ASPIRA
WOMEN'S HEALTH®

Aspira R&D Day: Updates on the Development of the Company's Ovarian Cancer and Endometriosis Tests

January 4, 2024

Today's Discussion

Welcome & Introductions

Overview of AWH's Proprietary Technology

Our Ovarian Cancer Test Portfolio

Our Endometriosis Test Portfolio

Portfolio Market Opportunity

Q&A

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Today's Speakers

Kevin Elias, MD

Kevin Elias, MD, is Associate Professor of Obstetrics, Gynecology and Reproductive Biology at Harvard Medical School; Director of Gynecologic Oncology Laboratory in the Division of Gynecologic Oncology at Brigham and Women's Hospital; Gynecologic oncologist and surgeon-scientist at Dana-Farber Cancer Institute.

Jody Berry, PhD

Jody Berry, PhD is Chief Scientific Officer, SVP of Innovation and Product Development, Aspira Women's Health

ASPIRA WOMEN'S HEALTH

Aspira Women's Health Investment Highlights

Revenue Generating Company	**Revenue generating commercial diagnostics company** to aid in the detection of ovarian cancer and endometriosis
Steady Growth Metrics	Year-over-year revenue and volume growth since Q2 2020 **21% three-year CAGR**
Innovative Products	OvaSuite℠ portfolio of proprietary, AI-powered blood tests to aid in diagnosis of ovarian cancer in women with pelvic masses ordered by physicians **~200,000 times**
Near-Term Pipeline	$1B pipeline opportunity for blood tests in both ovarian cancer and endometriosis
Market Access & Reimbursement	Medicare reimbursement of OvaWatch and Ova1Plus® established at $897 per test Reimbursement by several national/regional commercial and state Medicaid plans
Experienced Management	Mission-driven executives with relevant experience and **proven success** in **small and mid-cap women's health and diagnostic companies**

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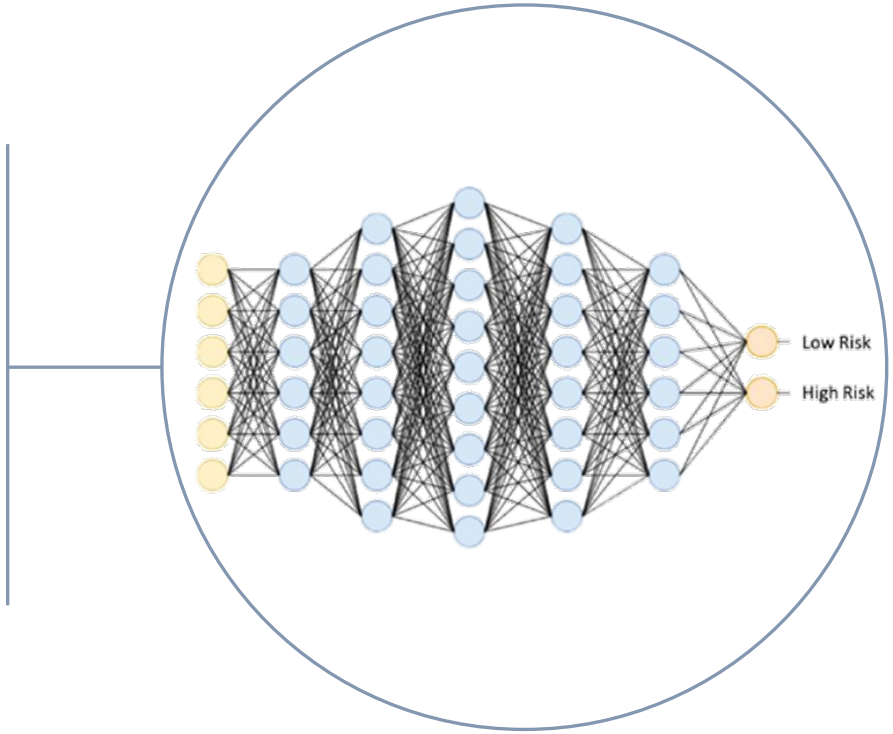
AI is the Cornerstone of Our Technology

For over 20 years, Aspira's products have leveraged artificial intelligence to develop personalized risk assessment scores.

Our tests use a variety of machine learning models (support vectors, decision trees, neural networks) to recognize relationships across multiple variables.

- For example, OvaWatch used a dynamic feed forward neural network with multiple hidden nodes to classify clinical and biomarker data against malignancy labels
- Models are selected to best suit the classification problem
- Data are curated to be representative and suitably variable
- Clinical data undergo thorough independent review before use in models



