

Improved Detection of Bladder Cancer in Diagnosis and Surveillance Patients Using a Point-of-Care Proteomic Assay

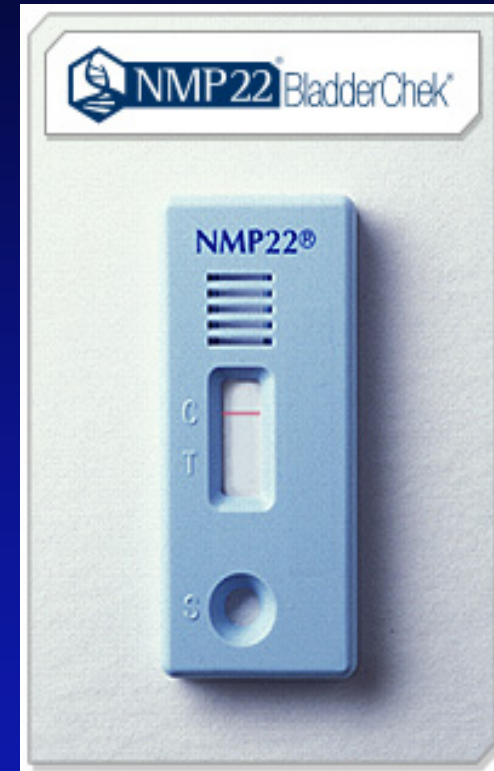
Barry Stein, M.D.

