PacificEdge®
CANCER DIAGNOSTICS

Bell Potter Healthcare Conference

Dr Peter Meintjes
Chief Executive Officer

November 17, 2026

PRESENTING TODAY



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Chief Executive Officer

PacificEdge®
CANCER DIAGNOSTICS

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INTRODUCTION TO PACIFIC EDGE

BLADDER CANCER – A SIGNIFICANT GLOBAL HEALTHCARE CHALLENGE

THE STANDARD OF CARE – CYSTOSCOPY – IS HIGHLY INVASIVE, UNCOMFORTABLE AND COSTLY

BLADDER CANCER: A COSTLY, RECURRING DISEASE

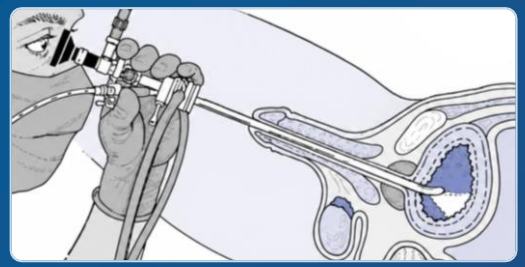
1st Costliest cancer to treat on a per-patient basis[1]

6th Most common cancer in men[2]

>50% Recurrence, driving years of repeat surveillance[3]

TODAY'S STANDARD OF CARE

Cystoscopy: a scope into the bladder



A camera on the end of a scope is inserted up the urethra to visually inspect the lining of the bladder wall[4]

Why it falls short

- Invasive and uncomfortable – patients defer or drop out of surveillance
- Costly, and consumes scarce urologist capacity
- Low yield – most patients scoped do not have cancer
- Have high variability between urologists, and only 81% sensitivity[5]

IMPROVED: NON-INVASIVE STANDARD OF CARE

Cxbladder: just pee in a cup



A simple urine test that detects and rules out bladder cancer – no invasive cystoscopy required

99.4%[6]
NPV: a negative result confidently rules out cancer

Grade A Rating[7]
AUA evidence rating in the 2025 Microhematuria Guideline

Why it solves the problem

- Collected at clinic or at home – no procedure, no discomfort
- Rules out cancer, reserving cystoscopy for those who need it
- Lower cost for payers and frees urologist capacity

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1. Sievert et al (2009) Economic aspects of bladder cancer: what are the benefits and costs? World J Urol. 2009 Mar 7;27(3):295–300. doi: 10.1007/s00345-009-0395-z
2. World Cancer Research Fund. Statistics are from 2022. Growth due to aging population.
3. Average recurrence for low grade non-muscle invasive bladder cancer as published in Palou J et al (2012): Eur Urol 2012; 62: 118.
4. Source: Nursing Skills
5. Guldhammer et al (2024), "Cystoscopy Accuracy in Detecting Bladder Tumors: A Prospective Video-Confirmed Study." Cancers. 2024;16(1):160. DOI: 10.3390/cancers16010160
6. Cxbladder Triage Plus Test Report, 07-QMS-091-US Rev A: NPV for scores below 0.15.
7. American Urological Association (AUA) 2025 Microhematuria Guideline.

ONE URINE SAMPLE, A CLEAR ANSWER AT EVERY STAGE OF CARE

CXBLADDER RULES OUT CANCER OR PRIORITIZES PATIENTS FOR CYSTOSCOPY

THE PATIENT JOURNEY

Symptoms

Hematuria (blood in urine)
The primary symptom of bladder cancer, ~7m US patients a year

Disease management

Cxbladder Triage Plus testing
Rule out cancer or prioritize patients for cystoscopy

Surgical intervention

TURBT – surgical resection
Tumor resected via cystoscope; pathology confirms stage and grade

Surveillance

Cxbladder Monitor · Surveillance Plus
Monitor NMIBC patients for recurrence

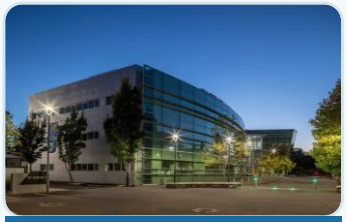
THE PATIENT EXPERIENCE

1 Collect



Pee in a cup, at clinic or home

2 Analyze



Pacific Edge labs
Dunedin, NZ · Hershey, PA

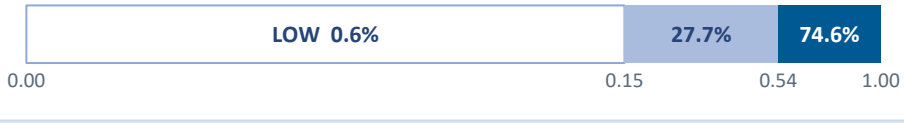
RNA + DNA biomarkers, one sample, Pacific Edge labs

3 Report

Cxbladder Triage Plus TEST REPORT

0.05

LOW PROBABILITY
of urothelial carcinoma: 0.6%
95% CI (0.02 – 0.10)



Sample result shown on the current Cxbladder Triage Plus report format. Not patient data.

4 Interpret

LOW <0.15
De-intensify patient work-up
84.1% of patients; 0.6% risk of UC

INTERMEDIATE 0.15–0.54
Further clinical evaluation
9.5% of patients; 27.7% risk of UC

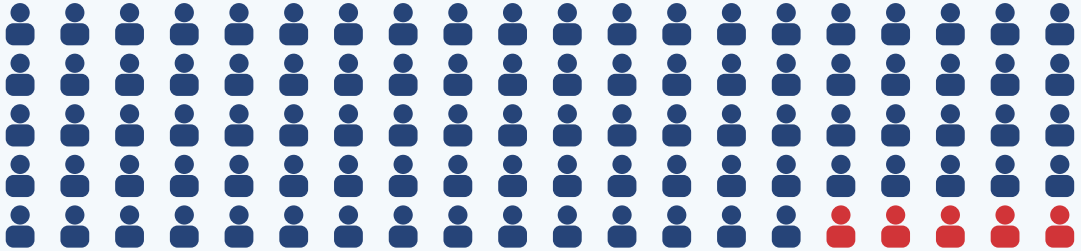
HIGH ≥0.54
Prioritize for cystoscopy
6.4% of patients; 74.6% risk of UC

TURBT: transurethral resection of a bladder tumor. NMIBC: non-muscle invasive bladder cancer. UC: Urothelial Carcinoma

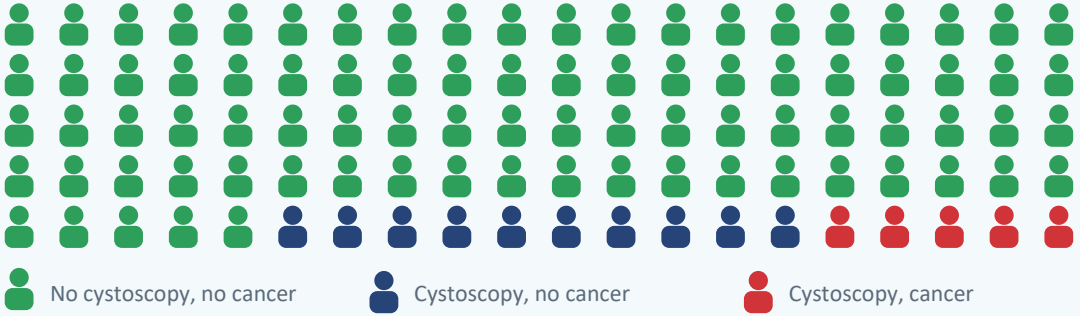
DRIVING ECONOMIC VALUE FOR PATIENTS, CLINICIANS, HOSPITALS AND PAYERS

CXBLADDER DELIVERS CLINICAL UTILITY, PATIENT SATISFACTION, IMPROVED ACCESS AND ECONOMIC VALUE

TODAY: 100 microhematuria patients, all receive a cystoscopy



WITH CXBLADDER TRIAGE PLUS: 85 avoid cystoscopy[1]



No cystoscopy, no cancer Cystoscopy, no cancer Cystoscopy, cancer

15% receive cystoscopy to find the same 5 cancer patients. Illustration assumes bladder cancer incidence in microhematuria populations of 5%[2]

85%
of cystoscopies safely avoided

62%
of US counties don't have a registered urologist[4]

