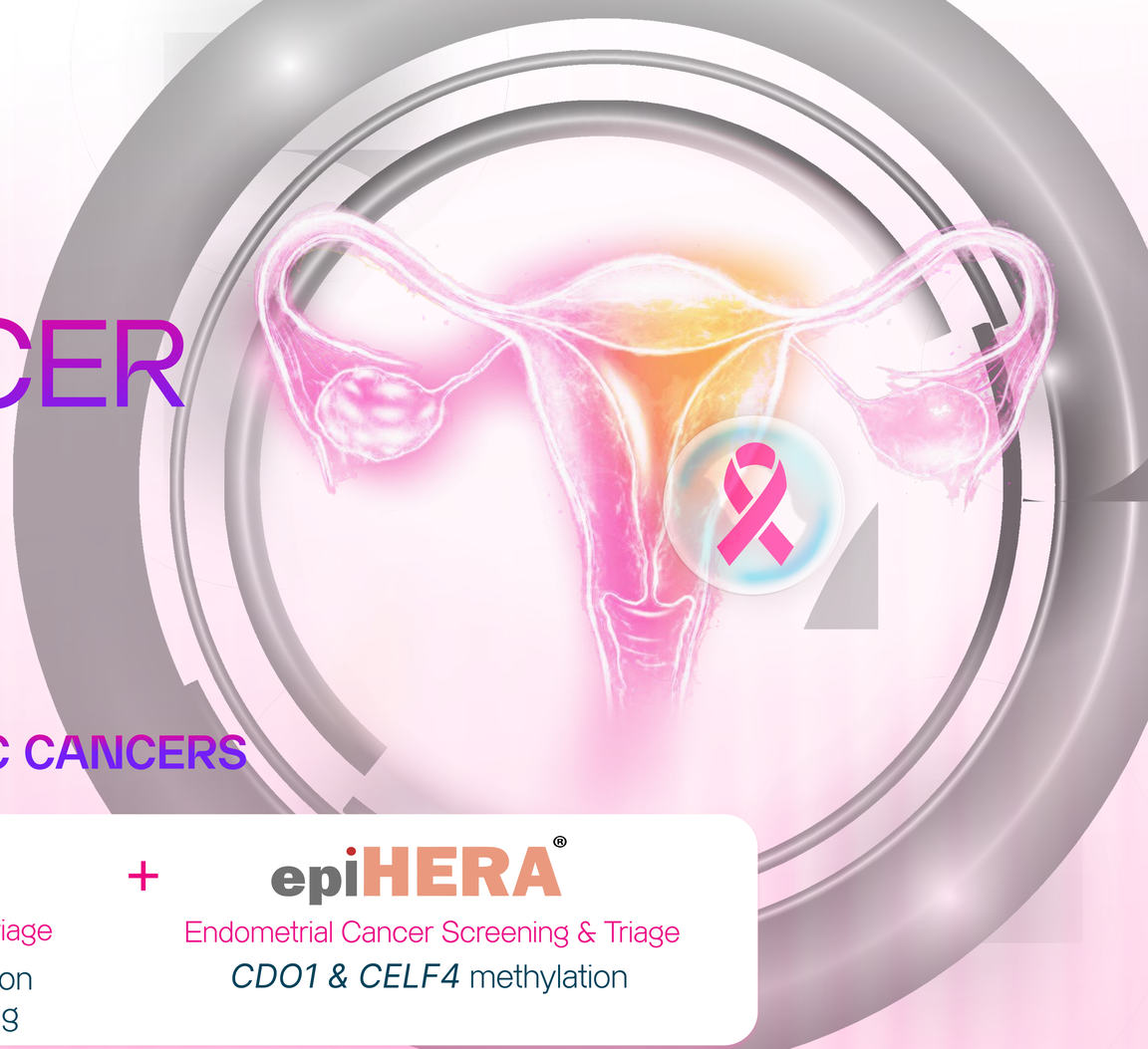
GENE SOLUTIONS

GYNECOLOGICAL CANCER SCREENING & TRIAGE

DNA methylation supports earlier detection, more precise risk stratification, and fewer unnecessary invasive biopsies.



