# PACIFIC EDGE INTERIM FINANCIAL RESULTS PRESENTATION

FOR THE SIX MONTHS ENDED 30 SEPTEMBER 2020







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### KEY EVENTS AND COMMERCIAL MILESTONES

- LOCAL COVERAGE DETERMINATION INCLUSION: Effective from 1 July for Cxbladder Detect and Cxbladder Monitor for patients covered under Centers for Medicare and Medicaid Services (CMS) in the USA. Three-month contribution in 1H21, inclusive of accruals.
- **COMMERCIAL AGREEMENT WITH KAISER PERMANENTE**: Back end integration and testing of supply chain logistics now completed. Commercial test orders have commenced and are expected to have a positive impact from 2H21 onwards.
- SCALE UP OF COMMERCIAL OPERATIONS IN THE USA: Expansion of U.S. executive and sales teams to leverage and deliver on the growth opportunities available to Cxbladder.
- COVID-19: Significant impact on Cxbladder test volumes April and May. Recovery June to September in both NZ and USA. Remains a challenge to rapid growth despite introduction of in-home sampling system.
- STRENGTHENED BALANCE SHEET: Successful completion of \$22m placement to ANZ Investments to provide additional growth capital to accelerate global growth initiatives.
- INCLUSION IN THE S&P/NZX 50, S&P/NZX 50 PORTFOLIO and S&P/NZX MIDCAP INDICES: Effective from 21 October 2020.





### **COVID-19 IMPACT AND RESPONSE**

- Restrictions on patients accessing medical care and testing.
- Significant reduction in Total Laboratory Throughput during April-May 2020.
- Recovery from June 2020 following the easing of restrictions and growing demand for Pacific Edge's Patient In-Home Sample System (PIHSS).
- While New Zealand has recovered strongly, USA is still experiencing continuing shutdowns and restricted access across a number of states.

- Pacific Edge operated as an essential business during COVID restrictions in NZ and the USA.
- Took steps to preserve cash and provide flexibility to employees.
- Global pandemic highlighted the need for novel ways to detect cancer early and guide patient treatment.
- Sales team driving business via virtual meetings with many healthcare providers and clinics closed.
- Telemedicine identified globally as a key element in healthcare provision during the pandemic and beyond.
- Growing recognition of the benefits of Cxbladder inhome sampling system as an enabler for telemedicine, leading to more tests in COVID-19 environment.



# ADAPTING TO COVID-19: TELEHEALTH and PATIENT IN-HOME SAMPLING

- Dramatic increase in the use of telehealth as the primary mode of consultation for patient<sup>1</sup>.
- Telehealth growth in the US supported by FDA and CMS, seen as a significant change in the US healthcare landscape.
- Cxbladder's patient in-home urine sample collection system (PIHSS) is an enabler of telehealth.
- Allows patient evaluation and assessment to be managed remotely.
   Benefits for older and 'COVID-at-risk' patients, removing the need to visit busy medical centres or collection points.
- Provides another strong point of difference for Cxbladder.
- Expected to continue as an additional option for urologists to better manage patients during COVID-19 and beyond as demand for telehealth services continues to grow.



1."The COVID19 pandemic has driven perhaps the greatest transformation in healthcare delivery in modern times". MEDPAGE TODAY July 2020, Dr Nancy Gin, Executive Vice-President of Quality and, Chief Clinical Quality Officer for the Kaiser Federation





# LCD INCLUSION IS A TRANSFORMATIONAL REIMBURSEMENT MILESTONE

Successful inclusion in Local Coverage Determination (LCD) facilitates reimbursement of Cxbladder Detect and Cxbladder Monitor tests performed on CMS patients on or after 1 July 2020, at USD \$760 per test.

- 1. The successful LCD decision has allowed Pacific Edge to start recognising revenue (under NZ IFRS 15) for tests that are performed on CMS patients (Medicare and Medicare Advantage) in the U.S. at the CMS price of US\$760 per test for Medicare. See note 1B in the Interim Financial Statements.
- 2. There is no certainty of any reimbursement on any of these tests performed prior to 30 June 2020, and there is no ability to reliably estimate the level of consideration that would be received if agreement can be reached with Novitas Solutions Inc over these previously performed tests.

