

How UROCASM Works

Patented Cytobay Filtration Chambers Capture virtually all cells of interest for morphology.

In-Liquid Immunostaining Collectively identifies malignant cells.

Result Significantly improved sensitivity and specificity.

Clinical Advantages

Early Detection

Low to high-grade cancers, enabling earlier intervention

Superior Reliability

High positive predictive value, fewer equivocal results

Enhanced Capability

Up to 3 complementary immunostains when indicated

Practical

Simple collection, ideal for surveillance, insurance supported



Who Should Be Tested?

Demographic:

- ✓ Age > 50
- ✓ Male (4x risk)
- ✓ High-risk ethnicity (White/Black)

Clinical Signs:

- ✓ Hematuria
- ✓ Pelvic/Bladder Pain
- ✓ Urinary Frequency/Urgency
- ✓ Elevated Sediment
- ✓ Recurrent UTIs

History:

- ✓ Prior Bladder Cancer
- ✓ Family History
- ✓ Tobacco/Alcohol Use
- ✓ Chemical Exposure

Findings:

- ✓ Abnormal cystoscopy
- ✓ Mass or wall thickening on imaging

Testing Protocol

- **Collection:** 80ml-120ml voided urine, preferably after some physical activity
- **Process:** Cytology performed. Up to 3 immunostains added when indicated. Results examined using Paris System criteria
- **Follow-up:** Based on ROHM—surveillance, cystoscopy with biopsy if indicated. Testing interval: 3-12 months

Clinical Performance

Comparative Accuracy vs. Current Methods

(Comparative Accuracy & Precision of High Grade, Suspicious for High Grade, and Low Grade Categories between The Paris System (TPS) vs Medprolab (MPL) Uroca Test.

DX Group	TPS HG	TPS SH	TPS LG	MPL HG	MPL SH	MPL LG
Sensitivity	38-46	10-30est	0-10	90-100	90-100	90-100
Specificity	98-99	10-50est	0-10	90-100	90-100	90-100
PosPredVal	71-96	40-70est	0-44	90-100	90-100	90-100
NegPredVal	68-95	low	low	90-100	90-100	90-100

Key: HG High Grade; SH Suspicious for HG (Interpolated); LG Low Grade.

Resulting Risks of High-Grade Malignancy

Comparative Risk of High-Grade Malignancy (ROHM%) projected for various Diagnostic Categories.

CATEGORY	ND	NHGUC	AUC	LGUN	SHGUN	HGUC
Paris Syst 2016	18	13	39	12	77	92
Paris Syst 2022	0-16	8-24	24-53	N/A	59-94	76-100
MPL Uroca Test	0-10	0-10	0-10	90-100	90-100	90-100

Key: UC Urothelial Carcinoma; ND Non Diagnostic/Unsatisfactory; NHGUC Negative for High Grade UC; AUC Atypical Urothelial Cells; LGUN Low Grade Urothelial Neoplasm; SHGUN Suspicious for High Grade UC; HGUC High Grade UC.

MPL (Medprolab) values are conservatively estimated due to small sampling and cellularity-poor samples.

Ref: Journal of Clinical and Transitional Pathology 2023 V3(2) p59-74 ; Journal of Personalized Medicine 2022,12,170

Positive Predictive Value of Immunostain Panel for Urothelial Carcinoma

Ppv%	0	55	60	60	62	85	95	100
CK17	-	-	-	+	+	+	-	+
Gata3	-	-	+	-	+	-	+	+
hTert	-	+	-	-	-	+	+	+

Key: Immunostain combo panel reliably predicts the occurrence of bladder cancer. It includes all grades of urothelial carcinoma.

The study conducted by Cytobay (2024 pub) found ppv to be Ck17(75), G3(100), G3+hT(100). Lesser, more conservative values for these are adopted in the above analytical table.

The PAP stain allows some classification into HG, LG, Atyp and N(normal/reactive)

