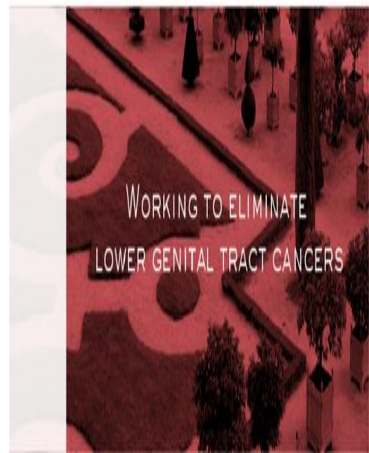


E7 Oncoprotein Test Clinical Value in Diagnosis of Cervical Precancerous Lesions

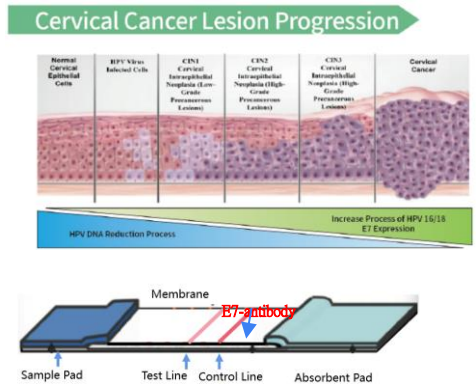
Chao Zhao

Peking University People's Hospital



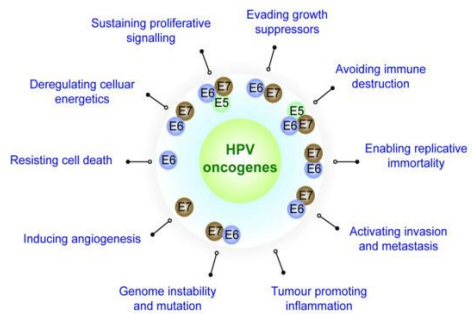
E7 Oncoprotein Clinical Application Overview

- ◆ HPV E7 oncoprotein rapid test is a novel technology for the detection cervical precancerous lesions and cancer.
- ◆ This test utilizes the principles of lateral flow technology and sandwich immunoassay, employing a colloidal gold method to detect HPV E7 oncoprotein in cervical exfoliated cells.
- ◆ This study preliminarily explores the role of HPV E7 oncoprotein detection in the diagnosis of cervical precancerous lesions.



E7 Oncoprotein Function

- ◆ The oncoprotein encoded by HPV E7 gene is a key factor in the development of cervical epithelial carcinoma.
- ◆ E7 protein inhibits retinoblastoma protein (pRb), allowing infected cells to proliferate indefinitely and undergo malignant transformation, ultimately leading to cancer.



E7 Oncoprotein Clinical Study Method

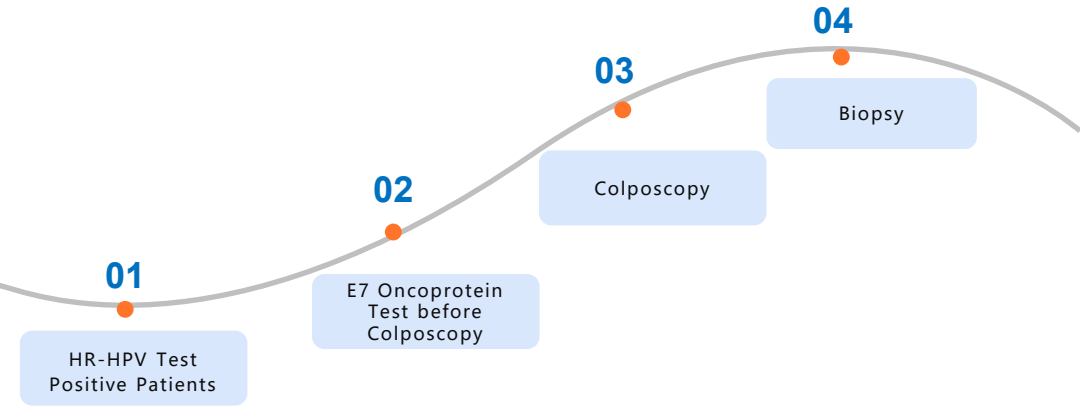
- Place: Peking University People's Hospital
- Date: August 8, 2025 and October 28, 2025

- Covered women at age of 20-70
- 219 participants enrolled
- 43 excluded for not meeting criteria
- **176 included in the study**

- Testing used E7 Oncoprotein Test Assay and had result in **15 minutes**
- Samples collected from the cervix using cervical brush
- E7 test results compared with Histopathological diagnosis

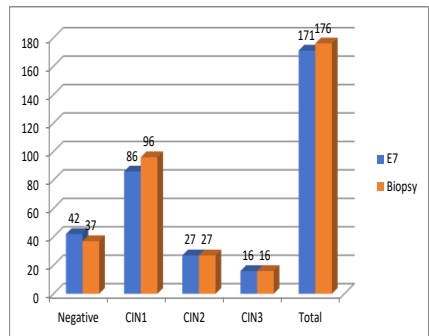


E7 Oncoprotein Clinical Study Work Flowchart



E7 Oncoprotein Test Results

Clinical Trial Test Results			
	Cut off : CIN1		
	Pathological Diagnosis Positive	Pathological Diagnosis Negative	Total
E7 Positive	129	5	134
E7 Negative	10	32	42
Total	139	37	176
Sensitivity	92.81%	Specificity	86.49%



E7 Oncoprotein Test Highlights

- The compliance rate between E7 and CIN1 is 89.58% (some CIN1 samples were close to the E7 protein cutoff value ≥ 11.45 ng/mL, cutoff value is defined as \geq CIN1), slightly higher or slightly lower, but all indicated E7 oncoprotein protein expression; follow-up is recommended.
- E7 and CIN2 compliance rate: 100% (E7 oncoprotein shows high compliance rate comparing with pathological results).
- E7 and CIN3 compliance rate: 100% (E7 oncoprotein shows high compliance rate comparing pathological results).
- Overall compliance rate: 91.48%.
- Sensitivity: 92.81%, Specificity: 86.49% (E7 oncoprotein not only has high sensitivity but also high specificity, making it suitable for cervical cancer screening, greatly reducing false positives and differentiating cervical precancerous lesion from HPV transient infection).

Clinical Study Highlights

➤	E7 and CIN1 compliance rate: 89.58%
➤	E7 and CIN2 compliance rate: 100%
➤	E7 and CIN3 compliance rate: 100%
➤	Overall compliance rate: 91.48%
➤	Positive predictive value (PPV): 96.27%
➤	Negative predictive value (NPV): 86.49%



Conclusions

- The rapid test results of E7 oncoprotein were largely consistent with the histopathological results of high-grade squamous intraepithelial lesions of the cervix.
- The clinical study demonstrates both high sensitivity and specificity of E7 oncoprotein test.
- This preliminary study had clinical application value in the diagnosis of high-grade squamous intraepithelial lesions.
- The rapid E7 oncoprotein test method is convenient, targets precancerous cells, requires no special equipment or laboratory, is non-invasive.
- It helps reduce high HPV positive patients referred for colposcopy and overtreatment.
- E7 test provides results within 15 minutes, making it clinically valuable.
- As a new cervical cancer screening and diagnostic technology, it still needs further extensive and large clinical studies.



THANKS FOR YOUR ATTENTION

Please contact me for any questions.

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