G. Katz, M.D.

NMP22 Clinical Investigation Group

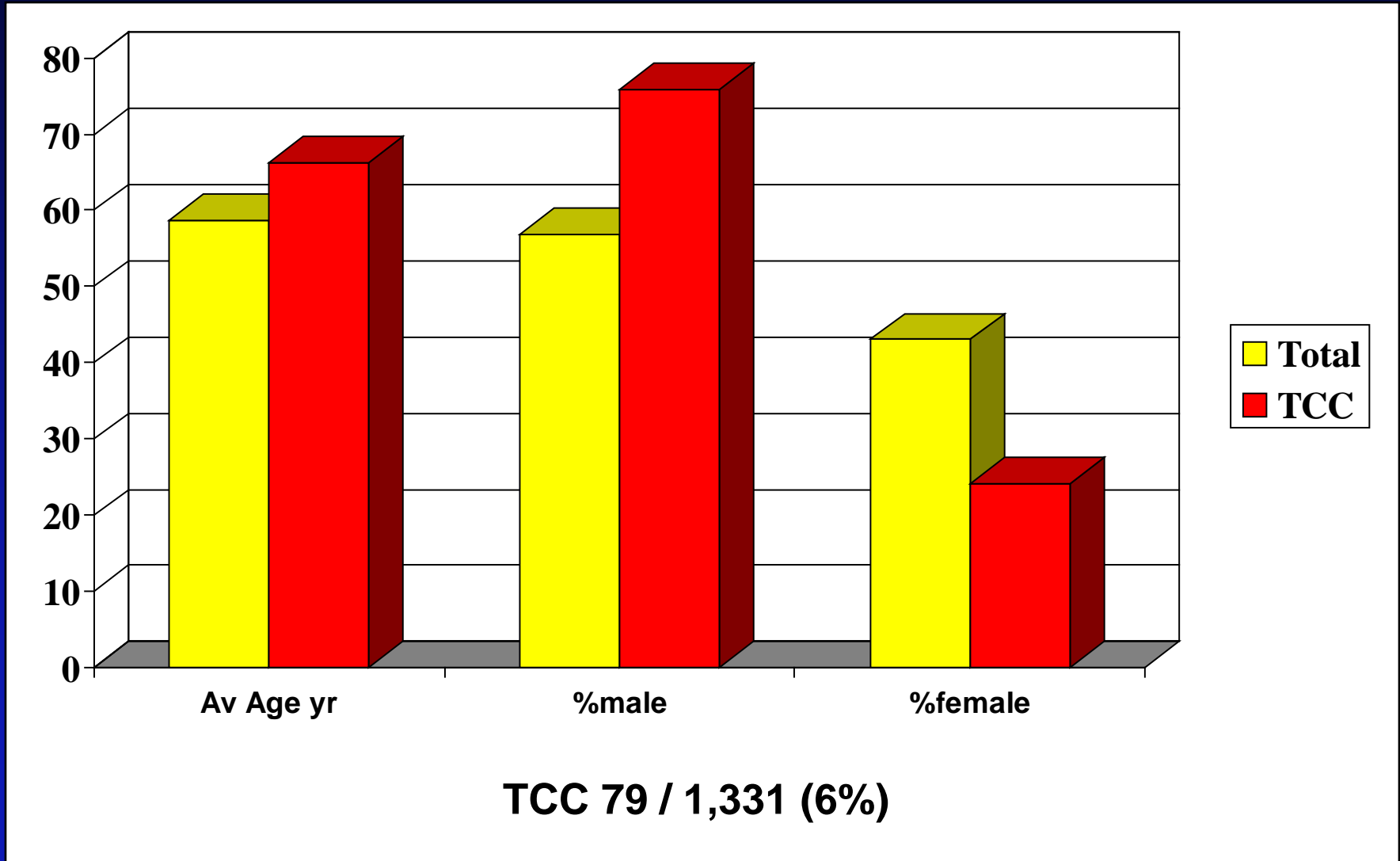
Study Design

- Two prospective studies: 23 facilities in 10 states; academic, private practice and VA
- 1,331 patients scheduled for cystoscopy due to increased risk of bladder cancer (hematuria (92%), history of smoking, irritative voiding symptoms), and 668 patients with a history of bladder cancer under surveillance for recurrence
- Voided urine sample for analysis of NMP22 marker (30 min, CLIA waived) and cytology prior to diagnostic cystoscopy
- Urologists were blinded to NMP22 and cytology results while performing and reporting the result of cystoscopy
- Further workup was based on clinical findings and results of cystoscopy and cytology
- TCC was diagnosed based on pathology

