



**AyuGen Biosciences  
brings you the latest in  
cervical cancer screening –  
The 3 in 1  
COBAS HPV DNA Test**



## INTRODUCTION

- COBAS Human papillomavirus (HPV) test is a qualitative in-vitro **screening** and **risk stratification** test for detection of HPV DNA. It is designed to provide precise and accurate information that would help clinician with actionable results.
- It's the only clinically validated, FDA-approved and CE-marked test that offers three high-risk tests in one (**3 in 1 test result**) by identifying HPV types (HPV 16 and HPV 18), while simultaneously detecting the rest of the high risk-HPV types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68).
- This is the only FDA approved test for **first line primary screening**, ASC-US reflex, adjunctive and co-testing with PAP.
- Validation of this test for primary screening was completed under the clinical study of Athena Trial with a sample size of 47000 women aging between **21-65 years**. It validated test for reflex of ASC-US cytology, co-testing of women >30, and as a primary screening in women >25. Study confirmed women with negative COBAS HPV test result have significantly lower risk of future disease when compared to negative Pap cytology test.



## INTRODUCTION

- The COBAS HPV test is trusted in national screening programs, and is the test of choice for primary HPV screening to help eradicate cervical cancer worldwide and has been proven by extensive evidence in primary screening populations (with over 216,000 women studied)
- **Sensitivity** of the test to detect CIN 2+ and CIN 3+ is 90 % & 94% resp. in the ASCUS population and 88 % and 93% resp. in women aged 25 years & above

### **Sample requirement:**

Cervical cells collected in any liquid-based cytology or HPV containers

### **Testing platform:**

The COBAS HPV Test is performed on the COBAS 4800 System (Roche) which is a **walk-away, fully-automated technique** used in many countries for large scale cervical cancer screening programme.

### **Turn around time:**

7 days

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**SOON TO COME: CERVIVAL – ONE CONTAINER FOR MULTIPLE TESTS (HPV, LBC, STI)**