Pacific Edge

1H 2026 Investor Presentation

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POSITIONING FOR MEDICARE-LED RECOVERY AFTER EVIDENCE AND PRICING WINS

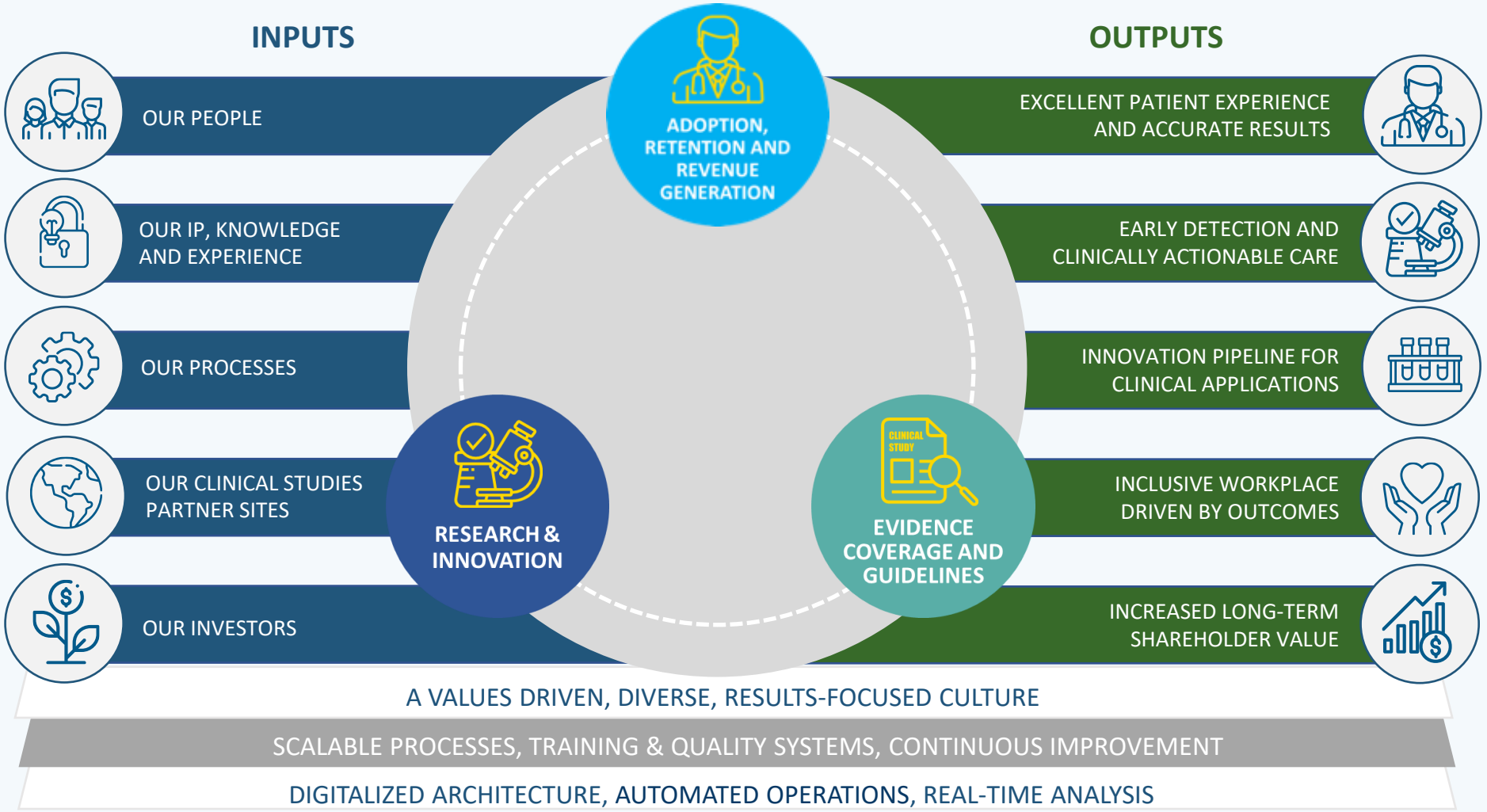
US Total Tests[1] 10,693, -13.1% on 2H 25; APAC Total Tests[1] 2,498 +5.4% on 2H 25	US Commercial Tests 8,386 -17.6% on 2H 25; APAC Commercial Tests 1,985 -7.2% on 2H 25	Total Revenue of $7.1M -42.8% on 2H 25	Operating Expenses of $26.2M 5.9% less on 2H 25 of $27.9M	1H 26 cash flow to Operating Activities of ($19.0M) 55.1% higher on ($12.3M) in 2H 25

- Maintaining US market presence to position Pacific Edge for Medicare appeals and re-coverage progress; operating revenue falls resulting in a rise in net losses and cash burn after coverage loss, partially offset by operating efficiencies
- Test volumes reflect loss of coverage and disruptions of migration to Triage from Detect; US test sales/FTE rise for Q2 26 +5.8% on Q1 26 following sales force reductions
- Expert Contractor Advisory Committee convened by Novitas acknowledges the weight of evidence supporting Cxbladder's clinical value
- Longer term economics reinforced by draft CMS pricing of Triage Plus at US$1,328 per test vs. US$760 per test for the current generation of tests
- Considering capital initiatives to meet longer than expected Medicare re-coverage timeline

1. Total Laboratory Throughput (TLT) including commercial, pre-commercial and clinical studies testing
2. Cash, short-term deposits and term deposits

PacificEdge® CANCER DIAGNOSTICS

VALUE CREATION THROUGH THREE PILLARS



PacificEdge®
CANCER DIAGNOSTICS

THE STRONGEST POSITION YET TO DRIVE MEDICARE POLICY CHANGE

POLICY DRIVERS – EVIDENCE AND CLINICAL OPINION – NOW IN CXBLADDER'S FAVOR

EVIDENCE COVERAGE AND GUIDELINES

NOVITAS CONVENES A CONTRACTOR ADVISORY COMMITTEE

- In September 2025, Novitas[1] called for an expert Contractor Advisory Committee (CAC)
  - CACs are generally convened ahead of developing new or substantially revised medical policy (LCD[2])
  - Precipitated by the company-defining February 2025 revision to the AUA Microhematuria Guideline (last revised in 2020), which allowed the use of biomarkers for the first time
  - Designed to systematically capture clinical opinion from practicing physicians in addition to published evidence and the AUA guidelines
- **CAC purpose:** **"**to discuss evidence for the use of urine-based biomarkers in patients with microhematuria."
  - Given the recent published evidence of Triage Plus (including the recently published Drive Study)[4] Pacific Edge expects the next generation test to be included in the discussion
- **Membership:** healthcare professionals, beneficiary representatives, and representatives of medical organizations
  - Pacific Edge has nominated urologists who are familiar with the latest evidence, the new AUA guideline and regularly use Cxbladder tests
- **Meeting date:** 19 February 2026 at 6pm (ET)[3]; open to the public and tone will be indicative of re-coverage success.

American Urological Association

"… [for] intermediate-risk patients who want to avoid cystoscopy and accept the risk of forgoing direct visual inspection of the bladder urothelium, ***clinicians may offer urine cytology or validated urine-based tumor markers to facilitate the decision regarding utility of cystoscopy****."*

– 2025 AUA Microhematuria Guideline Amendment

1. Novitas is Pacific Edge's Medicare Administrative Contractor (MAC)
2. LCD: Local Coverage Determination
3. 12.00pm Friday 20 February 2026 (NZT)
4. Savage et al (2025) Accepted October 6, 2025. Diagnostic Performance of Cxbladder® Triage Plus for the Identification and Stratification of Patients at Risk for Urothelial Carcinoma: The Multicenter, Prospective, Observational DRIVE Study

THE STRONGEST POSITION YET TO DRIVE MEDICARE POLICY CHANGE

A COMPELLING AND GROWING PORTFOLIO OF EVIDENCE TO ENTRENCH CXBLADDER IN CLINICAL PRACTICE

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[7]
5. STRATA second publication	- CU of Triage Plus (concordance[2])	Q2 2026
6. AUSSIE Clinical Validation	- CV of Triage Plus	Q2 2026
7. microDRIVE Clinical Validation	- CV of Triage Plus	Q4 2026
8. Surveillance Plus Analytical Validation	- AV of Surveillance Plus	Q3 2026
9. Pooled Analysis MH Clinical Validation[3]	- CV of Triage Plus	Q1 2027
10. Pooled Analysis GH Clinical Validation[3]	- CV of Triage Plus	Q1 2027
11. LOBSTER Clinical Validation	- CV of Monitor/Surveillance Plus	Q1 2027
12. CREDIBLE Clinical Utility	- CU of Triage Plus	Q1 2028
13. OCTOPUS Clinical Utility	- CU Surveillance Plus	Not started

[1] All dates are calendar year and our best current estimates
[2] Concordance will be demonstrated by comparing Triage and Triage Plus on identical samples
[3] The MH and GH pooled analysis brings together data from DRIVE, AUSSIE and microDRIVE

- Pacific Edge generates the compelling clinical evidence required to drive behavior change in physicians
- Clinical evidence is generated in a rigid framework of Analytical Validity (AV), Clinical Validity (CV) and Clinical Utility (CU)
- Clinical Studies have clearly defined patient populations with the endpoints and sample sizes required for coverage decisions and guideline inclusion
- We are seeking Medicare coverage for Triage, Monitor and Triage Plus through reconsideration requests to Novitas based on new evidence

New evidence to be presented to the CAC in February 2026 to support Medicare coverage reconsideration

PacificEdge® CANCER DIAGNOSTICS

MEDICARE RE-COVERAGE: ESTIMATED TIMELINES

COVERAGE DECISIONS, PRIOTIZATION AND TIMELINES ARE AT THE DISCRETION OF NOVITAS[1]

EVIDENCE COVERAGE AND GUIDELINES

MEDICARE COVERAGE REQUEST	CATALYST	2026*				2027*			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
L39365 Reconsideration request (Triage) March 2025	STRATA Study (May 2024) AUA Microhematuria Guideline (Feb 2025)								
L39365 Reconsideration request (Monitor) May 2025	AV of Triage, Detect & Monitor (Sept 2024) 2x RWE of Monitor (March 2025)								
New LCD request (Triage/Triage Plus) November 2025	AV of Triage Plus (Q2 25) CV of Triage Plus – DRIVE Study[2] (Q4 25)								

*Calendar year

Contractor Advisory Meeting (CAC) Meeting – February 19, 2026

Estimated opening of Novitas draft LCD

Estimated Novitas determination

12-months after opening (worst case, assuming opening)

- Medicare non-coverage of Cxbladder Triage, Monitor, Detect & Triage Plus was effective on 24 April 2025
- The review was limited to evidence submitted prior to 9 September 2023
- Pacific Edge has submitted Reconsideration Requests of L39365 for Triage and Monitor
- Pacific Edge has submitted a new LCD request for hematuria evaluation for Triage/Triage Plus
- Novitas controls the timing of the LCD opening, but must finalize the LCD within 12 months of opening
- Novitas announced a CAC to meet on 19 February 2026 (ET), increasing re-coverage expectations, but extending timelines
- Evidence published after the CAC can be submitted during the comment period of the LCD

