ASPiRA LABS' OVA1 Technology Receives "Level B" Recommendation in the Latest ACOG Clinical Management Guidelines for the Management of Adnexal Masses

Description

AUSTIN, Texas — ASPiRA LABS, a Vermillion company (NASDAQ: VRML), today announced the inclusion of the OVA1 /"Multivariate Index Assay" in The American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin Number 174, dated November 2016. This bulletin outlines ACOG's "new" clinical management guidelines for adnexal mass management.

These new clinical management guidelines replace the July 2007 version, Practice Bulletin 83. According to the ACOG website, "Practice Bulletins summarize current information on techniques and clinical management issues for the practice of obstetrics and gynecology. Practice Bulletins are evidence-based documents, and recommendations are based on the evidence." This is also the only clinical management tool used for Adnexal Masses. Guidelines DO NOT exist for Adnexal Masses, only Practice Bulletins. Please note Guidelines do exist however for Ovarian Cancer management.

The new guidelines now recommend that all obstetricians and gynecologists, in evaluating women with adnexal masses when the mass does not fulfill Level A criteria of a low risk transvaginal ultrasound (TVUS), should proceed with Level B clinical guidelines. Level B guidelines state that the physician should use risk assessment tools such as OVA1 ("Multivariate Index Assay") as listed in the bulletin. Based on this, OVA1 has now achieved parity with CA125 as a Level B recommendation for the management of adnexal masses, but it is the only recommended Level B tool with FDA clearance for use in assessing ovarian cancer risk in adnexal masses. CA125 does not have FDA clearance for use in assessing ovarian cancer risk in adnexal masses. The new guidelines suggest that if an elevated risk of malignancy does exist, then the provider must consult with or refer to a gynecologic oncologist. This is in direct relationship to the OVA1 FDA cleared label.

"These new guidelines will raise overall physician awareness of the importance of using a proactive risk assessment such as OVA1 when the TVUS does not meet Level A criteria," stated Valerie Palmieri, President and CEO of Vermillion, Inc. "Having OVA1 as a Level B recommendation is a milestone event for saving women and properly assessing the risk of ovarian cancer from the onset of disease."

About Vermillion

Vermillion, Inc. is dedicated to the discovery, development and commercialization of novel high-value diagnostic and bio-analytical solutions that help physicians diagnose, treat and improve gynecologic health outcomes for women. Vermillion, along with its prestigious scientific collaborators, discovers, develops, and delivers innovative diagnostic and technology tools that help women with debilitating diseases. The company's initial in vitro diagnostic test, OVA1®, was the first FDA-cleared, protein-based In Vitro Diagnostic Multivariate Index Assay, and represented a new class of software-based liquid biopsy in vitro diagnostics. In March 2016, Vermillion received FDA clearance for Overa™, a second generation OVA1 test with significantly improved specificity and ease of use. For additional information, including published clinical trials, visit www.aspirawh.com.

About OVA1®

- OVA1 is a proprietary FDA-cleared blood test designed to help physicians assess the risk of ovarian cancer prior to surgery, facilitating more effective referral of high risk patients to a specialist (gynecologic oncologist) for surgical treatment.
- The OvaCalc® proprietary algorithm combines five biomarker results into a single numerical “risk score” that stratifies patients into “higher risk” and “lower risk” when combined with clinical assessment.
- In two pivotal clinical trials, OVA1 plus clinical impression detected 96% of all malignancies vs. 75% for clinical impression alone. As a result, false negatives were reduced from 25% for clinical impression alone, to 4% with OVA1 plus clinical impression, a reduction of 83%.
- In a study focused on early-stage ovarian cancer detection, 31% of cases were missed by clinical impression alone. This was reduced to 5% when OVA1 was added to clinical impression, a reduction of 85%.
- OVA1 has shown clinical utility in increasing the rate of referrals of malignant adnexal masses to gynecologic oncologists. The increased involvement of specialists may lead to increased National Comprehensive Cancer Network-adherent cancer care, which is associated with improved cancer outcomes, including overall survival. In a study focused on specialist involvement in ovarian cancer treatment, 94% of patients with an elevated-risk OVA1 result who had primary ovarian malignancies were appropriately referred to a gynecologic oncologist.

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