



# TAGMe DNA Methylation Detection Kits(qPCR) for Cervical Cancer

PCT No.: PCT/CN2019/0967937

#### **■ PRODUCT FEATURES**

· Precision ·



/alidated over 36,000 clinical samples in double-blind multi-center studies, the product has a specificity of 94.3% and a sensitivity of 96.0%

· Convenient ·



The original Me-qPCR methylation detection technology can be completed in one step within 3 hours without bisulfite transformation.

· Early ·



Cervical cancer screening can be advanced to the stage of high-level lesions (precancerous lesions) stage.

· Automation ·



Accompanied by customized result analysis software, the interpretation of the results is automated and directly readable.

#### **■ INTENDED USE**

This product is used for in vitro qualitative detection of hypermethylation of the gene *PCDHGB7* in cervical specimens. A positive result indicates an increased risk of grade 2 or higher-grade/more advanced cervical intraepithelial neoplasia (CIN2+, including CIN2, CIN3, adenocarcinoma in situ, and cervical cancer), which requires further colposcopy and/or histopathological examination. Final diagnosis should be based on colposcopy and/or histopathological results.

*PCDHGB7* is a member of protocadherin family  $\gamma$  gene cluster. Protocadherin has been found to regulate biological processes such as cell proliferation, cell cycle, apoptosis, invasion, migration and autophagy of tumor cells through various signaling pathways, and its gene silencing caused by hypermethylation of the promoter region is closely related to the occurrence and development of many cancers. It has been reported that hypermethylation of *PCDHGB7* is associated with a variety of tumors, such as non-Hodgkin lymphoma, breast cancer, cervical cancer, endometrial cancer and bladder cancer.

## **■ DETECTION PRINCIPLE**

This kit contains nucleic acid extraction reagent and PCR detection reagent. Nucleic acid is extracted by magnetic-bead-based method. This kit is based on the principle of fluorescence quantitative PCR method, using methylation-specific real-time PCR reaction to analyze template DNA, and simultaneously detect the CpG sites of *PCDHGB7* gene and the quality control marker internal reference gene fragments G1 and G2. The methylation level of *PCDHGB7* in the sample, or the Me value, is calculated according to the *PCDHGB7* gene methylated DNA amplification Ct value and the Ct value of the reference. The *PCDHGB7* gene hypermethylation positive or negative status is determined according to the Me value.







#### **APPLICATION SCENARIOS**



Early Screening

**Healthy people** 



Cancer Risk Assessment

High-risk population (positive for high-risk human papillomavirus (hrHPV) or positive for cervical exfoliation cytology)



Recurrence Monitoring

Postoperative population (with a history of high-grade cervical lesions or cervical cancer)

## **CLINICAL SIGNIFICANCE**

Early screening for healthy population: Cervical cancer and precancerous lesions can be accurately screened out

Risk assessment in high-risk population: Risk classification can be performed in HPV-positive populations to guide subsequent triage detection

Recurrence monitoring for postoperative population: Postoperative population recurrence monitoring can be performed to prevent delays in treatment caused by recurrence

## **SAMPLE COLLECTION**

 $-20\pm5$ °C for up to 24 months.

Sampling method: Place the disposable cervical sampler at the cervical os, gently rub the cervical brush and rotate 4-5times clockwise, slowly remove the cervical brush, put it into cell preservation solution, and label it for the following examination.

Preservation of samples: Samples can be stored at room temperature for up to 14 days, at 2-8 °C for up to 2 months, and at

# **DETECTION PROCESS: 3 HOURS (WITHOUT MANUAL PROCESS)**



# TAGMe DNA METHYLATION DETECTION KITS(qPCR) FOR CERVICAL CANCER



	Clinical application	Clinical auxiliary diagnosis of cervical cancer
/	Detection gene	PCDHGB7
	Sample type	Female cervical specimens
	Test method	Fluorescence quantitative PCR technology
	Applicable models	ABI7500
	Packing specication	48Tests/kit
	Storage Conditions	Kit A should be stored at 2-30 $^{\circ}\mathrm{C}$ , kit B should be
		stored at -20 $\pm$ 5 $^{\circ}$ C, valid for up to 12 months.