



PacificEdge®
CANCER DIAGNOSTICS

2026 ANNUAL SHAREHOLDERS' MEETING PRESENTATION

Simon Flood
Chairman

Dr Peter Meintjes
Chief Executive Officer

20 August 2026

CHAIRMAN'S ADDRESS



SIMON FLOOD
Chairman

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DIRECTORS



SARAH PARK



ANATOLE MASFEN



BRYAN WILLIAMS



ANNA STOVE



TONY BARCLAY

AGENDA

1. CHAIRMAN'S ADDRESS
2. CHIEF EXECUTIVE'S ADDRESS
3. QUESTIONS
4. RESOLUTIONS
5. VOTING AND GENERAL BUSINESS
6. MEETING CLOSE

PACIFIC EDGE - THE FIRST MOVER IN BLADDER CANCER DIAGNOSTICS

MAJOR GROWTH CATALYST: DRAFT MEDICARE COVERAGE PROPOSED IN MAY 2026



US\$10.2b⁴

Global Market Opportunity



SCIENCE, TECH AND IP

Cxbladder tests are patented **non-invasive** urine tests that deliver **proven clinical, economic and patient value**



CLINICAL EVIDENCE

Cxbladder tests are supported by a **robust portfolio of clinical evidence**, and the AUA¹ has recognized Cxbladder Triage with a **‘Grade A’ evidence rating** – the only urine biomarker to achieve that rating



SUBSTANTIAL MARKET OPPORTUNITY

The primary symptom of bladder cancer is hematuria with ~7m diagnoses each year in the US driving a **global market opportunity of US\$10.2 billion**



GROWTH CATALYST WITH MEDICARE COVERAGE

Draft LCD² for Triage & Triage Plus **released in May 2026**. Final LCD expected by Jan 2027³. Novitas confirms **claim-by-claim reimbursement for both tests**



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1. AUA = American Urological Association,
2. LCD = Local Coverage Determination.
3. Novitas must publish the final LCD or retire the draft LCD within 365 days after publishing a draft LCD
4. See slides 44-46 for assumptions

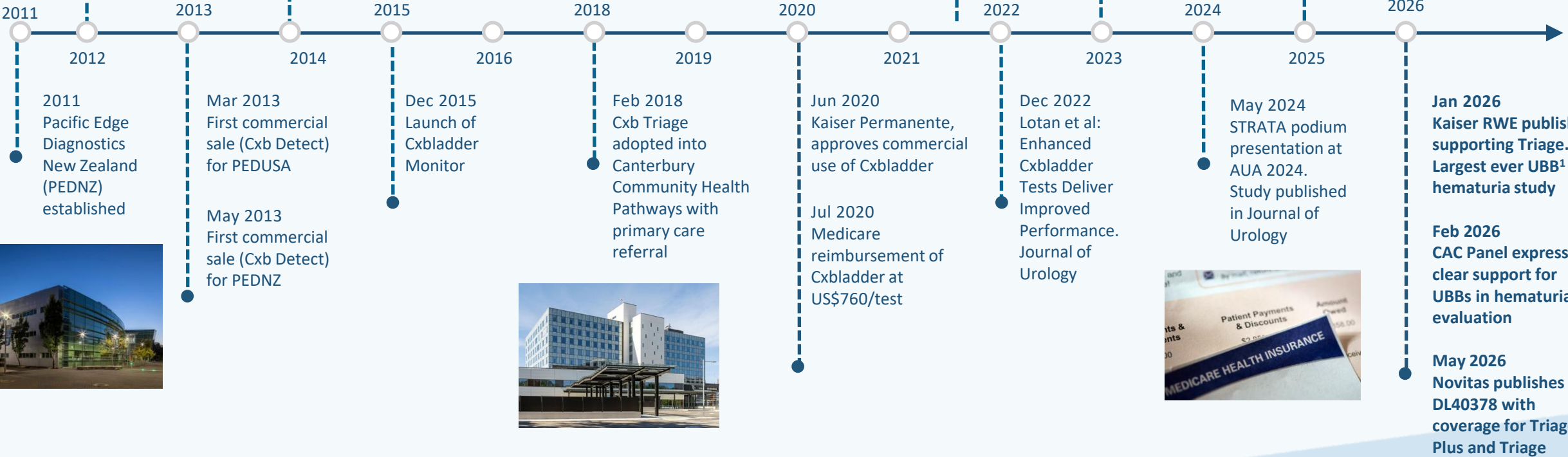
Timeline: Company Milestones



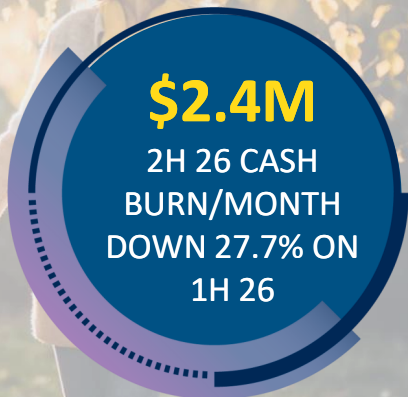
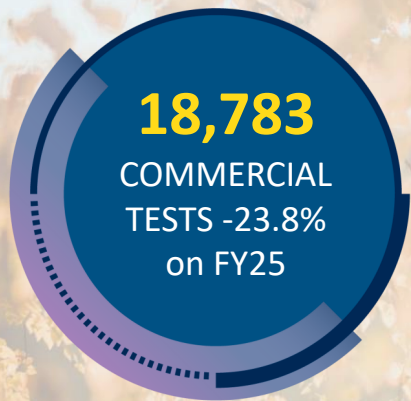
MICROHEMATURIA:
AUA/SUFU GUIDELINE (2020, AMENDED 2025)

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*



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



FY26: A YEAR OF STRATEGIC DELIVERY

ADVANCING MEDICARE COVERAGE GOALS; COSTS CONTAINED

STRATEGIC HIGHLIGHTS

- February 2026, CAC Panel expresses clear support for UBBs in hematuria evaluation
- May 2026, Novitas publishes draft LCD '*Urine-based Biomarkers in Patients with Microhematuria*' (DL40378) supporting coverage of Cxbladder Triage and Triage Plus
 - Expect final effective Medicare coverage by the end of 2026.
- Building US commercial payer momentum, with medical policy for hematuria evaluation tests from insurers covering 10.5 million lives.
- Asia Pacific operations advance towards profitability on a direct cost basis

