

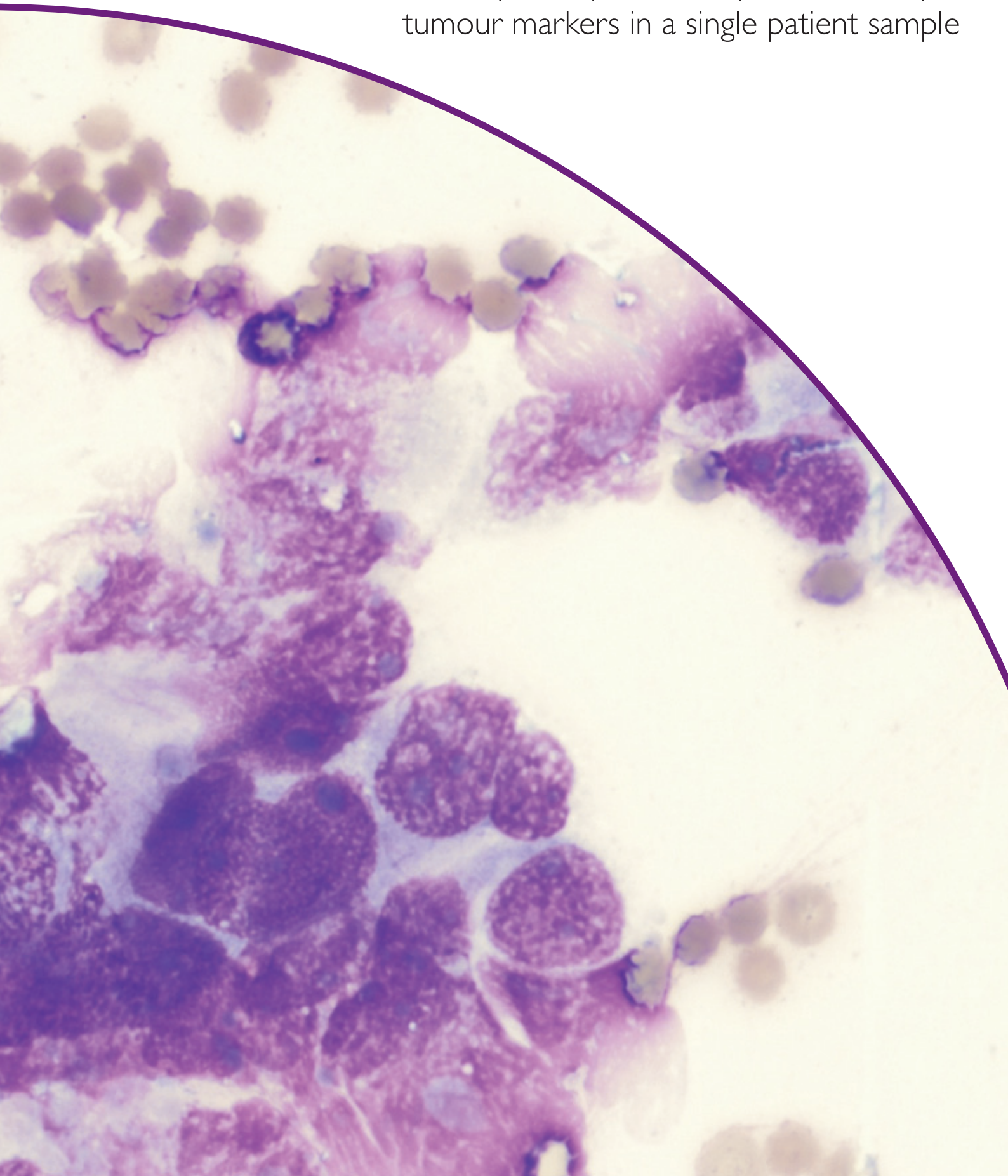


CE 0843

RANDOX

Tumour Marker Arrays

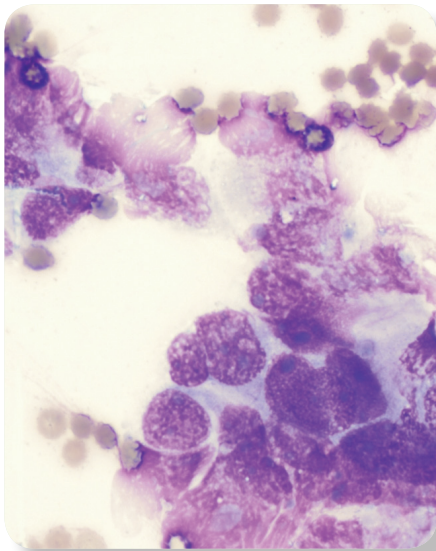
Simultaneously and quantitatively detect multiple
tumour markers in a single patient sample



Tumour Marker Arrays

FOR ACCURATE TESTING

Simultaneously and quantitatively detect multiple tumour markers in a single patient sample



TUMOUR PSA ARRAY ANALYTES

- Carcinoembryonic Antigen (CEA)
- Free Prostate Specific Antigen (fPSA)
- Total Prostate Specific Antigen (tPSA)

TUMOUR ARRAY 3 (MONITORING) ANALYTES

- Carcinoembryonic Antigen (CEA)
- Alpha-Fetoprotein (AFP)
- β -Human Chorionic Gonadotropin (β -hCG)

ABOUT TUMOUR MARKERS

Tumour markers are proteins found in the blood, tissues or urine that may be produced directly by a tumour or by other tissues in response to the presence of the tumour. They can therefore be used to screen for cancer and monitor the course of the disease.