EARLY SCREENING AND TIMELY TRIAGE IN GYNECOLOGIC CANCERS

SPOT-MAS EVA

02 Most Common Gynecologic Cancers
Screening & Triage

CERVIX 360
Cervical Cancer Screening & Triage
PAX1 & JAM3 methylation
HPV 28-Type genotyping

\+

epiHERA®
Endometrial Cancer Screening & Triage
CDO1 & CELF4 methylation

RESULT MANAGEMENT & COUNSELING RECOMMENDATIONS

This algorithm is based on the latest available research and current scientific evidence.
Clinical application should be guided by clinical judgment and individual patient assessment.

CERVIX 360

Cervical Cancer Screening & Triage

Sensitivity: 92.6%
Specificity: 95.7%
NPV: 97.6%
PPV: 87%

Reduce colposcopy referrals ~80% (1)

NOTE:
- *PAX1/JAM3* methylation testing is a non-invasive molecular test with a high negative predictive value (NPV).
- A positive result should be further evaluated by colposcopy and/or biopsy.
- A negative result should still be interpreted in the context of clinical risk to determine the need for follow-up or biopsy.

CERVICAL CANCER

PAX1 & JAM3 methylation, HPV 28-Type genotyping

- HPV Type 16, 18(+) → Colposcopy and biopsy
- HPV Type 16, 18 (-), 17 high-risk HPV (+) → **PAX1, JAM3 methylation**
  - POSITIVE → Colposcopy and biopsy
  - NEGATIVE → Repeat testing in 1 year
- HPV (-) or 9 low-risk HPV (+) → **PAX1, JAM3 methylation**
  - POSITIVE → Clinical assessment → Colposcopy and biopsy or repeat testing in 1-2 months
  - NEGATIVE → Repeat testing in 3–5 years

epiHERA®

Endometrial Cancer Screening & Triage

Sensitivity: 84.1%
Specificity: 98.8%
NPV: 98.2%
PPV: 89.2%

Reduce invasive biopsies >90% (2)

Clinical Consideration: In postmenopausal women with abnormal ultrasound findings and a positive methylation test result, hysteroscopy-guided biopsy should be prioritized to minimize the risk of missed diagnoses.
Source: Expert Consensus on the Clinical Application of Gene Methylation Screening Technology for Endometrial Cancer (2026 Version), The National Medical Journal of China.

ENDOMETRIAL CANCER

Symptomatic Individuals

Postmenopausal bleeding (PMB), abnormal uterine bleeding (AUB), or abnormal vaginal discharge.

Ultrasound (US) + Methylation Assay

- NORMAL ULTRASOUND → METHYLATION ASSAY
  - POSITIVE → BIOPSY: Curettage or hysteroscopy, followed by histopathology
  - NEGATIVE → FOLLOW-UP: Periodic clinical monitoring
- ABNORMAL ULTRASOUND → METHYLATION ASSAY
  - POSITIVE → BIOPSY: Histopathological confirmation
  - NEGATIVE → DEPENDS ON AGE
    Postmenopausal: Consider biopsy (high risk, recurrent bleeding)
    Premenopausal: Symptomatic treatment + follow-up.

High-Risk Individuals

Lynch syndrome, Cowden syndrome, and a strong family history of endometrial/colorectal cancer.

Annual Ultrasound + Methylation Assay

- NORMAL ULTRASOUND → METHYLATION ASSAY
  - POSITIVE → BIOPSY: Histopathological confirmation
  - NEGATIVE → GENETIC COUNSELING: Close monitoring + genetic testing
- ABNORMAL ULTRASOUND → METHYLATION ASSAY
  - POSITIVE → BIOPSY: Histopathological confirmation
  - NEGATIVE → DEPENDS ON AGE
    Postmenopausal: Consider biopsy (high risk, recurrent bleeding)
    Premenopausal: Symptomatic treatment + follow-up.

Elevated-Risk Individuals

Obesity, metabolic syndrome, unopposed estrogen exposure, and related factors.

Annual Ultrasound

- NORMAL ULTRASOUND → CLINICAL FOLLOW-UP: Periodic monitoring, no further testing required
- ABNORMAL ULTRASOUND → METHYLATION ASSAY
  - POSITIVE → BIOPSY: Histopathological confirmation
  - NEGATIVE → DEPENDS ON AGE
    Postmenopausal: Consider biopsy (high risk, recurrent bleeding)
    Premenopausal: Symptomatic treatment + follow-up.

