

New improved Prostate Cancer Screening Test



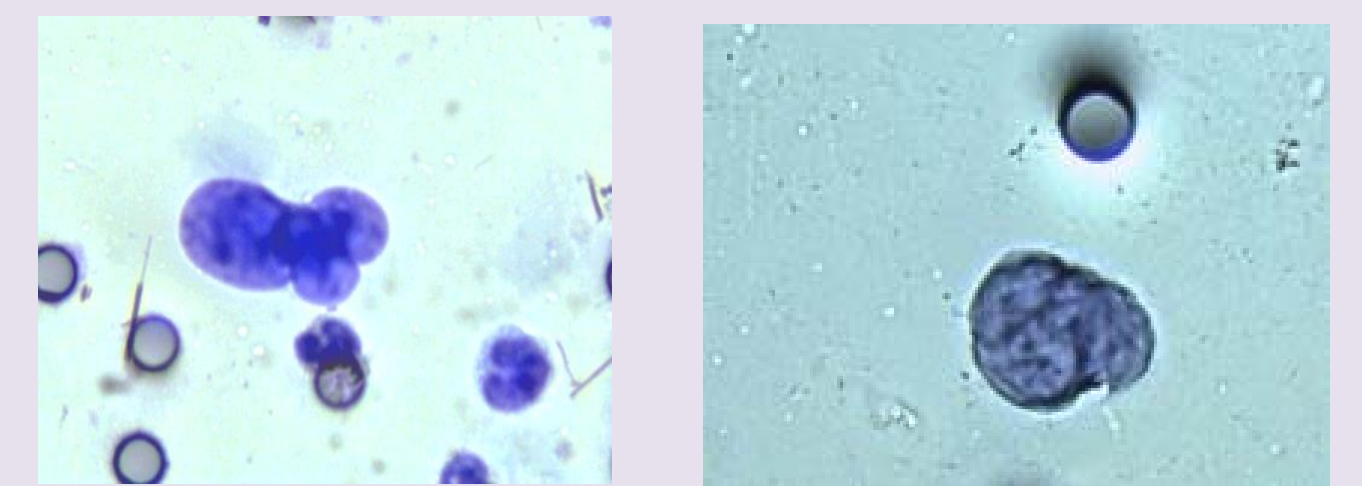
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Aim

To improve the current screening test for prostate cancer.

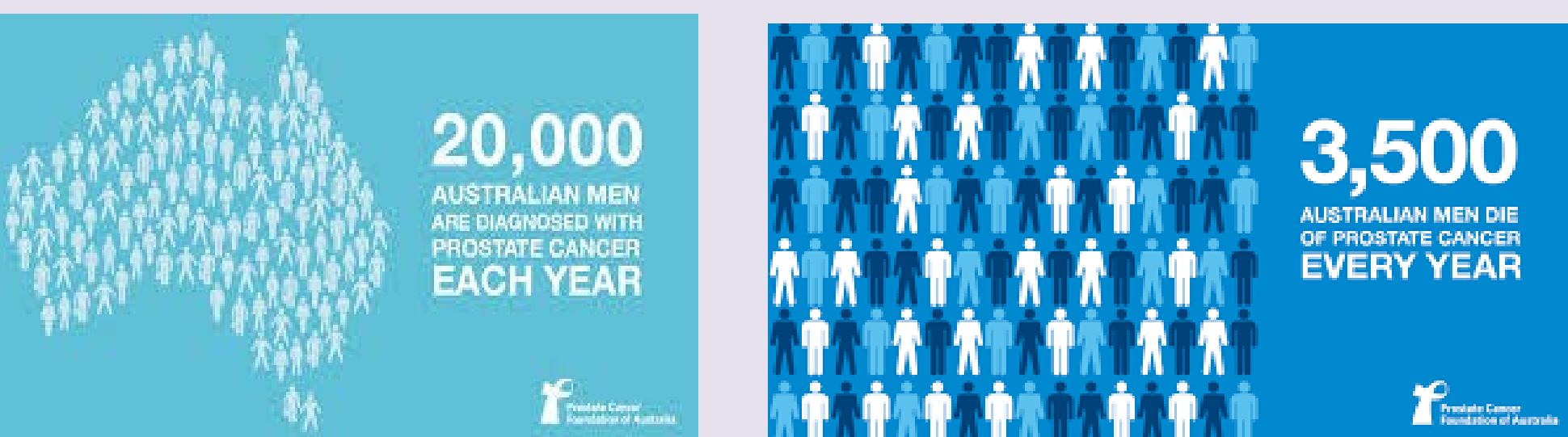
Background

Prostate Cancer

- **Prostate cancer (PC)** is the 2nd leading cause of death in men
- **Prevalence:** 1 in 7 men diagnosed in their lifetime
- 25% of all cancer cases
- 90,000 / 4 mill (22.5%) men live with PC in AUS¹
- >3,000 (3.7%) men die of PC each year in Australia¹