13%
of high-risk patients receive a cystoscopy[5]

Patients	Low risk avoid an invasive, uncomfortable procedures, high risk are prioritized for diagnostic cystoscopy
Clinicians	Confident rule-out (99.4% NPV) focuses cystoscopy on patients most likely to have cancer
Hospitals	Urologists per person over 65 are falling[6], potentially delaying diagnosis. Cxbladder frees scarce capacity
Payers	Save >US$500 per patient[3], as Medicare reimbursement for cystoscopy declines[7]

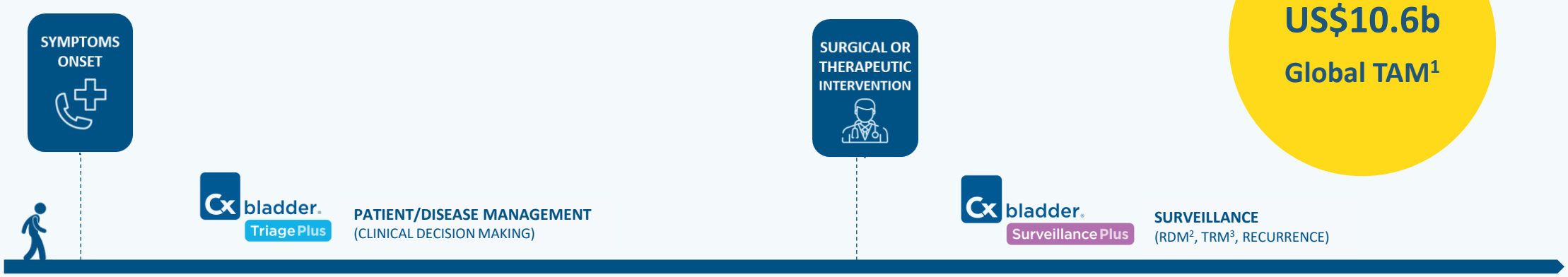
One urine test: better access, capacity and economics

1. Illustrative application of the observed risk distribution. Actual outcomes will vary, and no diagnostic test identifies every cancer
2. AUA Guidelines cite incidence of bladder cancer in microhematuria risk categories from 0.4-6%. 5% is an example
3. Tyson et al (2024) Budgetary Impact of Including the Urinary Genomic Marker Cxbladder Detect in the Evaluation of Microhematuria Patients - PubMed (PMID: 37914255)
4. https://www.auanet.org/research-and-data/aua-census/census-results
5. https://acsjournals.onlinelibrary.wiley.com/doi/full/10.1002/cncr.25048
6. Nam et al. (2021) Projected US Urology Workforce per Capita, 2020-2060 JAMA Network Open Published Online: November 16, 2021
7. https://www.cms.gov/medicare/physician-fee-schedule/search

CXBLADDER MARKET OPPORTUNITY

CXBLADDER OFFERS A SIGNIFICANT ADDRESSABLE GLOBAL MARKET ANNUALLY

US$10.6b
Global TAM[1]



	Population	All hematuria	Microhematuria[4] Low | Intermediate | High	Gross[4] Hematuria	Annual cases of bladder cancer	Living with bladder cancer	TAM	
	340m	~7m	0.20m | 1.14m | 1.46m	0.7m	~90k	~750k	US$6.7b	*Primary growth focus due to higher CMS pricing*
APAC	830m	~17m	0.47m | 2.71m | 3.46m	1.7m	~58k	~300k	US$2.0b	*NZ market mature. Australia and SEA in business development*
	600m	~12m	0.34m | 1.96m | 2.5m	1.7m	~180k	~1m	US$1.9b	*New market accessed via IVD / kitted tests*

1. Pacific Edge estimate combining US, APAC and Europe. See slides 31-33 for assumptions regarding eligible populations, testing frequency and pricing.
2. RDM: Residual Disease Monitoring
3. TRM: Therapeutic Response Monitoring
4. Management estimates derived from referred hematuria data in Woldu et al (2021), so do not add to ~7m figure for total incidence. See slides 36-38 for details.

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STRATEGY AND PROGRESS

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MEDICARE: FINAL LCD COVERS TRIAGE AND TRIAGE PLUS

ACCESS TO ~71M LIVES SUBJECT TO LCD ELIGIBILITY CRITERIA

EVIDENCE COVERAGE AND GUIDELINES

FINAL LCD (L40378): PUBLISHED 4 NOV 2026 | EFFECTIVE 20 DEC 2026

- **Sole coverage:** only Cxbladder Triage and Triage Plus are covered for intermediate-risk microhematuria (~1.14m patients/year)[1]; competing tests and generic codes are non-covered
- **Removes adoption barriers:** eliminates reimbursement and logistical objections from ordering clinicians
- **Higher ASP** [2]**:** Triage US$1,057 and Triage Plus US$1,328 per test, supporting revenue growth, operating leverage and cashflow
- **Medicare Advantage:** expected to reimburse in line with Medicare policy, boosting cashflow
- **Commercial payers:** Medicare coverage can be leveraged to drive policy adoption and appeals

~71M
Medicare lives

~2.8M
Microhematuria opportunities / yr[1]

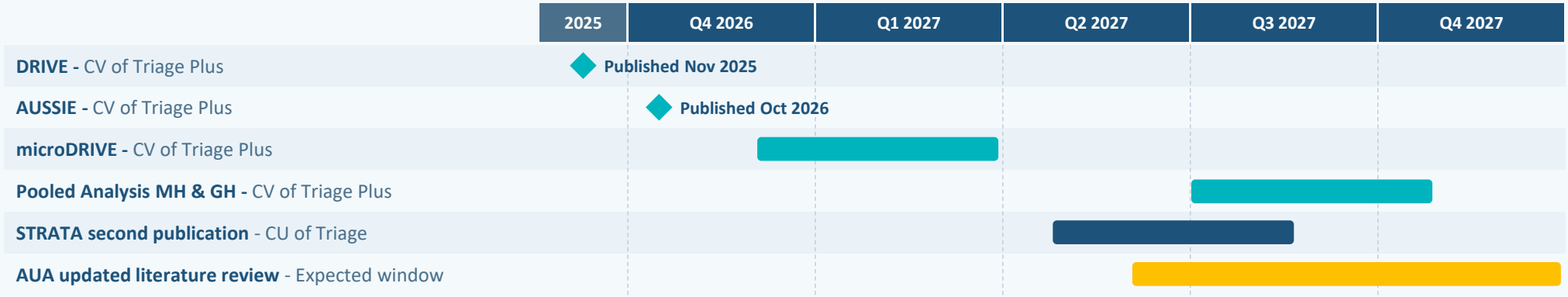
US$1,328
Triage Plus price per test

"Cxbladder Triage has the most published evidence specific to MH evaluation and is referenced in the AUA/SUFU 2025 guideline as one option that may be considered for appropriately counseled intermediate-risk patients…"

Novitas L40378, 'Urine-based Biomarkers in Patients with Microhematuria'

Medicare

PATH FORWARD: EVIDENCE TO EXPAND COVERED INDICATIONS AT NEXT UPDATED LITERTURE REVIEW BY AUA



American Urological Association

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1. Management estimate, see Slide 8.
2. Legacy tests had a Medicare approved price of US$760

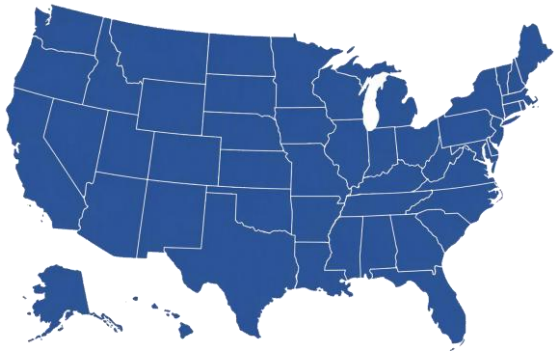
CU = clinical utility; CV = clinical validity; MH = microhematuria; GH = gross hematuria

US PAYER CONVERSION: FROM POLICY TO CONTRACT

EFFECTIVE MEDICARE COVERAGE FROM 20 DECEMBER 2026 EXPECTED TO UNLOCK COMMERCIAL VOLUMES

EVIDENCE COVERAGE AND GUIDELINES

US COMMERCIAL MARKET



223m	US private insured lives Source: US Census
1,200	US private health insurance payers Source: NAIC
71m	Medicare insured lives Source: CMS
9.18m	VA covered lives Source: VA