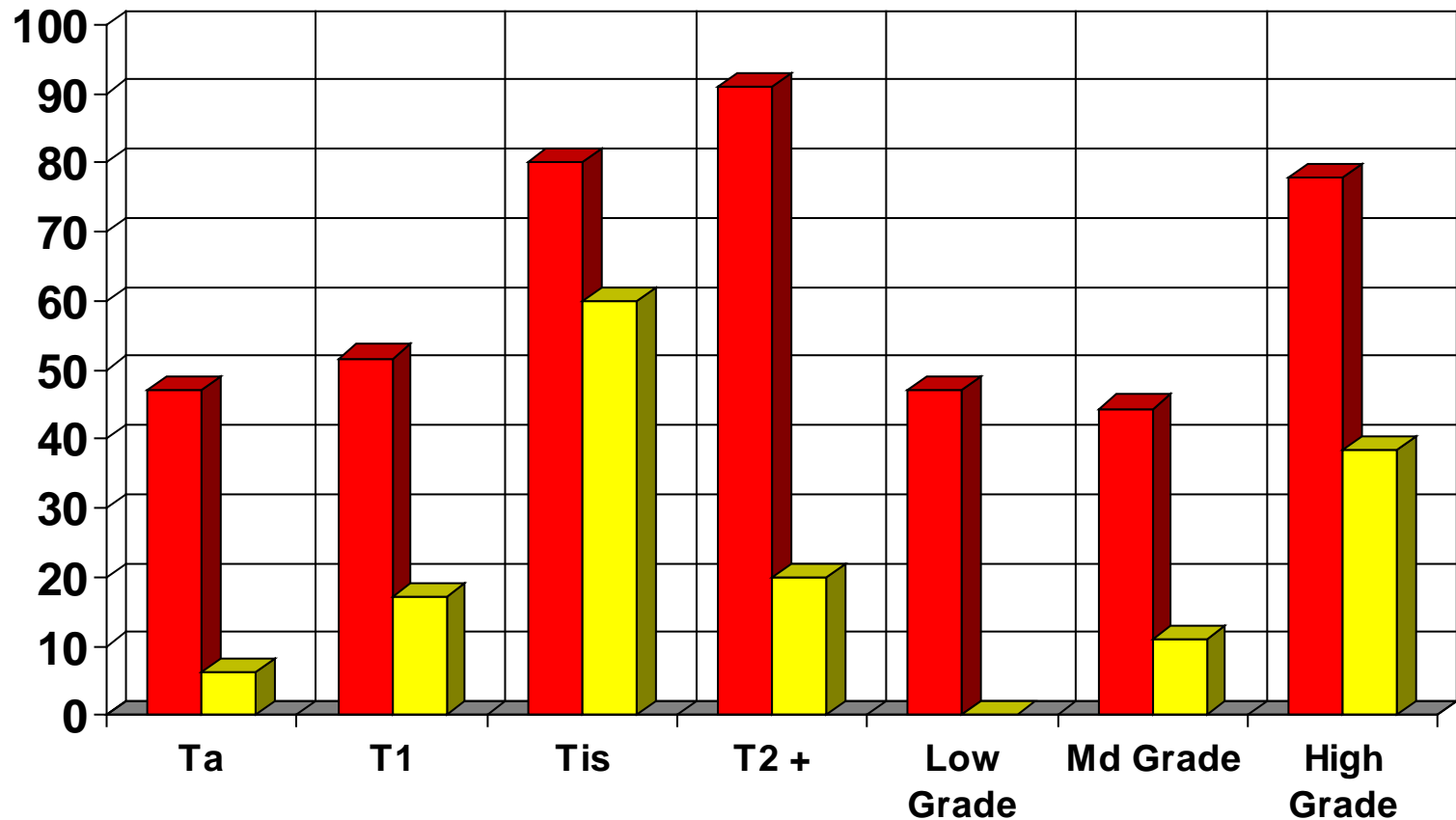


Diagnosis Demographics

Total Tested Population (1331) vs Patients with TCC (79)



Sensitivity for Detecting TCC: Diagnosis



NMP22 Test = 57%

Cytology = 16%

Improved Detection with NMP22 BladderChek Test and Cystoscopy

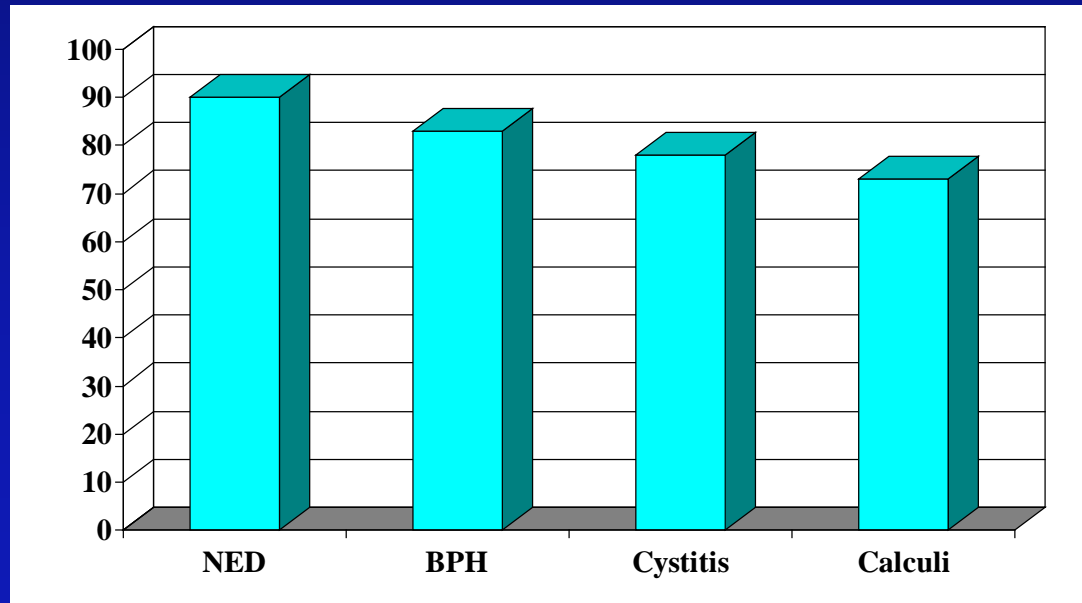
	Muscle Invasive	All Cancers	
Cystoscopy & NMP22 Test	91% (10/11)	94% (74/79)	} P=0.014
Cystoscopy alone	55% (6/11)	86% (68/79)	