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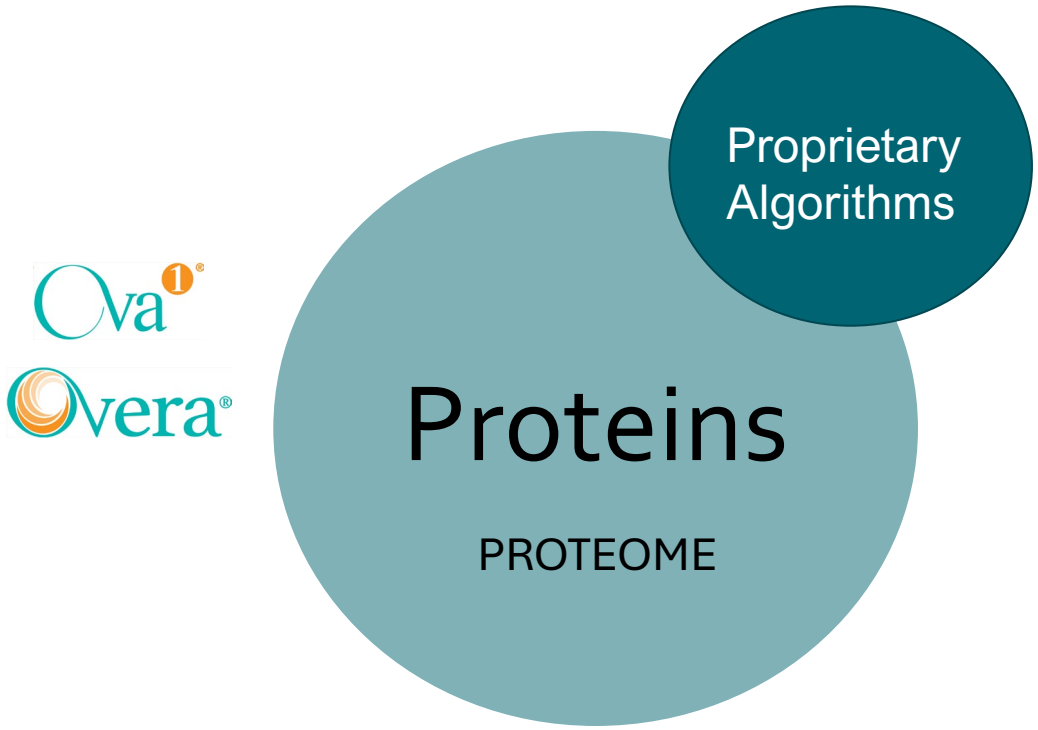
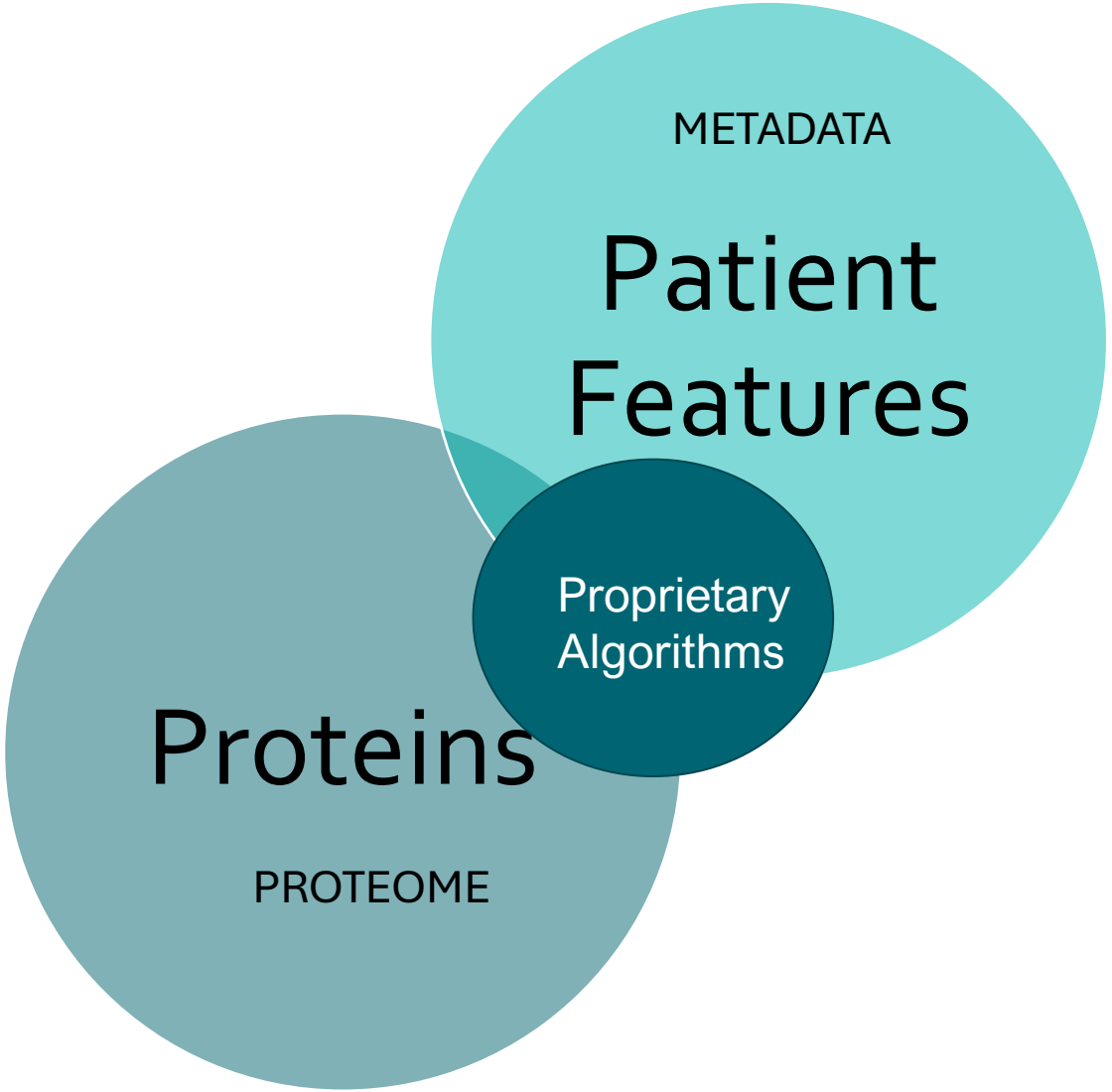
The Evolution of AWH Testing Technologies



The Evolution of AWH Testing Technologies



OvaWATCH℠

EndoCHECK℠

Ova1®

Overa®

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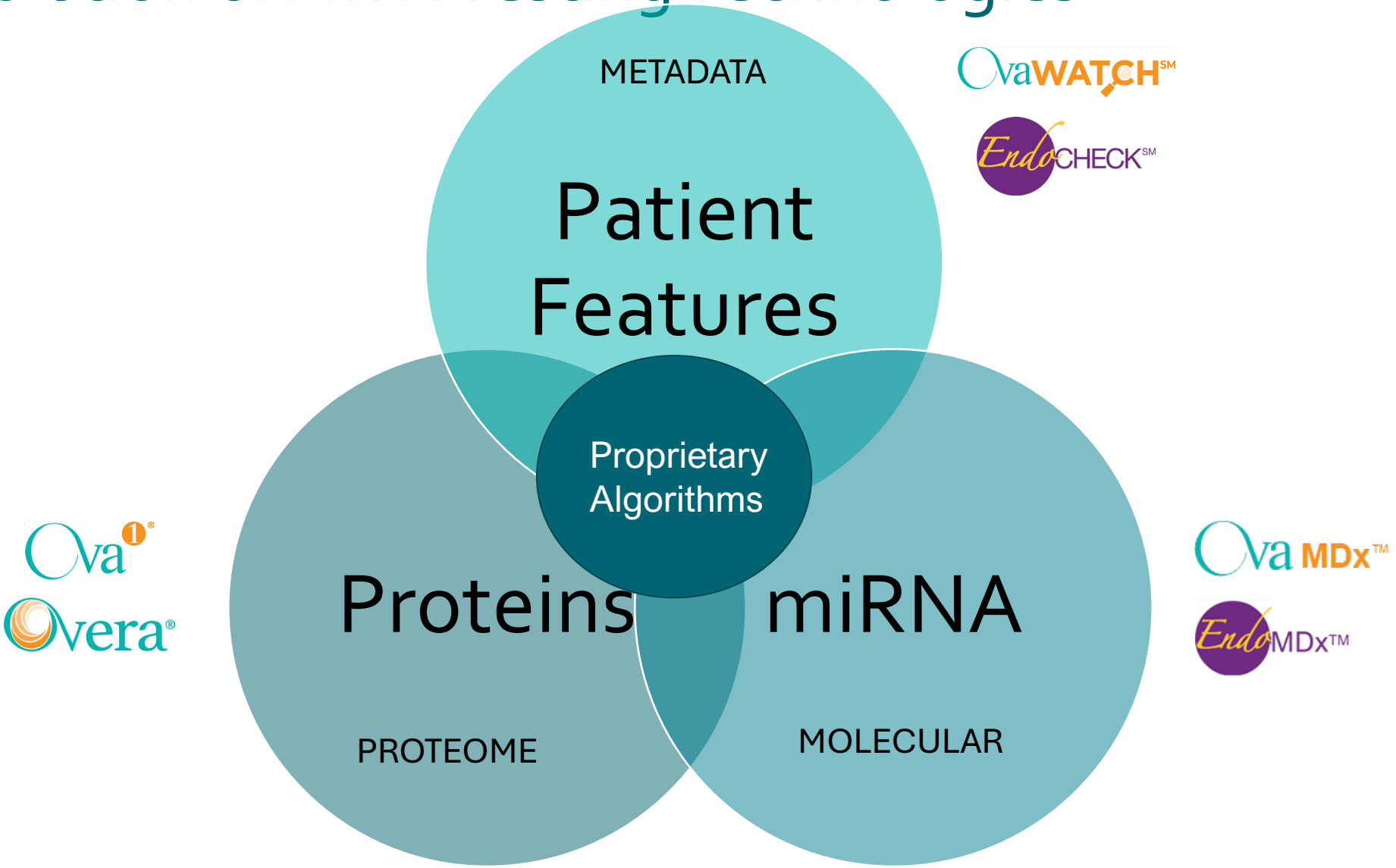
The Evolution of AWH Testing Technologies