PSA Blood Test

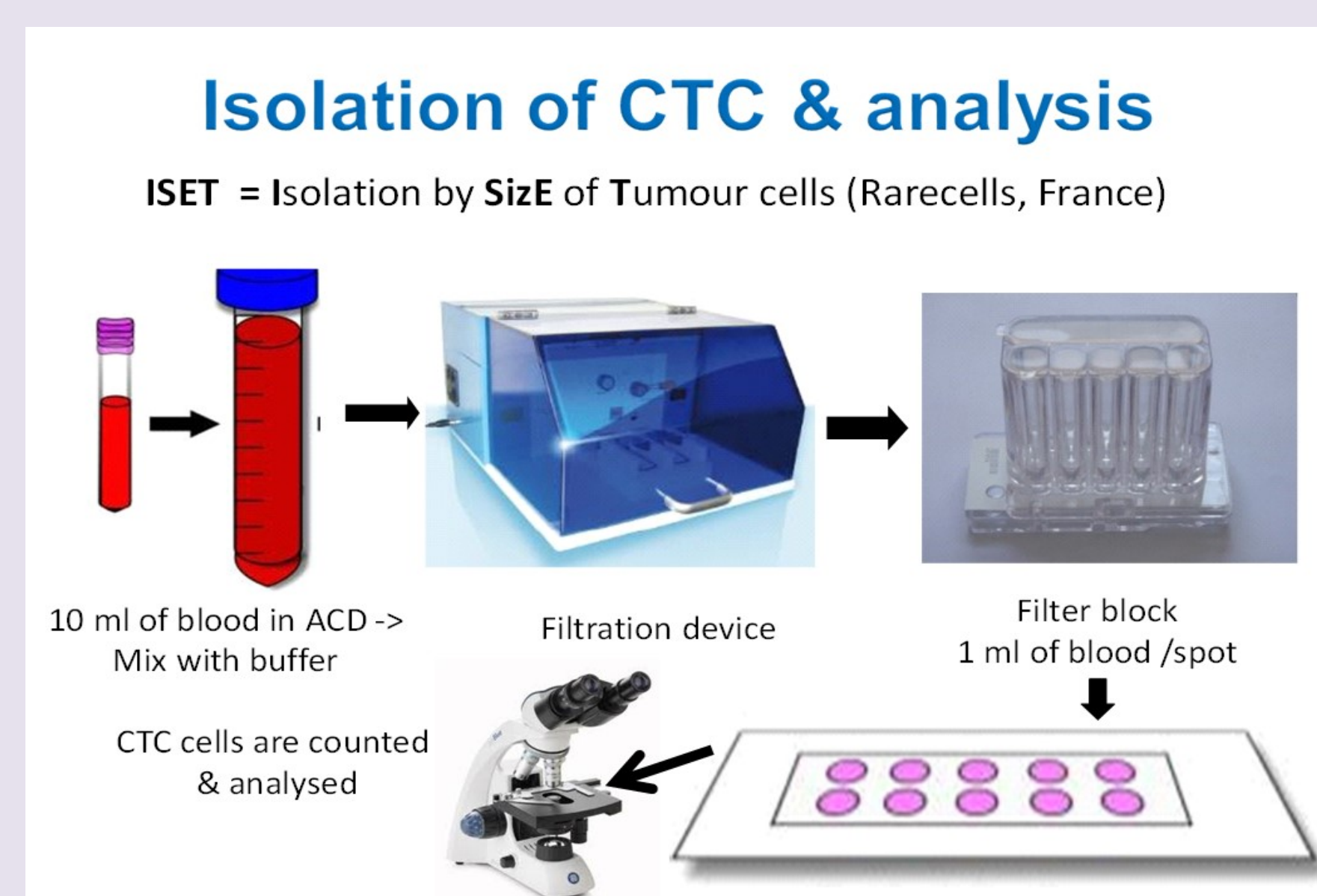
- The **PSA-blood test** has low sensitivity (25% true positives) and low specificity (14.5% true negatives).
- 85.5% false negatives, 75% false positives^{2,3}
- No longer recommended as screening test