**Cancers not seen by cystoscopy but detected by NMP22 Test:
Bladder CIS, T2, T3; Ureter T2; Renal Pelvis T1, T3**

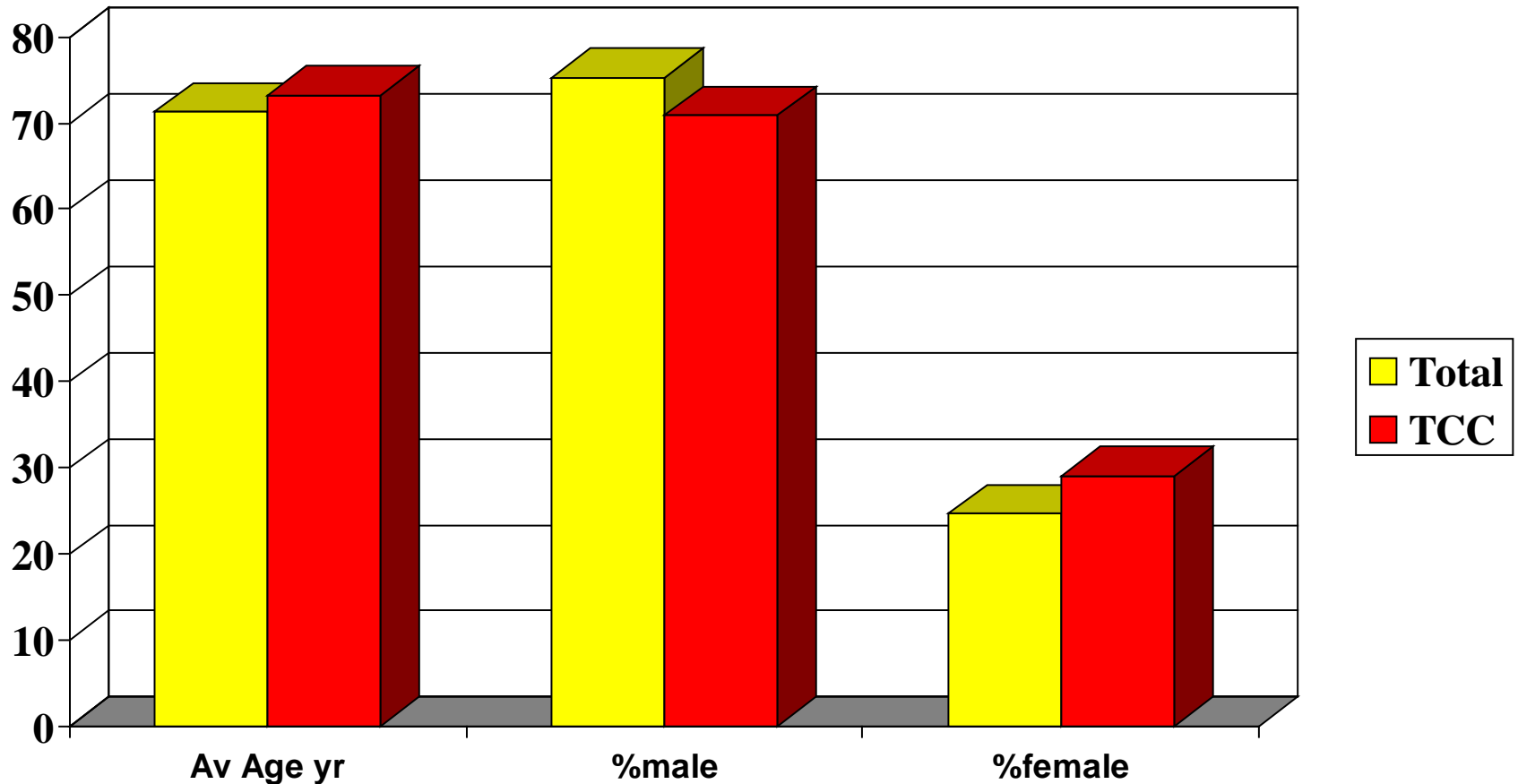
Specificity

	No GU Disease	No Cancer
NMP22	90%	86%