FINANCIAL HIGHLIGHTS

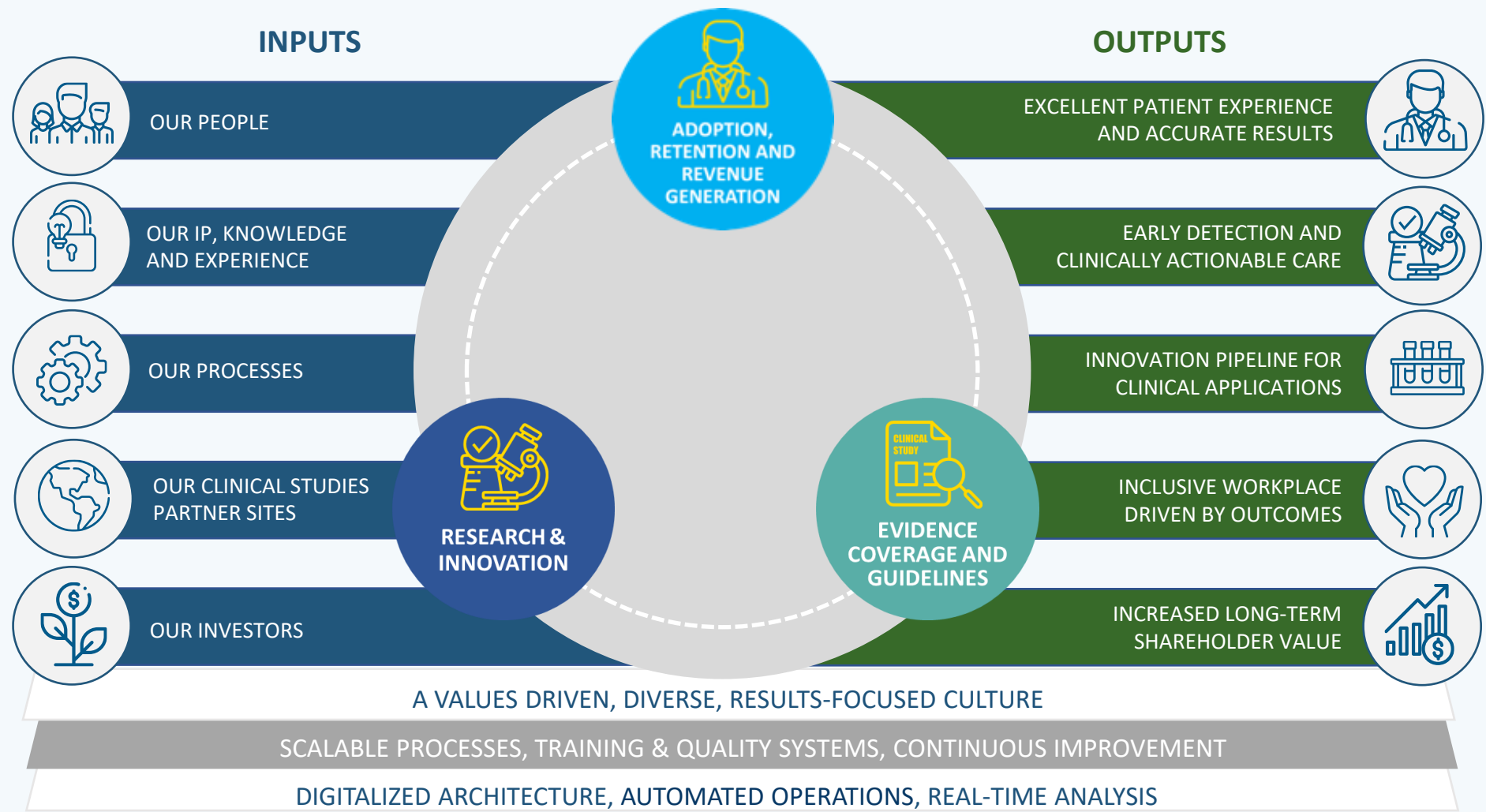
- FY26 operating revenue fell due to Medicare non-coverage determination; APAC shows steady growth on smaller volumes
- 2H 26 cash burn reduced through careful expense management; targeting a monthly average cash burn for FY27 of NZ\$2.5m vs NZ\$2.85m for FY26.
- A post balance date \$36.1 million capital raising to strengthen our balance sheet and drive revenue growth

CHIEF EXECUTIVE'S ADDRESS



DR PETER MEINTJES
Chief Executive Officer

VALUE CREATION THROUGH THREE PILLARS



PACIFIC EDGE: LEADER IN URINE-BASED BIOMARKER TESTING

STRONG EXECUTION ON EVIDENCE-PILLAR UNDERPINS FUTURE COMMERCIAL SUCCESS



- Draft LCD supporting Medicare coverage of Cxbladder Triage & Triage Plus; Final and effective LCD expected by end of 2026
- Rigorous clinical evidence program to extend risk thresholds in guidelines/medical policy to deliver a larger serviceable market



- US Commercial testing stabilizes; set to rise with final coverage
- Medical policy wins with US commercial payers increasing; over 10.5 million lives now covered with commercial policy for Cxbladder Triage
- Advancing APAC towards profitable operations on a direct cost basis



- Driving long-term enterprise value with product improvements and new products
- Triage Plus at \$1,328 and Surveillance Plus at \$1,800¹ create higher margin opportunity and improved unit economics

NOVITAS PROPOSED DRAFT COVERAGE FOR TRIAGE AND TRIAGE PLUS



FINALIZED LCD EXPECTED TO ACCELERATE PACIFIC EDGE'S PATH TO PROFITABILITY

- Triage and Triage Plus proposed for Medicare coverage
 - No other biomarkers proposed for Medicare coverage
- Final effective coverage expected before the end of the year
- Final LCD expected to catalyze reimbursement and testing volume
- Our immediate commercial focus is to:
 - Improve the unit economics of operating front line sales team
 - Shift our customer base to order Triage Plus (\$1,328) on every eligible patient
 - Ensuring payment success of >80% on commercial tests by operating where we have reliable history of commercial success or existing medical policy and contracting

"Use of validated multi-analyte UBBs may be reasonable and necessary to support risk-stratification in appropriately counseled, intermediate-risk patients with MH who are considering deferral of cystoscopy."

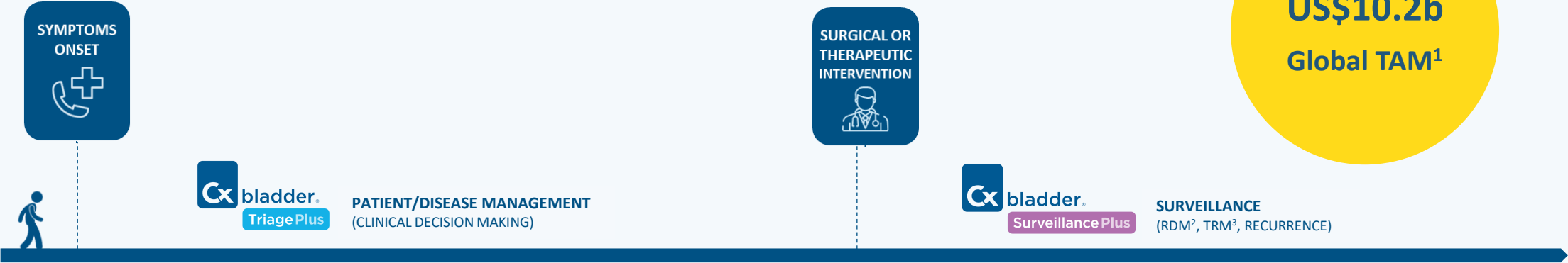
- DRAFT LCD: 'Urine-based Biomarkers in Patients with Microhematuria' (DL40378)



CXBLADDER MARKET OPPORTUNITY

CXBLADDER OFFERS A SIGNIFICANT ADDRESSABLE GLOBAL MARKET ANNUALLY

US\$10.2b
Global TAM¹



	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\$6.4b	Primary growth focus due to higher CMS pricing
	830m	~17m	0.47m 2.71m 3.46m	1.7m	~58k	~300k	US\$1.9b	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 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 44-46 for details.
2. RDM: Residual Disease Monitoring
3. TRM: Therapeutic Response Monitoring
4. Management estimates derived from referred hematuria data in Woldu et al (2021). MH estimated at 80% and GH at 20%. MH Risk categories: Low 7%, Intermediate 41%, High 52%. See Slide 44-46 for details.