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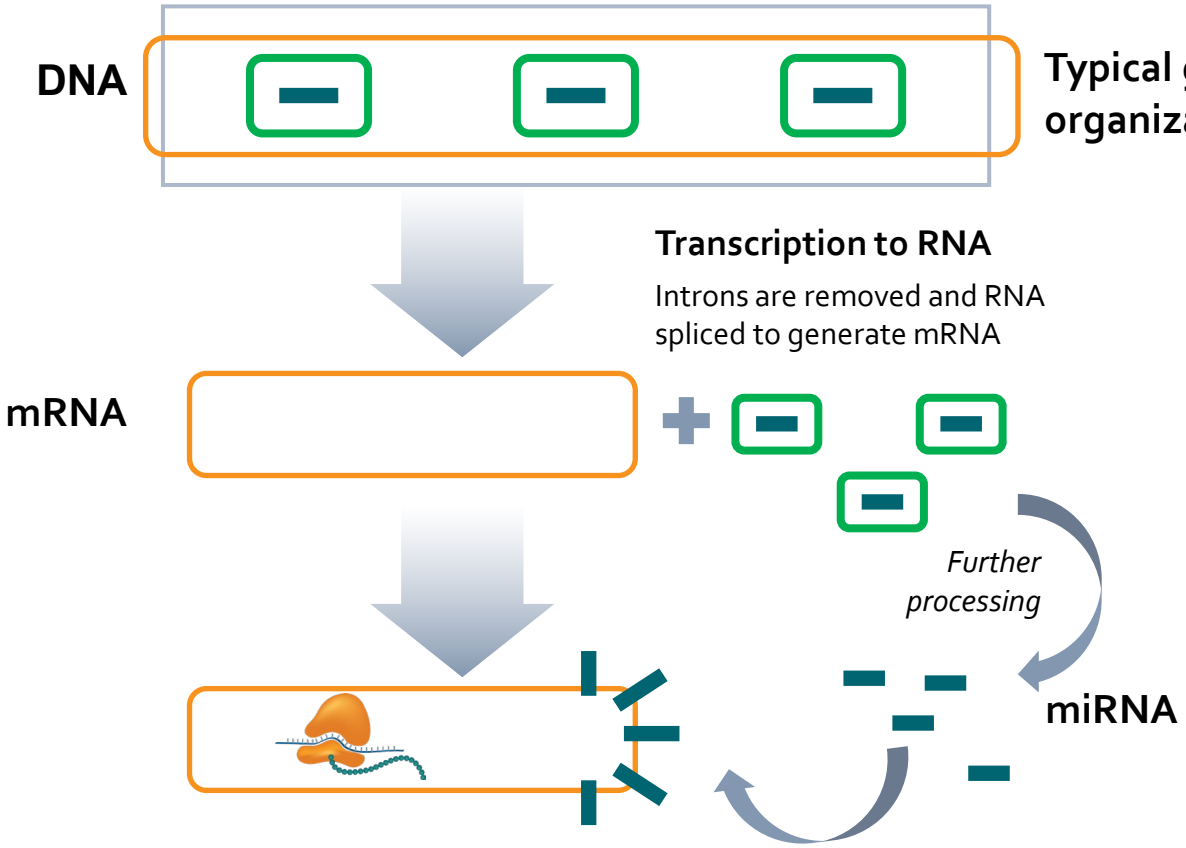
miRNAs as Complementary Biomarkers for Non-Invasive Diagnostics

Genes are regions of DNA that code for proteins.
The DNA between genes, "intragenic DNA", contains other regulatory information, including microRNAs (miRNA).



Normal protein translation

Ribosomes sit down on mRNA to translate protein

miRNA bind to complementary sequences in 3' end of mRNA Regulating protein expression

Protein translation I blocked or degradation mRNA enhanced Resulting in modification of protein output

Advantages of miRNA

- Detectable in all body fluids
- Stable at room temperature
- Amenable to amplification through PCR
- High-throughput
- LDTs on the market using miRNAs for other diseases
- Can be correlated to disease biology as the levels of expression are perturbed in unhealthy cells

Slides provided by Elias Laboratories

Ovarian Cancer Test Portfolio

Ovarian Cancer: A Diagnostic Dilemma

1.2M+ women will present with adnexal masses each year. Historical diagnostic methods result in poor outcomes.

Traditional methods are ineffective

Tissue sample may result in cancer spread

+

Lack of Non-invasive Diagnostic Tools

- Ultrasounds are rarely definitive
- Off-label use of CA-125 has been found to be ineffective

=

Late-Stage Detection

- 65% of ovarian cancer is diagnosed in Stages III and IV[1]
- Approx 200K oophorectomies with only 20K cases

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1 https://seer.cancer.gov/statfacts/html/ovary.html

OvaSuite℠ A Comprehensive Portfolio of Ovarian Cancer Blood Tests

OvaWATCH℠

Initial Clinical Assessment

For adnexal masses evaluated by initial clinical assessment as indeterminate or benign.

Optimized for Negative Predictive Value with an NPV of >99.4%[1].

Ova1 plus®

Planned for Surgery

For women with pelvic masses that are planned for surgical management.

Ova1® has a sensitivity of 96% with clinical assessment[2]. The addition of Overa® to the reflex process improves specificity to 72%[3].