MEDICARE AND FAVOURABLE MEDICAL POLICY

Cxbladder Triage

81.3m

Policy lives[1&5]

Kaiser Permanente · BlueCross BlueShield · Sentara · Geisinger · Medicare

Cxbladder Monitor

8.4m

Policy lives[3,5]

Kaiser Permanente · Highmark

MEDICARE AND IN-NETWORK CONTRACTS SECURED

Cxbladder Triage

78.6m

Contracted lives[2,5]

Kaiser Permanente · BlueCross BlueShield · Medicare

Cxbladder Monitor

4.9m

Contracted lives[4,5]

Kaiser Permanente

1. Medicare, Blue Cross Blue Shield (BCBS) North and South Carolina and Kansas City Missouri, Hawaii Medical Services Association (Hawaii BCBS), Southern California Permanente Medical Group (Kaiser SoCal), Sentara, Geisinger and MVP Healthcare
2. BCBS NC and SC, Kaiser SoCal and Medicare
3. Kaiser SoCal and Highmark
4. Kaiser SoCal
5. The figures represented are from Policy Reporter and are likely to be an underestimate of lives under policy and in-network due to some Insurers and their subsidiaries administering government and other third-party programmes, not included in Policy Reporter.

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CONVERTING POLICY AND CONTRACTING INTO REVENUE

INTEGRATED DELIVERY NETWORKS ARE OUR PRIORITY

ADOPTION, RETENTION AND REVENUE GENERATION

US SERVICEABLE MARKET

2.8m[1]

Medicare coverage is for 1.14m Intermediate Risk

INTEGRATED DELIVERY NETWORKS

1.68m

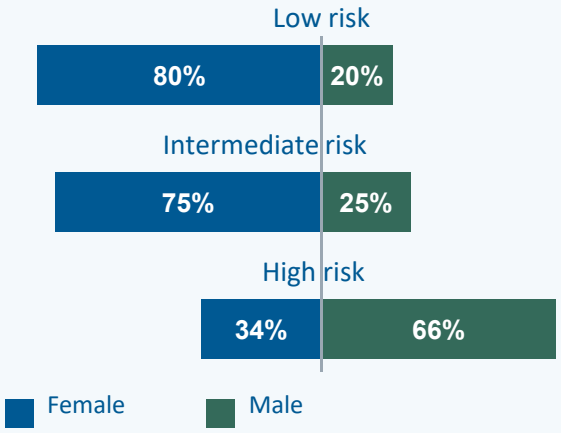
60% of patient volume

PRIVATE PRACTICE

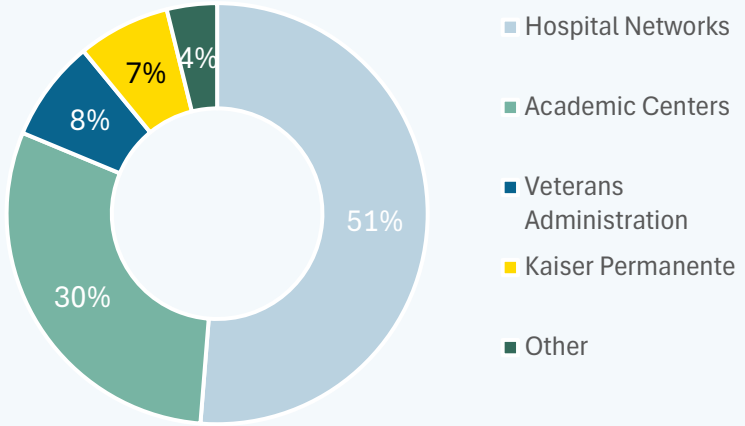
1.12m

40% of patient volume

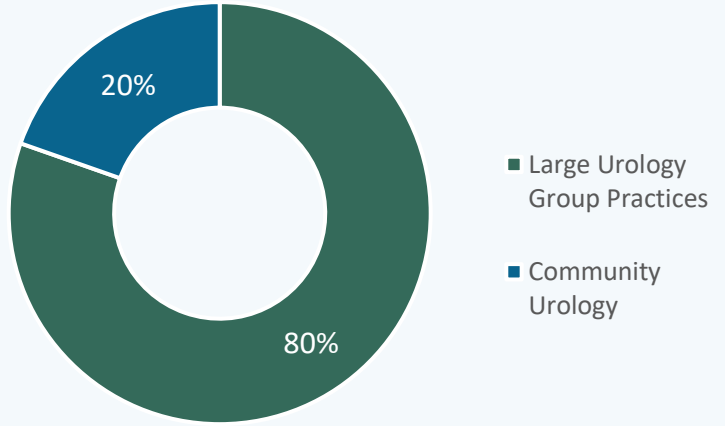
AUA RISK CATEGORY BY SEX (AT BIRTH)



PROVIDER MIX WITHIN CHANNEL[2]



PROVIDER MIX WITHIN CHANNEL[2]



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1. Management estimates derived from referred hematuria data in Woldu et al (2021). See slides 36-38 for details.
2. Share of patient volume figures are management estimates

FINANCIALS AND PATH TO PROFITABILITY

COST DISCIPLINE PRESERVES THE UPSIDE AS MEDICARE COVERAGE APPROACHES

Financial Period (NZ$M)	2H 26 (Unaudited)	1H 26 (Unaudited)	FY 26 (Audited)	2H 26 vs 1H 26
Operating Revenue	$5.6	$5.9	$11.5	(6.4%)
Total Revenue	$6.5	$7.1	$13.6	(9.3%)
Operating Expenses	$23.1	$26.2	$49.4	(11.9%)
Net Loss After Tax	**($16.7)**	**($19.1)**	**($35.8)**	**(12.8%)**
Net Cash Flows to Operating Activities	($12.9)	($19.0)	($31.9)	(32.1%)
Net Cash[1]	**$7.8**	**$22.1**	**$7.8**	**(64.8%)**
Monthly Cash Burn	$2.4	$3.3	$2.9	(27.7%)

NZ$36.1m raised

Raise completed in June 2026

Cash Burn <$2.5m/month

2H26 burn of NZ$2.4m/month, cash preservation measures continued

Key milestones on our path to profitability:

20 December 26
Final LCD

US pricing increases from 1 Jan 2027
Triage Plus US$1,328; Triage US$1,057[2] (↑39%)
Monitor US$1,026[2] (↑35%)

Jan 2028[3]
Surveillance Plus claims (targeted)