KEY BENEFITS

- Suitable for human serum samples
 - Measure multiple tumour markers simultaneously
 - Small sample volume - 25 μ l serum for a complete patient profile
 - Fast throughput
 - Excellent analytical performance
 - Applicable to fully automated and semi-automated analysers
- **Tumour PSA Array** - Prostate cancer is the second most common cause of cancer in men but if caught and treated early has a 90% cure rate, thus early detection is imperative. PSA is produced by the normal prostate but may be elevated in disease. PSA measurement alone is not sufficiently sensitive for prostate cancer diagnosis. Current diagnosis involves PSA measurement alongside a digital rectal examination. In the Tumour PSA Array, CEA is measured in addition to total and free PSA. CEA is a non-specific cancer antigen produced in response to malignant cells. Therefore testing for CEA simultaneously with PSA provides a more accurate screening of prostate cancer.
 - **Tumour Array 3 (Monitoring)** - The Tumour Array 3 contains CEA in addition to AFP and hCG. AFP is a protein produced by the developing foetus and also by certain tumours. AFP levels in healthy adults are low thus elevated levels may indicate the presence of a tumour such as testicular or ovarian tumours. hCG is a hormone produced in pregnancy and is not normally elevated in healthy adults. hCG, secreted by some cancers, is a very sensitive test for tumour presence. Simultaneous measurement of all three markers can be used in research and development to assess the effects of treatment and recurrence of disease.

TUMOUR PSA ARRAY PERFORMANCE OUTLINE ON EVIDENCE INVESTIGATOR

Analyte	Assay Range*	Sensitivity**
CEA (ng/ml)	0-500	0.29
tPSA (ng/ml)	0-100	0.045
fPSA (ng/ml)	0-75	0.02

06/880, 881/MAF

* This is a typical assay range and may vary slightly with batch of calibrators

**Sensitivity defined as the lowest concentration with imprecision <20% and recovery within 80-120% for 9 replicates.

Analyte	Intra-Assay Precision (n=20)					
	Level 1		Level 2		Level 3	
	Conc	%CV	Conc	%CV	Conc	%CV
CEA (ng/ml)	14.38	5.3	22.74	7.8	44.54	5.5
tPSA (ng/ml)	4.15	7.4	23.42	9.1	52.76	9.6
fPSA (ng/ml)	0.59	8.2	4.02	9.1	9.7	8.9

05/833/MAF

TUMOUR ARRAY 3(MONITORING) PERFORMANCE OUTLINE ON EVIDENCE

Analyte	Assay Range*	Sensitivity**
CEA (ng/ml)	0-500	0.24
AFP (IU/ml)	0-415	0.28
β-hCG (mIU/ml)	0-2000	1.00

06/1441/MA, 07/1461/MA

* This is a typical assay range and may vary slightly with batch of calibrators

** Sensitivity defined as the lowest concentration with imprecision <20% for 20 replicates

Analyte	Intra-Assay Precision (n=20)					
	Level 1		Level 2		Level 3	
	Conc	%CV	Conc	%CV	Conc	%CV
CEA (ng/ml)	19.4	6.95	35.8	9.2	79.3	8.0
AFP (IU/ml)	9.1	5.9	40.4	6.3	149.4	6.1
β-hCG (mIU/ml)	17.1	3.8	112.9	5.6	258.8	4.6

04/964/MA



—evidence— EVOLUTION

- Large laboratories • High throughput
- Random access, fully automated • Clinical/ research testing



—evidence— INVESTIGATOR

- Medium size laboratories • Medium throughput
- Semi-automated • Clinical/research testing



evidence

- Large laboratories • High throughput
- Fully automated • Clinical/research testing

Tumour PSA Array EV3515
Tumour Array 3 (Monitoring) EV3683

Tumour PSA Array EV3527 (360 Biochips)
EV3548 (180 Biochips)

TumourArray 3 (Monitoring) EV3531 (360 Biochips)
EV3549 (180 Biochips)

Tumour PSA Array Calibrators EV3553
Tumour Array 3 (Monitoring) Calibrators EV3526

Immunoassay Controls: EV3570

For screening, results obtained from the Tumour PSA Array should always be used in conjunction with a clinical examination, patient medical history and other findings. The Tumour Array 3 (Monitoring) is for research and development use only and not for diagnostic purposes.

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