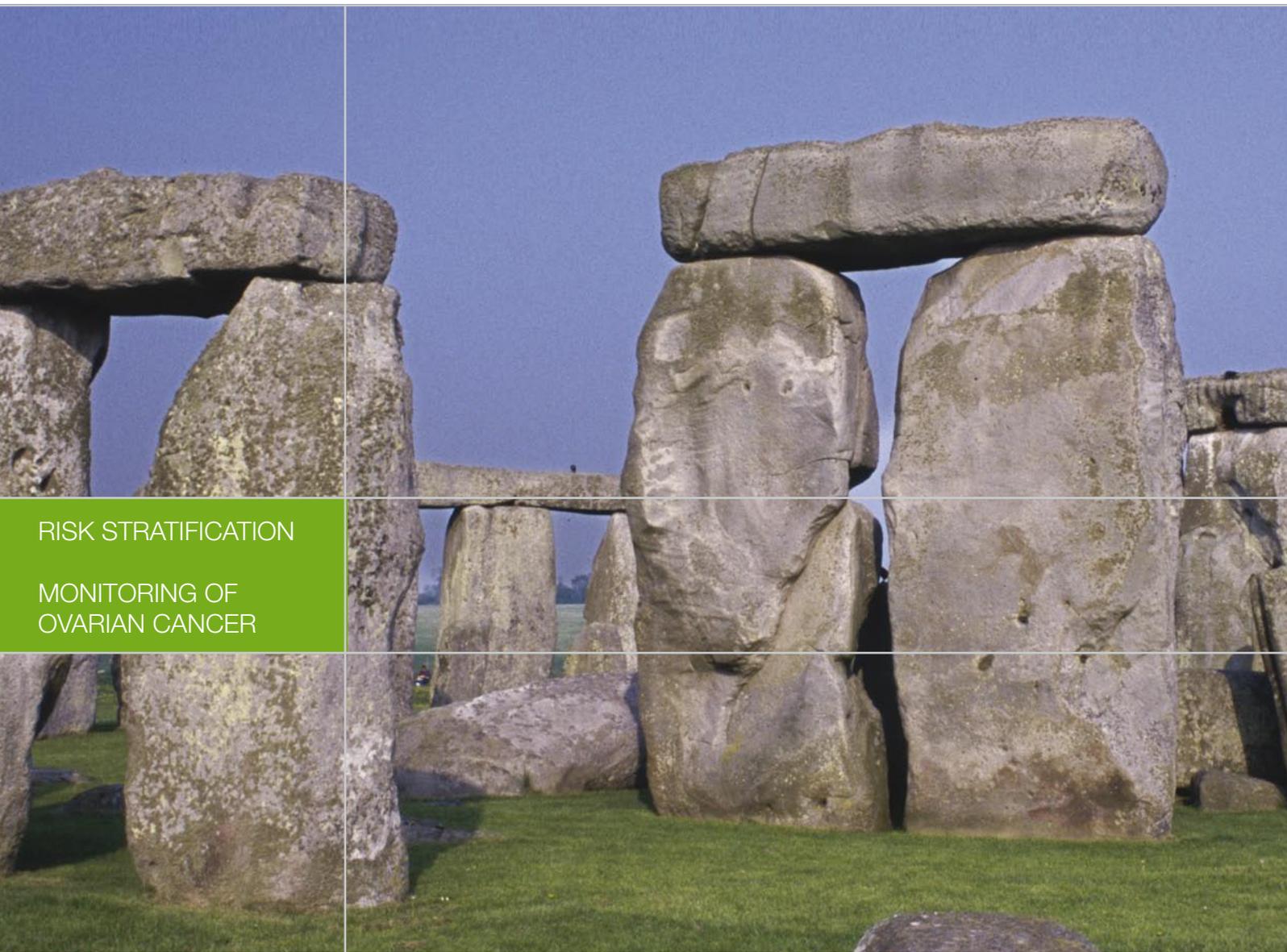# ARCHITECT HE4 + CA125
Two strong pillars in the management of ovarian cancer

RISK STRATIFICATION

MONITORING OF
OVARIAN CANCER

Put science on your side.

Abbott
A Promise for Life

HE4 – A New Biomarker in the Management of Ovarian Cancer

HUMAN EPIDIDYMIS PROTEIN 4 (HE4) has been introduced in the management of Epithelial Ovarian Cancer, and the biomarker complements CA125.