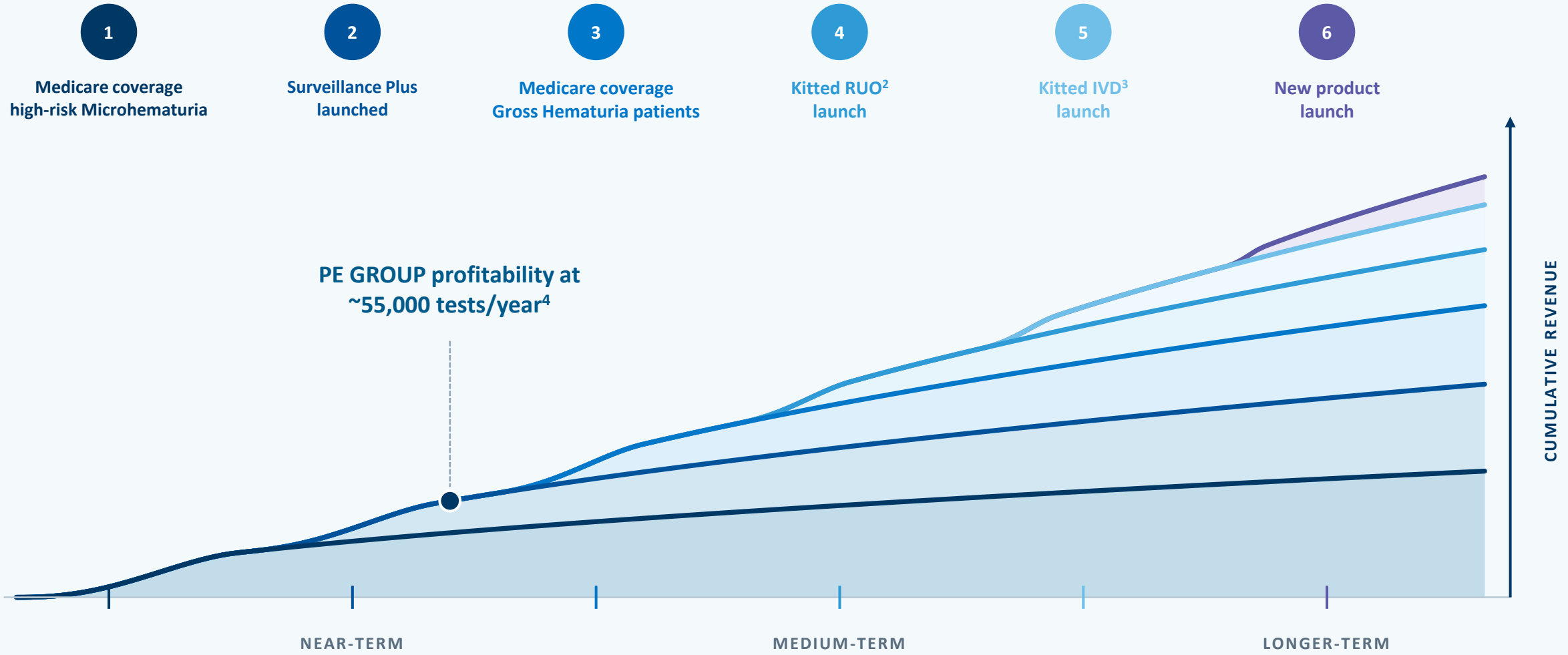
~55,000 tests/yr[4]
Profitability breakeven

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1. Net cash, cash equivalents and short-term deposits at the end of the period
2. Provisional CMS prices released Q2 27 expected to become final and effective 1 Jan 2027
3. Management Estimates
4. Profitability threshold determined on an annualized basis across all products with a blended ASP >$NZD 1,450. Actual breakeven will vary with payer mix, collection rates, product mix and operating investment

PACIFIC EDGE CATALYSTS FOR LONG-TERM SUSTAINABLE GROWTH[1]

AN EXPANDING SERVICEABLE MARKET AND REVENUE



1. Illustrative only. The curves indicate the sequence and relative scale of expected market expansion, not forecast revenue
2. RUO is for "research use only" and limits the clinical claims that can be made and the payment options
3. IVD is an in vitro diagnostic and subject to country-specific product registrations, regulations and reimbursement processes
4. Profitability threshold determined on an annualized basis across all products with a blended ASP >$NZD 1,450. Actual breakeven will vary with payer mix, collection rates, product mix and operating investment

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OUTLOOK: POSITIONED TO UNLOCK VALUE

FIRST MOVER; LARGE MARKET; BACKED BY EVIDENCE; KEY COMMERCIAL CATALYSTS

1st

First mover & market leader

Urine-based, non-invasive bladder cancer tests

US$10.6b[1]

Global market opportunity

Driven by ~7m US hematuria patients a year

Grade A

AUA[2] evidence rating

Cxbladder Triage: the only urine biomarker rated 'Grade A'

Medicare LCD

Triage and Triage Plus - the only tests covered by CMS in L40378

Coverage effective from 20 December 2026 for **71 million** US lives

Pricing

Improving sales force unit economics

Triage Plus US$1,328; Triage US$1,057; Monitor US$1,026 vs. US$760[3] on legacy products

Global commercial traction

Commercial payer and Medicare policy wins bring 78.6 million US lives under contract for hematuria evaluation; volume growth and favorable prices drive APAC towards profitability on a direct cost basis

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1. US$10.6b is a Pacific Edge estimate; see appendix for assumptions.
2. AUA: American Urological Association.
3. New Triage and Monitor prices provisional and subject to finalization; expected effective on 1 Jan 2027

APPENDIX

PacificEdge®
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PACIFIC EDGE IS FOUNDED ON DELIVERING POSITIVE OUTCOMES FOR SOCIETY

WE CREATE VALUE BY PRIORITISING OUR PATIENTS, OUR PHYSICIANS AND OUR PEOPLE

Our Mission

To help improve people's lives and patient outcomes by providing leading solutions for the early detection and management of cancer

Our Vision

A world where the early diagnosis and better treatment of cancer is within reach of everyone

WE PUT PATIENTS FIRST IN EVERYTHING WE DO

- **WE are committed to customer success**
- **WE are guided by data and evidence**
- **WE are trusting and transparent**
- **WE support our teammates**
- **WE celebrate successes, large and small**



PACIFIC EDGE – THE FIRST MOVER AND LEADER IN BLADDER CANCER DIAGNOSTICS

A GLOBAL COMPANY WITH A GLOBAL OPPORTUNITY

US$10.6b[1]

Global Market Opportunity





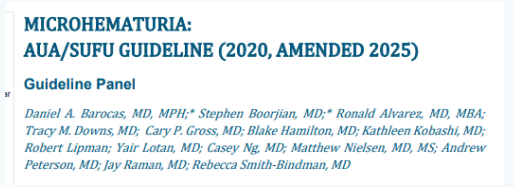
1. See slides 31 - 33 for assumptions

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TIMELINE: COMPANY MILESTONES







2011
Pacific Edge Diagnostics New Zealand (PEDNZ) established



Dec 2012
Launch of Pacific Edge Diagnostics USA and Cxb Detect

2012

2013

Mar 2013
First commercial sale (Cxb Detect) for PEDUSA

May 2013
First commercial sale (Cxb Detect) for PEDNZ

Dec 2014
Launch of Cxbladder Triage

2014

2015

Dec 2015
Launch of Cxbladder Monitor

2016

2018

Feb 2018
Cxb Triage adopted into Canterbury Community Health Pathways with primary care referral



2019

2020

Jun 2020
Kaiser Permanente, approves commercial use of Cxbladder

Jul 2020
Medicare reimbursement of Cxbladder at US$760/test

Aug 2021
Cxbladder reaches 70% public healthcare coverage in NZ

2021

2022

Dec 2022
Lotan et al: Enhanced Cxbladder Tests Deliver Improved Performance. Journal of Urology

2023

Nov 2023
Kaiser EMR integration goes live

2024

May 2024
STRATA podium presentation at AUA 2024. Study published in Journal of Urology



2025

Feb 2025
Triage included in AUA Microhematuria Guideline

Apr 2025
Medicare non-coverage effective

Nov 2025
Triage Plus gets CMS draft price of US$1,328

2026

Jan 2026
Kaiser RWE published supporting Triage. Largest ever UBB[1] hematuria study

May 2026
Novitas publishes Draft LCD DL40378 with coverage for Triage Plus and Triage

Nov 2026
Novitas Final LCD; effective 20 Dec 2026

1. UBBs are urine-based biomarkers – a term adopted by AUA in their guidelines

THE CXBLADDER SUITE: TRIAGE AND TRIAGE PLUS FOR HEMATURIA EVALUATION

TESTS TO RULE OUT BLADDER CANCER AND IDENTIFY THOSE MOST NEEDING SPECIALIST CARE

HEMATURIA EVALUATION		Cxbladder Triage	Cxbladder Triage Plus
NEGATIVE RESULT	**RULE OUT BLADDER CANCER** The test combines a **High Negative Predictive Value** with **High Sensitivity** (it picks up most cancers)	✓	✓
POSITIVE RESULT	**PRIORITIZE SPECIALIST CARE** The test combines a **High Positive Predictive Value** with **High Specificity** (it delivers few false positives)		✓
PERFORMANCE		Kavalieris et al. (2015)[1] • Sensitivity: 95% • Specificity: 45% • Negative Predictive Value: 99% • Positive Predictive Value: N/A	Harvey et al. (2025)[2] • Sensitivity: 93.6%* • Specificity: 98.2%** • Negative Predictive Value: 99.4%* • Positive Predictive Value: 74.6%**
WHEN IT IS USED:		Prior to cystoscopy	Prior to cystoscopy / as an adjunct / 3 weeks post cystoscopy
COMMERCIALLY AVAILABLE		Globally available	Globally available
AUA GUIDELINE		Grade A Evidence	Assessment expected in 2027
MEDICARE		**US$1,058[3] (Effective 20 December 2026)**	**US$1,328 (Effective 20 December 2026)**

