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### A NOVEL MICROBIOME TESTING PLATFORM IDENTIFIES ASSOCIATION BETWEEN VAGINAL LACTOBACILLUS COMPOSITION AND CLINICAL PREGNANCY OUTCOME

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**Title:**

A NOVEL MICROBIOME TESTING PLATFORM IDENTIFIES ASSOCIATION BETWEEN VAGINAL LACTOBACILLUS COMPOSITION AND CLINICAL PREGNANCY OUTCOME

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**Preferred Presentation Type:**

Oral or Poster

**Study Type:**

Prospective Observational/ Cohort

**Category - Subcategory(ies):**

**Technology & Innovation:** ART

**Technology & Innovation:** Infertility

**Technology & Innovation:** Reproductive Medicine (non-infertility)

**Funding:**

Yoni Solutions

**References:**

N/A

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**ACCME Disclosure**

In a Slide

**Did this abstract require approval by a local Institutional Review Board (IRB) or equivalent?**

This abstract has been approved by a local Institutional Review Board (IRB) or equivalent.

**Not applying for an award****Abstract Text:**

**OBJECTIVE:**

The vaginal microbiome appears to play a role in human reproduction. However, a reliable biomarker linking microbiome composition to in vitro fertilization (IVF) outcomes remains undefined. This study aims to evaluate a novel testing platform to identify potential associations between vaginal microbiome and reproductive outcomes in patients undergoing single euploid embryo transfer (SEET).

**MATERIALS AND METHODS:**

The prospective observational, cohort study was conducted at a private, academic infertility center and included patients who underwent IVF/PGT-a with a subsequent frozen/thaw SEET. The primary outcome was clinical pregnancy. Informed consent was obtained, and the study was IRB approved. Samples were collected from the cervix and posterior vaginal fornix prior to SEET in a programmed cycle. Microbiome analysis was carried out by YONI Solutions (Monthey, Switzerland). Samples were profiled for species of *Lactobacillus* and other microbes. The YONI platform employs Cycling Temperature Capillary Electrophoresis for microbial quantification. Data was analyzed using Partial Least Square Discriminant analysis (PLS-DA) to identify microbiome biomarkers associated with IVF outcome.

**RESULTS:**

Of the 33 patients who enrolled in the study, 57.5% (n=19) achieved a clinical pregnancy. In those patients, an increased level of the specific *Lactobacillus* species was observed compared to patients who did not achieve a clinical pregnancy (n=14). Within this species, the PLS-DA model showed rises in *L. iners*, *L. gasseri* and *L. acidophilus*. While no single *Lactobacillus* can confirm outcome, *L. iners* was indicative of a suboptimal pregnancy outcome, while *L. gasseri* and *L. acidophilus* demonstrated to be indicative of optimal conditions for achieving a clinical pregnancy. The model has a ROC Area-under-the-curve (AUC) of 0.78 with a P-Value < 0.001, with predicted clinical pregnancy outcomes summarized in the table.

Clinical Pregnancy Outcome	Mean Value of Predictor Variable	Standard Deviation	P-Value Wilcoxon Rank Test
Yes (n=19)	-0.73	0.39	P-Value < 10 <sup>-4</sup>
No (n=14)	1.217889	0.52	

**CONCLUSIONS:**

Growing evidence supports an association between vaginal microbiome composition and clinical pregnancy outcome. This study provides a detailed analysis and highlights the presence and significance of various *Lactobacillus* species. Future study could involve the introduction of specific probiotics to shift the vaginal microbiome and then track potential effects on endometrial receptivity and ultimately on IVF outcome

**IMPACT STATEMENT:**

A novel microbiome test identifies specific *Lactobacillus* species associated with clinical pregnancy outcomes, offering a potential pathway for microbiome-targeted IVF interventions.

First Presenting Author**Presenting Author**

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Yoni Solutions  
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Monthey

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Within the past 2 years, have you or your spouse/partner had any potential COI?

Yes

Organization Name	Relationship Type	Who has this Relationship?	
YONI Solutions SA	Direct Stockholder Relationship Began - Monday, August 2, 2021 Relationship Ended -	Self	

Signature: Paulo Refinetti

Second Author

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Biographical Sketch Early success, marked by his first publication in CELL at Harvard Medical School, inspired Joseph to continue his research endeavors in reproductive endocrinology and infertility. Joseph has been with Reproductive Medicine Associates of New York since 2011. Joseph has authored over 400 peer-reviewed abstracts & manuscripts. Passionate about development, he cultivates relationship with investors & entrepreneurs to advance reproductive endocrinology & infertility care.

Within the past 2 years, have you or your spouse/partner had any potential COI?

No

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**CV Upload:**

 [Joseph Lee CV.docx](#)

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Within the past 2 years, have you or your spouse/partner had any potential COI?

Yes

Organization Name	Relationship Type	Who has this Relationship?
YONI Solutions	Direct Stockholder Relationship Began - Monday, August 2, 2021 Relationship Ended - Full-Time Company Employee Relationship Began - Monday, August 2, 2021 Relationship Ended -	Self

Signature: Virginia Franco Silva



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Progyny	Company Officer Relationship Began - Friday, August 25, 2017 Relationship Ended - Thursday, June 1, 2023 Paid Consultant Relationship Began - Relationship Ended - Direct Stockholder Relationship Began - Friday, August 25, 2017 Relationship Ended - Friday, November 1, 2024	Self

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**CV Upload:**

 Alan B. Copperman M.D. - CV (March 2024).docx

**Fifth Author**

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No

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No

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