# CONSECUTIVE RECORD REVENUE MONTHS OVER THE FOUR MONTHS POST LCD IN JULY.

- Two-months of cash contribution included in the 1H21 reporting period, plus accruals for expected cash receipts for tests not yet paid<sup>1</sup> to 30 September.
- Cxbladder Detect and Cxbladder Monitor accounted for 94% of U.S. commercial test volume in 1H21.
- CMS related tests (Medicare and Medicare Advantage) accounted for 67% of U.S. commercial test volume in 1H21.
- Significant increase in recognised revenue and cash receipts, with CMS tests paid in approximately 30 days; with strong positive impact on operating cashflow.
- Negotiations continue with CMS for reimbursement of previous 22,000+ tests done for CMS patients<sup>2</sup>.





# COMMERCIAL TESTING UNDERWAY WITH KAISER PERMANENTE

Agreement reached with Kaiser Permanente, one of the USA's largest non-profit healthcare providers, to commercially use all Cxbladder products nationally.

#### **ACTIVITY TO DATF:**

- Focus on integration of Cxbladder into Kaiser Permanente's systems.
   Completed testing to ensure a gold standard user-experience.
- National agreement for all Cxbladder products, initially with Cxbladder Monitor, other Cxbladder products to follow.
- More than 95% of Kaiser Permanente's medical consultations are now telehealth providing an opportunity to utilise Cxbladder in-home sampling system.
- Commercial testing now underway; expected to positively impact from 2H21 onwards.



### SCALE-UP OF COMMERCIAL OPERATIONS IN USA

Strengthened leadership team, recruited sales executive and sales reps to drive the growth following LCD and Kaiser Permanente commercial outcomes.

- LARGE UROLOGY GROUPS, COMMUNITY PRACTICES AND PRIVATE PAYERS: Strengthened frontline
  US commercial team addition of specialist sales and commercialisation skills, five sales reps
  added to new sales territories, a medical affairs expert and VP Payer Relations to lead the charge
  on private payer negotiations.
- LARGE INSTITUTIONAL CUSTOMERS: Specialist sales executives focussed on converting other large institutional customers in the US.
- PRIVATE PAYERS: Dedicated contracted team of specialists to carry out negotiations with the top private payers to gain coverage and inclusion in their reimbursement networks.
- CUSTOMER SUPPORT: Expansion of the customer services liaison team to support Kaiser Permanente and others who are using the Cxbladder patient in-home sampling program.
- SUFFICIENT CAPACITY IN US LABORATORY to support the expected increase in demand for Cxbladder with 260,000 tests per annum design capacity for Hershey P.A laboratory.





# GROWING EVALUATION AND USE OF CXBLADDER BY LARGE HEALTHCARE INSTITUTIONS

### **USA**

- Kaiser Permanente
- Carolina Urologic Research Center
- City of Hope
- Cleveland Clinic
- Cornell
- Fox Chase CC
- Johns Hopkins CC
- MD Anderson
- Moffitt CC
- Ohio State University CC
- Penn State Milton S. Hershey Medical Center
- Rush University
- Thomas Jefferson University
- TriStar Medical Center
- UCLA

#### **USA**

- University of California-San Diego
- University of California-San Francisco
- University of Chicago
- University of Colorado
- University of Michigan
- University of Minnesota
- University of Oklahoma
- University of Pennsylvania
- University of Southern California
- UT Southwestern
- VA Accounts
- Wellstar

### **SOUTH EAST ASIA**

- Singapore General Hospital
- Tan Tock Seng
- Khoo Tech Puat Hospital
- KK Women's and Children's Hospital
- National University Hospital
- Raffles Medical Group
- Gleneagles Private Hospital