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	Q3 2026 (+1Q)
7. microDRIVE Clinical Validation	- CV of Triage Plus	Q1 2027 (+1Q)
8. Surveillance Plus Analytical Validation	- AV of Surveillance Plus	Q2 2027 (+3Q)
9. Pooled Analysis MH Clinical Validation ²	- CV of Triage Plus	Q2 2027 (+1Q)
10. Pooled Analysis GH Clinical Validation ²	- CV of Triage Plus	Q2 2027 (+1Q)
11. LOBSTER Clinical Validation	- CV of Monitor/Surveillance Plus	Q3 2027 (+3Q)
12. CREDIBLE Clinical Utility	- CU of Triage Plus	Q1 2028 (at risk)
13. 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

AUA 2027 HEMATURIA GUIDELINE REVIEW IN FOCUS

- **STRATA second publication**
 - Simplify Triage utility messaging; will include the clinical outcomes of imaging
- **AUSSIE and microDRIVE**
 - Clinical validation of Triage Plus
- **MH & GH Pooled Analyses**
 - Demonstrate concordance between Triage and Triage Plus
 - Demonstrate equivalent performance in all MH risk categories and GH
 - Analyze across age, gender and ethnicity

Collectively, these studies are expected to re-define the AUA risk stratification thresholds for greater serviceable market

1. 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

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	Q3 2026
NZ Hematuria Pathway comparing T/D with Triage Plus on AUSSIE samples	Canterbury DHB	CU of Triage Plus	Q3 2026
Retrospective concordance 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

1.

2.

3.

4.

All dates are calendar year and our best current estimates

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.

BCG: Bacillus Calmette–Guérin is a bacterium instilled into the bladder that triggers an immune response that targets and destroys cancer cells.

MIBC: Muscle Invasive Bladder Cancer

COMMERCIAL TESTS STABILIZED; SET TO RISE WITH FINAL COVERAGE



US TOTAL TEST VOLUME¹ AND COMMERCIAL PRODUCT MIX



COMMERCIAL AND TOTAL THROUGHPUT STABILIZED

- Commercial and total throughput stable over last three quarters
- Sales efficiency improved as sales FTE lowered to address cash burn
- Seeking to shift commercial product mix to Triage Plus for higher margins

1. Total Laboratory Throughput including commercial, pre-commercial and clinical studies testing
2. Pacific Edge has previously used Total Lab Throughput, but has changed its reporting to focus on Commercial throughput, which accounts for the differences in reported figures compared to previous quarterly and half yearly reporting

COMMERCIAL STRATEGY WITH DRAFT MEDICARE COVERAGE

CONFIGURING OUR SALES TEAM AROUND INTERMEDIATE RISK PATIENTS

- Pacific Edge’s near-term success relies on reducing our cash burn:
 - Identify call points with high numbers of intermediate risk microhematuria (IRMH) patients
 - Migrate customers to Triage Plus
- Targeting intermediate risk microhematuria (IRMH) patients
 - Women’s health providers are a major opportunity, because IRMH patients are predominantly female
 - IRMH patients are commonly seen by URPS, urogyns, OBGYN and FPMRS¹
 - Systems integrated between primary care and secondary care are another major opportunity
 - Urologists frequently triage IRMH patients with APPs, NPs and PAs²
- Commercial sales teams focused concentrations of demand:
 - Integrated Delivery Networks
 - Hospital Systems, Academic Institutions, Veterans Association
- Pacific Edge is making selective investments aimed at growing Triage Plus volume ordered on IRMH patients that have the highest chance of reimbursement success and delivering consistent revenue