Medicare

Pacific Edge® CANCER DIAGNOSTICS

1. Novitas is the Medicare Administrative Contractor (MAC) charged with making the Medicare local coverage determination for Pacific Edge's US laboratory
2. Savage et al. (2025). Diagnostic Performance of Cxbladder® Triage Plus for the Identification and Stratification of Patients at Risk for Urothelial Carcinoma: The Multicenter, Prospective, Observational DRIVE Study. Urol Oncol. Oct 31 2025;doi:10.1016/j.urolonc.2025.10.008

INDEPENDENT STUDIES SUPPLEMENT OUR EVIDENCE PORTFOLIO

INVESTIGATOR INITIATED TRIALS AND INDEPENDENT STUDIES DELIVER CLINICAL UTILITY AT MODEST SCALE

EVIDENCE COVERAGE AND GUIDELINES

INDEPENDENT STUDY FOCUS	INSTITUTION/ LOCATION	TEST AND EVIDENCE	PUBLICATION DATE
Real World Utility of Triage in MH: A Matched Cohort Study	Kaiser Permanente, US	CU Triage (RWE)	Q4 2025
Patient preference and satisfaction of “biomarkers vs cystoscopy”	Mayo Clinic, US	CU Monitor	Q1 2026
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[2] in high-grade bladder cancer patients	University of Miami, US	CU Monitor CU Surveillance Plus	2027
Test utility for the surveillance of MIBC[3] 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

New evidence to be presented to the CAC in February 2026 to support Medicare coverage reconsideration

LATEST INVESTIGATOR INITIATED TRIAL (IIT) SHOWS PATIENT PREFERENCE FOR CXB MONITOR

- New study ready for publication led by Mark Tyson at the Mayo Clinic, comparing Cxbladder Monitor to cystoscopy in bladder cancer surveillance[1]
  - 74.2% preferred Monitor vs Cystoscopy
  - Comparable diagnostic performance
  - Abstract to be submitted to AUA 2026

PacificEdge® CANCER DIAGNOSTICS

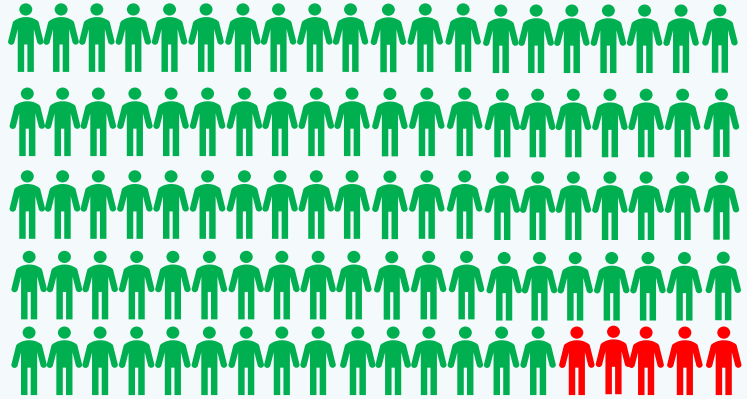
1. Mestas et al (2025) A Randomized Multicenter Crossover Study to Evaluate Patient Preference and Satisfaction with Urine-Based Molecular Testing versus Cystoscopy for Surveillance of Non-Muscle-Invasive Bladder Cancer (NMIBC). Unpublished Manuscript.
2. BCG: Bacillus Calmette–Guérin is a bacterium instilled into the bladder that triggers an immune response that targets and destroys cancer cells.
3. MIBC: Muscle Invasive Bladder Cancer

BUDGET IMPACT MODELS DEMONSTRATE ECONOMIC VALUE FOR CXBLADDER

BIMS[1] DEMONSTRATE CLINICAL UTILITY AND ECONOMIC SAVINGS FOR HEALTHCARE SYSTEMS

EVIDENCE COVERAGE AND GUIDELINES

CANCER INCIDENCE IN MICROHEMATURIA PATIENTS

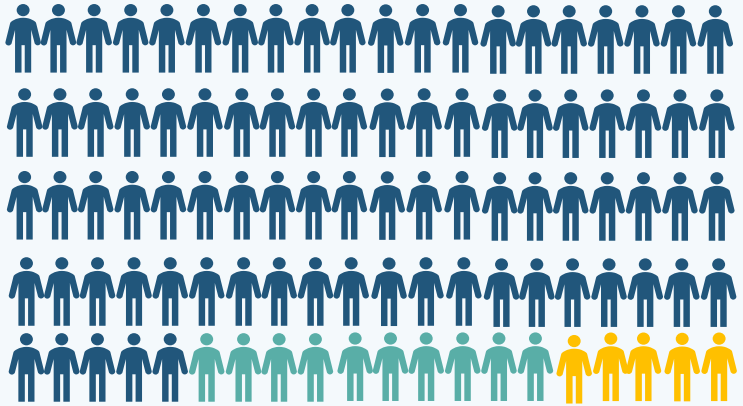


Microhematuria patient with no cancer

Microhematuria patient with cancer

Incidence of bladder cancer in microhematuria populations is 5%

CYSTOSCOPIES SAFELY AVOIDED USING CXBLADDER[2]



Cystoscopy avoided

Normal Cystoscopy

Cystoscopy undertaken and cancer found

With Cxbladder, 85% of patients can avoid cystoscopy, 15% receive cystoscopy, 5 cancers found

REDUCTIONS IN CYSTOSCOPY DRIVE SAVINGS FOR HEALTHCARE PAYERS

- Published BIMs help shift payer policy and can be tailored to specific payer needs; our models already show meaningful savings
  - In the U.S., Cxbladder at scale could spare ~1.5 million hematuria patients from cystoscopy and save >US$500 per patient[3]
  - In bladder-cancer surveillance protocols, Cxbladder can save payers ~US$680 per patient over five years[4]
- Economic and Sustainability Publications in progress:
  - Triage Plus BIM — targeting publication FY27
  - Surveillance Plus BIM — work commencing FY28
  - Carbon Footprint impact of implementing Cxbladder at primary care for hematuria evaluation — targeting FY27

PacificEdge® CANCER DIAGNOSTICS

1. BIM is a Budget Impact Model
2. Harvey et al (2025) Analytical Validation of Cxbladder® Triage Plus Assay for risk stratification of hematuria patients for urothelial carcinoma Diagnostics 2025, 15, 1739.
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. Tyson et al (2025) Economic Impact Model of Incorporating Cxbladder Monitor in the Surveillance of Non-muscle Invasive Bladder Cancer JU Open Plus 3(4):e00028, April 2025.

VOLUMES REFLECT REDUCED SALES REACH AND MEDICARE UNCERTAINTY

ADOPTION, RETENTION AND REVENUE GENERATION

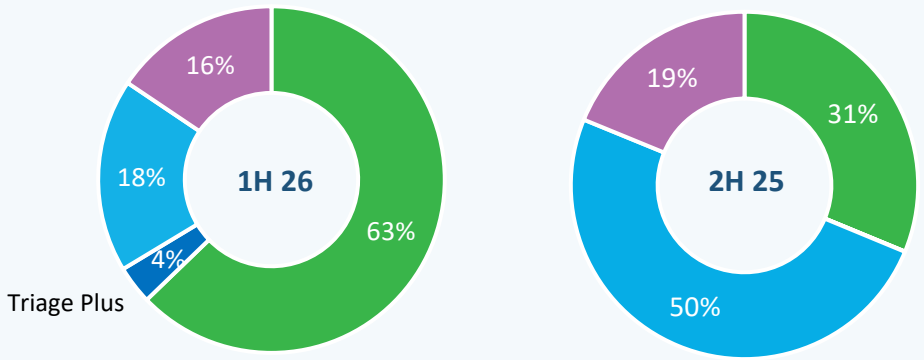
FY 25 TOTAL LAB THROUGHPUT (TLT*)

- Global Commercial test volumes of 13,191 for 1H 26 down 10.1% on 2H 25 amid US challenges of selling a test not covered by Medicare, the reduced reach sales force, offset by 5.4% uplift in APAC

MEDICARE NON-COVERAGE RESPONSE

- Cxbladder Detect migrated to Triage, accelerating a plan previously intended to coincide with the commercial launch of Triage Plus
- Seeking reimbursement through the Medicare Appeals Process
- The sales force is focused on patients suitable for Triage, which are younger patients with microhematuria and commercial insurance

TEST VOLUMES BY TYPE (TLT*)



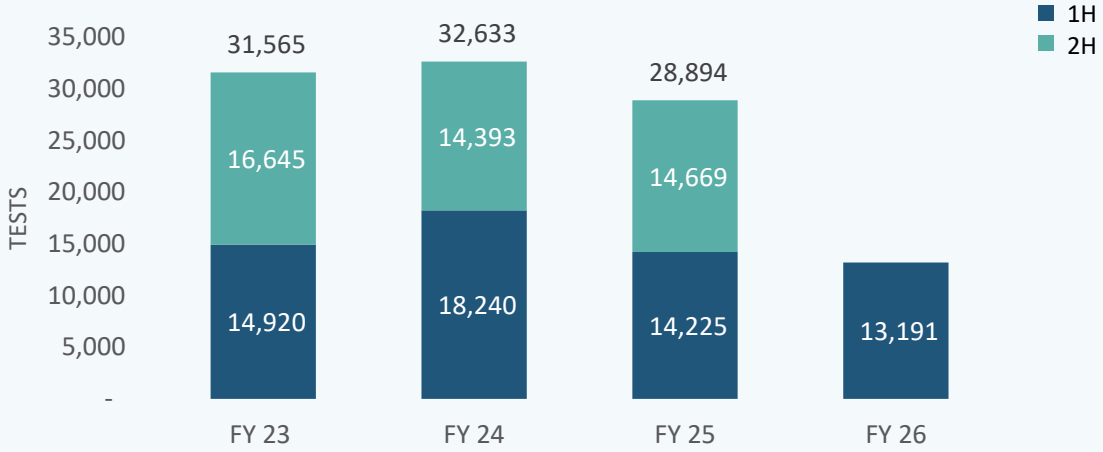
Cxbladder Triage

Cxbladder Detect

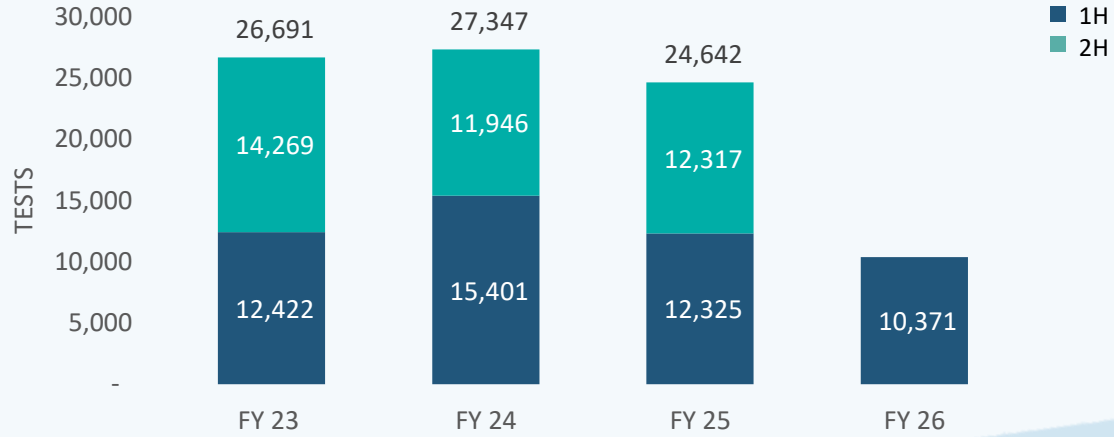
Cxbladder Monitor

Cxbladder Triage Plus

GLOBAL TOTAL TEST VOLUMES (TLT[1])



GLOBAL COMMERCIAL TEST VOLUMES*



PacificEdge® CANCER DIAGNOSTICS

1. TLT is the Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing. Commercial volumes, and test type are only updated at the half and full year results of each financial year.