### **NEW ZEALAND**

 Majority of public healthcare providers





# FINANCIAL RESULT

For six months ended 30 September 2020

### A BIG STEP FORWARD FOR PACIFIC EDGE IN 1H21

OPERATING REVENUE INCREASED

+46% to \$3.3 million

OPERATING EXPENSES REDUCED

Down 8% to \$11.2 million

AVERAGE MONTHLY CASH BURN REDUCED

2Q21 down 23% driven by CMS reimbursement

TOTAL COMPREHENSIVE LOSS REDUCED

Improved 25% to \$(7.1)m

NET CASH, CASH EQUIVALENTS AND SHORT TERM DEPOSITS

Increased to \$29.3m

TOTAL LABORATORY THROUGHPUT

Down 16% on pcp due to COVID-19

6,864 tests

**COMMERCIAL TESTS** 

Down 15% on pcp due to COVID-19

5,591 tests

USA: down 25%

Rest of World: up 18%

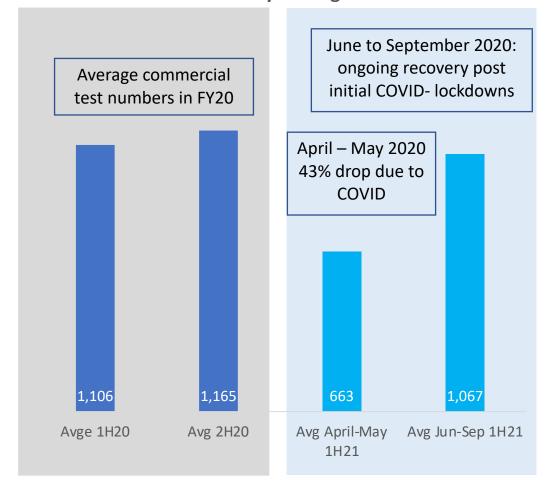
# TOTAL LABORATORY THROUGHPUT AND COMMERCIAL TESTS



COVID-19 restrictions affecting access to medical centres and testing for patients, particularly in April and May. Significant impact on test throughput, particularly in USA which is ongoing. Strong recovery being seen from June onwards.

- Total Laboratory Throughput (TLT) 6,864 tests, down 16% on pcp.
- **Commercial Tests** 5,591, down 15% on pcp. Percentage of commercial tests remains consistent at 81% of TLT.
- Strong recovery in ROW (+18%) partially offsetting decline in USA (-25%).
- Continuing recovery with commercial test numbers ramping up: tests in September increased 11% on pcp.

# COMMERCIAL TEST NUMBERS Monthly Average



<sup>\*</sup>See Slide 27 for definition of Commercial Tests







### <u>USA</u>

72% of TLT 71% of commercial tests 87% of Operating Revenue

6,864
Total Laboratory
Throughput (TLT)

5,591 Commercial Tests

### **Rest of World**

28% of TLT 29% of commercial tests 13% of Operating Revenue South East Asia

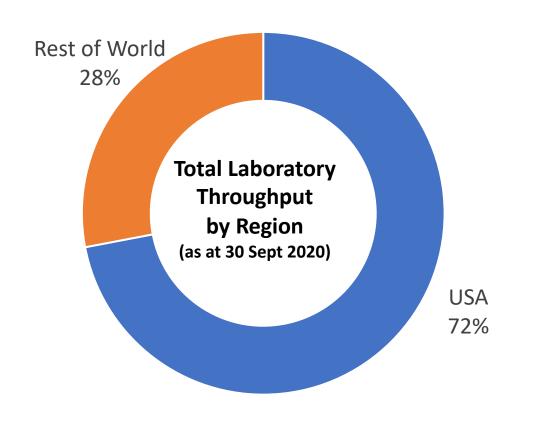
Australia

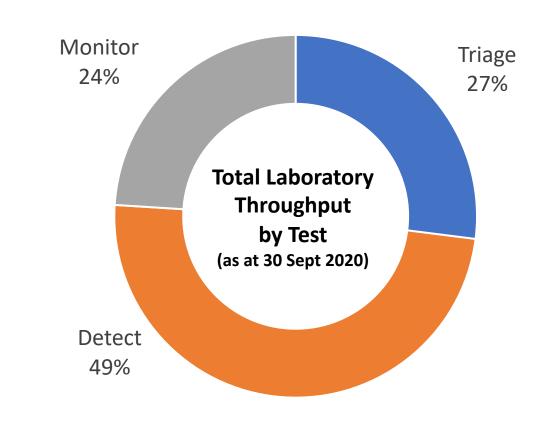
**New Zealand** 





# MULTIPLE CXBLADDER PRODUCTS ADDS DEPTH TO OUR MARKET











(NZ\$'000)	1H21 <sup>1</sup>	1H20 <sup>1</sup>	% Change	
Operating Revenue <sup>2</sup> (test sales)	3,326	2,285	46%	$\checkmark$
Total Revenue	4,060	2,701	50%	$\checkmark$
Operating Expenses	11,153	12,090	(8)%	$\checkmark$
Total Comprehensive Loss	7,079	9,406	(25)%	<b>√</b>
Cash Receipts from Customers	2,553	2,350	9%	<b>√</b>
Net Operating Cash Outflow	7,679	7,405	4%	_
Net cash, cash equivalents and short term deposits	29,283	4,737	518%	<b>√</b>

<sup>1.</sup> Half year ended 30 September

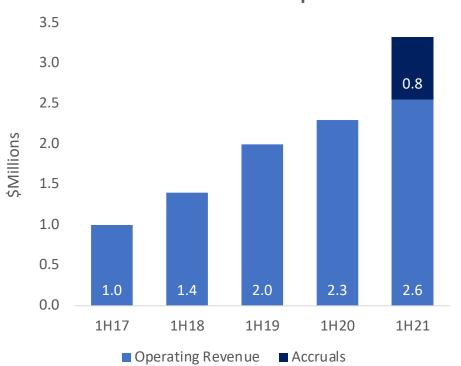
<sup>2</sup> The Group has included in Operating Revenue an accrual for tests performed from 1 July 2020 (date at which Cxbladder was included within the LCD and reimbursement commenced) to 30 September 2020 for which payment has not been received by 30 September 2020. The accrual included in both Operating Revenue in the Statement of Comprehensive Income and in Receivables in the Balance Sheet is NZ\$769,835.