1. Chen X, Jiang H, Xu H, Wang L, Liu P, Ma D, Wang H, Shou H, Fang X. Cervical cancer screening: efficacy of *PAX1* and *JAM3* methylation assay in the triage of atypical squamous cell of undetermined significance (ASC-US). BMC Cancer. 2024 Nov 11;24(1):1385. doi: 10.1186/s12885-024-13082-z. PMID: 39528979; PMCID: PMC11556146
2. Lee, Ho-Sze Jacqueline, et al. "Prospective Evaluation of Cervical Scrapings *CDO1* and *CELF4* Methylation (epiHERA®) Assay in Detection of Endometrial Cancer." Cancers 17.18 (2025): 3010.

MOLECULAR PRECISION TRIAGE IN GYNECOLOGICAL CARE

One Swab. Greater Clarity

Test Name	Target Disease	Biomarkers	Target Patient Profile	Testing Contraindications
CERVIX360	Cervical Cancer	*PAX1 & JAM3* Methylation HPV 28-Type Genotyping	• Proactive screening for women ≥ 30 years old • Early detection of cervical cancer in symptomatic patients • Post-treatment monitoring for patients with cervical lesions / cervical cancer	1. Ongoing menstruation. 2. Active pelvic inflammatory disease, cervicitis, lower genital tract infection, endometritis, or any other pelvic inflammatory or infectious condition. 3. Sexual intercourse within 24 hours prior to the gynecological examination. 4. Use of vaginal medications, vaginal contraceptives, or vaginal douching within 48 hours prior to the gynecological examination. 5. Endocervical sampling performed within the past 30 days (e.g., Pap smear).
epiHERA®	Endometrial Cancer	*CDO1 & CELF4* Methylation	• Selective screening for women ≥ 18 years old with high-risk factors • Early detection of endometrial cancer in symptomatic patients • Post-treatment monitoring for patients with endometrial hyperplasia / endometrial cancer	1. Ongoing pregnancy. 2. Ongoing menstruation. 3. Active pelvic inflammatory disease, cervicitis, lower genital tract infection, endometritis, or any other pelvic inflammatory or infectious condition. 4. Sexual intercourse within 24 hours prior to the gynecological examination. 5. Use of vaginal medications, vaginal contraceptives, or vaginal douching within 48 hours prior to the gynecological examination. 6. Endocervical sampling performed within the past 30 days (e.g., Pap smear).
SPOT-MAS EVA	02 Most common gynecologic cancer: Cervical & endometrial cancer	*PAX1 & JAM3* Methylation HPV 28-Type Genotyping *CDO1 & CELF4* Methylation	• Proactive screening for high-risk women ≥ 30 years old for endometrial cancer, including: - Obesity, diabetes, metabolic syndrome - Unopposed estrogen exposure, such as: polycystic ovary syndrome (PCOS), infertility, long-term tamoxifen use, early menarche, late menopause - Genetic factors, such as: Lynch syndrome, Cowden syndrome • Early detection of cervical cancer and endometrial cancer in patients with clinical symptoms	

SEAMLESS OPERATIONAL WORKFLOW



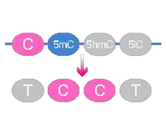
Step 1

Collect endocervical cells using a **cervical sampling broom.**



Step 2

Preserve specimens in **liquid-based cytology (LBC) medium.**



Step 3

Perform **DNA extraction and bisulfite conversion.**



Step 4

Run **multiplex real-time PCR assays.**

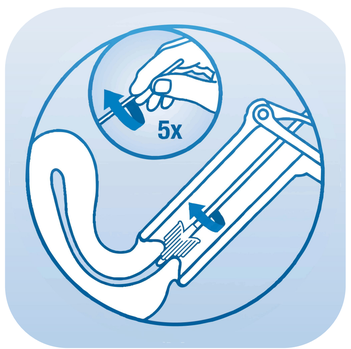


Step 5

Turnaround time (TAT): **7 working days(*)**

(*)TAT may vary depending on the country.

SAMPLE COLLECTION INSTRUCTIONS



Sampling

- Insert the brush into the cervix.
- Gently push and rotate the brush clockwise 3 times. If bleeding occurs, stop. If there is no bleeding, rotate an additional 2 times for a total of 5 rotations.
- Remove the brush.



Rinsing the Brush

- Completely submerge the brush head in the preservation solution. Rinse the brush as quickly as possible by dipping the brush to the bottom of the vial 10 times.
- Swirl the brush vigorously to ensure maximum sample release.
- Drop the brush head into the preservative solution vial (remove the shaft)



Capping

- Tighten the vial cap securely and send it to the laboratory. Ensure the cap is tightly secured with no leakage.

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For more information or to request a brochure, please contact us:

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