

Serum RECAF™

SERUM ASSAYS TO DETECT RECAF™ (THE RECEPTOR FOR ALPHA-FETOPROTEIN) IN SERUM

FORMATS: ELISA (450 nm), flash Chemiluminescence Immunoassay (CIA) and ¹²⁵I Radioimmunoassay (RIA).

RECAF™ is a novel biochemical marker which is expressed in the cells of cancer patients.



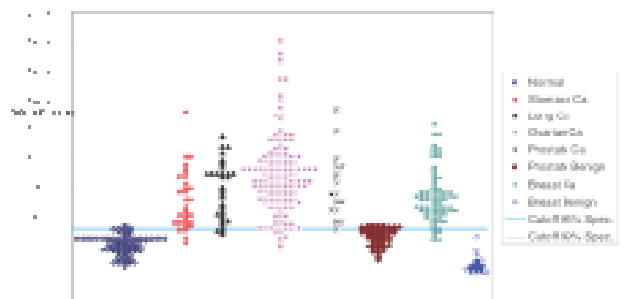
Available for research use only/investigational use only. Reagents available for AnalyteSpecific Reagent (ASR) in the United States and Canada.

PRODUCT FEATURES

- Catalog Numbers: CIA-92001, RIA 92001
- 96 Well Microplate Format
- Detection System: CIA or RIA
- Individual Strips/Wells: Yes
- High Sensitivity: 80-90%
- High Specificity: 95%
- Rapid Assay Time: 3 hours
- Sample Type: Serum
- Sample Size: 5 microliters
- Sample Size: < 50 microliters
- Applicable to Multiple Cancer Types: Ovarian, Prostate, Breast, Stomach, Pancreas, Lymphomas, Cervical, LungLung

DATA SUMMARY#

Cancer type	Sensitivity with 95% Specificity	Sensitivity with 99% Specificity	Number
Ovarian Ca	96%	92%	162
Stomach Ca	90%	87%	31
Lung Ca	91%	87%	32
Breast Ca	93%	90%	88
Prostate Ca vs. Normal	99%	95%	20
TOTAL	94%	91%	333
Breast Benign*	0	0	22
Prostate Benign*	25%	5%	77



Distribution of RECAF levels in serum for various cancer types and benign conditions. The horizontal line indicates the 95% specificity cutoff value.

*At the 95% cutoff value, a small percentage of benign breast and prostate samples were positive. Increasing the cut-off value to include 99% of normal individuals reduces the percentage of false positives, at the expense of a slight decrease in sensitivity

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In a study comparing normal patients, patients with BPH (Benign Prostate Hyperplasia) and patients with prostate cancer:

- 1) RECAF™ detected early stage prostate cancer
- 2) RECAF™ discriminated prostate cancer from BPH substantially better than total-PSA (tPSA) or free-PSA (fPSA)
- 3) RECAF™ discriminated between BPH and prostate cancer significantly better than the generally accepted discrimination obtainable with tPSA or fPSA using tPSA or

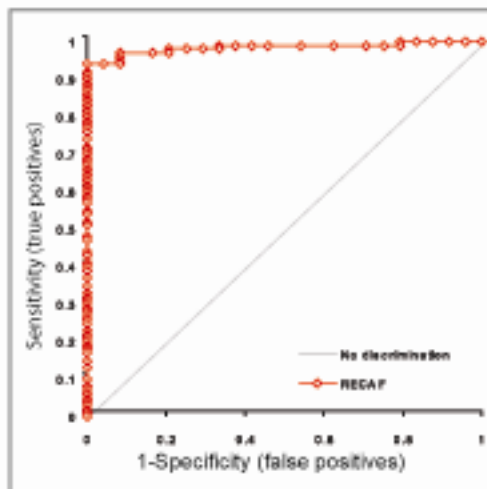


Figure 1
Prostate Cancer vs. Normal
(AUC 0.984)

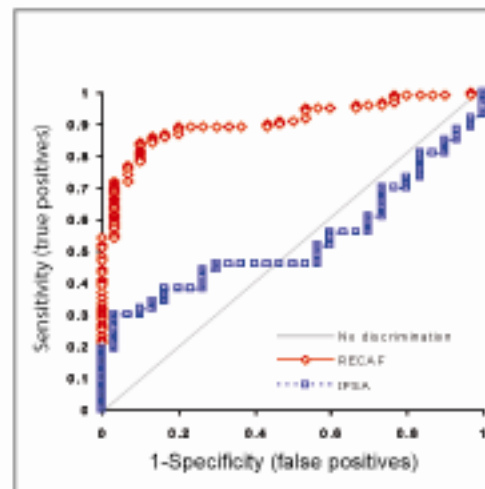


Figure 2
Prostate Cancer vs. BPH
AUC [RECAF™] = 0.906
AUC [PSA] = 0.531

In a blinded study RECAF™ has been shown to detect early stage breast cancers. Data collected on Stage I and Stage II cancers are shown below.

Cancer Stage	SENSITIVITY	SPECIFICITY	NUMBER OF SAMPLES
Stage I	90%	100%	42
Stage II	93%	100%	45

#Typical data obtained with a Radioimmunoassay (RIA).