Sampling for Cervical Cancer Screening: A Field Comparison of the Acceptability of Three Sampling Tests in a Rural Community of Cuenca, Ecuador. Received: 23 July 2022, Accepted: 22 August 2022, Published: 25 August 2022. Healthcare 2022, 10, 1614. <https://doi.org/10.3390/healthcare10091614>
10. WENTING JI<sup>1,2</sup>, WEIHUA LOU<sup>1,2</sup>, ZUBEI HONG<sup>1,2</sup>, LIHUA QIU<sup>1,2</sup> and WEN DI<sup>1,2</sup>. Genomic amplification of HPV, h-TERC and c-MYC in liquid-based cytological specimens for screening of cervical intraepithelial neoplasia and cancer, Received February 17, 2018; Accepted September 18, 2018. ONCOLOGY LETTERS 17: 2099-2106, 2019
11. Rianne van den Helder<sup>1,2</sup>, Renske D.M. Steenbergen<sup>2</sup>, Annina P. van Splunter<sup>2</sup>, Constantijne H. Mom<sup>3</sup>, Ming Y. Tjiong<sup>3</sup>, Ivonne Martin<sup>4</sup>, Fleur M.F. Rosier-van Dunne<sup>5</sup>, Irene A.M. van der Avoort<sup>6</sup>, Maaike C.G. Bleeker<sup>2</sup>, and Nienke E. van Trommel<sup>1</sup>, HPV and DNA Methylation Testing in Urine for Cervical Intraepithelial Neoplasia and Cervical Cancer Detection. 2022 American Association for Cancer Research
12. Cong Huang<sup>1,7,8</sup>, Xiangmin Lv<sup>1,8</sup>, Peichao Chen<sup>1,2,8</sup>, Jiyuan Liu<sup>1,8</sup>, Chunbo He<sup>1,3</sup>, Li Chen<sup>1,4</sup>, Hongbo Wang<sup>1</sup>, Madelyn L. Moness<sup>1</sup>, Jixin Dong<sup>3</sup>, Bo R. Rueda<sup>1</sup>, John S. Davis<sup>3,5,6</sup>, Cheng Wang<sup>1</sup>, Human papillomavirus targets the YAP1-LATS2 feedback loop to drive cervical cancer development. Published in final edited form as:Oncogene. 2022 July ; 41(30): 3761–3777.
13. Haikong Lu, Xin Gu, MicroRNA-221 inhibits human papillomavirus 16 E1-E2 mediated DNA replication through activating SOCS1/Type I IFN signaling pathway. Received November 10, 2018; Accepted December 25, 2018; Epub May 1, 2019; Published May 15, 2019, Int J Clin Exp Pathol 2019;12(5):1518-1528
14. September 18, 2020, by National Cancer Institute Staff, ACS's Updated Cervical Cancer Screening Guidelines Explained.
15. Juan Luo<sup>1†</sup>, Liang Deng<sup>2†</sup>, Hailin Zou<sup>1</sup>, Yibo Guo<sup>1</sup>, Tongyu Tong<sup>1</sup>, Mingli Huang<sup>2</sup>, Gengqiang Ling<sup>4</sup> and Peng Li<sup>1,5\*</sup>, New insights into the ambivalent role of YAP/TAZ in human cancers. Luo et al. J Exp Clin Cancer Res (2023) 42:130, Journal of Experimental & Clinical Cancer Research
16. Anneliese Velez-Perez, Min Li, Xiaohong Wang, MD, PhD, Songlin Zhang, MD, PhD, FASCP, University of Texas Health Science Center at Houston, Sirtuin1 Is a Promising Marker for Predicting Progression of Cervical Intraepithelial Neoplasms to Invasive Carcinoma. Am J Clin Pathol 2015;144:A300, American Society for Clinical Pathology
17. Ahmed Alrajjal, MD, Vaishali Pansare, MD, Moumita Saha Roy Choudhury, MD, Mir Yousufuddin Ali Khan, MD, and Vinod B. Shidham, MD, FIAC, FRC Path, Squamous intraepithelial lesions (SIL: LSIL, HSIL, ASCUS, ASC-H, LSIL-H) of Uterine Cervix and Bethesda System. Published online 2021 Jul 17. doi: 10.25259/Cytojournal\_24\_2021
18. Pui-Wah Choi<sup>1</sup>, Tin Lun Liu<sup>2†</sup>, Chun Wai Wong<sup>1</sup>, Sze Kei Liu<sup>1</sup>, Yick-Liang Lum<sup>1</sup> and Wai-Kit Ming<sup>3\*</sup>, The Dysregulation of MicroRNAs in the Development of Cervical Pre-Cancer—An Update. Received: 30 May 2022, Accepted: 24 June 2022, Published: 27 June 2022, Int. J. Mol. Sci. 2022, 23, 7126. <https://doi.org/10.3390/ijms23137126>
19. Daming Chu<sup>1\*</sup>, Tengteng Liu<sup>1</sup> and Yuan Yao<sup>2</sup>, Implications of viral infections and oncogenesis in uterine cervical carcinoma etiology and pathogenesis, RECEIVED 27 March 2023; ACCEPTED 05 May 2023; PUBLISHED 24 May 2023, Frontiers in Microbiology.