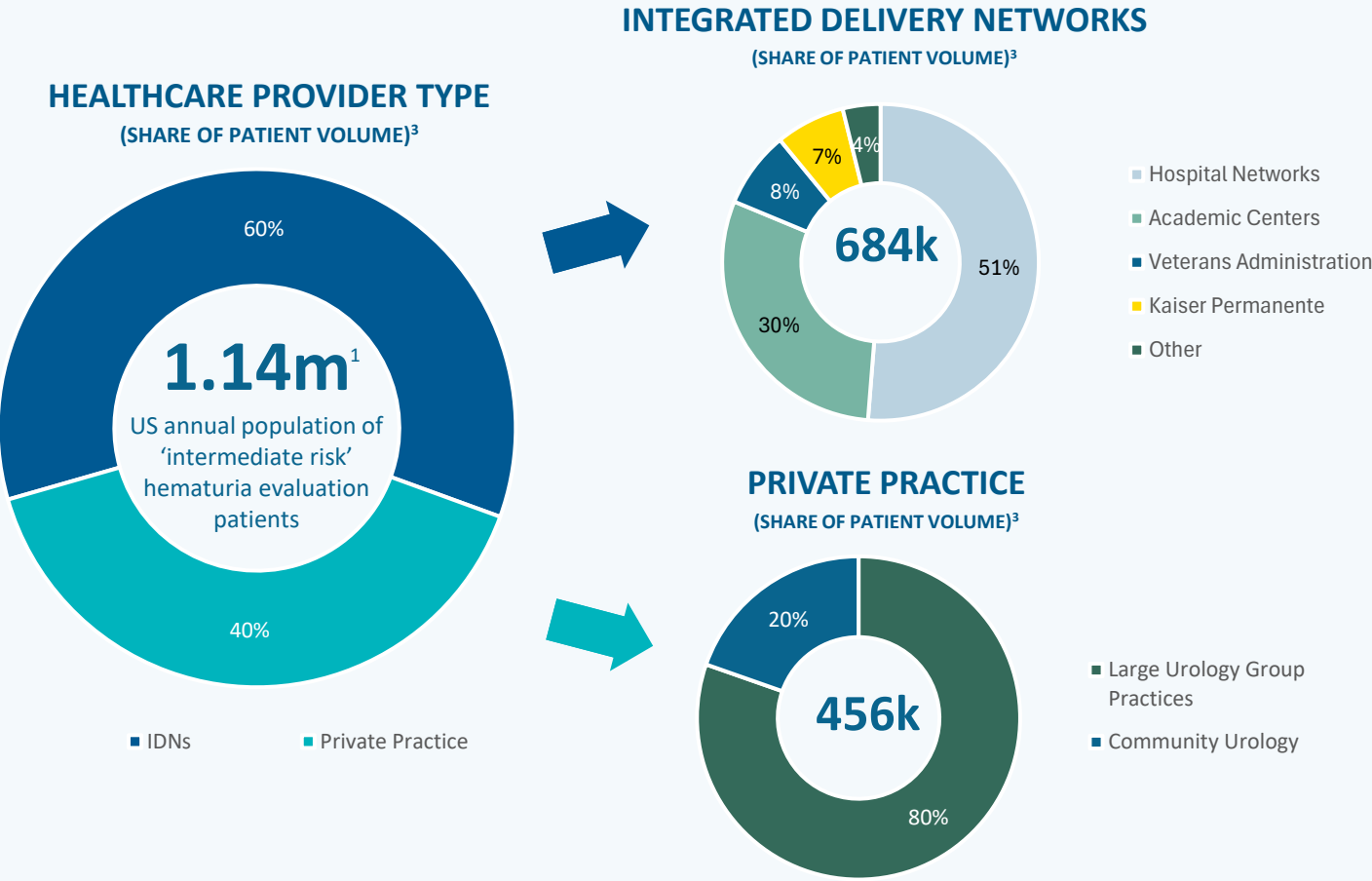
SEX ASSIGNED AT BIRTH FOR HEMATURIA PATIENTS³

PATIENT	FEMALE	MALE
Low risk	80%	20%
Intermediate risk	75%	25%
High risk	34%	66%

1. URPS is Urogynaecology and Reconstructive Pelvic Surgery, urogyn is urogynaecologist, OBGYN is Obstetrician-Gynaecologist and FPMRS is Female Pelvic Medicine and Reconstructive Surgery
2. Advanced Practice Providers (APPs), Nurse Practitioners (NPs) and Physicians Assistants (PAs)
3. Management estimates derived from referred hematuria data in Woldu et al (2021)

INTERMEDIATE RISK MICROHEMATURIA SALES APPROACH

INTEGRATED DELIVERY NETWORKS (IDNs) ARE THE TOP TARGET FOR INTERMEDIATE RISK MICROHEMATURIA



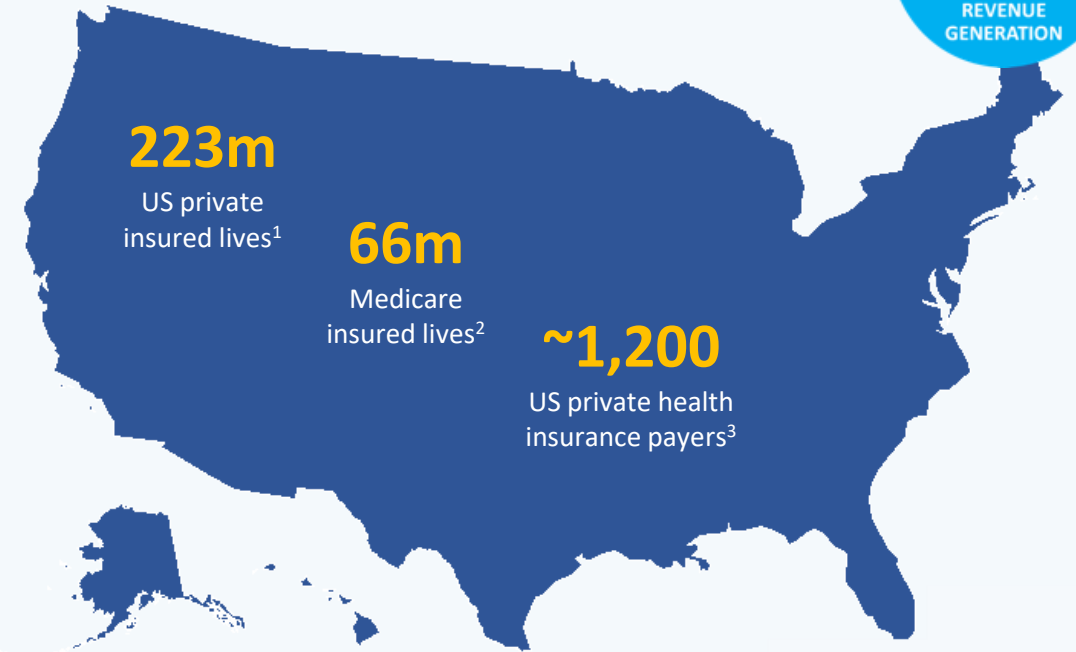
1. Management estimates derived from referred hematuria data in Woldu et al (2021). MH estimated at 80% and GH at 20%. MH Risk categories: Low 7%, Intermediate 41%, High 52%. See slides 44-46 for details.

US COMMERCIAL PAYERS: MEDICARE POLICY EXPECTED TO UNLOCK VOLUMES

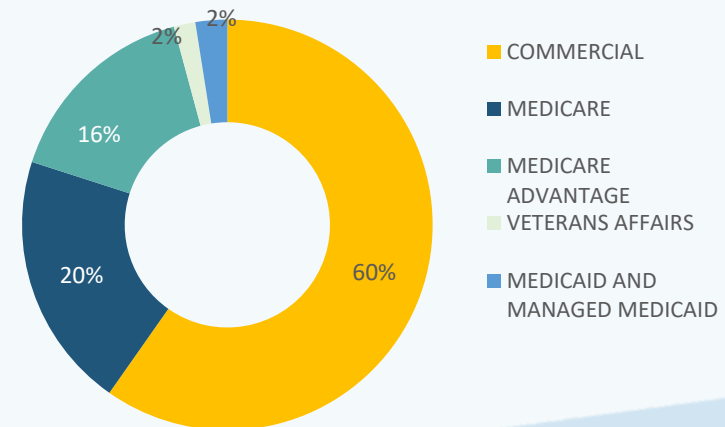


THE US PRIVATE HEALTH INSURANCE MARKET IS A LARGE OPPORTUNITY

- Commercial payers cover almost four times more lives than Medicare
- IRMH patients skew younger, female and commercially insured
- Final coverage policy from Medicare is expected to unlock revenue from Commercial Payers by:
 - Removing a key reason to deny reimbursement
 - Providing additional evidence to overturn denials on appeal
 - Providing language that commercial payers can adopt in their own policies
 - Leveraging State Biomarker Laws to mandate payment from commercial payers
- We focus on establishing medical policy directly with payers or through third parties like Avalon, EviCore, Carelon, Concert Genetics and ECRI⁴