Physicians have ordered ~200,000 OvaSuite tests since launch

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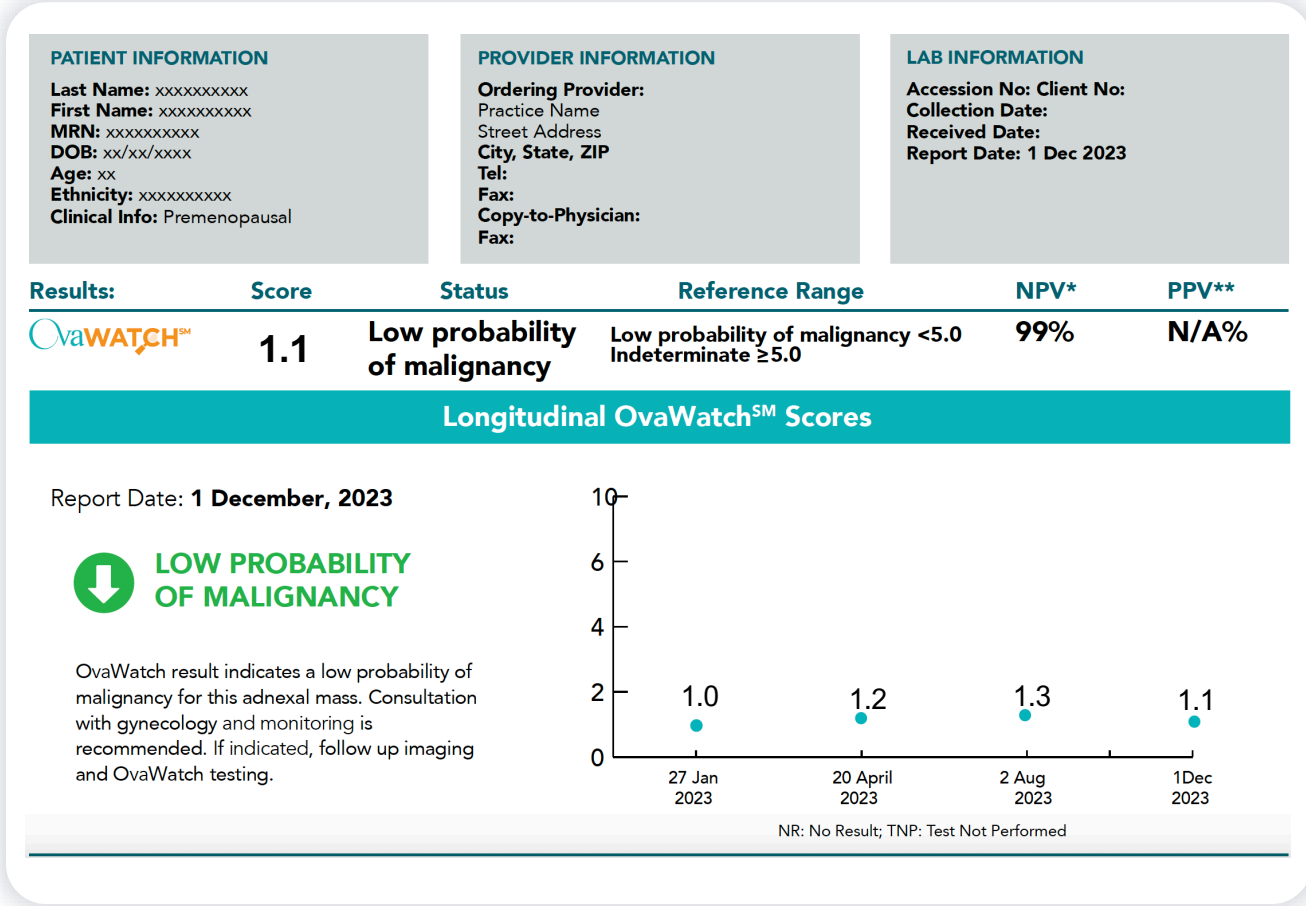
1. Reilly, G., Bullock, R. G., Greenwood, J., Ure, D. R., Stewart, E., Davidoff, P., ... & Northrop, L. E. (2022). Analytical validation of a deep neural network algorithm for the detection of ovarian cancer. JCO Clinical Cancer Informatics, 6, e2100192. Reilly, G. P., Dunton, C. J., Bullock, R. G., Ure, D. R., Fritsche, H., Ghosh, S., ... & Phan, R. T. (2023). Validation of a deep neural network-based algorithm supporting clinical management of adnexal mass. Frontiers in Medicine, 10, 1102437.; 2. Bristow, R. E., Smith, A., Zhang, Z., Chan, D. W., Crutcher, G., Fung, E. T., & Munroe, D. G. (2013). Ovarian malignancy risk stratification of the adnexal mass using a multivariate index assay. Gynecologic oncology, 128(2), 252-259. 3. Fritsche, H. A., & Bullock, R. G. (2023). A reflex testing protocol using two multivariate index assays improves the risk assessment for ovarian cancer in patients with an adnexal mass. International Journal of Gynecology & Obstetrics.

Near-Term Portfolio Expansion Update

OvaWatch was launched as an LDT in 2022 for the initial assessment of ovarian cancer risk.

- All commercial and operational steps complete for expansion of OvaWatch for longitudinal mass monitoring upon publication of submitted manuscript.
- FDA 510(k) submission is planned and in process.
- Two manuscripts submitted for peer review publication:
  - *Longitudinal Monitoring of Ovarian Cancer Risk for Adnexal Mass Utilizing A Neural Network-derived Multivariate Index Assay*
  - *Multivariate Index Assay MIA3G improves the patient selection for surgery in ovarian cancer management*

Example Report - Not real patient data



PATIENT INFORMATION
Last Name: xxxxxxxxxx
First Name: xxxxxxxxxx
MRN: xxxxxxxxxx
DOB: xx/xx/xxxx
Age: xx
Ethnicity: xxxxxxxxxx
Clinical Info: Premenopausal

PROVIDER INFORMATION
Ordering Provider:
Practice Name
Street Address
City, State, ZIP
Tel:
Fax:
Copy-to-Physician:
Fax:

LAB INFORMATION
Accession No: Client No:
Collection Date:
Received Date:
Report Date: 1 Dec 2023

Results:	Score	Status	Reference Range	NPV*	PPV**
OvaWATCH℠	1.1	Low probability of malignancy	Low probability of malignancy <5.0 Indeterminate ≥5.0	99%	N/A%

Longitudinal OvaWatch℠ Scores

Report Date: **1 December, 2023**

LOW PROBABILITY OF MALIGNANCY

OvaWatch result indicates a low probability of malignancy for this adnexal mass. Consultation with gynecology and monitoring is recommended. If indicated, follow up imaging and OvaWatch testing.

NR: No Result; TNP: Test Not Performed

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OvaMDx™ | Enhanced Assay for Identification of Ovarian Cancer

Aspira's Advantages

- Existing protein-based FDA approved test
- Exclusive rights to miRNA identified by Dana Farber
- Experience in AI developed tests and proprietary algorithms
- Brand recognition with healthcare providers
- Access to large biobank for verification and validation

OvaMDx Assay Features

A promising new AI-powered blood test to aid in the identification of ovarian cancer in women diagnosed with an adnexal mass.