# STRONG REVENUE GROWTH DRIVEN BY ACCELERATING REIMBURSEMENT



### First Half Revenue Comparison



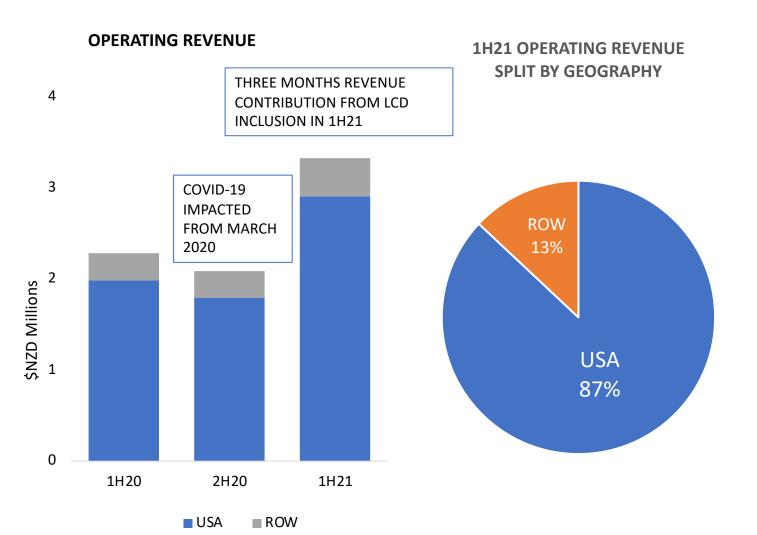
- Total operating revenue increased 46% on pcp.
- Revenue growth primarily driven by reimbursement of CMS tests from 1 July onwards.
- 1H21 included a 3 month revenue contribution from CMS.
- Average cash receipts for August and September (excluding accruals) increased 77% on pcp.
- Escalation in operating revenue in August and September is expected to continue into 2H21.

1. LCD inclusion has allowed Pacific Edge to start accruing revenue (under NZ IFRS 15) for tests that are performed on CMS patients (Medicare and Medicare Advantage) in the U.S. CMS tests performed after 1 July 2020 have been recognised on an accrual basis based on expected future cash receipts (previously cash basis). Tests for other non-CMS payers continue to be accounted for on a cash basis. The accrual included in the 1H21 result is \$0.8m. See Note 1b in the 1H21 Financial Statements.



## STRONG REVENUE GROWTH DESPITE COVID-19





Total operating revenue:

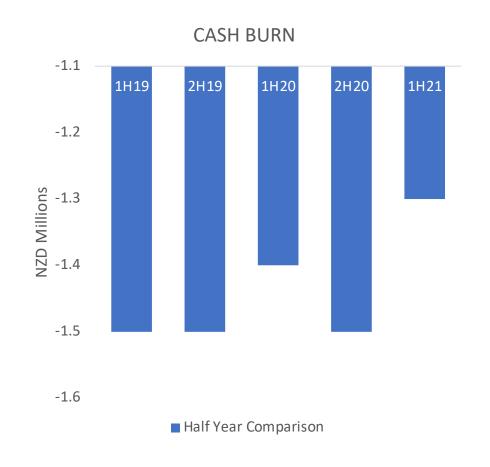
- U.S. increased 46% v 1H20
- ROW increased 40% v 1H20
- U.S. accounted for 87% of total operating revenue.
- Growing momentum in the U.S. market - reimbursement rates up significantly.
- NZ continued to show strong momentum – operating revenue well ahead of plan and pcp.





### REDUCTION IN MONTHLY CASH BURN

- 1H21 average monthly cash burn reduced 6% on pcp and 15% on 2H20.
- Q221 average monthly cash burn reduced 23% on pcp – driven by CMS reimbursement.
- LCD coverage has significantly improved cash conversion.

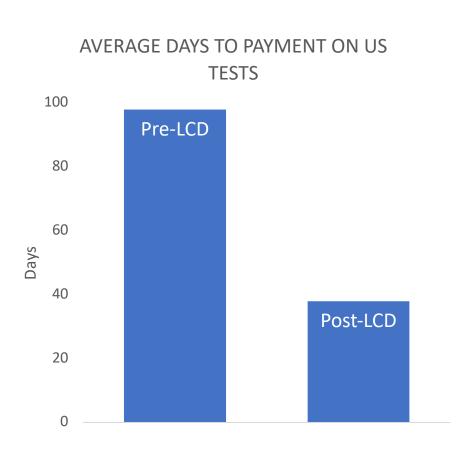






### SIGNIFICANT IMPROVEMENT IN CASH PAYMENT TERMS

- Key reimbursement events driving improving time to payment for most tests.
- Significant improvement in cash conversion driven by LCD inclusion.
- CMS tests paid in approximately 30 days.
- Other US providers average 1 to 3 months.
- Cash receipts from customers increased 9% on pcp to \$2.6m, which includes only a two month contribution from the CMS for tests completed in July and August.
- Strong cash receipts from 1 October 2020 onwards.







# GROWTH CATALYSTS AND OUTLOOK

For all markets our key objectives remain; achieving commercial contracts with large institutional healthcare customers, growing sales to existing customers, gaining stronger inclusion in guidelines and targeting private payers for coverage inclusion

# SIGNIFICANT RECENT PROGRESS UNDERPINS FUTURE GROWTH

# SIGNIFICANT COMMERCIAL AND REIMBURSEMENT MILESTONES ACHIEVED IN THE US

 Inclusion in LCD and commercial agreement with Kaiser Permanente

#### COMPETITIVE ADVANTAGE CONTINUES TO GROW

 Clinical validation, published evidence, inclusion in guidelines, Intellectual Property

#### **GROWING USE OF TELEHEALTH**

 Patient In-Home Sampling System supports the dramatic increase in the use of telehealth as the primary mode of consultation for patients

### SCALE UP OF OPERATIONS IN US

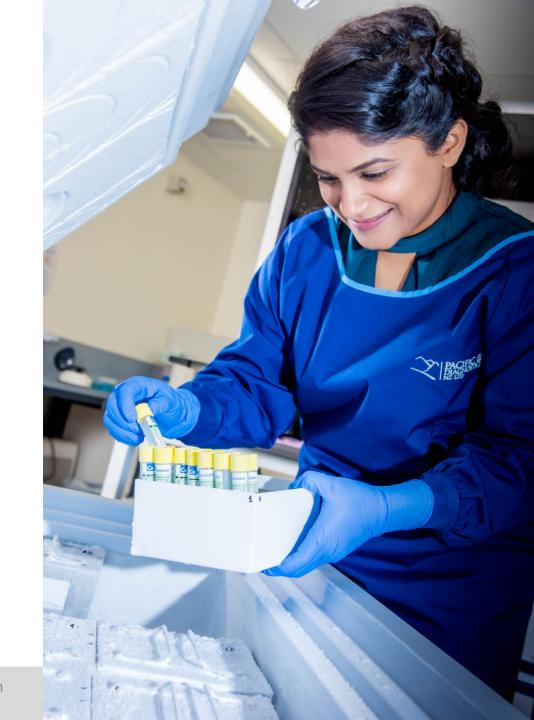
 Growth capital invested to drive growth. Addition made to the commercial team in commercial executive roles, sales reps and medical affairs





# ACCELERATING U.S. GROWTH IS OUR KEY OBJECTIVE

- Investment into expanded commercial operations in USA.
- Leverage LCD inclusion to gain reimbursement coverage with private payers (insurance companies).
- Leverage Kaiser Permanente agreement to complete commercial agreements with other healthcare institutions of scale.
- 'Gas-up' the commercial tests for Kaiser Permanente and support ramp up in demand for PIHSS.
- Publication of additional clinical evidence supporting the outperformance of Cxbladder, to enable greater recognition of Cxbladder in guidelines.
- Commercial launch of fourth Cxbladder test (Cxbladder Resolve) planned for FY22.





# CONTINUING PROGRESS IN 'REST OF WORLD' MARKETS

#### **NEW ZEALAND**

- Bring NZ business to a cash-flow positive position.
- Extend commercial coverage by public healthcare providers in NZ from 65% towards 100%.
- Grow out the number of Cxbladder products in use with each of the existing public healthcare customers.
- Publication of additional clinical evidence supporting the clinical utility of Cxbladder to drive further reimbursement, coverage and guideline inclusion.

### AUSTRALIA AND SOUTH EAST ASIA (SEA)

- Transition Australia and Singapore public health care providers from their clinical studies to a commercial customer model.
- