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FDA CLEARS NEXT-GENERATION BIOMARKER TEST TO DETERMINE LIKELIHOOD OF OVARIAN CANCER IN WOMEN WHO PRESENT WITH ADNEXAL MASS

Fujirebio Diagnostics' ROMA™ (HE4 EIA + ARCHITECT CA 125 II™) Test is New Option to Evaluate the Likelihood of Ovarian Cancer

MALVERN, Pa. September 6, 2011 – Fujirebio Diagnostics, the industry leader in oncology biomarker assays, announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market the company's HE4 Test in an algorithm called ROMA™ (HE4 EIA + ARCHITECT CA 125 II™)* to aid in assessing whether a premenopausal or postmenopausal woman who presents with an ovarian adnexal mass is at high or low likelihood of finding malignancy on surgery.

The ROMA (Risk of Ovarian Malignancy Algorithm) test uses the results from simple blood tests, CA125 and HE4, to identify patients presenting with adnexal mass as high or low likelihood for finding malignancy on surgery. HE4 has been shown to be elevated in epithelial ovarian cancers (EOC), the most common type of ovarian cancer, but is not elevated in many benign gynecologic diseases. Combining physician assessment with the independently validated ROMA algorithm enables physicians to identify those patients at high likelihood of malignancy who should have their surgery performed by a gynecologic oncologist.

“Using ROMA with HE4 and CA125 significantly improves our ability to identify women who are at high or low likelihood of having ovarian cancer when they present with an ovarian cyst or mass,” said Richard G. Moore, MD, Associate Professor of Obstetrics and Gynecology at the Alpert School of Medicine at Brown University and Director of the Center for Biomarkers and Emerging Technologies in the Program for Women's Oncology at Women and Infants' Hospital in Providence, RI. “Patients who have ovarian cancer have better outcomes when their surgery is performed by a gynecologic oncologist at centers experienced in the management of this disease. This combination test will allow physicians to identify those patients who should be treated by a gynecologic oncologist and equally important allow women with benign disease to stay in their communities with the physician who knows them best. It will change the way doctors diagnose and treat ovarian cancer,” added Dr. Moore, who is the lead researcher for the team that developed ROMA and author of two multi-center studies investigating the use of HE4 and CA125 and ROMA.

Ovarian cancer is recognized as difficult to diagnose because its symptoms are easily confused with other non-cancerous conditions. Three quarters of cases of ovarian cancer are diagnosed at an advanced stage, when it is more difficult to treat. Of patients who are diagnosed early (Stage I-II), more than 90 percent will live past five years. However, only one quarter of cases are diagnosed in the early stages.

“The clearance of ROMA is a major advance for the gynecologist and will become an important component of the preoperative assessment of women presenting with a pelvic mass,” said Lee P. Shulman, MD, Professor of Obstetrics and Gynecology, Chief of the Division of Clinical Genetics and Co-Director of the National Ovarian Cancer Early Detection Program at Northwestern University.

There is a vast body of published, multinational, peer-reviewed clinical evidence supporting the use of the HE4 test in combination with the CA 125 test. To date there have been nine original peer reviewed publications validating the performance of ROMA in populations as diverse as Korean, Chinese, Italian, Dutch, and American.^{1,2,3,4,5,6,7,8} Its utility as a stratification tool is supported by results from a prospective, double-blind, multicenter trial involving 472 women with pelvic mass who were scheduled for surgical intervention.⁹

Data from a study of 472 patients presented at this year's annual meeting of the Society of Gynecologic Oncologists and published in the August 2011 issue of *Obstetrics and Gynecology*, the journal of the American Congress of Obstetricians and Gynecologists show that ROMA alone was highly accurate in assigning a combined pre- and postmenopausal patient population to likelihood groups, with 93.8 percent of EOCs correctly classified as high likelihood. Looking at the postmenopausal group, ROMA had a sensitivity of 92.3%, a specificity of 76.0%, and a negative predictive value (NPV) of 97.4%. Looking at the premenopausal group, ROMA had a sensitivity of 100%, a specificity of 74.2%, and an NPV of 100%.

Data from a study of 462 patients reviewed by the FDA and published in the Instructions for Use for the test show that, when combined with the methods a physician would normally use to assess likelihood of ovarian cancer in a combined pre- and postmenopausal patient population, ROMA had a sensitivity of 88.4%, a specificity of 67.2% and an NPV of 96.2%.¹⁰

“The ROMA test, by improving the sensitivity of methods used to stratify patients with an adnexal mass who are already scheduled for surgery, is expected to help thousands of physicians determine their patient’s likelihood for ovarian cancer and enable those who are at high likelihood to be referred to a gynecologic oncologist – a benefit that will improve treatment outcomes,” said Paul Touhey, President and Chief Executive Officer of Fujirebio Diagnostics. “With this increased ability to improve referral patterns, as well as a price that is comparable to CA125 testing, the health care costs involved with cancer diagnosis and treatment should decrease significantly.”