- Non-invasive, blood-based assay utilizing multiple, differentiating biomarkers
- Combines Aspira's proprietary protein biomarker technology with miRNAs licensed from Dana Farber
  - Improved specificity for all stage cancers vs. proteins alone
  - Improved sensitivity for early-stage cancers vs. proteins alone
- Platform migration in process with commercial CRO partner

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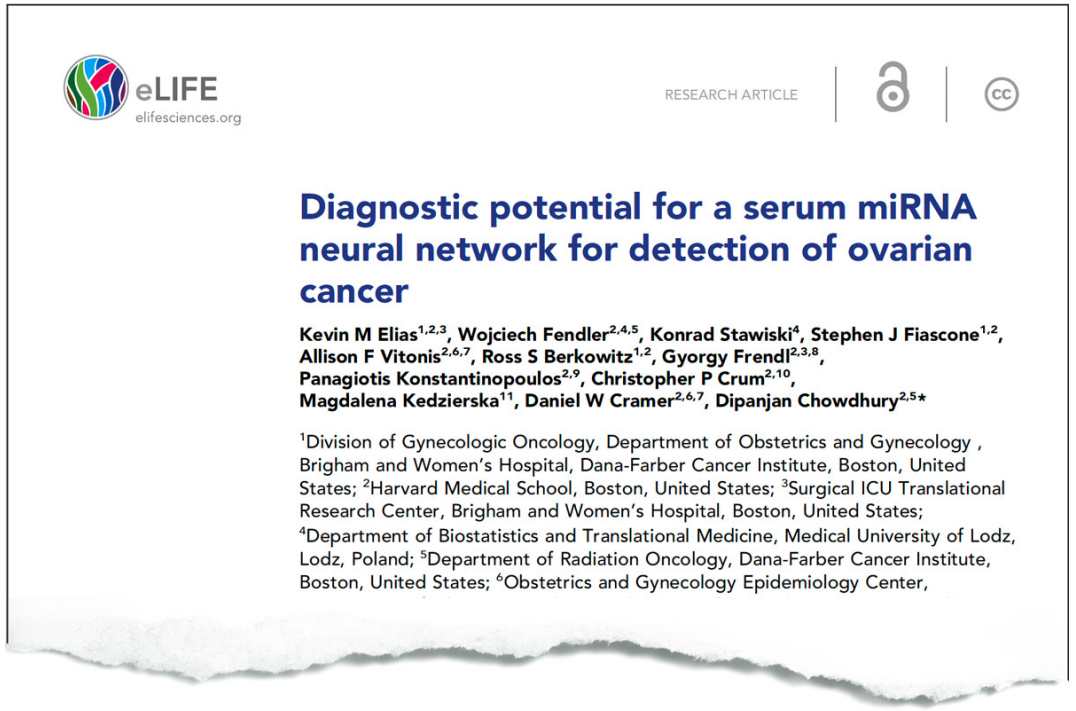
Use of miRNA in the detection of Ovarian Cancer

Kevin Elias, M.D.

Diagnostic potential for a serum miRNA neural network for detection of ovarian cancer

- First peer-reviewed publication describing 179 subjects was released in 2017
- Combined serum miRNA-sequencing with neural network analysis. Outperformed traditional protein biomarkers alone.



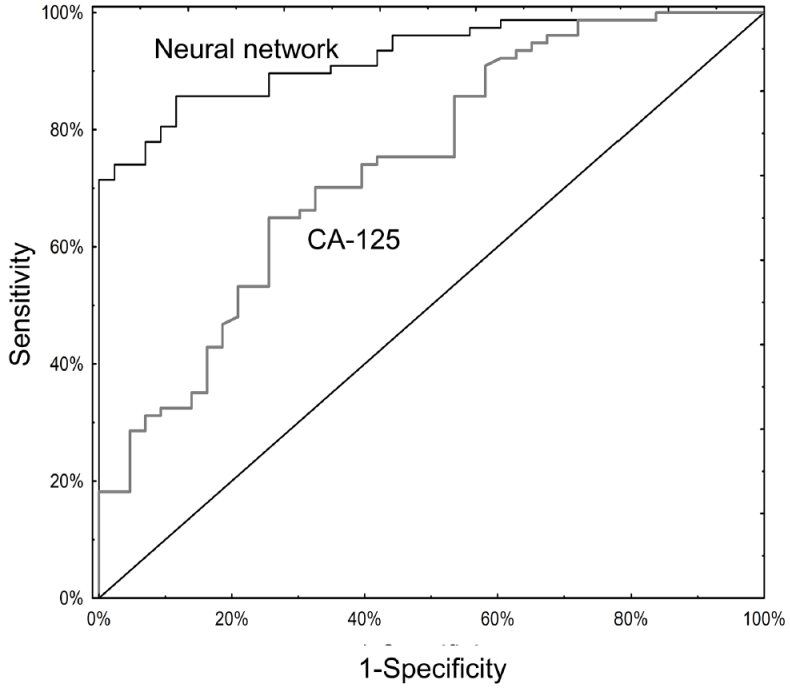
eLIFE elifesciences.org

RESEARCH ARTICLE

Diagnostic potential for a serum miRNA neural network for detection of ovarian cancer

Kevin M Elias[1,2,3], Wojciech Fendler[2,4,5], Konrad Stawiski[4], Stephen J Fiascone[1,2], Allison F Vitonis[2,6,7], Ross S Berkowitz[1,2], Gyorgy Frendl[2,3,8], Panagiotis Konstantinopoulos[2,9], Christopher P Crum[2,10], Magdalena Kedzierska[11], Daniel W Cramer[2,6,7], Dipanjan Chowdhury[2,5]*

[1]Division of Gynecologic Oncology, Department of Obstetrics and Gynecology , Brigham and Women's Hospital, Dana-Farber Cancer Institute, Boston, United States; [2]Harvard Medical School, Boston, United States; [3]Surgical ICU Translational Research Center, Brigham and Women's Hospital, Boston, United States; [4]Department of Biostatistics and Translational Medicine, Medical University of Lodz, Lodz, Poland; [5]Department of Radiation Oncology, Dana-Farber Cancer Institute, Boston, United States; [6]Obstetrics and Gynecology Epidemiology Center,



Second independent study of 275 subjects focused on 75 Stage I/II cases, 100 benign adnexal masses, and 100 healthy controls: 73% sensitivity at 91% specificity for distinguishing early-stage ovarian cancers (2022).

Elias KM . . . Chowdhury D. eLife, 2017; Patent US20200123614A1; Gockley A. . . Elias KM. Front Oncol, 2022

Slides provided by Elias Laboratories

Improving the diagnostic accuracy of an ovarian cancer triage test using a joint miRNA-protein model

Can diagnostic performance be improved even further when using a combination of approaches, including miRNA, proteins, and metadata?

The goals of this work are:

1. **Can we improve a currently deployed ovarian cancer triage test?**
   The current test from AWH is based on proteins and metadata. We aimed to investigate whether adding miRNA can improve the current test either alone or in combination.

2. **Testing and comparison:**
   We compared model performance on blinded internal and external validation sets provided by Aspira and Brigham and Women's Hospital.

3. **Identifying patients for surgery:**
   The patients are presenting with an ovarian mass, and the goal is to determine who should be referred to a gynecologic oncologist. We aim to investigate whether miRNA can improve model sensitivity, particularly among early-stage and serous cancers.

Presented at AACR Ovarian Cancer conference in Boston in October 2023.