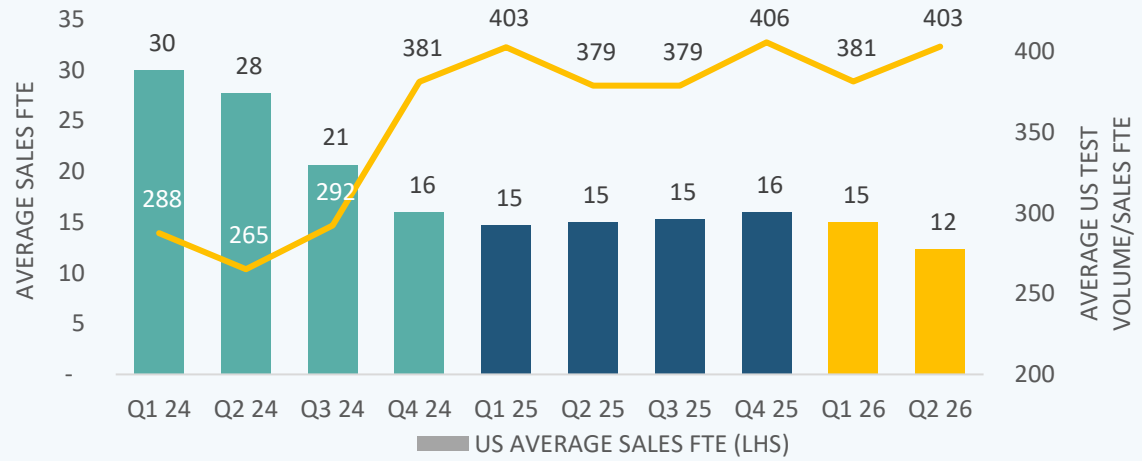
SALES PERFORMANCE IMPROVEMENTS SUSTAINED IN 1H 26

WE REGULARLY SEE OPPORTUNITIES TO EDUCATE ON THE AUA GUIDELINE

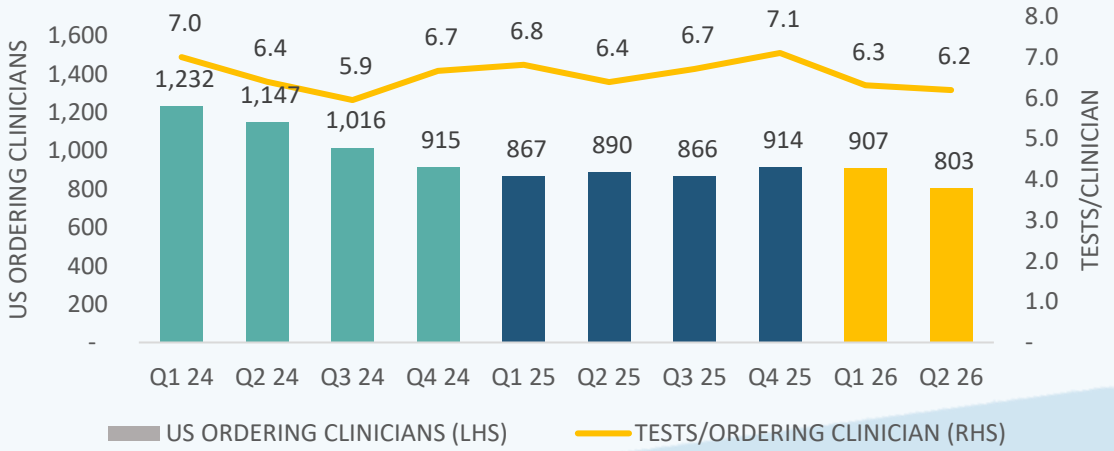
ADOPTION, RETENTION AND REVENUE GENERATION

- Clinical commitment (tests/ordering clinician) fall in Q2 26 reflecting the disruptions of transition to Triage from Detect and challenges of selling a test not covered by Medicare
- Sales force efficiency (tests volume / sales FTE) at 403 in Q2 26 is well ahead of the low point of 160 in Q3 22
- Sales FTE down to an average of 12 in Q2 26 from >30 in Q1 24 before restructure to focus on cash conservation

US SALES FORCE EFFICIENCY



US CLINICAL COMMITMENT



PacificEdge® CANCER DIAGNOSTICS

1. ASP: US Operating Revenue in USD / US Commercial Test Volumes. Commercial volumes, and ASP are only updated at the half and full year results of each financial year.

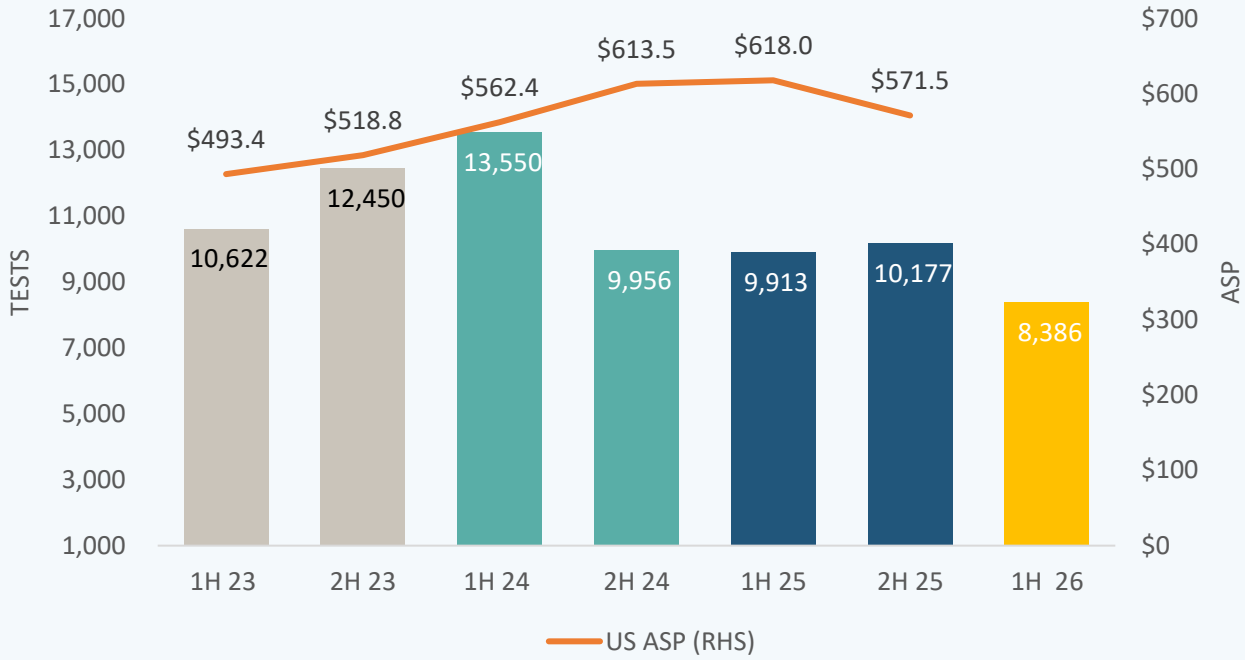
FOUNDATIONS FOR GROWTH – US CASH COLLECTIONS PROCESSES IMPROVE

ADOPTION, RETENTION AND REVENUE GENERATION

REIMBURSEMENT & CASH COLLECTIONS

- Loss of Medicare Coverage impacts US test volumes
  - Denied Triage Medicare tests will be appealed to an Administrative Law Judge (ALJ) given its guideline inclusion, making the case that it is medically reasonable and necessary
  - Appealing to the ALJ typically takes 6-9 months
  - Medicare tests completed in 1H 26 that have been denied for payment have had no revenue recognized in the half, with revenue to be added if tests are successfully appealed
- Measures in place to mitigate the loss of Medicare coverage are delivering
  - Enhanced Patient Responsibility - patients with non-contracted private insurance (i.e. non-Kaiser) pay a fixed dollar amount "maximum out of pocket"
  - Increased utilization of appropriate patient types from Kaiser Permanente after EMR integration
  - Improved medical necessity documentation to improve billing and appeals processes for Commercial payers
- Improved cash collections are typically permanent improvements that we expect to maintain as we scale

US COMMERCIAL TEST VOLUMES[1] AND AVERAGE SELLING PRICE[2]



1. Total Laboratory Throughput in the US including commercial, pre-commercial and clinical studies testing
2. ASP: US Operating Revenue in USD / US Commercial Test Volumes; ASP not reported in 1H 26 due to accounting changes in revenue accrual while Medicare tests are being appealed.

