

Aspira Women's Health Releases Analytical and Initial Clinical Validation Performance for OVASight at ASCO 2021

Description

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Data demonstrates the performance of OVASight in a low prevalence population-89% Specificity, 91% Sensitivity and a Negative Predictive Value of 99.6% for the management of suspected Benign Pelvic Masses

AUSTIN, Texas; June 3, 2021 – Aspira Women's Health Inc. (Nasdaq: AWH), a bioanalytical-based women's health company focused on gynecologic disease, released the analytical and initial clinical data for OVASightTM in an abstract titled "Serum-based Assay for Adnexal Mass Risk of Ovarian Malignancy". Registrants attending the American Society of Clinical Oncology ("ASCO") 2021 virtual meeting gained access to the poster on May 19, 2021, and the on-demand presentation will be released to the ASCO virtual meeting registrants at 9:00 a.m. EDT on June 4, 2021.

OVASight (MIA3G) is third-generation OVA technology and is a laboratory-developed, blood-based pelvic mass risk assessment test for ovarian cancer in a low prevalence population. It was developed to increase specificity, maintain high sensitivity with early-stage disease, and allow for conservative management of women with a suspected benign mass. A total of 596 samples collected from real-world patients were used to validate the OVASight diagnostic algorithm. Validation data demonstrated 89% Specificity, 91% Sensitivity and a Negative Predictive Value of 99.6% in a low prevalence population (3.8%). In addition, overall sensitivity as well as sensitivity in early-stage disease were significantly better than CA-125 alone. See table below:

MIA3G (OVASight) CA125

Overall Sensitivity (All Stages)	21/23 (91.3%)	15/23 (65.2%)
Early-Stage (Stage I & II) Sensitivity	y 10/12 (83.0%)	6/12 (50.0%)

"Based on this promising data, we are thrilled with the performance of this new test." stated Elena Ratner, M.D., Global Chief Global Medical Advisor, Clinical and Translational Medicine at Aspira Women's Health. Dr. Ratner further explained that "it is important to give providers better tools to help provide personalized risk assessment for women with pelvic masses and expectant management for those masses that are most likely benign."

Below are details of the abstract accepted at ASCO. All posters will be available to ASCO 2021 virtual meeting registrants on-demand beginning at 9:00 a.m. EDT on June 4, 2021.

Title: Serum-based assay for adnexal mass risk of ovarian malignancy



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