Ongoing Evaluation of Real-World Clinical Performance of a Multi-Omic Blood-Based Molecular Test (HerResolve™) for Detection of Endometriosis in Symptomatic Women

Cory Dunn, M.S., M.Ed, Lori Scala, Austin Bischoff, Wing Wong, Ph.D., and Farideh Bischoff, Ph.D.

HerAnova Lifesciences, Inc., Burlington MA, United States

HerAnova Lifesciences

BACKGROUND

- Diagnosis of endometriosis can be delayed by up to 10 years
- The current gold standard involves invasive laparoscopy surgery with histology which has variable sensitivity/ specificity performance driven by operator experience.
- HerResolve is an LDT, AI-trained and validated, multi-omic, non-invasive blood-based molecular diagnostic test designed to detect endometriosis in clinically suspected women. Performance of 94% AUC, 80% Sensitivity, and 97.5% Specificity is published in JMIG 2026.
- This study evaluates real-world utilization and performance characteristics of HerResolve in clinically suspected endometriosis cases in a clinical setting.

METHODS

- De-identified real-world data were collected from clinical HerResolve testing performed in symptomatic women undergoing evaluation for suspected endometriosis.
- Clinical indications included infertility, pelvic pain, and abnormal uterine bleeding.
- Two datasets were analyzed: 1) Aggregate case summary dataset and 2) Patient-level dataset including demographics, biomarkers, and algorithm output probabilities.
- The HerResolve algorithm integrates circulating biomarkers (including microRNAs and protein markers) using a machine learning classifier (random forest-based model) to generate a prediction probability score and binary result (DETECTED vs NOT DETECTED).
- Descriptive statistics were used to characterize patient demographics, clinical presentation, and test result distribution.

RESULTS

- A total of 197 clinical cases were analyzed.
- 104 cases (53%) were Detected (positive for endometriosis) and 93 cases (47%) were Not detected.
- Patient Characteristics included: Mean age: 35 years; Median age: 35 years.
- Patients were referred for testing primarily due to infertility, pelvic pain and/or abnormal uterine bleeding.
- Testing was distributed across multiple ordering providers, with five centers accounting for the majority of cases reflecting broad early adoption across diverse clinical practices.
- Algorithm Output provided continuous prediction probabilities, demonstrating clear stratification between DETECTED and NOT DETECTED groups.
- High-probability outputs (>0.9) were frequently associated with DETECTED classification, supporting internal model consistency.

	HerResolve Detection Results n=197
Endometriosis Detected	**104 (53%)**
Endometriosis NOT Detected	**93 (47%)**

Reference: Wong et al., J Minim Invasive Gynecol. 2026 Mar 4:S1553-4650(26)00151-2. doi: 10.1016/j.jmig.2026.02.042.

CONCLUSION

- **In this real-world commercial cohort, HerResolve demonstrated:**

1) Clinically meaningful detection rates (~53%) in a population with suspected endometriosis;

2) Consistent performance across diverse clinical providers and indications;

3) Feasibility as a non-invasive adjunct tool in the diagnostic pathway for endometriosis.

- These findings support the utility of HerResolve in real-world clinical practice and highlight its potential to reduce diagnostic delays associated with invasive procedures.
- HerAnova is currently conducting a larger performance study for regulatory submission as a noninvasive aide to diagnosing endometriosis among symptomatic women.

Contact

Cory Dunn
cory.dunn@heranova.com