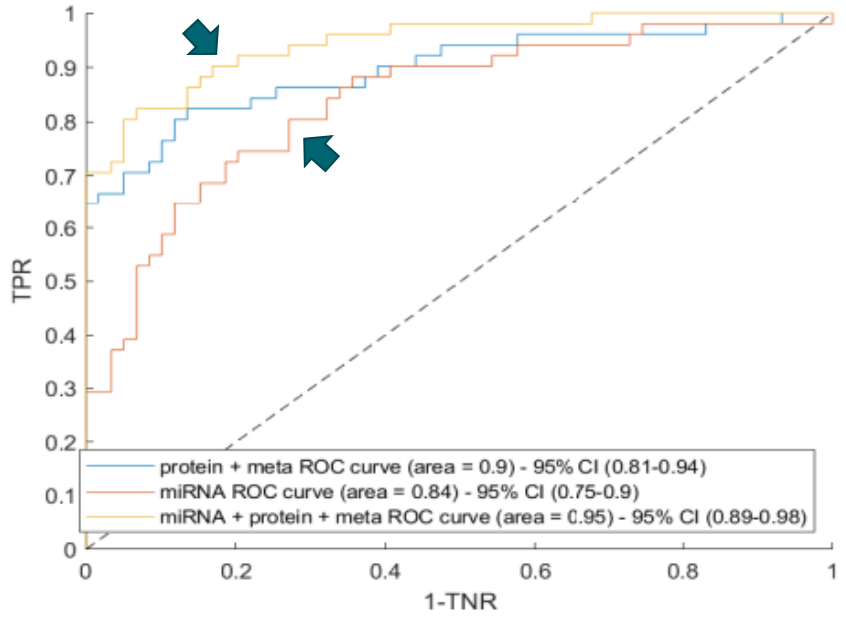
Slides provided by Elias Laboratories

Improving the diagnostic accuracy of an ovarian cancer triage test using a joint miRNA-protein model

- Training cohort of pre-op patients (AWH)
- Independent set from external validation cohort (AWH)
- Includes protein biomarkers and clinical metadata from and miRNAs from BWH

Cohort	Overall	Controls	Cases
Training (AWH)	468	277	191
Internal validation (AWH)	100	56	44
External validation (BWH)	110	59	51
Total	**678**	**392**	**286**

ROC plots on external validation set



Triple test AUC = 0.95 (95% CI 0.89-0.98)
Sensitivity for early-stage ovarian cancer 65% → 90%
Sensitivity for early-stage, serous ovarian cancers 67% → 89%
Overall sensitivity 97% serous and 94% non-serous cancers

Slides provided by Elias Laboratories

NIH NCI RO1 PAR-21-166
Academic-Industrial Partnerships for Translation of Technologies for Diagnosis and Treatment (R01 - Clinical Trial Not Allowed)

Title of Grant: Clinical translation of microRNA digital PCR technologies for diagnosis and treatment of ovarian cancer

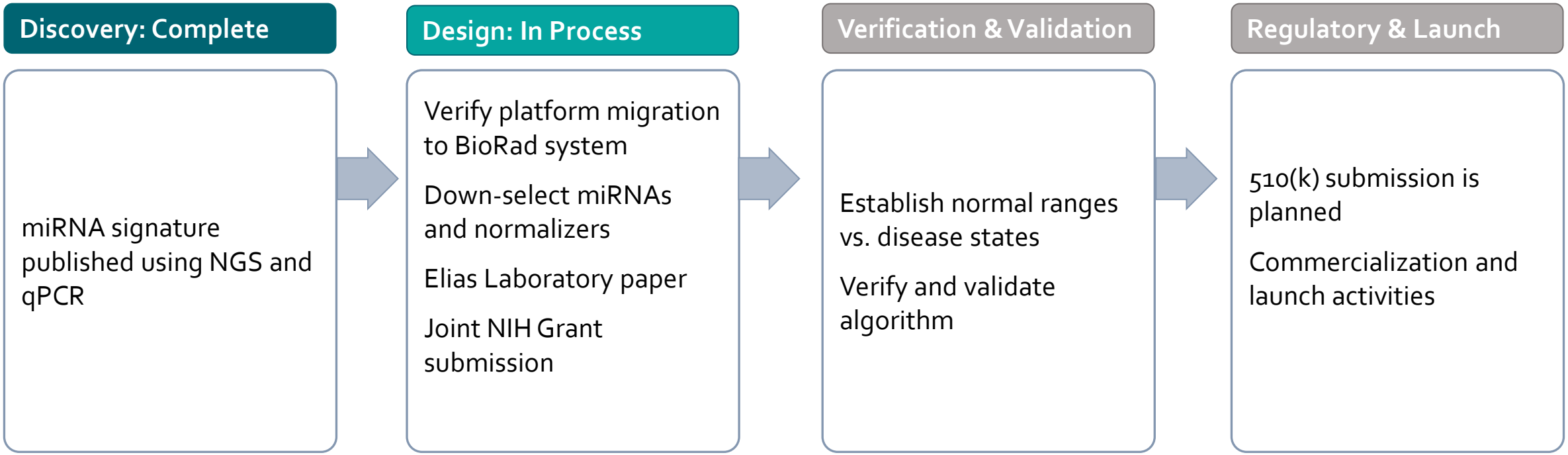
Specific Aims

1. To compare data collection strategies for quantification of serum and plasma miRNAs between digital droplet PCR and nanoplate-based commercial platforms.
2. To establish references ranges and quality control performance measures for digital PCR analysis of circulating miRNAs.
3. To generate statistical software to improve the reliability, reproducibility, and interpretation of digital PCR data for miRNA analysis.
4. Translate and verify the findings towards a locked-in FDA approvable diagnostic test. (Prospective clinical testing will be beyond this grant)

Slides provided by Elias Laboratories

OvaMDx™ Development Pathway

OvaMDx is an AI-powered blood test for the identification of ovarian cancer in women diagnosed with an adnexal mass. AWH has an exclusive license for the Dana Farber miRNA technology.



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Endometriosis Test Portfolio

Endometriosis: A Diagnostic Dilemma

Endometriosis is a debilitating condition in which tissue similar to the lining of the uterus grows outside the uterus.

