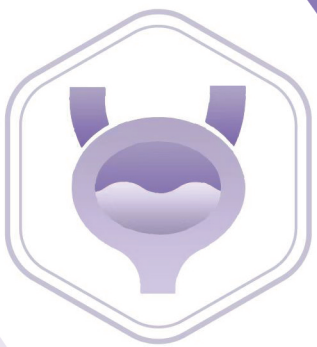


EPIPROBE

TAGMe DNA Methylation Detection Kits (qPCR) for Urothelial Cancer

PCT No.: PCT/CN2019/096793

PRODUCT FEATURES

· Precision ·

Validated over 3,500 clinical samples in double-blind multi-center studies, the product has a specificity of 92.7% and a sensitivity of 82.1%%.

· Convenient ·

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

· Non-invasive ·

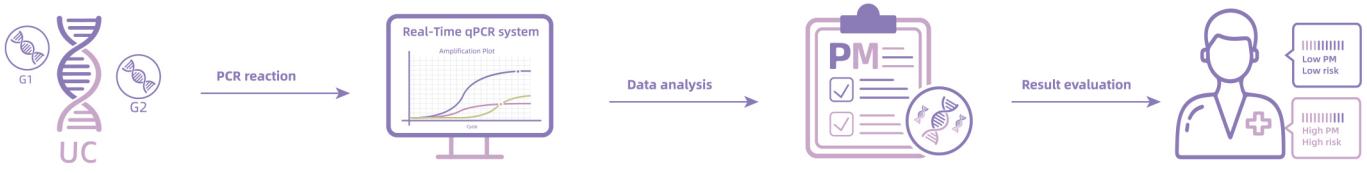
Only 30 mL of urine sample is required to detect 3 types of cancer, including renal pelvis cancer, ureteral cancer, bladder cancer at the same time.

INTENDED USE

This product is used for in vitro qualitative detection of hypermethylation of the Urothelial Carcinoma(UC) gene in urothelial specimens. A positive result indicates an increased risk of UC, which requires further cystoscope and/or histopathological examination. Final diagnosis should be based on cystoscope and/or histopathological results.

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 UC gene and the quality control marker internal reference gene fragments G1 and G2. The methylation level of UC gene, termed as Me value, is calculated according to the UC gene methylated DNA amplification Ct value and the Ct value of the reference. The UC gene hypermethylation positive or negative status is determined according to the Me value.



EPIPROBE

APPLICATION SCENARIOS

Auxiliary Diagnosis

Population suffering from painless hematuria/ suspected of having urothelial (ureteral cancer/ renal pelvis cancer)

Cancer Risk Assessment

Surgery/ chemotherapy-requiring population with urothelial carcinoma;

Recurrence Monitoring

Postoperative population with urothelial carcinoma

CLINICAL SIGNIFICANCE

Auxiliary diagnosis: Patients with urothelial cancer can be screened out in a non-invasive manner to assist in clinical diagnosis.

Surgery/chemotherapy efficacy assessment: Evaluate the efficacy of surgery/chemotherapy to assist clinical improvement of therapeutic effect.

Postoperative population recurrence monitoring: Patients with urothelial cancer can be monitored for recurrence in a non-invasive manner non-invasive manner, which improves patient compliance.

SAMPLE COLLECTION

Sampling method: Sampling method: Collect a urine sample (morning urine or random urine), add urine preservation solution and mix well, store it at room temperature 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 ℃ for up to 2 months, and at -20±5℃ for up to 24 months.

DETECTION PROCESS: 3 HOURS (WITHOUT MANUAL PROCESS)

Sample Collection » DNA Extraction (1h) » qPCR Detection (2h) » Result Analysis

DNA METHYLATION DETECTION KITS (qPCR) FOR UROTHELIAL CANCER

Clinical application	Clinical auxiliary diagnosis of urothelial cnacer; surgery/chemotheray treatment efficacy assessment; postoperative recurrence monitoring
Detection gene	UC
Sample type	Urine exfoliated cell sample (urine sediment)
Test method	Fluorescence quantitative PCR technology
Applicable models	ABI7500
Packing specication	48Tests/kit
Storage Conditions	Kit A should be stored at 2-30℃, kit B should be stored at -20±5℃, valid for up to 12 months.

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