***About ROMA**

The ROMA test is the second FDA cleared indication of Fujirebio Diagnostics’ HE4 assay, which was cleared in 2008 by the FDA as an aid in monitoring recurrence or progressive disease in patients with epithelial ovarian cancer. The Risk of Ovarian Malignancy Algorithm (ROMA™) is a qualitative serum test that combines the results of HE4 EIA, ARCHITECT CA 125 II™ and menopausal status into a numerical score. ROMA is intended to aid in assessing whether a premenopausal or postmenopausal woman who presents with an ovarian adnexal mass is at high or low likelihood of finding malignancy on surgery. The ROMA test is indicated for women who meet the following criteria: over age 18; presence of an ovarian pelvic mass for which surgery is planned, and not yet referred to an oncologist. ROMA must be interpreted in conjunction with an independent clinical and radiological assessment. The test is available through many clinical reference laboratories.

Important Safety Information

PRECAUTION: ROMA (HE4 EIA + ARCHITECT CA 125 II) should not be used without an independent clinical /radiological evaluation and is **not** intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of ROMA (HE4 EIA + ARCHITECT CA 125 II) carries the risk of unnecessary testing, surgery, and/or delayed diagnosis.

About Ovarian Cancer

Ovarian cancer is the leading cause of death from gynecologic cancers in the United States and the fifth-leading cause of cancer death in women. It accounts for 3% of all female cancers and is the ninth most common cancer among women. There are an estimated 22,000 new cases annually in the United States.¹¹ Women who are postmenopausal are at the greatest likelihood for ovarian cancer.¹² In their lifetimes, 1 in 71 women will develop ovarian cancer.

About Fujirebio Diagnostics, Inc.

Fujirebio Diagnostics is the premier cancer diagnostics company and the industry leader in cancer biomarker assays. The company pioneered and introduced the CA125 test, the first FDA-approved ovarian cancer biomarker over 25 years ago. Fujirebio Diagnostics specializes in the clinical development, manufacturing and commercialization of in-vitro diagnostic products for the management of human disease states, with an emphasis in oncology. Fujirebio Diagnostics is one of the group companies of Miraca Holdings Inc. in Japan, set up in July 2005 to combine Fujirebio Inc., the leading in-vitro diagnostics company, and SRL, Inc., the top provider of clinical laboratory testing services in Japan. Fujirebio Diagnostics has a worldwide distribution network, which enables physicians and patients to access its diagnostic products. For more information about Fujirebio Diagnostics, please call 610-240-3800 or visit <http://www.fdi.com>.

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¹ Moore RG, et al. A novel multiple marker bioassay utilizing HE4 and CA 125 for the prediction of ovarian cancer in patients with a pelvic mass. *Gynecol Oncol*. 2009;112:40-46.

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⁴ Montagnana M, et al. The ROMA (Risk of Ovarian Malignancy Algorithm) for estimating the risk of epithelial ovarian cancer in women presenting with pelvic mass: is it really useful? *Clin Chem Lab Med*. 2011;49(3):521-525.

⁵ Moore RG, et al. Comparison of a novel multiple marker assay vs the Risk of Malignancy Index for the prediction of epithelial ovarian cancer in patients with a pelvic mass. *Am J Obstet Gynecol*. 2010;203(3):228.e1-6.

⁶ Ruggeri G, et al. HE4 and epithelial ovarian cancer: comparison and clinical evaluation of two immunoassays and a combination algorithm. *Clin Chem Acta*. 2011;412(15-16):1447-1453.

⁷ Van Gorp T, et al. HE4 and CA 125 as a diagnostic test in ovarian cancer: prospective validation of the Risk of Ovarian Malignancy Algorithm. *Br J Cancer*. 2011;104(5):863-870.

⁸ Molina R, et al. HE4 is a novel tumour marker for ovarian cancer: comparison with CA 125 and ROMA algorithm in patients with gynecological diseases. *Tumour Biol*. 2011 Aug 24. [Epub ahead of print]

⁹ Moore RG, Miller C, DiSilvestro P, et al. Evaluation of the Diagnostic Accuracy of the Risk of Ovarian Malignancy Algorithm in Women With a Pelvic Mass. *Obstet Gynecol*. 2011;118(2):280-288

¹⁰ ROMA™ (HE4 EIA + ARCHITECT CA 125 II™) prescribing information. Fujirebio Diagnostics, Inc., 2011.

¹¹ What are the key statistics about ovarian cancer? American Cancer Society Web site.

<http://www.cancer.org/Cancer/OvarianCancer/DetailedGuide/ovarian-cancer-key-statistics>. Revised October 13, 2010. Accessed May 10, 2011.

¹² American College of Obstetricians and Gynecologists. ACOG Committee Opinion: number 280, December 2002. The role of the generalist obstetrician-gynecologist in the early detection of ovarian cancer. *Obstet Gynecol*. 2002;100(6):1413-1416.