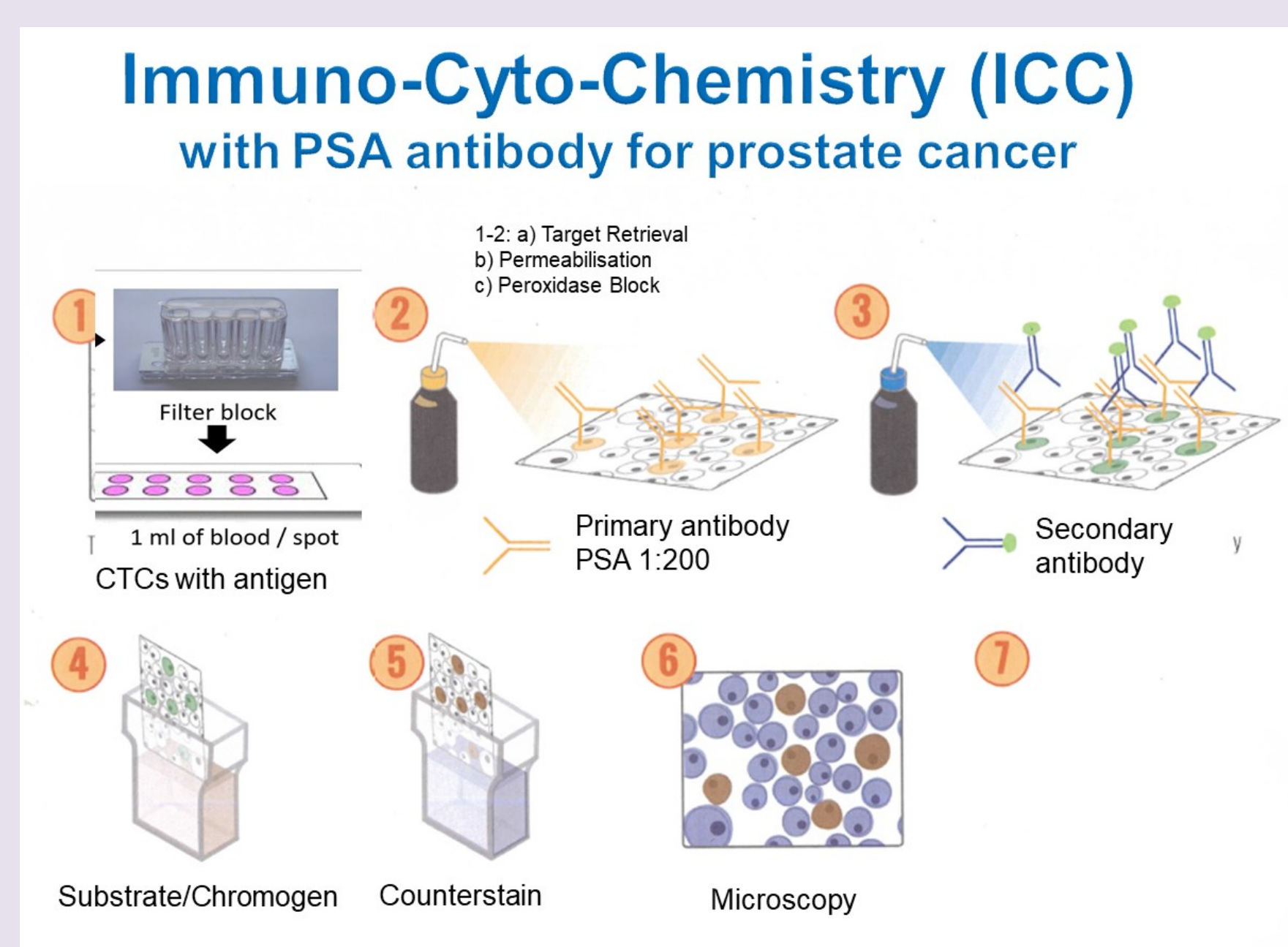
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Methods

Step 1. ISET-CTC test:



Step 2. ICC with PSA antibody:



References

1. Cancer Australia. Prostate Cancer Statistics. <https://prostate-cancer.canceraustralia.gov.au/statistics>
2. Thompson IM et al. Prevalence of prostate cancer among men with a prostate-specific antigen levels ≤ 4.0 ng per milliliter. *N Eng J Med* 2004;350:2239-46.
3. Barry MJ. Prostate-specific-antigen testing for early diagnosis of prostate cancer. *N Eng J Med* 2001;344:1373-7.
4. Ried K, Eng P, Sali A. Screening for Circulating Tumour Cells allows early detection of cancer and monitoring of treatment effectiveness: an observational study. *A Pac J Cancer Prev* 2017; 18: 2275-2285.
5. Ried K, Tamanna T, Matthews S, Eng P, Sali A. New Screening Test improves Detection of Prostate Cancer Using Circulating Tumour Cells and Prostate-Specific Markers. *Frontiers Oncol* 2020, 10, 582.

Acknowledgements Research assistant: Nikolaj Travica

Results

ISET-CTC testing

- Between Sept-2014 and Nov-2019 we undertook 2100 CTC tests.⁴
- 50% (n=1000) of tests were CTC screening requests.
- CTC were detected in all cancer patients and in 50% of those screened.

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- All men diagnosed with **prostate cancer** had **CTC with positive PSA markers** (n=20). (Tbl 1+ Fig 1)
- **Early detection:** Follow-up imaging PSMA-PET scans & biopsies within 1-40 months revealed **early prostate cancer** in **all screened men with positive PSA markers** and normal PSA blood test levels (n=20/27, 75%).
- **Prostate imaging scans were negative** in men with **PSA negative CTC** (n=5), and other **non-prostate cancers** were detected in 2 out of 7 men screened.
- **No CTC** were detected in screened men with **prostatitis / inflammatory condition**.

ICC on ISET-CTC with PSA-antibody[#]

Group	Patients	N	CTC/ml range (mean)	PSA marker result	Prostate Scan/ Biopsy result
1a	Positive Control M prostate cancer	20	1-23 (6.5)	+	Prostate cancer before CTC test
1b	Negative Control F other cancer	2	2-3 (2.5)	-	Breast / Ovarian cancer before CTC test
2	All Males screening *	27	1-13 (5.5)		
2a	Males screening *	9	1-11 (3.4)	+	Prostate cancer 1 m - 3.5 y after CTC test
2b	Males screening *	11	2-7 (3.4)	+/-	Prostate cancer
2c	Males screening *	5	1-2 (1.5)	-	Prostate scan negative / Other cancer detected (2)
2d	Males screening *	2	No CTC	na	atypical inflammatory cells / prostatitis

[#] Ried et al 2020, Frontiers in Oncology

PSA = prostate-specific-antigen

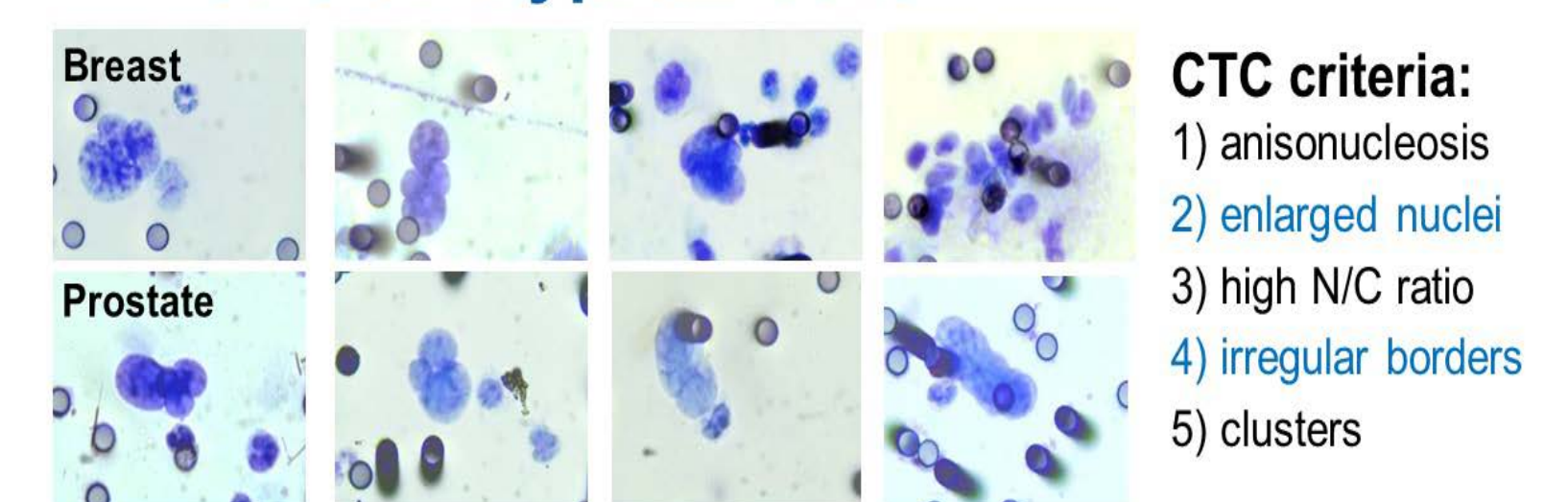
Table 1: Positive ICC results using PSA antibody on ISET®-CTC were found in males with confirmed (scan/biopsy) prostate cancer (group 1a, group 2a), and subgroup of males screened positive for CTC (group 1b).