Symptoms overlap with other conditions

- Painful periods
- Pain with sex
- Excessive bleeding
- Infertility

+

Lack of non-invasive diagnostic tools

Laparoscopy with or without histologic verification

=

Potentially long times to diagnosis

4-11 years from first symptom onset to surgical diagnosis[1]

Only 50% who undergo a laparoscopic procedure will receive a diagnosis of endometriosis.[2]

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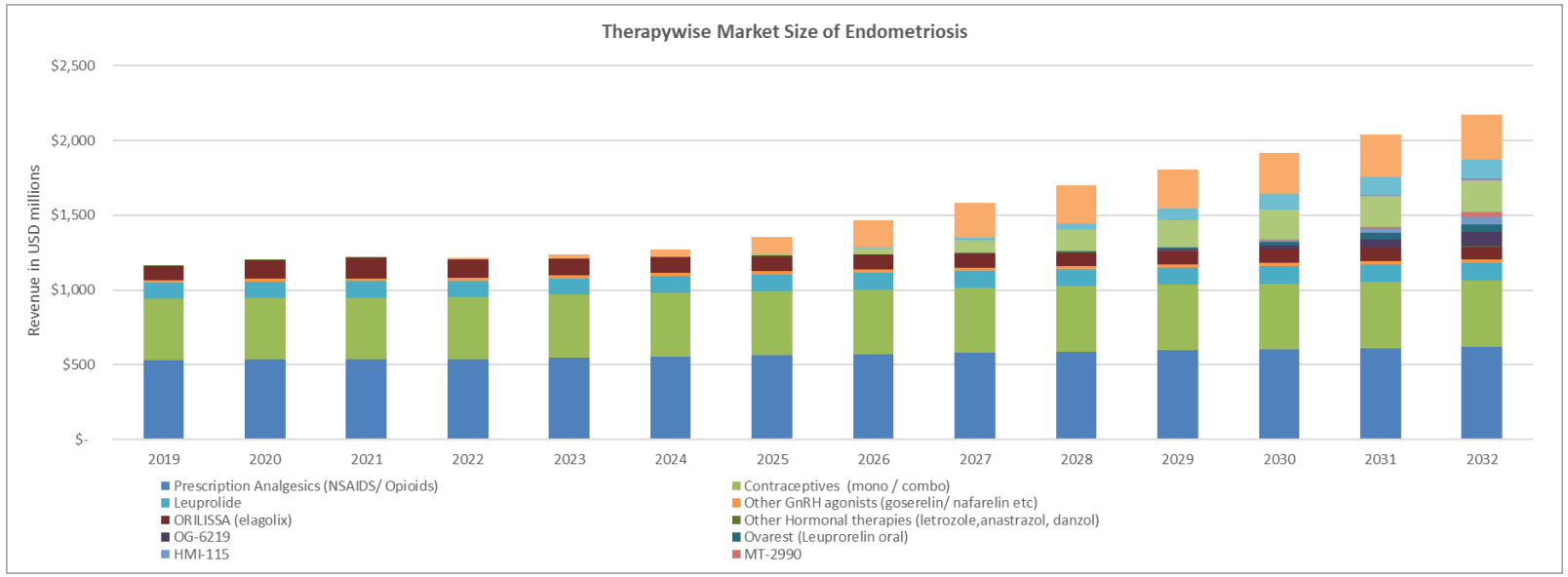
1. Agarwal SK, Chapron C, Giudice LC, Laufer MR, Leyland N, Missmer SA, et al. Clinical diagnosis of endometriosis: A call to action. American Journal of Obstetrics and Gynecology. 2019;220(4). doi:10.1016/j.ajog.2018.12.039 ; 2. https://obgyn.onlinelibrary.wiley.com/doi/10.1002/ Walter AJ, Hentz JG, Magtibay PM, Cornella JL, Magrina JF. Endometriosis: correlation between histologic and visual findings at laparoscopy. *Am J Obstet Gynecol* 2001; **184**: 1407–1413.

Significant Unmet Need for Patients and Pharma

6.5+ Million Women Impacted by Endometriosis [1]

- Endometriosis costs the U.S. economy **$78–$119 billion annually**
- Patient direct and indirect annual costs average **$12,118 and $16,000, respectively**.



·Chart from DelveInsights

New Treatment Options Require a Diagnosis

New medications in development including enhancements to both currently available drugs: Orilissa and Myfembree

1. Frontiers | Endometriosis Is Undervalued: A Call to Action (frontiersin.org)

First-ever Protein-based Assay for Diagnosis of Endometrioma

Aspira's Advantages

- FDA-approved platform
- Validating in CLIA/CAP/NY/CA/MD/PA/RI state-approved laboratory
- Experience in AI-powered tests utilizing protein biomarkers and proprietary algorithms

EndoCheck Assay Features

EndoCheck was designed to aid in the diagnosis endometrioma, one of the most common forms of endometriosis.

- Non-invasive, blood-based assay utilizing multiple, differentiating biomarkers
- Proprietary algorithm leverages core Aspira technologies and experience
- Developed with histology confirmed endometriosis and appropriate control cohorts
- Validated in CLIA-certified laboratory environment

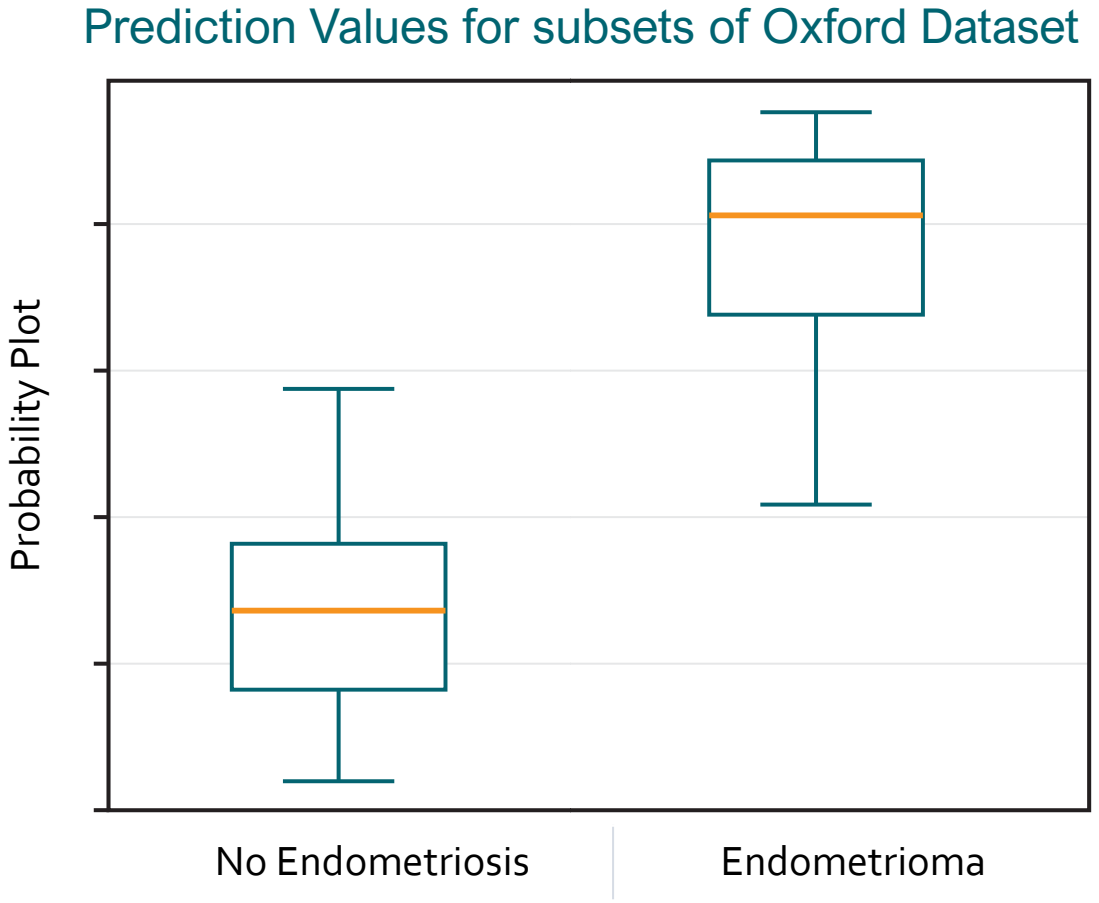
Other supportive biomarkers in discovery phase may increase performance and/or expand intended use.