PacificEdge® CANCER DIAGNOSTICS

CONSOLIDATING NEW ZEALAND AND DEVELOPING AUSTRALIA AND APAC

ADOPTION, RETENTION AND REVENUE GENERATION

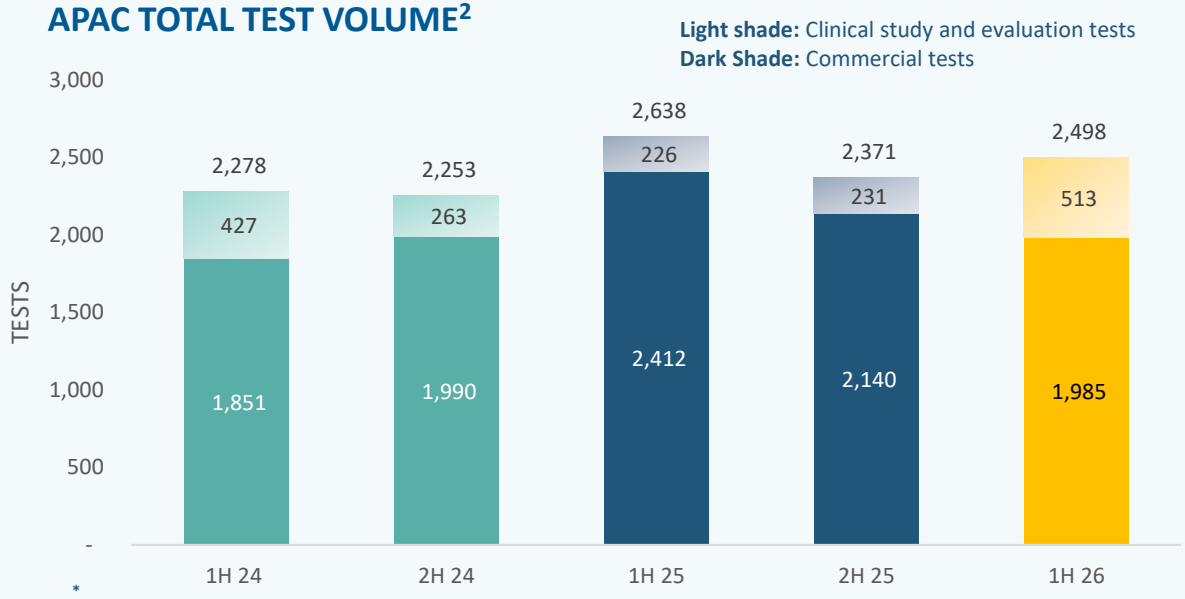
SEEKING A NATIONAL HEMATURIA EVALUATION PATHWAY IN NZ

- Quarterly total test volumes rise lifted by an increase in clinical studies and non-billable tests
- STRATA[1] and AUA Microhematuria Guideline are well understood in *Te Whatu Ora*/Health New Zealand; Pacific Edge is focused on a national pathway for hematuria evaluation

AUSTRALIA & ASIA PACIFIC

- Southeast Asia is still in business development, and we are extending our reach into the market through a distributor network which has seen testing volumes grow
- While our primary near-term focus remains on the US, Southeast Asia has large population centers, private healthcare systems, and favorable cultural and demographic considerations to be a high-volume market for an IVD-kitted product

APAC TOTAL TEST VOLUME[2]



1. Lotan et al. (2024) . A Multicenter Prospective Randomized Controlled Trial Comparing Cxbladder Triage to Cystoscopy in Patients With Microhematuria. The Safe Testing of Risk for Asymptomatic Microhematuria Trial. The Journal of Urology Vol 212 1-8 Jul 2024.
2. Total Laboratory Throughput in Asia and Pacific including commercial, pre-commercial and clinical studies testing

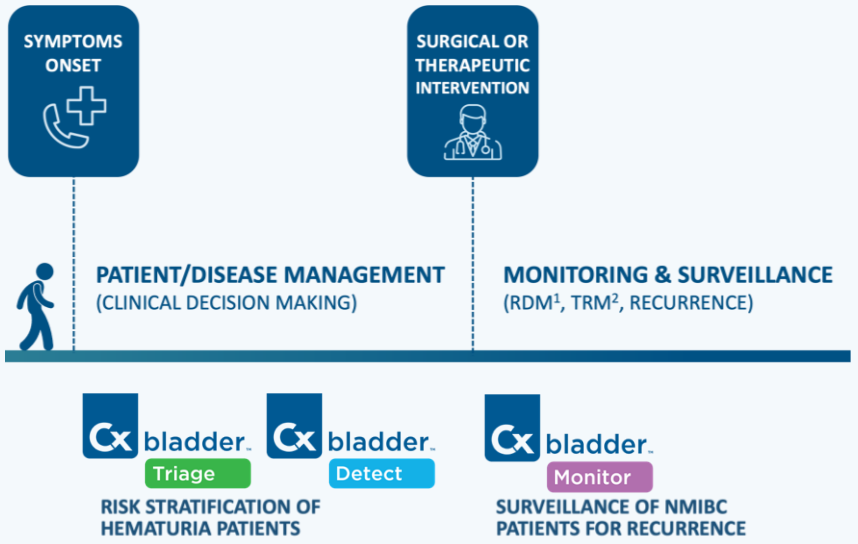
DRIVING VALUE THROUGH PRODUCT INNOVATION

NEXT GENERATION TESTS HAVE SUPERIOR PERFORMANCE AND PRICING

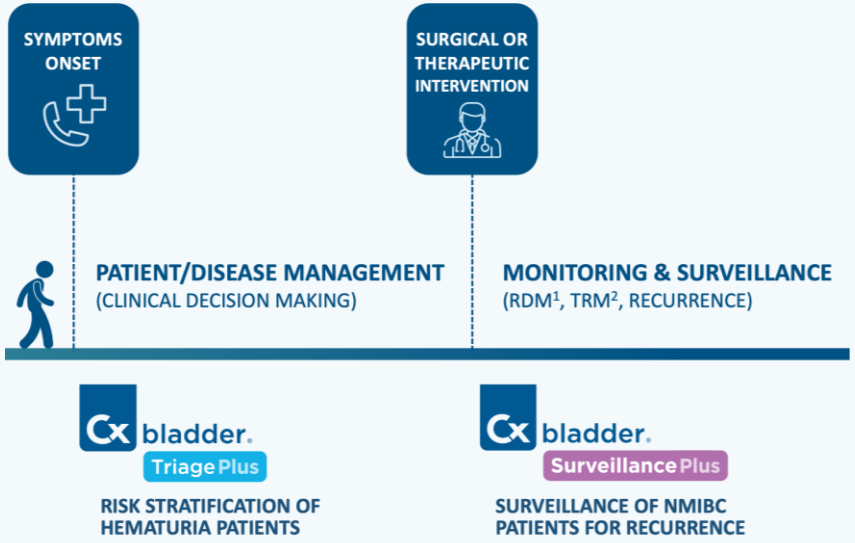
RESEARCH & INNOVATION

- Cxbladder Triage Plus has been analytically validated and clinically validated for all hematuria patients (micro and gross)
  - Triage Plus has provisional patents filed, AV published, CV published, priced at $1,328/ test, and coverage has been requested from Novitas.
  - The draft price is significant premium to the US$760 CMS price for our existing tests, promising to strengthen the economics of the company
  - Triage Plus is being trialed in 'early access' and we are seeking to be added to the AUA microhematuria guideline alongside Triage in FY27
- Cxbladder Surveillance Plus tests for recurrent disease in NMIBC[1] patients.
  - Surveillance Plus is in development and is expected to be analytically validated and clinically validated during FY27
  - Surveillance Plus uses ddPCR[4] technology, has 'Freedom to Operate' review completed, and has provisional patenting in progress
  - We are seeking a technology crosswalk for Surveillance Plus to an US$1800 ddPCR[4] test, and claim-by-claim reimbursement until a local coverage determination incorporating Surveillance Plus is developed

CURRENT STATE



FUTURE STATE

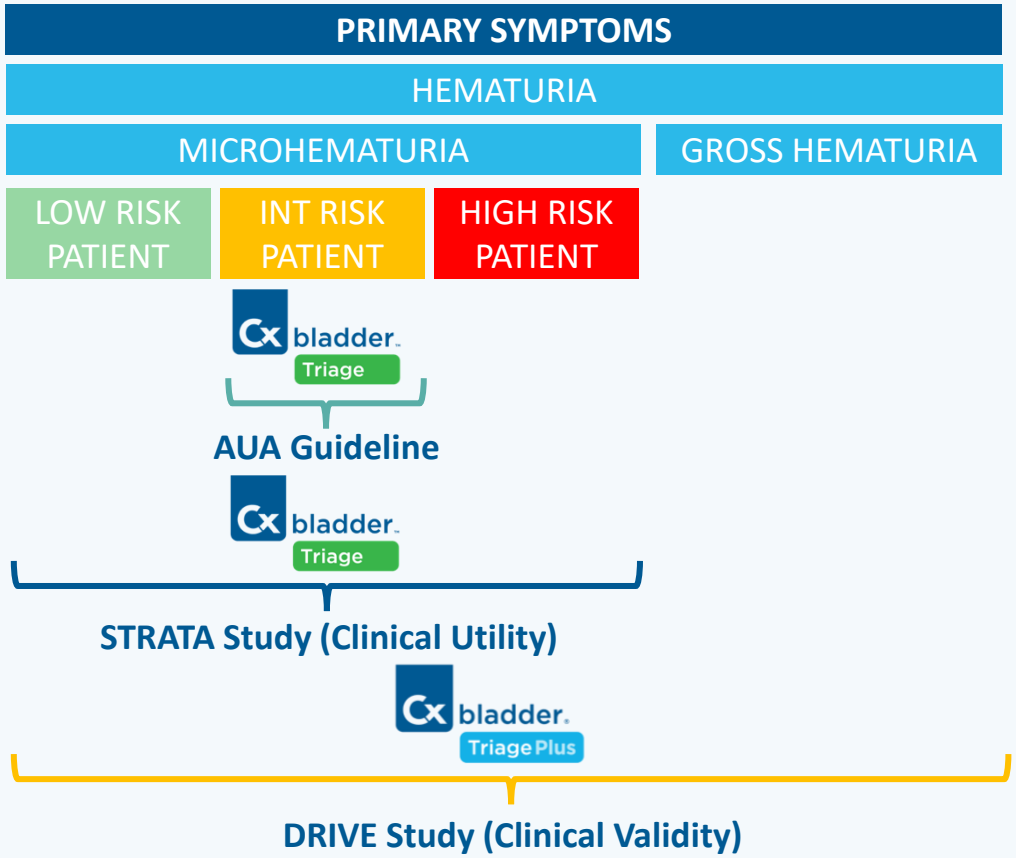


PacificEdge® CANCER DIAGNOSTICS

1. NMIBC is non-muscle invasive bladder cancer
2. RDM: Residual Disease Monitoring
3. TRM: Therapeutic Response Monitoring
4. ddPCR is droplet digital Polymerase Chain Reaction

DRIVE STUDY VALIDATES CXBLADDER TRIAGE PLUS IN A BROAD POPULATION

RESEARCH & INNOVATION



THE DRIVE STUDY – CLINICAL VALIDATION OF TRIAGE PLUS

- The DRIVE Study — the Diagnostic Performance of Cxbladder Triage Plus for the Identification and Priority Evaluation of Veterans at Risk for Urothelial Carcinoma — was published in the Journal of Urologic Oncology in October 2025[1]
- The study confirmed the superior performance characteristics in both gross and microhematuria patients, validating the proof-of-concept study[2] and the analytical validation study[3]
- Supports:
  - Medicare coverage request for patients with microhematuria and gross hematuria
  - An amendment to the AUA Microhematuria Guideline

"These findings indicate that Cxbladder Triage Plus may be safely used to rule out or detect [urothelial cancer] in patients with hematuria."