Test	(512/567)	(1072/1249)
Cytology	99%	99%
	(544/547)	(1198/1208)

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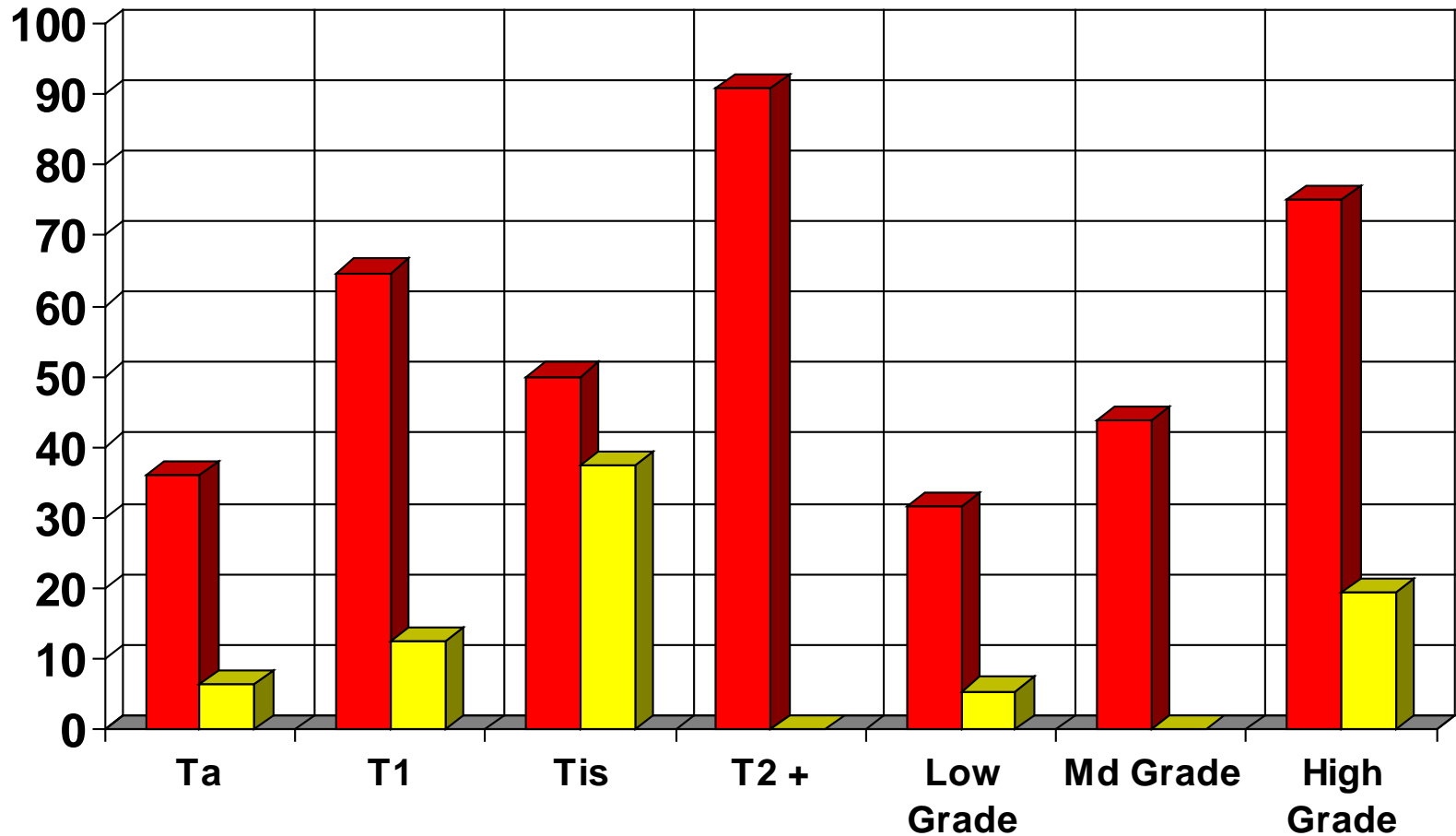
Monitoring (Surveillance) Demographics