Identification Endometrioma with an AI-powered Protein Algorithm

Clear grouping of the endometrioma populations from non-endometriomas.

First-of-its-kind blood test with 85% accuracy for the identification of endometriomas (rule-in test with specificity between 90-93%)

Performance of the EndoCheck algorithm was **verified using statistically significant set of histologically confirmed samples** obtained from the University of Oxford.



" If a physician can rule out ovarian cancer with OvaWatch and rule in or out endometrioma using EndoCheck, it allows for more confidence in understanding the diagnosis prior to initiating a treatment plan." -Kevin Elias M.D.

EndoCHECK℠ | Development Pathway

EndoCheck is a blood test to aid in the diagnosis of endometrioma, an endometriosis mass located on the ovary.

Discovery: Complete	Design: Complete	Verification & Validation	Regulatory & Launch
Protein signature pattern discovered at Aspira has been verified for endometrioma with samples from Oxford University	Down-select protein biomarkers and refined algorithm for endometrioma	Training set and two separate cohorts Third external verification set from DFCI Refinement of model if needed and analysis	LDT launch and 510(k) submission is planned Commercialization and launch activities underway

- Abstract and manuscript in development with Oxford and DFCI authors.
- Discovery in process with additional biomarkers to expand intended use and/or improve performance.
- Additional NIH grant submission in process.

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Protein + miRNAs-based Assay for Diagnosis for All Types of Endometriosis

Aspira's Advantages

- Leverages OvaMDx platform development
- Large number of existing samples to complete verification
- AI expertise

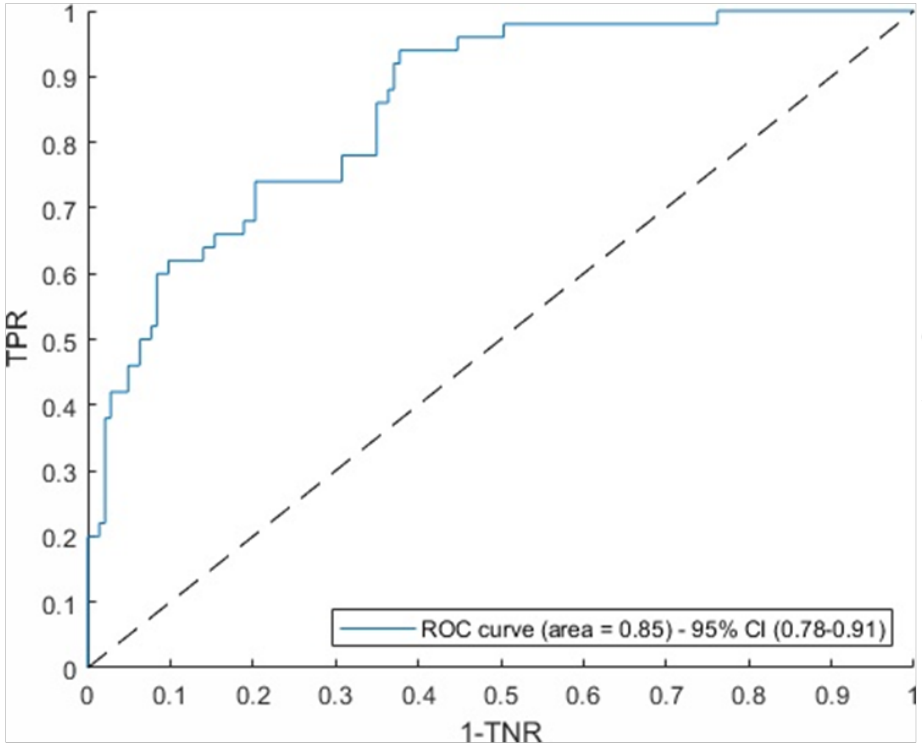
EndoMDx Assay Features

EndoMDx was designed to aid in the diagnosis of all endometriosis.

- Expands patient population beyond endometrioma
- Non-invasive, blood-based assay utilizing proteins, clinical factors, and miRNAs
- Proprietary IP for miRNAs identified by DFCI under terms of our Sponsored Research Agreement
- Platform migration underway for simple ddPCR test for OvaMDx; EndoMDx will follow on same BioRad platform

EndoMDx Preliminary Data

Using feature selection on protein and miRNA.
Metadata selected based on clinical relevance.



Overall Accuracy	83%
Sensitivity	91%

Metadata contributes the most to model accuracy, with miRNA and protein a close second and third, respectively.

The protein and metadata scores are highly correlated.

The miRNA feature is largely independent of both protein and metadata features, indicating a significant miRNA contribution in terms of predictive power.

AUC optimized choosing $K_1 = 4$ features from the proteins, and $K_2 = 10$ miRNA. Model validated using LOO on 193 test patients. 193 is number of patients with miRNA, protein, and metadata available.

Development Pathway

EndoMDx was designed to aid in the diagnosis of all endometriosis.

Discovery: Complete	Design: In Process	Verification & Validation	Regulatory & Launch
MiRNA signature for endometriosis developed at DFCI under sponsored RD agreement	Transfer to FDA approved ddPCR platform Optimization of the number of required miRNAs and normalizers Elias Laboratory paper	Test disease states and normal Develop AI models and neural network if needed 2 independent cohorts Refinement of model if needed and analysis	510(k) submission is planned Commercialization and launch activities

Portfolio Market Opportunity

Commercial Products with Rich Pipeline - $1B Potential Domestic Revenue Potential

Ovarian Cancer

	U.S. TAM Patients/Year	In Development	Marketed
OvaSuite℠ $600M-$715M Annual Revenue Potential			
OVA1 plus®	200-400K		
OvaWATCH℠	1.2-1.5M		
OvaWATCH℠ Longitudinal Monitoring	2.0-3.0M		
OVA MDx™	1.2-1.5M	Dana-Farber Cancer Institute	

Endometriosis

$1B+ Annual Revenue Potential			
EndoCHECK℠	2.5M		
EndoMDx™	6.5M		Dana-Farber Cancer Institute; Medical University of Lodz; Brigham and Women's Hospital, Founding Member, Mass General Brigham

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Total Addressable Market (TAM)

2024 Milestones

1. Publication of OvaWatch Longitudinal Monitoring Manuscript and Commercial Launch of Expanded Application
2. Publication of OvaWatch Surgical Selection Manuscript
3. Publication and Presentation of EndoCheck Abstract (with Oxford University)
4. Publication of Elias Laboratory OvaMDx and EndoMDx Manuscripts
5. NIH Grant Approvals
6. Launch of EndoCheck as LDT
7. FDA Submission for OvaWatch
8. BioRad platform migration for OvaMDx and EndoMDx

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