- DRIVE Study Authors

1. Savage et al (2025) Accepted October 6, 2025. Diagnostic Performance of Cxbladder® Triage Plus for the Identification and Stratification of Patients at Risk for Urothelial Carcinoma: The Multicenter, Prospective, Observational DRIVE Study
2. Lotan et al (2024) Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. The Journal of Urology, 10-109
3. Harvey et al (2025) Analytical Validation of Cxbladder® Triage Plus Assay for risk stratification of hematuria patients for urothelial carcinoma Diagnostics 2025, 15, 1739.

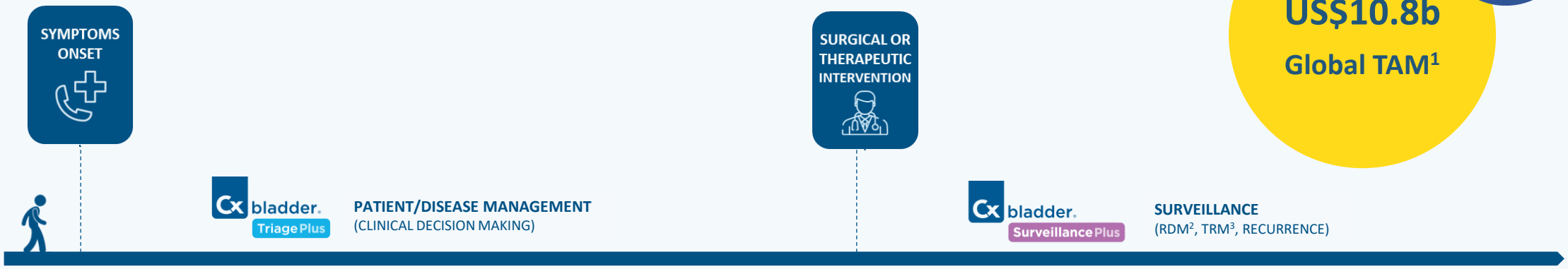
PacificEdge® CANCER DIAGNOSTICS

CMS TRIAGE PLUS PRICING HAS EXPANDED THE GLOBAL OPPORTUNITY

DRAFT PRICE OF US$1,328/TEST IS A 75% PREMIUM TO CURRENT TESTS

US$10.8b
Global TAM[1]

RESEARCH & INNOVATION



	Population	Present with hematuria	Referred for clinical workup	Receive cystoscopy	Annual cases of bladder cancer	Living with bladder cancer	TAM	
	340m	~7m	~3.5m	~1.1m	~90k	~750k	US$6.7b	*Primary growth focus due to higher CMS pricing*
APAC	830m	~17m	~8.5m	~3.3m	~58k	~300k	US$2.1b	*NZ market mature. Australia and SEA in business development*
	600m	~12m	~6m	>4.0m	~180k	~1m	US$2.0b	*New market accessed via IVD / kitted tests*

PacificEdge® CANCER DIAGNOSTICS

1. Pacific Edge estimate using US$1,328 price for hematuria testing (priced by Medicare) in the US and US$1,800 for NMIBC surveillance (seeking crosswalk price – not yet priced by Medicare) with next generation products Triage Plus and Surveillance Plus. Other market assumptions for APAC and Europe. See slide 38 for details.
2. RDM: Residual Disease Monitoring
3. TRM: Therapeutic Response Monitoring

EXPANDING MARKET OPPORTUNITIES WITH INNOVATION

DEVELOPING AN IVD[1] IS THE PRIMARY AVENUE FOR INTERNATIONAL OPPORTUNITIES

RESEARCH & INNOVATION

ADVANCING IVD DEVELOPMENT FOR INTERNATIONAL MARKETS

- Pacific Edge is following a well-worn model of development and execution in the US with a CAP/CLIA-approved LDT[2] providing service to the entire USA
- International markets require a different approach in which Pacific Edge seeks to create a 'kitted' IVD medical device
- Benefits of this approach:
  - IVDs can be run by any accredited lab partner in any geography
  - Customer-side logistics are easier, faster and customer service is local
  - Partner labs make a margin by running the IVD test – increases sales opportunities and motivation to increase volumes
  - Decentralized deployment allows faster scalability
  - Research Use Only versions of the product can be used to develop business, select partners and run evaluation programs in preparation for IVD launch
- Pacific Edge is simplifying its tests and accelerating the development of an IVD called Triage Plus IVD, for decentralized lab deployment and international market expansion. Key objectives:
  - Establishing IVD regulatory framework for our next generation tests that includes IVD-R (Europe), FDA (USA) and ISO-13485[3] (Rest of World)
  - Targeting prototypes by the end of FY26; manufacture and commencement of clinical and analytical validation commencing in FY27

Chief Scientific Officer Parry Guilford (center) and Chief Technology Officer Justin Harvey (right)

PacificEdge® CANCER DIAGNOSTICS

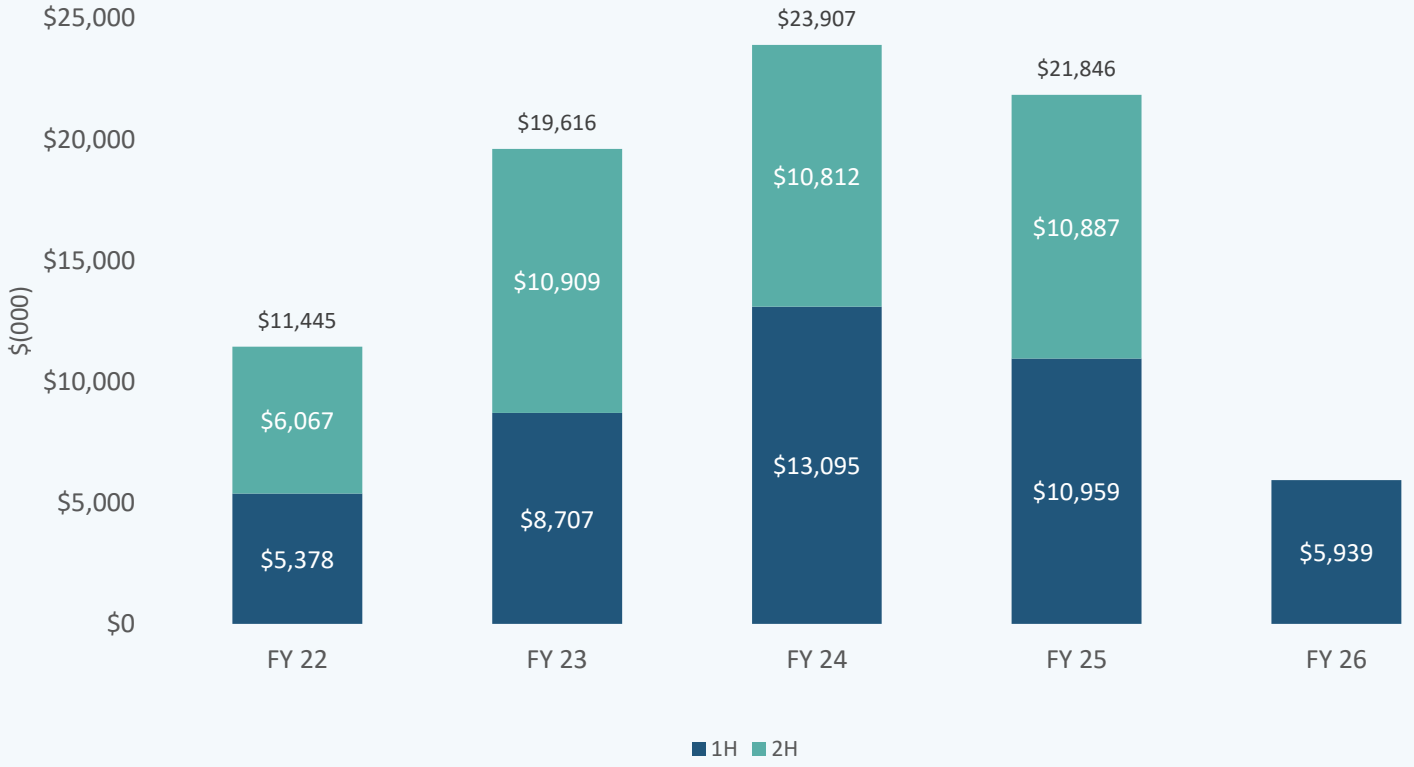
1. IVD stands for *in vitro* diagnostic – a type of medical device for regulatory purposes
2. CAP is the College of American Pathologists, CLIA is the Clinical Laboratory Improvement Amendments and LDT is a laboratory developed test
3. IVD-R European In Vitro Diagnostic Regulation; FDA, US Food and Drug Administration; ISO International Organization for Standardization

FINANCIAL PERFORMANCE

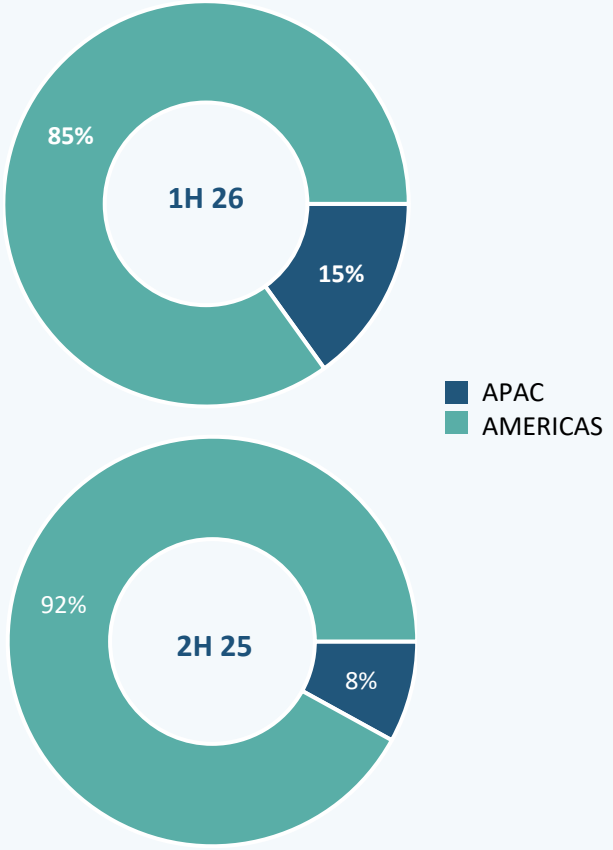
PacificEdge®
CANCER DIAGNOSTICS

LOOKING TO US CATALYSTS TO DRIVE A RECOVERY IN REVENUE

PACIFIC EDGE OPERATING REVENUE[1]



REGIONAL REVENUE CONTRIBUTION



1. No accrual accounting for revenue for tests performed for Medicare patients, even though a substantial number of tests have been undertaken. This revenue will be recognized in 2H 26 if the appeals against non-reimbursement are successful.