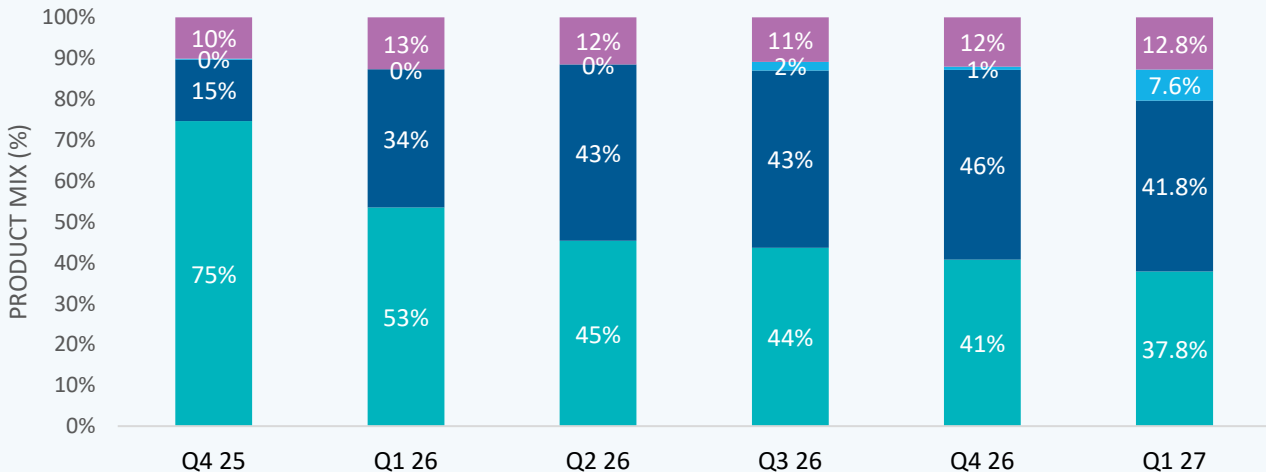
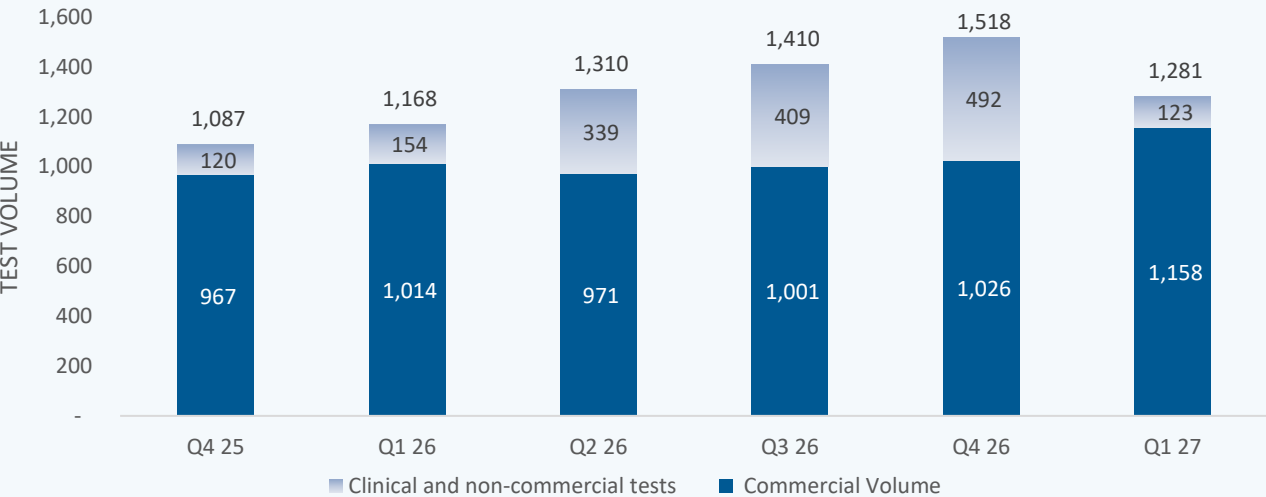
PACIFIC EDGE PAYER MIX (2H 26)



APAC CHARTING A PATH TO PROFITABILITY



APAC TOTAL TEST VOLUME¹ AND COMMERCIAL PRODUCT MIX



APAC – SMALL BUT SIGNIFICANT

- APAC contributed 19% of operating revenue in 2H 26 with \$2.0m in FY26
- APAC cash burn rate² of \$0.17m in Q1 FY27,
- Repricing in 2025 created on average 25% more revenue per test
- Triage Plus increased to 8% of product mix in Q1 27
 - Triage Plus has the potential for ~20% more revenue per test
- APAC proves the ROW concept that can be replicated in the Middle East, UK and Europe pending IVD development

1. Total Laboratory Throughput in Asia and Pacific including commercial, clinical, and non-commercial studies testing
2. APAC Commercial and Clinical Operations cash burn figure is calculated on a director cost basis and excludes R&D costs

NEXT GENERATION PRODUCTS ALREADY DELIVERING STRATEGIC VALUE

TRIAGE PLUS AND SURVEILLANCE PLUS OFFER SUPERIOR PERFORMANCE, PRICING AND MARGIN



ADVANCING IVD DEVELOPMENT FOR INTERNATIONAL MARKETS

- Triage Plus and Surveillance Plus will be offered as CAP/CLIA-approved LDTs¹ providing service to the entire USA
- International markets require a different approach in which Pacific Edge seeks to create a 'kitted' IVD medical device
- Pacific Edge is simplifying its tests to create 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-13485² (International)
 - Prototype development plan is in place and ready to be implemented subject to budget approval

OUTLOOK



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OUTLOOK

POSITIONED TO UNLOCK VALUE THROUGH UPCOMING COMMERCIAL, CLINICAL AND INNOVATION MILESTONES

NEAR-TERM VALUE CREATION COMMERCIAL CATALYSTS

- Case-by-case reimbursement for Triage and Triage Plus under draft LCD
- Final LCD published by end of 2026
- US customers adopt Triage Plus at US\$1,328/test
- Building US Commercial payer medical policy momentum
- Health New Zealand National Pathway for Cxbladder

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
- Targeting Surveillance Plus CPT-PLA coding submission in June 2027 and claim-by-claim revenue after 1 Jan 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



SIMON FLOOD
Chairman

QUESTIONS



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RESOLUTIONS



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VOTING

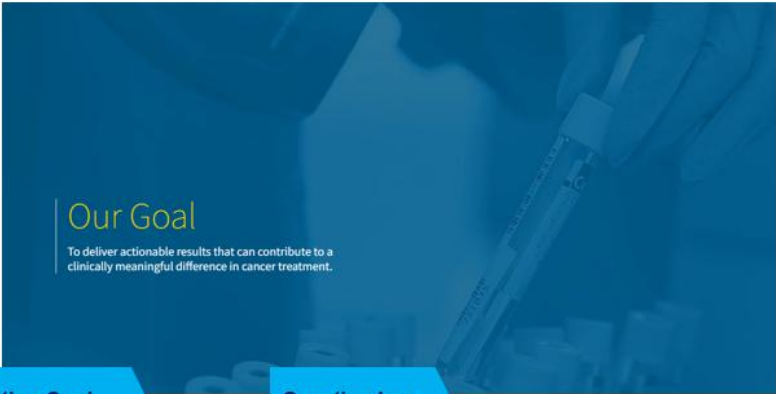


HELP NUMBER
0800 200 220

Ask a Question

Get a Voting Card

Exit Meeting 



Our Goal
To deliver actionable results that can contribute to a clinically meaningful difference in cancer treatment.

Voting Card

Question box



Get a Voting Card



Ask a Question

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Virtual Meeting

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27

RESOLUTION 1: AUDITORS' REMUNERATION

“To authorise the Directors to fix the auditors' remuneration for the ensuing year.”

RESOLUTION 2: BRYAN WILLIAMS RE-ELECTION

“That Bryan Williams, who retires in accordance with NZX Listing Rule 2.7.1 and is eligible for re-election, be re-elected as a Director of the Company.”

RESOLUTION 3: SIMON FLOOD ELECTION

“That Simon Flood, who retires in accordance with NZX Listing Rule 2.7.1 and is eligible for election, be elected as a Director of the Company.”

RESOLUTION 4: PAYMENT TO SIMON FLOOD

“That the payment in cash of \$12,699 to Simon Flood, being unpaid Director remuneration that has accrued to him in respect of the period from 19 December 2025 to 31 March 2026, as described in the Explanatory Notes, be approved for all purposes, including NZX Listing Rule 2.11.1.”

RESOLUTION 5: APPROVAL OF SHARE ISSUE

“That the issue of 152,561,001 Shares under NZX Listing Rule 4.5.1, being Shares issued under the Placement, Shares issued to certain participants in the Retail Offer, and Shares issued in consideration for professional services provided in connection with the Placement and Retail Offer, be approved and ratified for all purposes, including NZX Listing Rule 4.5.1(c)

RESOLUTION 6: ISSUE OF SHARES TO CERTAIN PARTICIPANTS

“That the issue of 59,998,716 Shares under NZX Listing Rule 4.3.1(c), being Shares issued to certain participants in the Retail Offer, be approved and ratified for all purposes, including paragraph (a) of the definition of “share purchase plan” in the NZX Listing Rules.”

PROXY VOTING DIRECTIONS

RESOLUTION	FOR*	OPEN*	AGAINST*	TOTAL**
1. Auditors' remuneration	571,843,459 (97.4%)	14,836,084 (2.5%)	406,612 (0.7%)	587,086,155 (47.3%)
2. Re-election of Bryan Williams	570,426,875 (97.1%)	14,839,284 (2.5%)	2,067,893 (0.4%)	587,334,052 (47.3%)
3. Election of Simon Flood	571,784,791 (97.4%)	14,839,284 (2.5%)	657,390 (0.1%)	587,281,465 (47.3%)
4. Payment to Simon Flood	571,026,067 (98.1%)	10,250,528 (1.8%)	1,072,708 (0.2%)	582,349,303 (46.9%)
5. Approval of share issue	383,502,592 (97.3%)	10,250,528 (2.6%)	448,731 (0.1%)	394,201,851 (31.7%)
6. Issue of shares to certain participants	521,723,100 (97.1%)	14,835,739 (2.8%)	945,324 (0.2%)	537,504,163 (43.3%)
*Percentage figures in the 'For', 'Open' and 'Against' columns indicate proportion of total votes notified (excludes abstentions) ** Percentage figures in the 'Total' column indicate total votes notified (excludes abstentions) against issued capital.				

GENERAL BUSINESS



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MEETING CLOSE



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APPENDIX

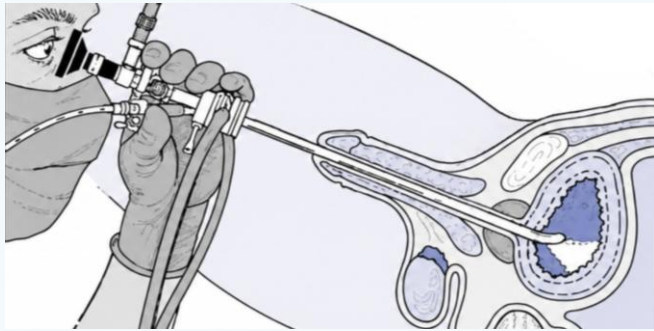


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BLADDER CANCER – A SIGNIFICANT GLOBAL HEALTHCARE CHALLENGE

AN INVASIVE STATUS QUO – A NON-INVASIVE OPPORTUNITY

CYSTOSCOPY



Source: Nursing Skills

- Cystoscopy – an invasive, uncomfortable and costly procedure to visually inspect the bladder by inserting a camera into the urethra
 - The standard hematuria workup, where the majority of patients are found to have no cancer
 - In a survey⁴ of US NMIBC patients under surveillance, 78% said they experienced some pain, with 25% saying it was moderate to “worst imaginable”
- The result is systemic over-proceduralization: millions of avoidable cystoscopies every year, adding cost, patient discomfort, infection risk and urology backlog
- Non-invasive genomic urine testing like Cxbladder can rule out cancer and prioritize patients who truly need cystoscopy – a large unmet clinical need
 - Women are an under-served market, with hematuria frequently dismissed as urinary tract infections (UTI)

CXBLADDER TEST



1st

Costliest cancer to treat on a per-patient basis¹

6th

Most common cancer in men²

9th

Most common cancer world-wide²

~614K

Annual cases and growing²

>220K

Annual Deaths²

>50%

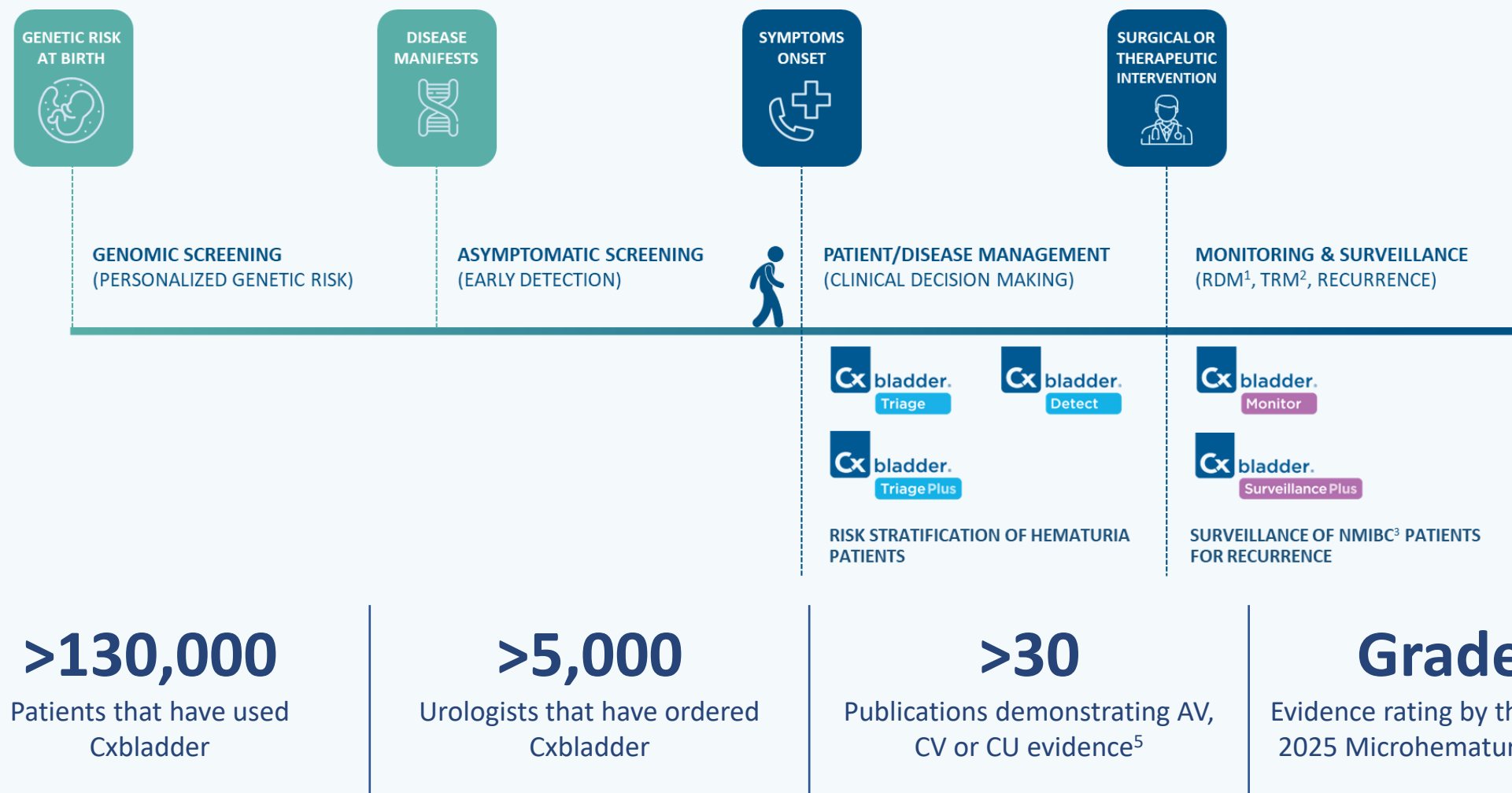
Recurrence³

4.9m⁵

Annual cystoscopies avoided globally if Cxbladder tests were used to evaluate intermediate risk patients presenting with hematuria⁵

CXBLADDER: TESTS TO RULE OUT CANCER OR PRIORITIZE PATIENTS

THE PATIENT CARE PATHWAY



1. RDM: Residual Disease Monitoring
2. TRM: Therapeutic Response Monitoring
3. NMIBC: non-muscle invasive bladder cancer
4. AUA: American Urological Association
5. AV, CV, CU are Analytical Validity, Clinical Validity, and Clinical Utility which are required for medical policy and guidelines

DRIVING ECONOMIC VALUE FOR PATIENTS, HOSPITALS AND PAYERS

CXBLADDER DELIVERS CLINICAL UTILITY, PATIENT SATISFACTION AND ECONOMIC VALUE

CANCER INCIDENCE IN MICROHEMATURIA PATIENTS

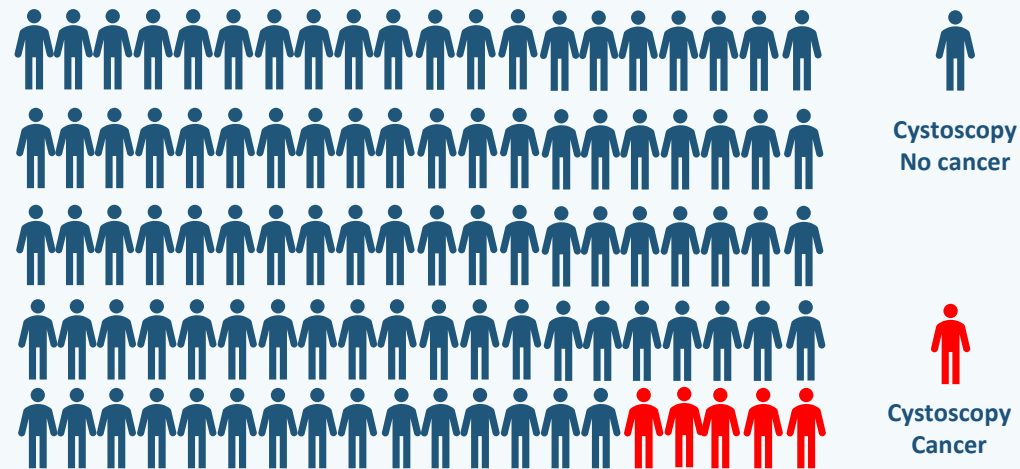
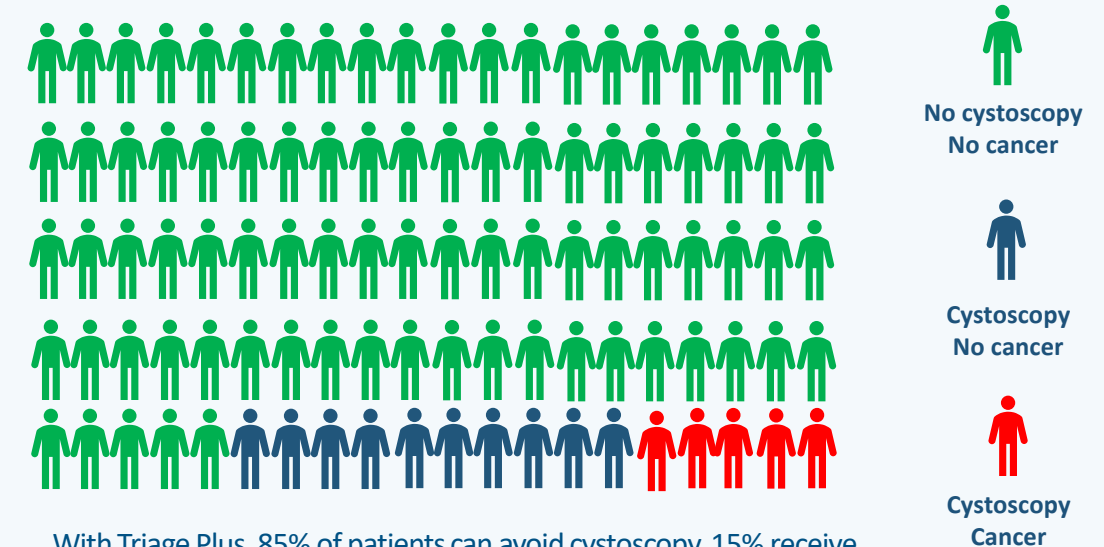


Illustration shows incidence of bladder cancer in microhematuria populations at 5%¹

CYSTOSCOPIES SAFELY AVOIDED USING CXBLADDER



With Triage Plus, 85% of patients can avoid cystoscopy, 15% receive cystoscopy to find the same 5 cancer patients

- Cxbladder avoids invasive, unnecessary procedures saving >US\$500/patient driving down costs for health systems and payers²
- Only 63% of counties in the US have a registered urologist³ and only 13% of high-risk microhematuria patients receiving a cystoscopy⁴
- The US population is ageing and the urologists per person over 65 is falling (from 23.8/100k to 15.8/100k in 2035⁵) potentially delaying diagnosis
- Medicare reimbursement for cystoscopy has declined from US\$204.80 in 2023 to US\$172.80 in 2026⁶

1. AUA Guidelines cite incidence of bladder cancer in microhematuria risk categories from 0.4-6%. 5% is an example

2. Tyson et al (2024) Budgetary Impact of Including the Urinary Genomic Marker Cxbladder Detect in the Evaluation of Microhematuria Patients - PubMed (PMID: 37914255)

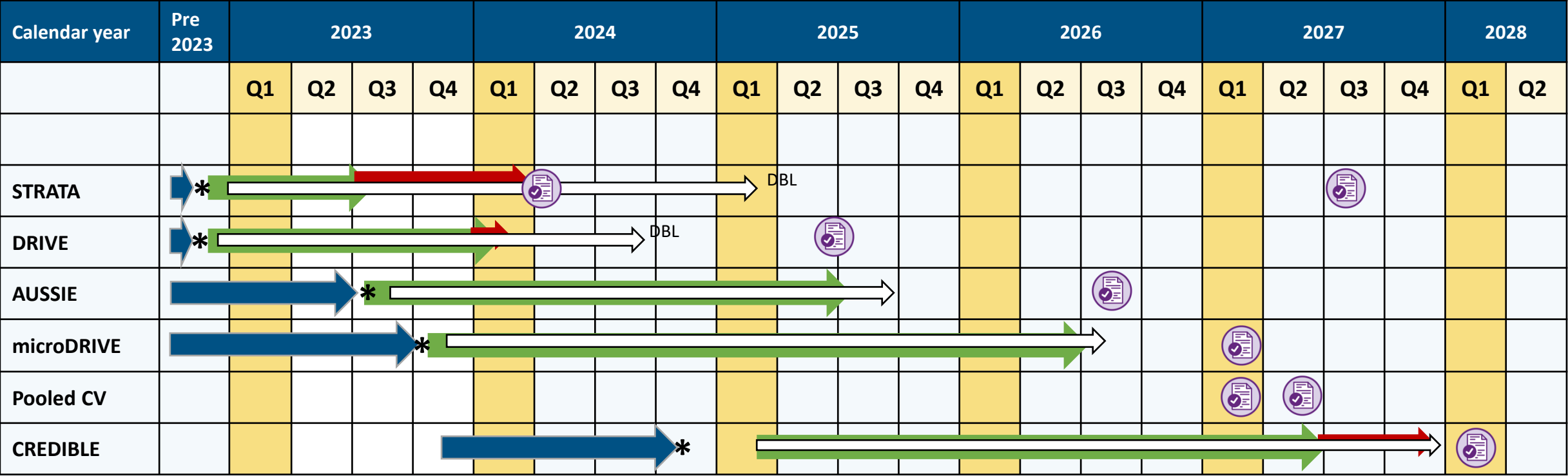
3. <https://www.auanet.org/research-and-data/aua-census/census-results>

4. <https://acsjournals.onlinelibrary.wiley.com/doi/full/10.1002/cncr.25048>

5. Nam et al. (2021) Projected US Urology Workforce per Capita, 2020-2060 JAMA Network Open Published Online: November 16, 2021

6. <https://www.cms.gov/medicare/physician-fee-schedule/search>

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

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

THE CXBLADDER SUITE

Hematuria Evaluation				NMIBC ¹ Surveillance	
Cxbladder Product	Triage	Detect	Triage Plus	Monitor	Surveillance Plus
Product Summary	Risk stratification of microhematuria patients to rule out the majority of those patients from further workup for bladder cancer	Adjunctive use with cystoscopy on hematuria patients to resolve diagnostic dilemmas (e.g. equivocal cystoscopy and atypical cytology)	Risk stratification and adjunctive use on any hematuria patient with improved performance over Triage and Detect	Alternative to cystoscopy for NMIBC patients undergoing surveillance for recurrence	Alternative to cystoscopy for NMIBC patients undergoing surveillance for recurrence. Currently in development, showing improved performance
Analytical composition	5 RNA biomarkers + patient clinical factors	5 RNA biomarkers	5 RNA biomarkers + 6 DNA SNVs from 2 genes (FGFR3/ TERT)	5 RNA biomarkers + patient tumor history	13 SNVs across 5 genes 2 fusions associated with 1 gene 1 methylation marker 2 control markers
Test Performance	Hematuria ² Sn: 95% Sp: 45% NPV: 99% PPV: N/A	Hematuria ³ Sn: 82%** Sp: 94%* NPV: 97%** PPV: 68%*	Hematuria ⁴ Sn: 93.6%**** Sp: 98.2%*** NPV: 99.4%**** PPV: 74.6%***	All risk groups ^{5,6} Sn: 93% Sp: N/A NPV: 97% PPV: N/A	All Risk Groups Sn: Not yet published Sp: Not yet published NPV: Not yet published PPV: Not yet published
When is it used?	Prior to cystoscopy	Prior to cystoscopy / as an adjunct / 3 weeks post cystoscopy		As a non-invasive surveillance alternative	
Commercially available?	✓		Commercially available in APAC and under “early access” in US, pending coverage	✓	CPT-PLA code targeted for Dec 2026 Reimbursed on A58917 in Jul 2027
Medicare Pricing (USD)	\$760		\$1,328	\$760	\$1,800 (seeking by crosswalk)

* When higher 0.23 cut point on test report is used
** When lower 0.12 cut point on test report is used

*** When higher 0.54 cut point on test report is used
**** When lower 0.15 cut point on test report is used

1. NMIBC: non-muscle invasive bladder cancer
2. 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.
3. O’Sullivan et al. (2012) A multigene urine test for the detection and stratification of bladder cancer in patients presenting with hematuria. J Urol 2012; 188:741–7.
4. 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>
5. 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.
6. 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.



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	4,416,066	Pacific Edge estimate
	Price of Cxbladder (US\$)	\$1,328 for Cxbladder Triage Plus, \$1,800 for Cxbladder Monitor	
	TAM (US\$billion)	\$6.4	

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	7,010,000	Pacific Edge estimate
	Price of Cxbladder EURO	€245	Pacific Edge estimate
	TAM (US\$billion)	\$1.9	

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	3,531,000	Pacific Edge estimate
	Price of Cxbladder (US\$)	\$550	Pacific Edge estimate
	TAM (US\$billion)	\$1.9	

FOR MORE INFORMATION:

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