Total population = 668

Patients with tumors = 103 (15%)

Sensitivity for Detecting Cancer: Monitoring



NMP22 Test = 50%

Cytology = 12%

Improved Detection with NMP22 BladderChek Test and Cystoscopy

	Muscle Invasive	All Cancers	
Cystoscopy & NMP22 Test	91% (10/11)	99% (102/103)	} P=0.005
Cystoscopy alone	64% (7/11)	91% (94/103)	

**Cancers not seen by cystoscopy but detected by NMP22 Test:
Ta G1, 2 Cis G3, T1 G3, 2 T2 G3, 2 T4 G3**

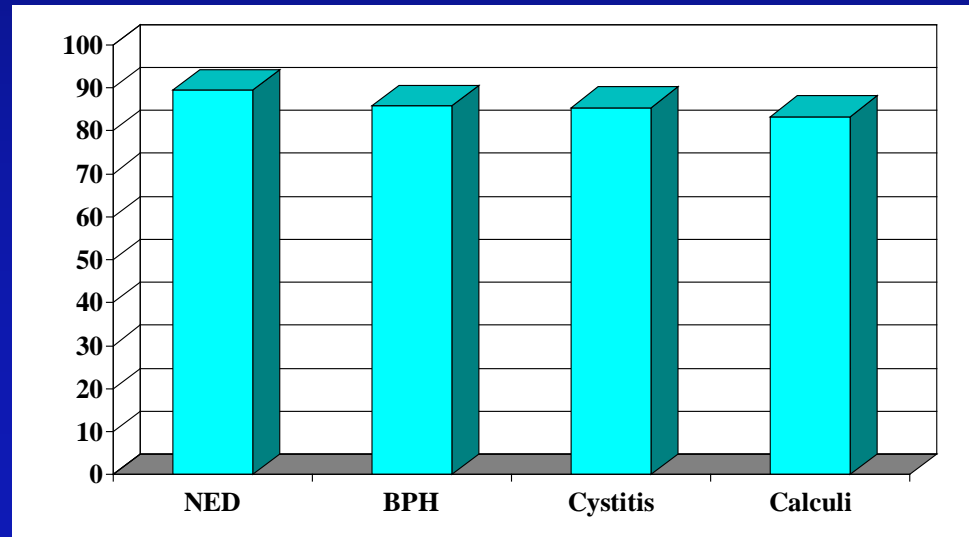
Specificity

NMP22 Test **87%** **(493/565)**

Cytology **97%** **(535/552)**

Cystoscopy **98%** **(556/565)**

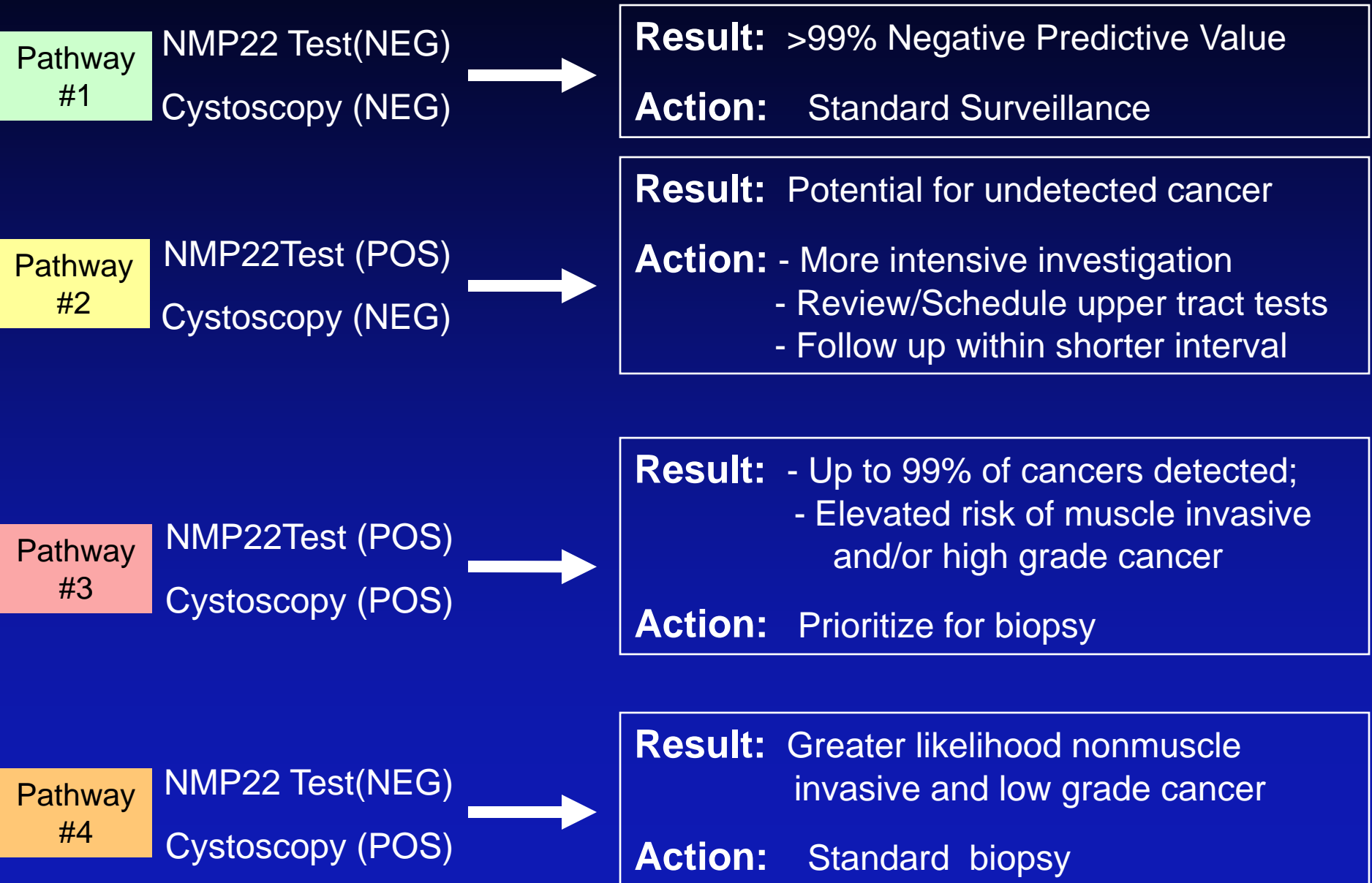
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Predictive Value

	PPV	NPV
NMP22 Test	41% (51/123)	91% (493/545)
Cytology	41% (12/29)	86% (535/621)
Cystoscopy	91% (94/103)	98% (556/565)

Bladder Cancer Detection Algorithm



Conclusions

- **Cystoscopy combined with the NMP22 BladderChek Test detected significantly more bladder tumors than cystoscopy alone**
- **NMP22 test detected high grade cancers not visualized by cystoscopy**
- **NMP22 test is significantly more sensitive than cytology for detecting cancer**
- **Negative Predictive Value of the NMP22 test is greater than cytology (P = 0.012) with equivalent Positive Predictive Value**
- **Test can be performed in the office with results available in 30 minutes at half the cost of cytology**