- The combination of both assays raises the sensitivity for detecting Stage I/II disease.[1]

- HE4 and CA125 together improve the therapy monitoring of patients with Ovarian Cancer.[1]

- When used together CA125 and HE4 provide a more accurate preoperative determination of the risk of malignancy in women presenting with pelvic mass.[2]

RISK STRATIFICATION PELVIC MASS PATIENTS

MONITORING OF OVARIAN CANCER

ARCHITECT HE4+ CA125
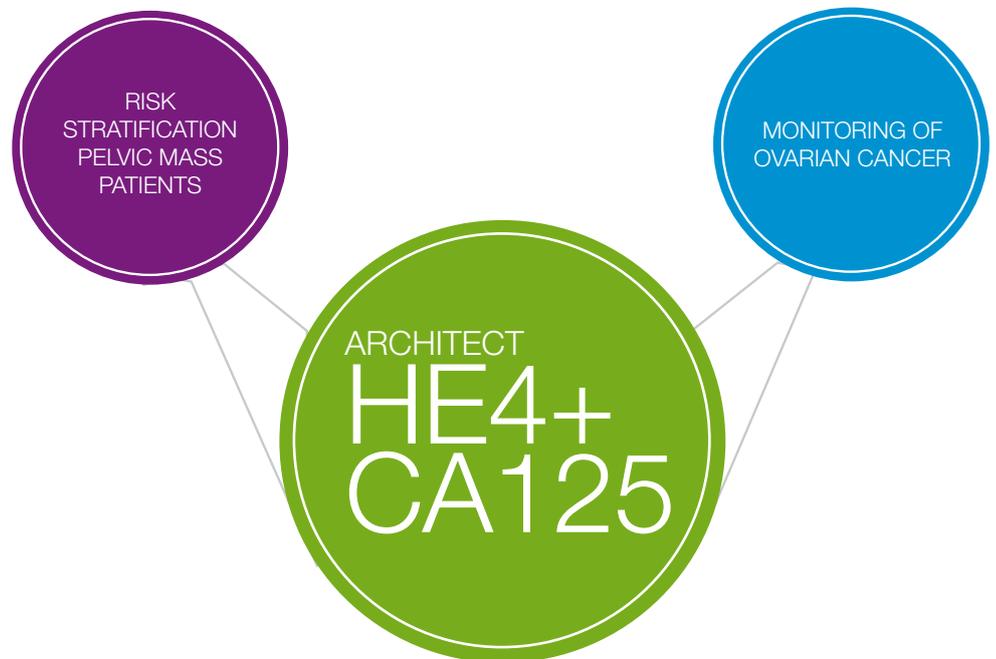
EXPRESSION PROFILE OF HE4

- HE4 is a precursor protein to the epididymal secretory protein.[3]

- HE4 is consistently expressed in ovarian carcinoma with minimal expression in normal ovarian tisue.[3]

- HE4 is highly up-regulated in early and late stage ovarian cancer, with high sensitivity in early stage disease.[3]

ROMA (RISK OF OVARIAN CANCER MALIGNANCY ALGORITHM)[2]

The combined results of HE4 and CA125 provide the physician a risk stratification index for pre- and postmenopausal women presenting pelvic mass, to distinguish between a low or high risk of finding Epithelial Ovarian Cancer (EOC).

In combination with the outcome of the current standard practices (e.g., pelvic exam, ultra sound, CT scan, biopsy etc.) ROMA provides the physician a useful tool for the optimal treatment for the patient.