ISET-CTC & PSA marker screening test improves detection of prostate cancer

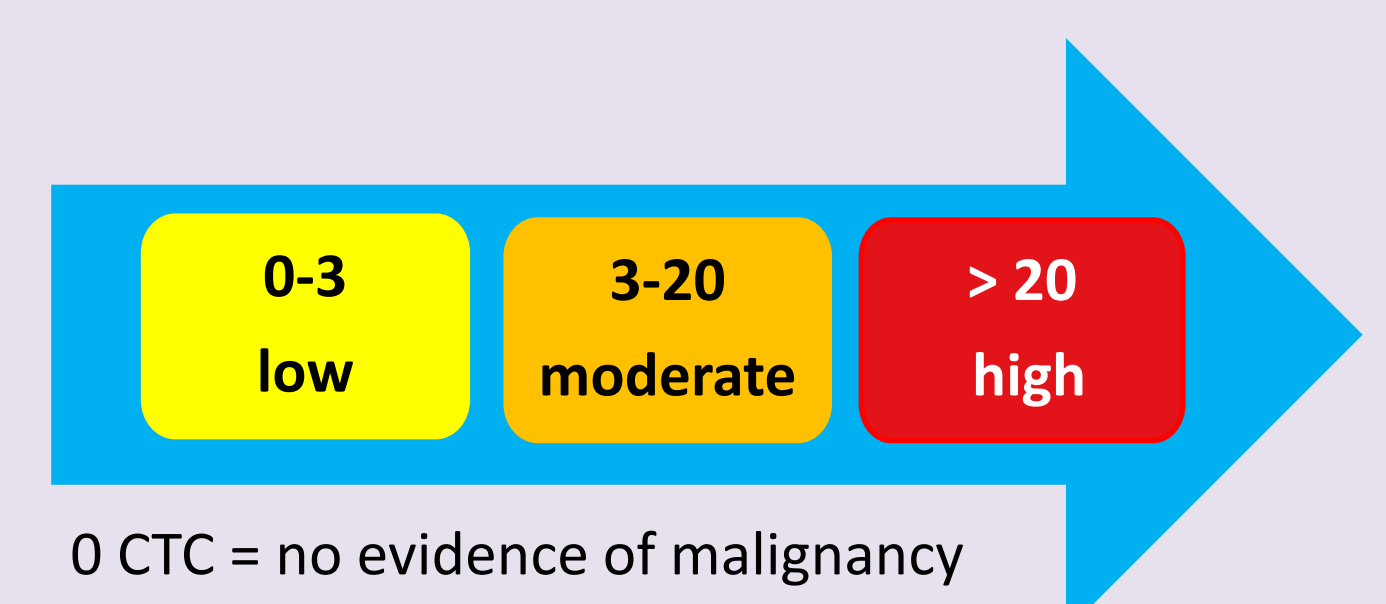
PSA Blood Test		ISET-CTC & PSA marker Test	
True positives	True negatives	True positives	True negatives
25%	14.5%	99%	97%
False positives	False negatives	False positives	False negatives
75%	85.5%	1%	3%