* When lower 0.15 cut point on test report is used

** When higher 0.54 cut point on test report is used

1. Kavalieris et al. (2015) A segregation index combining phenotypic (clinical characteristics) and genotypic (gene expression) biomarkers from a urine sample to triage out patients presenting with hematuria who have a low probability of urothelial carcinoma. BMC Urol 2015;15:23.
2. Harvey et al. (2025) Analytical Validation of the Cxbladder® Triage Plus Assay for Risk Stratification of Hematuria Patients for Urothelial Carcinoma. Diagnostics. 2025; 15(14):1739. https://doi.org/10.3390/diagnostics15141739
3. Provisional CMS prices released Q2 27 expected to become final and effective 1 Jan 2027

PacificEdge® CANCER DIAGNOSTICS

THE CXBLADDER SUITE: MONITOR AND SURVEILLANCE PLUS

ALTERNATIVE TO CYSTOSCOPY FOR NMIBC[1] PATIENTS UNDERGOING SURVEILLANCE FOR RECURRENCE

NMIBC[1] CANCER SURVEILLANCE RECURRENCE		CxBladder Monitor	CxBladder Surveillance Plus
NEGATIVE RESULT	**RULE OUT BLADDER CANCER RECURRENCE** The test combines a **High Negative Predictive Value** with **High Sensitivity** (it picks up most cancers)	✓	• In development, showing improved performance
PERFORMANCE		• Sensitivity: 93%[2,3] • Specificity: N/A • Negative Predictive Value: 97%[2,3] • Positive Predictive Value: N/A	• Sensitivity: not yet published • Specificity: not yet published • Negative Predicative Value: not yet published • Positive Predictive Value: not yet published
WHEN IT IS USED:		At any surveillance time point 9 months after the most recent cancer diagnosis	At any surveillance time point after the first surveillance cystoscopy (6 weeks)
COMMERCIALLY AVAILABLE		Globally available	• USA: CPT-PLA code targeted for Jun 2027, reimbursement from Jan 2028 • APAC: Soft launch from Q2 FY28
GUIDELINES		NCCN[4] 2b	Not yet available for assessment
MEDICARE		**US$1,026[5] (non-covered)**	Seeking **US$1,800[6] (not yet covered)**

1. NMIBC: non-muscle invasive bladder cancer
2. Kavalieris et al. (2017) Performance Characteristics of a Multigene Urine Biomarker Test for Monitoring for Recurrent Urothelial Carcinoma in a Multicenter Study. J Urol 2017;197:6,1419-1426.
3. Lotan et al. (2017) Clinical comparison of noninvasive urine tests for ruling out recurrent urothelial carcinoma. Urologic Oncology: Seminars and Original Investigations. Elsevier; 2017; 1–8.
4. NCCN: National Comprehensive Cancer Network
5. Provisional CMS prices released Q2 27 expected to become final and effective 1 Jan 2027
6. Seeking pricing by way of crosswalk

PacificEdge® CANCER DIAGNOSTICS

FY 26 FINANCIAL PERFORMANCE: POSITIONING FOR MEDICARE RE-COVERAGE

COST SAVINGS MINIMIZE CASH BURN; $36.1 MILLION CAPITAL RAISE IN MAY 2026 STRENGTHENS BALANCE SHEET

Financial Period (NZ$M)	1H 26 (Unaudited)	2H 26 (Unaudited)	FY 26 (Audited)	FY 25 (Audited)	2H 26 vs 1H 26	FY 26 vs FY 25
Operating Revenue	$5.9	$5.6	$11.5	$21.8	(6.4%)	(47.4%)
Total Revenue	$7.1	$6.5	$13.6	$24.6	(9.3%)	(44.8%)
Operating Expenses	$26.2	$23.1	$49.4	$54.6	(11.9%)	(9.5%)
Net Loss After Tax	**($19.1)**	**($16.7)**	**($35.8)**	**($30.0)**	**(12.8%)**	**19.5%**
Cash Receipts from Customers	$8.0	$5.2	$13.2	$21.6	(34.3%)	(38.7%)
Net Cash Flows to Operating Activities	($19.0)	($12.9)	($31.9)	($24.7)	(32.1%)	29.1%
Net Cash[1]	**$22.1**	**$7.8**	**$7.8**	**$22.6**	**(64.8%)**	**(65.5%)**
Monthly Cash Burn	$3.3	$2.4	$2.9	$2.3	(27.7%)	23.4%

1. Net cash, cash equivalents and short-term deposits at the end of the period

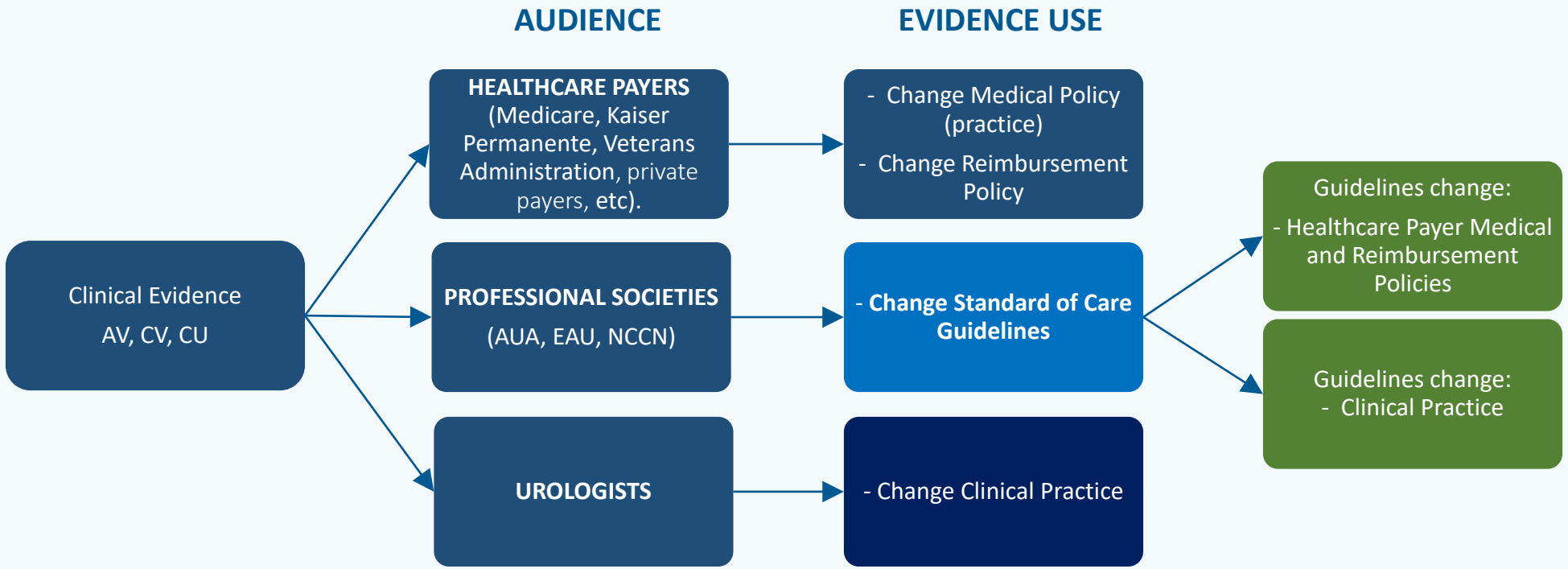
FINANCIAL PERFORMANCE OPERATING EXPENSES

ALL COSTS REDUCED WITH LARGEST REDUCTION IN SALES AND MARKETING

Financial Period (NZ$M)	1H 26 (Unaudited)	2H 26 (Unaudited)	FY 26 (Audited)	FY 25 (Audited)	2H 26 vs 1H 26	FY 26 vs FY 25
Laboratory Operations	$5.9	$5.7	$11.6	$12.5	(2.8%)	(7.1%)
Research	$7.1	$6.4	$13.4	$14.6	(9.9%)	(8.2%)
Sales and Marketing	$8.5	$6.8	$15.2	$17.5	(20.0%)	(13.2%)
General Administration	$4.8	$4.3	$9.1	$9.9	(11.8%)	(8.1%)
Total operating expenses	**$26.2**	**$23.1**	**$49.4**	**$54.6**	**(11.9%)**	**(9.5%)**