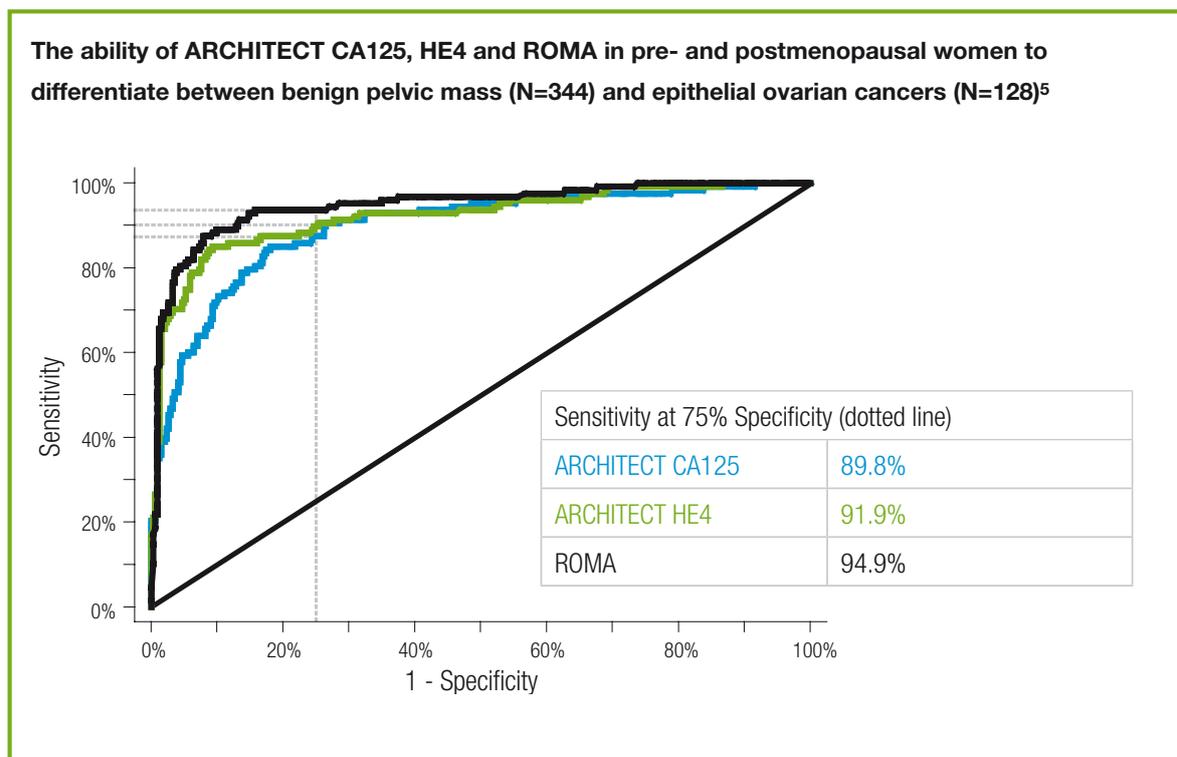### ROMA VALUE SPECIFIC TO ABBOTT ARCHITECT[4]

Premenopausal
- ≥ 7.4% High risk of finding EOC
- < 7.4% Low risk of finding EOC

Postmenopausal
- ≥ 25.3% High risk of finding EOC
- < 25.3% Low risk of finding EOC

ROMA increases the sensitivity and specificity of CA125 alone.

The ability of ARCHITECT CA125, HE4 and ROMA in pre- and postmenopausal women to differentiate between benign pelvic mass (N=344) and epithelial ovarian cancers (N=128)[5]

Sensitivity at 75% Specificity (dotted line)	
ARCHITECT CA125	89.8%
ARCHITECT HE4	91.9%
ROMA	94.9%

When using the ROMA algorithm the ROC-AUC* raises up to 94.9%

RIGHT PATIENT, RIGHT PHYSICIAN, RIGHT OUTCOME

*ROC-AUC: Receiver Operator Curve – Area Under the Curve

ARCHITECT HE4 PRODUCT INFORMATION

Method and Systems	Two-step CMIA, ARCHITECT *i*1000SR/*i*2000SR/*i*2000
Time to first result	28 minutes
Throughput *i*2000SR	Up to 200 tests per hour (*i*2000/*i*2000SR)
Limit of Quantitation - LOQ	≤ 20 pmol/L
Calibration Range	0 – 1500 pmol/L; Liquid, ready-to-use, 6-point calibration
Controls	3 levels (50 pmol/L, 175 pmol/L, 700 pmol/L)
Sample Type and Volume	Type: Human serum, including serum separator tubes volume: 150 µL routine and 50 µL for additional test from the same sample cup
Reagent On Board Stability	30 days

ORDERING INFORMATION

Product	List number	Kit configuration
Reagents	2P54 -25	100 Test Kit
Calibrator	2P54 -01	6 x 4.0 ml
Controls	2P54 -10	3 x 8.0 ml
*i*1000 ARCHITECT Software	1P61	1 Disk
*i*2000 ARCHITECT Software	3K52	1 Disk

Abbott ARCHITECT
Oncology Assays

*part of the comprehensive
ARCHITECT menu*

AFP
CA125
CA15-3
CA19-9
CEA
CYFRA 21-1*
Free PSA
HE4
NSE*
ProGRP
SCC
Total PSA

*In development

[1] Moore, R.G. et al., *Gynecol Oncol.* 2007; 108:402-8
[2] Moore, R.G. et al., *Gynecol. Oncol.* 2009; 112:40-46
[3] Drapkin, R. et al., *Cancer Res.* 2005; 6-65
[4] ARCHITECT HE4 Package Insert
[5] Abbott data on file

ARCHITECT, *i*1000SR, *i*2000SR, *i*2000, and *Put science on your side*.
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