POSITIONING PACIFIC EDGE FOR A MEDICARE APPEALS SUCCESS AND COVERAGE

COST SAVINGS MINIMIZE CASH BURN; ANY MEDICARE APPEALS SUCCESS LIKELY RECOGNISED AS REVENUE IN 2H 26

FINANCIAL PERIOD	1H 26	2H 25	1H 25	FY 25	1H 26 vs. 1H 25	1H 26 vs. 2H 25
	$000	$000	$000	$000	△ %	△ %
Operating revenue	$5,939	$10,887	$10,959	$21,846	-45.8%	-45.4%
Total revenue	$7,123	$12,461	$12,155	$24,616	-41.4%	-42.8%
Operating expenses	$26,239	$27,894	$26,658	$54,552	-1.6%	-5.9%
Net Loss After Tax	**-$19,116**	**-$15,433**	**-$14,503**	**-$29,936**	**31.8%**	**23.9%**
Cash receipts from customers	$7,985	$10,447	$11,125	$21,572	-28.2%	-23.6%
Net cash flows to operating activities	$19,026	$12,266	$12,474	$24,740	52.5%	55.1%
Net cash, cash equivalents and short term deposits[1]	**$22,121**	**$22,568**	**$35,931**	**$22,568**	**-38.4%**	**-2.0%**

- Operating revenue falls after loss of Medicare and Medicare Advantage coverage and reduced test volumes
- We have not accrued any revenue from Medicare tests while we determine the success of the appeals strategy
  - Success will result in revenue for 1H 26 tests being recognised in 2H 26
- We continue to maintain a US market presence that positions the company for an affirmation of Medicare coverage, while focusing on reducing operating expenses, which fell 5.9% against 2H 25
- Operating Cash Flows of (19.0M), higher than the ($12.3M) in 2H 25 due to the revenue fall. Cash outflow in the first half of each financial year is generally higher than the second half of the financial year with payments that cover a 12-month period weighted towards the first half of the year
- Secured $20.7 million in new equity in August 2025, but with delay to re-coverage we expect we will need to complete capital initiatives and/or reduce cash burn; we are considering our options

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

OPERATING EXPENSES CONTAINED AMID CAPTIAL PRESERVATION DRIVE

INVESTMENT FOCUSSED ON LONG-TERM STRATEGIC INITIATIVES

FINANCIAL PERIOD	1H 26 $000	2H 25 $000	1H 25 $000	FY 25 $000	1H 26 vs. 1H 25 △ %	1H 26 vs. 2H 25 △ %
Laboratory operations	$5,884	$6,532	$5,958	$12,490	-1.2%	-9.9%
Research	$7,065	$7,401	$7,230	$14,631	-2.3%	-4.5%
Sales and marketing	$8,453	$9,285	$8,245	$17,530	2.5%	-9.0%
General and administration	$4,837	$4,676	$5,225	$9,901	-7.4%	3.4%
Total operating expenses	**$26,239**	**$27,894**	**$26,658**	**$54,552**	**-1.6%**	**-5.9%**

- Operating expenses down 5.9% on 2H 25 as cost management initiatives implemented.
- Laboratory operations down 9.9% driven by lower test volumes.
- Research costs down 4.5% on 2H 25 as some clinical study costs decrease for those near completion
- Sales and marketing costs down 9.0% on 2H 25 impacted by the reduction in sales FTE.
- General and administration expenses up 3.4% on 2H 25 reflecting higher legal costs from the proceedings undertaken at the end of FY25 attempting to prevent the loss of Medicare coverage

OUTLOOK 1/2

INNOVATION DRIVES LONG-TERM VALUE CREATION

- Triage Plus has a US$1,328 price, is being tested in ‘early access’ and needs only Medicare coverage for wider commercial adoption
- Surveillance Plus remains in development, but we are seeking a direct technology crosswalk price to US$1,800 based on its final product configuration
- Investing in innovation and product development for IVD kits to support entry into international markets in a de-centralized deployment model

CLINICAL EVIDENCE DRIVES MEDIUM-TERM VALUE CREATION

- The DRIVE publication[1] provides the clinical validation of Triage Plus and has been submitted to Novitas and the AUA for coverage consideration and guidelines inclusion
- The clinical evidence generation program is scheduled out for over four years to deliver strategic milestones that driven sustained value creation for shareholders
- AUA guideline inclusion demonstrates the success of this strategy that can be repeated to expand the indications for exist products and establish new indications for new products

1. Savage et al., Accepted October 6, 2025. Diagnostic Performance of Cxbladder® Triage Plus for the Identification and Stratification of Patients at Risk for Urothelial Carcinoma: The Multicenter, Prospective, Observational DRIVE Study.

OUTLOOK 2/2

COMMERCIAL HEADWINDS FOR NEAR-TERM VALUE CREATION

- Non-coverage determinations for Triage, Detect, Monitor and Triage Plus continue to create a challenging sales and marketing environment, and additional challenges for reimbursement
- The convening of the Contractor Advisory Committee is a positive move towards the reinstatement of coverage, but delays our expected timeline for re-coverage necessitating the Board to consider capital initiatives and/or reduce cash burn.

COMMERCIAL CATALYSTS FOR NEAR-TERM VALUE CREATION

- AUA microhematuria guideline enables sales, marketing and reimbursement activities. We are determined to maximize this milestone through existing and new initiatives
- Seek payment from Medicare for all Triage tests performed on Medicare patients through the Medicare Appeals process, relying on the AUA Guideline
- Advance medical policy with commercial payers as the market for Triage on microhematuria patients shifts the payer mix towards commercial payers
- Increase the percentage of electronically ordered tests and patients with commercial insurance
- Cxbladder is under consideration by *Te Whatu Ora* for a National Pathway in New Zealand in FY27

APPENDIX

PacificEdge®
CANCER DIAGNOSTICS

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 IS A GLOBAL COMPANY WITH A GLOBAL OPPORTUNITY

US$10.8b[1]

Global Opportunity

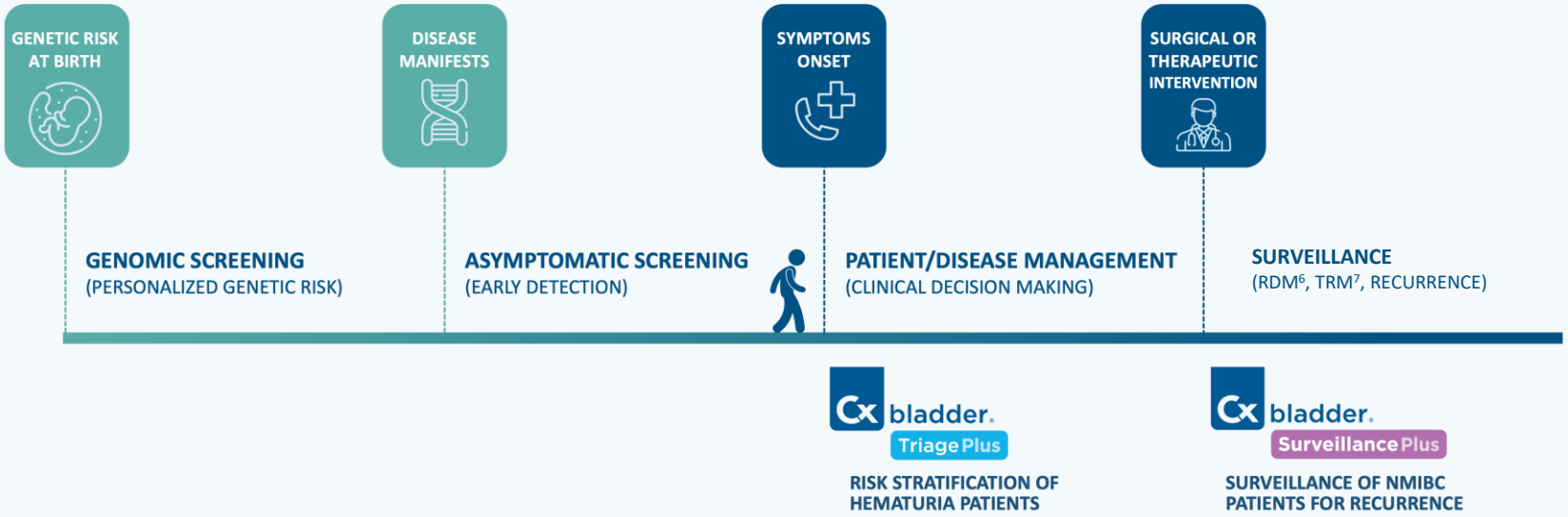
1. Pacific Edge estimate using US$1,328 price for hematuria testing (priced by Medicare) and US$1800 for NMIBC surveillance (seeking crosswalk price – not yet priced by Medicare) with next generation products Triage Plus and Surveillance Plus. Other market assumptions for APAC and Europe. See slide 38 for details

PacificEdge® CANCER DIAGNOSTICS

MOLECULAR DIAGNOSTICS VALUE CHAIN: PATIENT JOURNEY

CXBLADDER – FIRST MOVER AND MARKET LEADER IN BLADDER CANCER DIAGNOSTICS

- **Technology**: RNA/DNA patent-protected urine biomarker tests for hematuria evaluation and NMIBC[1] surveillance
- **Clinical Evidence**: AV/CV/CU[2] evidence generated in a structured framework compliant with GCP[3] and IVD[4] standards
- **Clinical Guidelines**: Recognized by the American Urological Association (AUA) Guideline as 'Grade A' evidence
- **Economic Utility**: offering improved patient care and significant health system cost savings, estimated at >US$500 per US patient[5]
- **Commercial**: 'first-mover' advantage, national sales coverage in the USA, market dominant in NZ, business development in APAC
- **Pricing:** Triage Plus priced by CMS at $1,328, Surveillance Plus pricing sought at $1,800 by crosswalk



1. NMIBC is non-muscle invasive bladder cancer
2. AV/CV/CU is analytical validation, clinical validation and clinical utility evidence
3. GCP is 'Good Clinical Practice' needed for FDA or other medical device certification
4. IVD is an *in vitro* diagnostic medical device
5. Tyson et al (2024) Budgetary Impact of Including the Urinary Genomic Marker Cxbladder Detect in the Evaluation of Microhematuria Patients - PubMed (PMID: 37914255)
6. RDM: Residual Disease Monitoring
7. TRM: Therapeutic Response Monitoring

DRIVING ECONOMIC VALUE FOR PATIENTS, HOSPITALS AND PAYERS

CXBLADDER DELIVERS CLINICAL UTILITY, PATIENT SATISFACTION AND ECONOMIC VALUE

- The number of urologists is falling in the USA – forecast to drop from 23.8/100k to as low as 15.8/100k in 2035[1]
- The population in the USA is ageing, with an increasing number of patients requiring urology care
- Cxbladder avoids invasive, unnecessary procedures for patients driving down costs for health systems and payers[2]
- At scale, Cxbladder can spare up to 1.5m patients in the US from cystoscopy and save >US$500/US patient[2]

CANCER INCIDENCE IN MICROHEMATURIA PATIENTS

Incidence of bladder cancer in microhematuria populations is 5%

CYSTOSCOPIES SAFELY AVOIDED USING CXBLADDER

With Cxbladder, 85% of patients can avoid cystoscopy, 15% receive cystoscopy, 5 cancers found

1. Nam et al. (2021) Projected US Urology Workforce per Capita, 2020-2060 JAMA Network Open Published Online: November 16, 2021
2. Tyson et al (2024) Budgetary Impact of Including the Urinary Genomic Marker Cxbladder Detect in the Evaluation of Microhematuria Patients - PubMed (PMID: 37914255)

BACKGROUND ON BLADDER CANCER AND HEMATURIA EVALUATION

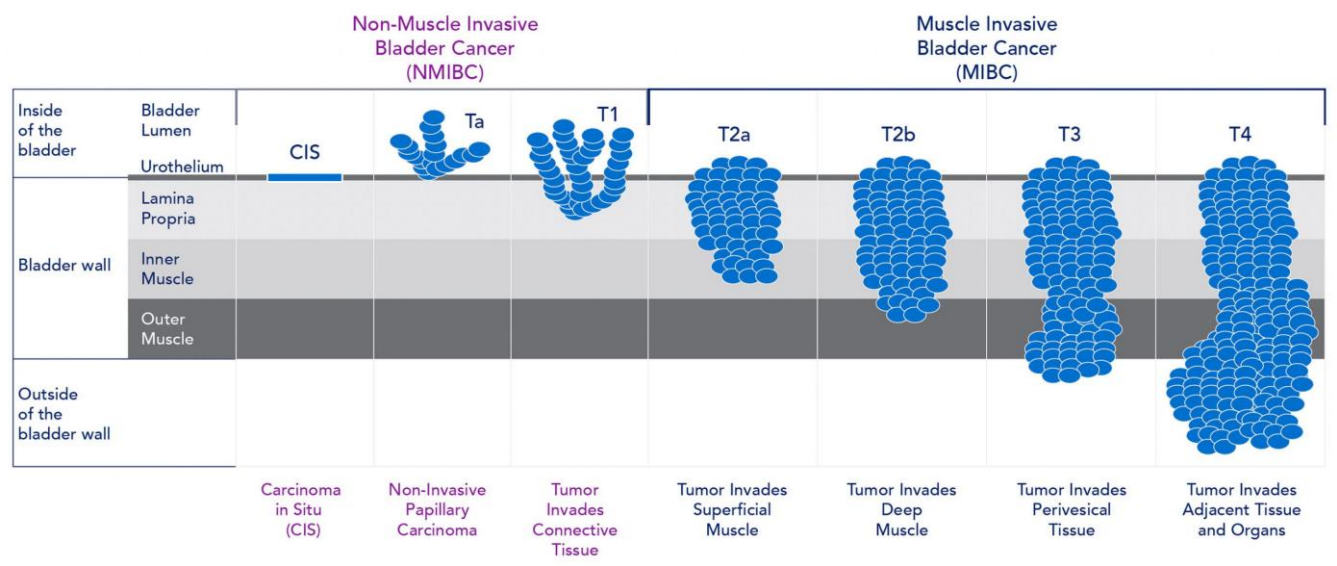
- Bladder Cancer
  - Bladder Cancer is the 10th most commonly occurring cancer, but is more common in men (6th most commonly occurring cancer in Men)
  - An estimated 83,190 patients were diagnosed with bladder cancer in the USA in 2024 at an average age of 73[1]
- Hematuria Evaluation
  - Hematuria (Blood in the urine) is the most common sign of bladder cancer with ~7m patients diagnosed each year in the US
    - Microhematuria (MH) visible with microscopy or gross hematuria (GH) visible with the naked eye
  - Hematuria can be caused by bladder cancer or other causes, including BPH, infection, stones, idiopathic, etc.
  - NMIBC[2] is easily treated by tumor resection, but requires surveillance due to >70% chance of recurrence
- Standard of Care
  - Current standard of care requires that every patient presenting with MH receives a cystoscopy to determine if the cause is bladder cancer
- Cystoscopy
  - Cystoscopy is an invasive and costly procedure that involves a visual inspection of the lining of the bladder by inserting a camera into the urethra
  - 78% of patients reported experiencing pain during cystoscopy and 25% rated as moderate to severe[3]

PacificEdge® CANCER DIAGNOSTICS

1. American Cancer Society (https://www.cancer.org/cancer/types/bladder-cancer/about/key-statistics.html)
2. NMIBC is non-muscle invasive bladder cancer (~70% of all diagnoses)
3. Survey conducted by the Bladder Cancer Advocacy Network (patient advocacy group) and published at WSAUA Meeting 2024

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

PACIFIC EDGE – TAKING NEW ZEALAND INNOVATION GLOBAL

2011
Pacific Edge Diagnostics New Zealand (PEDNZ) established

Dec 2012
Launch of Pacific Edge Diagnostics USA and Cxb Detect

Mar 2013
First commercial sale (Cxb Detect) for PEDUSA

May 2013
First commercial sale (Cxb Detect) for PEDNZ

Dec 2014
Launch of Cxbladder Triage

Dec 2015
Launch of Cxbladder Monitor

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

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

Oct 2021
PEB raises $103.5m (~US$72.5m)

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

Nov 2023
Kaiser Permanente EMR integration goes live

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

Feb 2025
Triage included in AUA Microhematuria Guideline

Apr 2025
Medicare non-coverage Effective

Oct 2025
Triage Plus gets CMS draft price of US$1328

2011 2012 2013 2014 2015 2016 2018 2019 2020 2021 2022 2023 2024 2025

APPROVED BY THE AUA BOARD OF DIRECTORS FEBRUARY 2025

Authors' disclosure of potential conflicts of interest and author/staff contributions appear at the end of the article.

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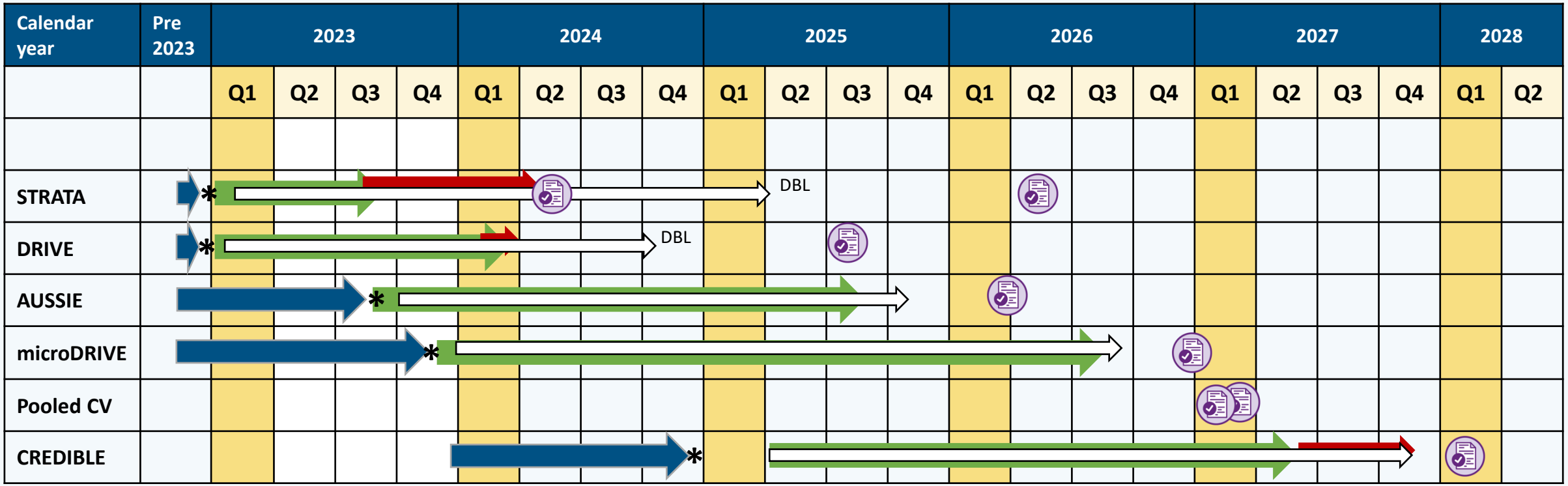
MICROHEMATURIA:
AUA/SUFU GUIDELINE (2020, AMENDED 2025)

Guideline Panel

Daniel A. Barocas, MD, MPH; Stephen Boorjian, MD;* Ronald Alvarez, MD, MBA; Tracy M. Downs, MD; Cary P. Gross, MD; Blake Hamilton, MD; Kathleen Kobashi, MD; Robert Lipman; Yair Lotan, MD; Casey Ng, MD; Matthew Nielsen, MD, MS; Andrew Peterson, MD; Jay Raman, MD; Rebecca Smith-Bindman, MD*

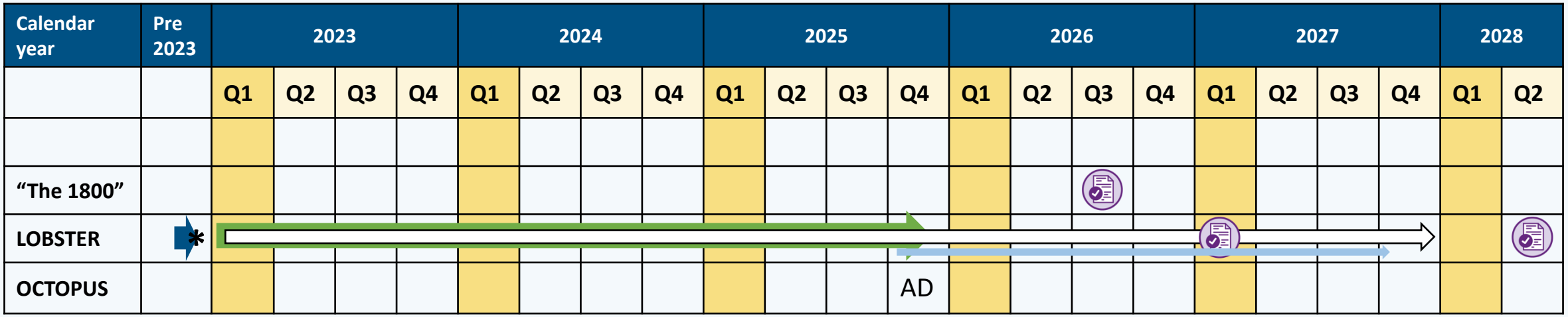
PacificEdge® CANCER DIAGNOSTICS

HEMATURIA EVALUATION FIVE YEAR CLINICAL STUDIES ROADMAP



PacificEdge® CANCER DIAGNOSTICS

SURVEILLANCE FIVE YEAR CLINICAL STUDIES ROADMAP



Note – "The 1800" is the Surveillance Plus development dataset
Note AD; Advisory Board at SUO to confirm OCTOPUS design

Legend:

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

PacificEdge® CANCER DIAGNOSTICS

PERFORMANCE CHARACTERISTICS OF CXBLADDER PRODUCTS

	Sensitivity (Sn)	Specificity (Sp)	NPV	PPV	ROR	Comment
Triage Plus	94%	77%	99.3%	26%	71%	Clinical Validation of Triage Plus in a veterans cohort[1]
Triage	89-96%	34-63%	98-99%	11-15%	35-63%	Range determined by 5 publications[2,3,4,5,6] that meet specific criteria[7]
Monitor	92%	-	96%	-	32%	Clinical Validation of Monitor in development dataset (n=543 from 424 patients, non-bootstrapped)[8]

1. Savage et al (2025)
2. Kavaliers et al (2015)
3. Davidson et al (2019)
4. Lotan et al (2023)
5. Davidson et al (2020)
6. Lotan et al 2024)
7. The specific criteria are:
8. Kavalieris et al (2017)

NOTE #1: Full references provided on later slide

Abbreviations - MH: Microhematuria, GH: Gross Hematuria, Sn: Sensitivity, Sp: Specificity, NPV: Negative Predictive Value, PPV: Positive Predictive Value, ROR: Rule Out Rate

SUMMARY OF CXBLADDER CLINICAL EVIDENCE

		Publication or Study	Population	Sn	NPV	Sp	PPV	ROR	Comment
Triage Plus	**AV**	Harvey et al., (2025)	Synthetic Analytes MH (382) + GH (605)	93.6%	99.4%	90.8%	46.4%	84.1%	Development dataset includes MH (38.7%) & GH (61.3%) to establish AV performance characteristics
	CV	DRIVE (Savage et al., 2025)	MH (254) + GH (267)	94%	99.3%	77%	26%	71%	Publication accepted; Note: at upper 0.54 threshold, PPV = 51% & Sp = 95%
		AUSSIE	MH + GH						Study in progress on MH + GH patients
		microDRIVE	MH						Study in progress on MH + GH patients
	CU	CREDIBLE	MH						Study in progress on MH patients
Triage	**AV**	Harvey et al., 2024	Synthetic Analytes	N/A	N/A	N/A	N/A	N/A	Multi-product analytical validation of Cxbladder Triage, Detect and Monitor
	CV	Kavalieris et al., 2015	GH (587)	95%	98.5%	45%	-	40%	Sn, Sp, NPV values when TNR is 40%
		Davidson et al., 2019	MH (185) + GH (366)	95.5%	98.6%	34.3%	-		Cxb Triage & imaging combined performance had a Sn of 97.7% & NPV of 99.8%
			MH (185)	100%	100%	42.6%	-		
			GH (366)	95.1%	98%	32.8%	-		
		Lotan et al., 2023	MH (320) + GH (484)	89%	99%	63%	16%	59%	Pooled data from US (GH) and Singapore (MH+GH) cohorts (n=804)
		DRIVE (Savage et al., 2025)	MH (254) + GH (267)	93%	98.5%	38%	11%	35%	Publication accepted
	CU	Davidson et al., 2020	MH (318) + GH (566)	89.4%	98.9%	59%	-	53%	Study wide CV: Cxb Triage & imaging combined performance: Sn 98.1%, NPV 99.9%, Sp 98.4%
		Lotan et al., 2024	LR MH (135) + NLR GH (255)	90%	99%	56%	15%	63%	Low risk MH patients (n=135) randomised; 59% relative cystoscopy reduction; 22 UC cases (270 overall)
Monitor	**AV**	Harvey et al., 2024	Synthetic Analytes	N/A	N/A	N/A	N/A	N/A	Multi-product analytical validation of all Cxbladder products
	CV	Kavalieris et al., 2017	NMIBC (1036) (all risk categories)	93%	97%	-	-	34%	Internally validated "bootstrap corrected estimates" from development dataset (n=1036), Sn of CxbM was 97% (N = 70/72) for HG tumors and 85% (N = 66/78) for LG tumors
		LOBSTER	NMIBC (all risk categories)						Study in progress on NMIBC patients. 1183 patients estimated
	CU	Koya et al., 2020	NMIBC (257) (low risk only)	N/A	N/A	N/A	N/A	77.4%	Modest real world evidence study with no comparison to cystoscopies that safely reduced cystoscopies by 39% as the primary endpoint
		Li et al., 2023	NMIBC (92)	100%	100%	78%	33%	72%	Small (n=92), real world study, at-home Monitor testing safely reduced cystoscopy by ~72%, with no missed recurrences & high patient satisfaction
		Guduguntla et al., 2025	NMIBC (98)	N/A	N/A	N/A			Small real world evidence study with no comparison cystoscopy that safely reduced cystoscopies by 59% as the primary endpoint

NOTE #1: Full references provided on following slide
NOTE #2: Development, feasibility and/or proof of concept studies are detailed within the references on the following slide
Abbreviations - MH: Microhematuria, GH: Gross Hematuria, Sn: Sensitivity, Sp: Specificity, NPV: Negative Predictive Value, PPV: Positive Predictive Value, ROR: Rule Out Rate

REFERENCES SUMMARY OF CLINICAL EVIDENCE

	References	Comment
Proof of Concept	Holyoake et al., (2008). Development of a Multiplex RNA Urine Test for the Detection and Stratification of Transitional Cell Carcinoma of the Bladder. Clin Cancer Res 14(3): 742-749	Feasibility of urine-based assay including biomarker discovery for urothelial cancer detection initial algorithm development
	O'Sullivan et al., (2012). A multigene urine test for the detection and stratification of bladder cancer in patients presenting with hematuria. The Journal of urology, 188(3), 741-747.	Development/feasibility of Cxbladder Detect assay and algorithm based on RNA expression biomarkers
	Lotan et al., (2023). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. The Journal of Urology, 10-1097.	Pooled data from MH and GH cohorts (*n*=804) for 'multi-modal' (RNA+DNA) assay and algorithm development for next generation Cxbladder product including TERT and FGFR3 SNPs. Called Detect+ in publication.
	Tyson et al., (2024). Budgetary Impact of Including the Urinary Genomic Marker Cxbladder Detect in the Evaluation of Microhematuria Patients. Urol Prac 11(1):54-60	Budget impact model for hematuria pathway, incorporating Cxbladder Detect into patient management
Triage Plus	Harvey et al., submitted. Analytical Validation of Cxbladder® Triage Plus Assay for risk stratification of hematuria patients for urothelial carcinoma Diagnostics 2025, 15, 1739.	Analytical validation of Triage Plus
	Savage et al., Accepted October 6, 2025. Diagnostic Performance of Cxbladder® Triage Plus for the Identification and Stratification of Patients at Risk for Urothelial Carcinoma: The Multicenter, Prospective, Observational DRIVE Study.	Clinical validation of Triage Plus (DRIVE Study)
Triage	Kavalieris et al., (2015). A segregation index combining phenotypic (clinical characteristics) and genotypic (gene expression) biomarkers from a urine sample to triage outpatients presenting with hematuria who have a low probability of urothelial carcinoma. BMC urology, 15(1), 1-12.	Algorithm development and clinical validation of Cxbladder Triage
	Harvey et al., (2024). Analytical Validation of Cxbladder® Detect, Triage, and Monitor: Assays for Detection and Management of Urothelial Carcinoma. Diagnostics. 2024; 14(18):2061.	Analytical validation of all Cxbladder products Triage, Detect and Monitor
	Davidson et al., (2019). Inclusion of a molecular marker of bladder cancer in a clinical pathway for investigation of haematuria may reduce the need for cystoscopy. NZ Med J, 132(1497), 55-64.	Clinical validation of Cxbladder Triage
	Davidson et al., (2020). Assessment of a clinical pathway for investigation of haematuria that reduces the need for cystoscopy. The New Zealand Medical Journal (Online), 133(1527), 71-82.	Clinical utility of Cxbladder Triage
	Lotan et al., (2023). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. The Journal of Urology, 10-1097.	Clinical validation of Cxbladder Triage from pooled data (USPrimary and Singapore pooled analysis; n=804)
	Lotan et al., (2024). A Multicenter Prospective Randomized Controlled Trial Comparing Cxbladder Triage to Cystoscopy in Patients With Microhematuria. The Safe Testing of Risk for Asymptomatic Microhematuria Trial. The Journal of Urology Vol 212 1-8 Jul 2024.	Clinical utility of Cxbladder Triage from STRATA study showing a 59% relative reduction in cystoscopy when comparing test and control arms
Monitor	Harvey et al., (2024). Analytical Validation of Cxbladder® Detect, Triage, and Monitor: Assays for Detection and Management of Urothelial Carcinoma. Diagnostics. 2024; 14(18):2061.	Analytical validation of all Cxbladder products Triage, Detect and Monitor
	Kavalieris et al., (2017). Performance characteristics of a multigene urine biomarker test for monitoring for recurrent urothelial carcinoma in a multicenter study. The Journal of Urology, 197(6), 1419-1426.	Algorithm development and clinical validation of Cxbladder Monitor
	Koya et al., (2020). An evaluation of the real-world use and clinical utility of the Cxbladder Monitor assay in the follow-up of patients previously treated for bladder cancer. BMC urology, 20(1), 1-9.	Clinical utility of Cxbladder Monitor with low risk NMIBC patients
	Li et al., (2023). Cxbladder Monitor testing to reduce cystoscopy frequency in patients with bladder cancer. Urologic Oncology: Seminars and Original Investigations, 41 (7), 326.e1 – 326.38.	Clinical utility of Cxbladder Monitor with NMIBC patients
	Tyson et al., accepted. Economic Impact Model of Incorporating Cxbladder Monitor in the Surveillance of Non-Muscle Invasive Bladder Cancer. JU Open Plus, accepted	Budgetary impact model when Cxbladder Monitor was incorporated into patient management

SOURCES AND ASSUMPTIONS - TOTAL ADRESSABLE MARKET

REGION	STATISTIC		SOURCE
US	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
	Receive a cystoscopy	>1,000,000	Kenigsberg, A, et al. The Economics of Cystoscopy: A Microcost Analysis, Urology 157: 29–34, 2021
	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 using 1 test per hematuria patient and 1.5 tests/year per NMIBC patient
	Price of Cxbladder (US$)	US$1,328 (Triage Plus) US$1800 (Surveillance Plus)	Triage Plus has been priced by Medicare. Surveillance Plus has not yet been priced – we are seeking a crosswalk
	TAM (US$b)	US$6.7	

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
	Receive a cystoscopy	4,000,000	Rindorf, D, et al. The extent of experiencing availability issues and deteriorating performance associated with reusable cystoscopies, a multicentre study.
	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$b)	US$2.0	

APAC (excluding India and China)	Population	830,000,000	World population - Southeast Asia; Population Pyramid - Japan;
	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
	Receive a cystoscopy	3,320,000	Pacific Edge estimate
	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	3,755,000	Pacific Edge estimate
	Price of Cxbladder (US$)	$550	Pacific Edge estimate
	TAM (US$b)	US$2.1	

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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

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