The ISET-CTC Test is cytology based

CTC or atypical cells



Number of CTC/ml and cancer risk



ICC on ISET®-CTC with PSA-antibody

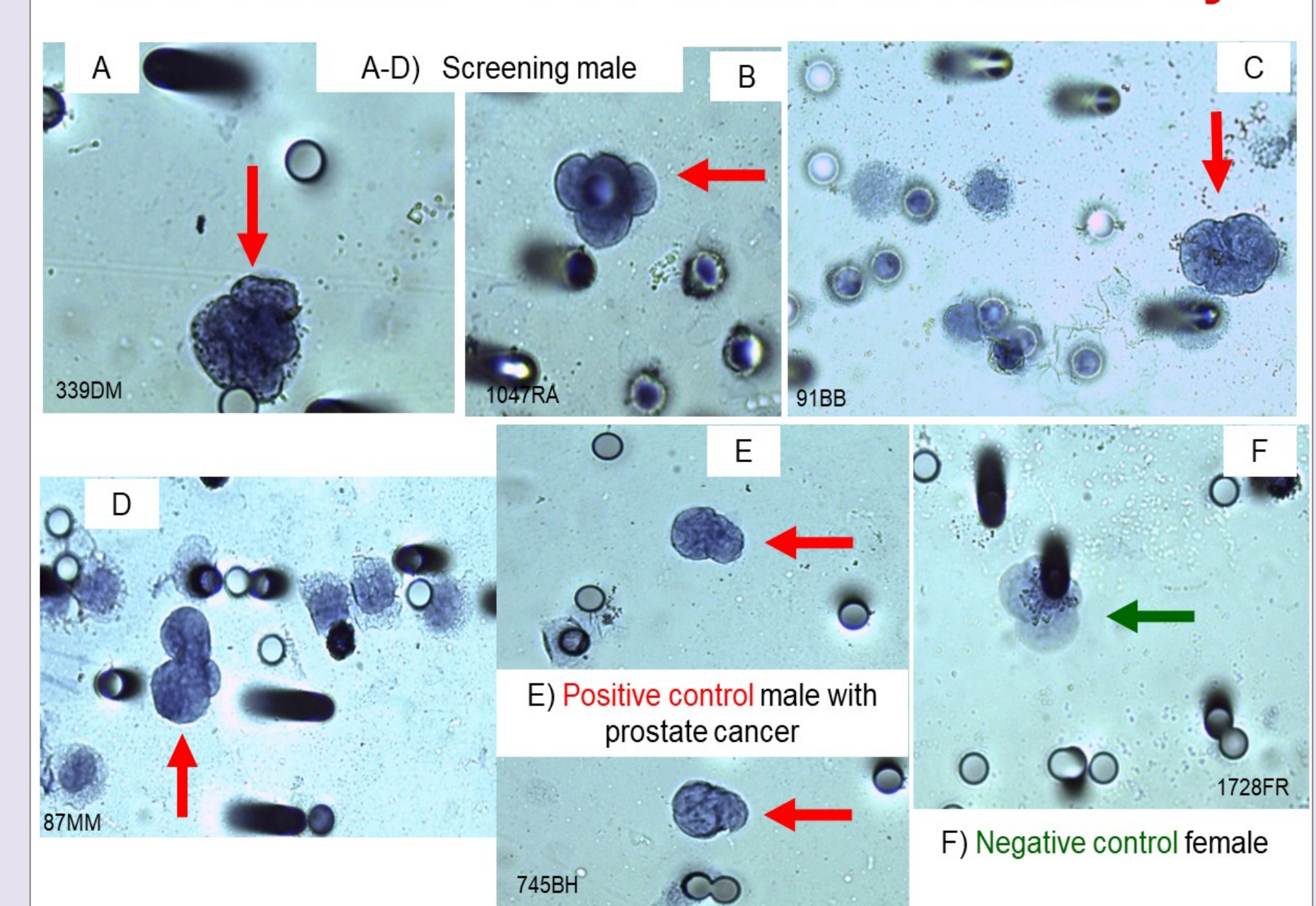


Figure 1: A-D) screened men with PSA (+) stained CTC (red arrows), E) men with prostate cancer with PSA (+) CTC (positive control), and F) female breast cancer patient with PSA (-) CTC (green arrow) (negative control).

Conclusions

- CTC screening provides a sensitive tool for the **early detection** of patients at risk of developing cancer.
- **ISET®-CTC & PSA-marker testing** has **high sensitivity (97%)** and **specificity (99%)** and is a **better screening test** and **predictor for prostate cancer** than the standard PSA blood testing.
- Evidence-based **integrative nutritional therapies**, including vitamin D, curcumin, Kyolic garlic, green tea, and mushroom extract, can **reduce CTC count** and cancer risk.