PacificEdge® CANCER DIAGNOSTICS

PACIFIC EDGE'S EVIDENCE PROGRAM SEEKS TO CHANGE CLINICAL PRACTICE



American Urological Association

NCCN National Comprehensive Cancer Network®

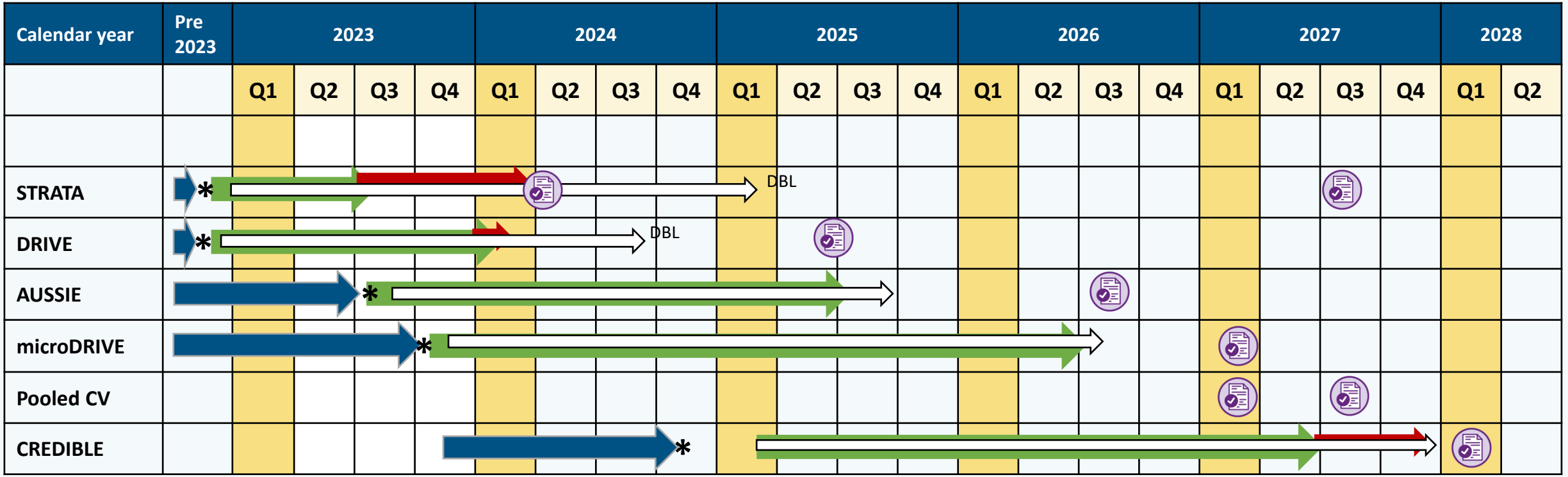
eau European Association of Urology

EVIDENCE DEVELOPED IN A STRUCTURED FRAMEWORK:

- **Analytical Validity (AV)**: Evidence that a test is repeatable in the lab for a given indication and population
- **Clinical Validity (CV):** Evidence a test works in the same way on an independent eligible population for a given indication
- **Clinical Utility (CU):** Evidence that a test changes clinical practice in the hands of a physician; CU evidence obtained through randomized control trials can provide a high level of support for guideline change (in addition to AV and CV evidence)
- **Real World Evidence (RWE)**: CU verification of the real-world use of the test in clinical practice, usually through regular use of the test by physicians

PacificEdge® CANCER DIAGNOSTICS

HEMATURIA EVALUATION FIVE-YEAR CLINICAL STUDIES ROADMAP



Legend:

- Pre-activation (docs, CTA etc)
- SIV
- Enrollment
- Data Cleaning
- Publication Submitted
- Records review / follow-up
- DBL — Database lock

PacificEdge® CANCER DIAGNOSTICS

SURVEILLANCE FIVE-YEAR CLINICAL STUDIES ROADMAP

Calendar year	Pre 2023	2023				2024				2025				2026				2027				2028	
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
"The 1800"[1]																							
LOBSTER	*																						
OCTOPUS													CAB[2]										

Legend:

- Business case approved
- * SIV
- Enrollment
- Data Cleaning
- Publication Submitted
- Records review / follow-up
- DBL Database lock
- Scheduled surveillance visits

1. "The 1800" is the Surveillance Plus development dataset
2. CAB is the Pacific Edge Clinical Advisory Board. It was convened at SUO in Arizona to review and confirm the clinical study trial design for OCTOPUS

DRIVING CLINICAL VALUE FOR PHYSICIANS, HOSPITALS AND PAYERS

COMPELLING CLINICAL EVIDENCE CHANGES CLINICAL PRACTICE, MEDICAL POLICY AND GUIDELINES

STUDY	TEST AND EVIDENCE	PUBLICATION DATE [1]
1. STRATA Clinical Utility	- CU of Triage	Published May 2024
2. Automated RNA & DNA extraction	- AV of Triage, Detect and Monitor	Published September 2024
3. Triage Plus Analytical Validation	- AV of Triage Plus	Published July 2025
4. DRIVE Clinical Validation	- CV of Triage Plus	Published October 2025
5. STRATA second publication	- CU of Triage	Q3 2027
6. AUSSIE Clinical Validation	- CV of Triage Plus	Published October 2026
7. microDRIVE Clinical Validation	- CV of Triage Plus	Q1 2027
8. Surveillance Plus Analytical Validation	- AV of Surveillance Plus	Q2 2027
9. Pooled Analysis MH & GH Clinical Validation[2]	- CV of Triage Plus	Q3 2027
10. LOBSTER Clinical Validation	- CV of Monitor/Surveillance Plus	Q3 2027
11. CREDIBLE Clinical Utility	- CU of Triage Plus	Q1 2028
12. OCTOPUS Clinical Utility	- CU Surveillance Plus	No timeline at this point

[1] All dates are calendar year and our best current estimates
[2] The MH and GH pooled analysis brings together data from DRIVE, AUSSIE and microDRIVE

Already published evidence

Expected to be published before AUA microhematuria guideline committee initiates next literature review in Q3 2027

Clinical Utility (CU) - Evidence a test that can usefully change patient management within the context of care for the defined population and indication Clinical Validity (CV) - Evidence a test works in the same way on an independent eligible population for a given indication. Analytical validity (AV) - Evidence a test is repeatable in the lab for a given indication and population

PacificEdge® CANCER DIAGNOSTICS

INDEPENDENT STUDIES SUPPLEMENT OUR EVIDENCE PORTFOLIO

HIGH IMPACT RESEARCH AT LOW COST

INDEPENDENT STUDY FOCUS	INSTITUTION	TEST AND EVIDENCE TYPE	PUBLICATION DATE[1]
Real World Utility of Triage in MH: A Matched Cohort Study	Kaiser Permanente, US	CU Triage (RWE)	Q1 2026[2]
Patient preference and satisfaction of "biomarkers vs cystoscopy"	Mayo Clinic, US	CU Monitor	Q4 2026
NZ Hematuria Pathway comparing T/D with Triage Plus on AUSSIE samples	Canterbury DHB	CU of Triage Plus	Q1 2027
Retrospective comparison of Triage and Triage Plus in the Kaiser System	Kaiser Permanente, US	CU Triage Plus	2027
Test utility in screening patients at risk for bladder cancer	UT Southwestern, US	CU Triage Plus	2027
Test utility in assessing therapy success in a reduced chemotherapy protocol for upper tract tumors	Israel Institute of Technology, Israel	CU Monitor CU Surveillance Plus	2027
Test utility in assessing response to BCG[3] in high-grade bladder cancer patients	University of Miami, US	CU Monitor CU Surveillance Plus	2027
Test utility for the surveillance of MIBC[4] treated with bladder sparing methods (PRESERVE Trial)	Cleveland Clinic, US	CU Monitor CU Surveillance Plus	2028
A Randomized Trial of Apalutamide in Non-Muscle Invasive Bladder Cancer	National Institutes of Health, US	CU Monitor CU Surveillance Plus	2029

Already published evidence

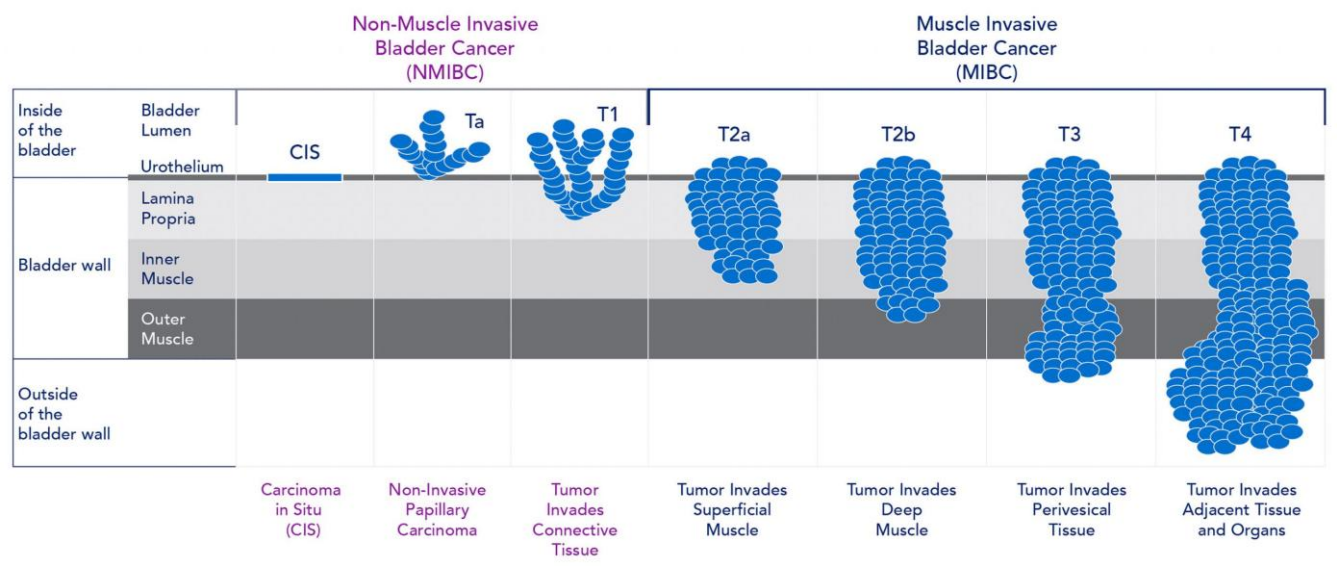
- Investigator initiated trials (IITs) are independent studies in which Pacific Edge typically provides free testing, so provide significant value at low cost
- IITs extend the evidence portfolio for new indications of existing tests and may inform new 'core' clinical trials
- IITs are an important part of Key Opinion Leader (KOL) engagement and generate publications or podium presentations that give profile to Cxbladder and Pacific Edge

PacificEdge® CANCER DIAGNOSTICS

1. All dates are calendar year and our best current estimates. Timelines are controlled by the investigator
2. Filson et al (2026); Real-World Utility of Cxbladder Triage for Patients with Microhematuria: A Matched Cohort Study, Urology Practice® (2026), doi: 10.1097/UPJ.0000000000000972.
3. BCG: Bacillus Calmette–Guérin is a bacterium instilled into the bladder that triggers an immune response that targets and destroys cancer cells.
4. MIBC: Muscle Invasive Bladder Cancer

BACKGROUND ON NMIBC AND MIBC

- Bladder Cancer
  - An estimated 83,190 patients were diagnosed with bladder cancer in the USA in 2024 at an average age of 73[1]
- Non-muscle invasive Bladder Cancer (NMIBC)
  - NMIBC tumors represent approximately 75% of the bladder cancer diagnoses each year (CIS, Ta and T1)
  - NMIBC tumors *are localized* and present on the lining of the bladder wall and shed cancer cells and cell-free DNA/RNA into the urine in the bladder
  - NMIBC tumors are highly treatable with surgery/resection and deemed *cancer free* after surgery/resection
  - NMIBC patients are placed on a *surveillance protocol* after surgery/resection, because *recurrence can be 50-70% within the first two years*[2]
  - **NMIBC → TURBT → Surveillance**
- Muscle-invasive Bladder Cancer (MIBC)
  - MIBC tumors represent approximately 25% of the bladder cancer diagnoses each year (T2-4)
  - MIBC tumors differ from NMIBC tumors, because they shed cells/nucleotides to the blood
  - MIBC patients have advanced/serious disease, require high-levels of intervention (radical cystectomy followed by multiple therapies)
  - MIBC patients are *not deemed cancer free* after cystectomy and *frequently monitored for residual and metastatic disease*
  - **MIBC → Cystectomy → Monitoring**



1. American Cancer Society. *Cancer Facts & Figures* 2024
2. Holzbeierlein J, Bixler BR, Buckley DI, et al. Diagnosis and treatment of non-muscle invasive bladder cancer: AUA/SUO guideline: 2024 amendment. J Urol. 2024;10.1097/JU.0000000000003846.

PacificEdge® CANCER DIAGNOSTICS

NMIBC STANDARD OF CARE: INTERVENTION AND SURVEILLANCE

- NMIBC Standard of Care – Intervention
  - After NMIBC diagnosis, the standard intervention is a Trans-Urethral Resection of a Bladder Tumor (TURBT)
    - TURBT involves inserting a camera into the urethra and the use of small instruments like a wire loop or laser to cut or burn away the tumor tissue
    - Patients are deemed *cancer free post TURBT when muscles and tumor margins are confirmed free of disease by pathology*
  - A resection biopsy taken during surgery is used to stage the tumor (T0, Ta, CIS, T1-4) and determine the grade (low or high grade) which also provides the risk of recurrence.
  - All NMIBC patients are then classified into risk categories based on this information (low, intermediate and high risk).
- NMIBC Standard of Care - Surveillance
  - BCG (bacillus calmette guérin) is administered for several weeks after TURBT to initiate an immune response towards the tumor. Some patients are 'non-responders'
  - A cystoscopy at 3 months is recommended for every patient
  - Following the 3-month cystoscopy, patients are recommended for routine surveillance protocols involving cystoscopy and imaging among others based on their risk category
  - Due to the high burden of these protocols, the average patient only stays on surveillance for 1.8 years not 5[1] as recommended by most guidelines

1. AUA AQUA Registry

PacificEdge® CANCER DIAGNOSTICS

SOURCES AND ASSUMPTIONS - TOTAL ADDRESSABLE MARKET (US)

REGION	STATISTIC		SOURCE
UNITED STATES	Population	341,762,685	https://www.census.gov/popclock/
	Incidence of hematuria	7,000,000	Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019
	Referred for clinical workup	3,500,000	Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019
	Proportion of gross hematuria amongst those referred for clinical workup	700,000	Pacific Edge estimate
	Proportion of microhematuria amongst those referred for clinical workup	2,800,000	Pacific Edge estimate
	Proportion of low-risk microhematuria	200,000	Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; Pacific Edge estimates to account for AUA 2025 guidelines
	Proportion of intermediate-risk microhematuria	1,140,000	Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; Pacific Edge estimates to account for AUA 2025 guidelines
	Proportion of high-risk microhematuria	1,460,000	Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; Pacific Edge estimates to account for AUA 2025 guidelines
	Annual cases of bladder cancer	84,870	National Cancer Institute
	Patients living with bladder cancer	744,044	National Cancer Institute
	Test opportunities	4,616,066	Pacific Edge estimate
	Price of Cxbladder (US$)	$1,328 for Cxbladder Triage Plus, $1,800 for Cxbladder Surveillance Plus	Surveillance Plus is a target price sought by crosswalk and has not yet been established or covered
	TAM (US$billion)	$6.7	

SOURCES AND ASSUMPTIONS - TOTAL ADDRESSABLE MARKET (EUROPE)

REGION	STATISTIC		SOURCE
EUROPE (EXCLUDING RUSSIA)	Population	600,000,000	World-population - Europe World-population - Russia
	Incidence of hematuria	12,000,000	Science Direct
	Referred for clinical workup	6,000,000	Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019
	Proportion of gross hematuria amongst those referred for clinical workup	1,200,000	Pacific Edge estimate
	Proportion of microhematuria amongst those referred for clinical workup	4,800,000	Pacific Edge estimate
	Proportion of low-risk microhematuria	340,000	Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; Pacific Edge estimates to account for AUA 2025 guidelines
	Proportion of intermediate-risk microhematuria	1,960,000	Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; Pacific Edge estimates to account for AUA 2025 guidelines
	Proportion of high-risk microhematuria	2,500,000	Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; Pacific Edge estimates to account for AUA 2025 guidelines
	Annual cases of bladder cancer	180,000	Uroweb
	Patients living with bladder cancer	900,000	Pacific Edge estimate - 5 years of annual cases
	Test opportunities	7,350,000	Pacific Edge estimate
	Price of Cxbladder EURO	€245	Pacific Edge estimate
	TAM (US$billion)	$2.0	

SOURCES AND ASSUMPTIONS - TOTAL ADDRESSABLE MARKET (APAC)

REGION	STATISTIC		SOURCE
APAC (EXCLUDING INDIA AND CHINA)	Population	830,000,000	World population - Southeast Asia Population Pyramid - Japan Population Pyramid - Hong Kong
	Incidence of hematuria	16,600,000	Science Direct
	Referred for clinical workup	8,300,000	Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019
	Proportion of gross hematuria amongst those referred for clinical workup	1,660,000	Pacific Edge estimate
	Proportion of microhematuria amongst those referred for clinical workup	6,640,000	Pacific Edge estimate
	Proportion of low-risk microhematuria	470,000	Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; AUA 2025 guidelines
	Proportion of intermediate-risk microhematuria	2,710,000	Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; AUA 2025 guidelines
	Proportion of high-risk microhematuria	3,460,000	Woldu, S, et al. Evaluation of the New American Urological Association Guidelines Risk Classification for Hematuria; AUA 2025 guidelines
	Annual cases of bladder cancer	58,000	WHO Hong Kong
	Patients living with bladder cancer	290,000	Pacific Edge estimate - 5 years of annual cases
	Test opportunities	3,494,000	Pacific Edge estimate
	Price of Cxbladder (US$)	$550	Pacific Edge estimate
	TAM (US$billion)	$1.9	

KEY CLINICAL ADVISORS AND CONSULTANTS



Professor Yair Lotan, MD
Institution: UT Southwestern Medical Center
Relationship: Consultant, CAB member, IIT PI, CT PI
Brief Bio: Published >500 articles. Contributor to AUA/ASCO/ASTRO MIBC and Hematuria Guidelines. Chair of AUA Core Curriculum. BCAN Adboard



Professor Sam Chang, MD, MBA
Institution: Vanderbilt Cancer Center
Relationship: Consultant, CAB member
Brief Bio: Published >200 articles. Chair of AUA NMIBC Guidelines, SUO Executive Board, ABU/AUA Examination Committee, BCAN Adboard, AUA representative to the AJCC



Assistant Professor John Sfakianos
Institution: Icahn School of Medicine at Mount Sinai
Relationship: Consultant, CAB member
Brief Bio: Published >20 articles. Reviewer for J Urol and Urologic Oncology



Professor Dan Barocas, MD, MPH, FACS
Institution: Vanderbilt University Medical Center
Relationship: Consultant, CAB member
Brief Bio: Published >100 articles. AUA Guidelines panel for microscopic hematuria. Reviewer for AUA educational materials



Associate Professor, Siamak Daneshmand, MD
Institution: Keck School of Medicine at USC
Relationship: Consultant, CAB member, CT PI
Brief Bio: Published >200 articles. Editorial board of the J Urol, Bladder Cancer Journal, Current Opinions in Urology, BCAN Adboard, AUA/SUO Guideline Committee on NMIBC



Associate Professor Katie Murray, DOMS, FACS
Institution: NYU Langone
Relationship: Consultant, CAB member,
Brief Bio: Published >80 articles. Deputy Editor for J Urol. Leadership roles for SUO Young Urologic Oncology Clinical Trials



Professor Jonathan Wright, MD, MS, FACS
Institution: Fred Hutchinson Cancer Center at UW
Relationship: Consultant, CAB member, CT PI
Brief Bio: Member of ACS, SUO, AUA



Professor Wade Sexton, MD
Institution: University of South Florida & Moffitt Cancer Center
Relationship: Consultant, CAB member
Brief Bio: Published >100 articles. NCCN Bladder Cancer Guidelines, AUA Annual Board Review Course



Professor Jay Raman, MD
Institution: Penn State and Hershey Medical Center
Relationship: Consultant, CAB member, CT PI
Brief Bio: Published >350 articles. Chair of AUA Office of Education and Past-President of the Mid-Atlantic AUA section. Urology Advisory Council for ACS, Hematuria Guidelines member



Associate Professor Kristen Scarpato, MD, MPH, FACS
Institution: Vanderbilt University Medical Center
Relationship: Consultant, CAB member, CT PI
Brief Bio: SUO Education Committee, AUA Core Curriculum, Urology Practice Editorial Committee

ASCO: American Society of Clinical Oncology
ASTRO: American Society of Radiation Oncology
AUA: American Urological Association
BCAN: Bladder Cancer Advocacy Network
CAB: Clinical Advisory Board
CT PI: Clinical Trials Principal Investigator
FACS: Fellow of the American College of Surgeons
IIT PI: Investigator Initiated Trial Principal Investigator
J Urol: Journal of Urology
KOL: Key Opinion Leader
MPH: Master of Public Health
SUO: Society of Urologic Oncology

PacificEdge® CANCER DIAGNOSTICS

OUTLOOK: POSITIONED TO UNLOCK VALUE

MULTIPLE COMMERCIAL, CLINICAL AND INNOVATION CATALYSTS

NEAR-TERM VALUE CREATION COMMERCIAL CATALYSTS

- Case-by-case reimbursement for Triage and Triage Plus under draft LCD, with first Novitas payments received
- New LCD effective from 20 Dec 2026
- US customers adopt Triage Plus at US$1,328/test
- Building US Commercial payer medical policy momentum

MEDIUM-TERM VALUE CREATION CLINICAL EVIDENCE GENERATION

- Evidence generation program delivers sustained strategic value
- US commercial payer policy for Triage and Triage Plus drives test adoption
- AUA guideline review (2027/28) expected to expand serviceable market
- Investigator initiated trials (IITs) generate novel evidence for new indications

LONG-TERM VALUE CREATION RESEARCH INNOVATION

- Triage Plus and Surveillance Plus deliver better patient outcomes at higher margin pricing for improved unit economics
- Surveillance Plus CPT-PLA coding submission in June 2027 and claim-by-claim revenue from Jan 1, 2028
- Seeking US$1,800 CMS pricing for Surveillance Plus in FY28
- Product simplification and kitted IVD products enable de-centralized deployment in international markets

PACIFIC EDGE BOARD AND MANAGEMENT



SIMON FLOOD
Chairman
Simon has spent more than 25 years in the global investment management industry having held senior Investment and Business Leadership roles in some of the world's pre-eminent investment management firms including Merrill Lynch Investment Managers Lion Global Investors and AXA Investment Managers



DR PETER MEINTJES
Chief Executive Officer
Peter is a molecular diagnostics and genomics leader focused on nascent market development of disruptive innovations to drive commercial success. Prior to joining Pacific Edge, he was based in Boston in a succession of diagnostic leadership roles. Most recently he was the Chief Commercial Officer at Eurofins Transplant Genomics and before that he was CEO at Omixon

INDEPENDENT DIRECTORS

SARAH PARK
ANATOLE MASFEN
BRYAN WILLIAMS
ANNA STOVE
TONY BARCLAY

SENIOR LEADERSHIP TEAM

GRANT GIBSON
Chief Financial Officer
GLEN COSTIN
President Asia Pacific
PROFESSOR PARRY GUILFORD
Chief Scientific Officer
DR TAMER ABOUSHWAREB
Chief Medical Officer
DARRELL MORGAN
Chief Operating Officer
WILLY IGLESIAS
Chief Digital Officer
DR JUSTIN HARVEY
Chief Technology Officer
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PacificEdge® CANCER DIAGNOSTICS

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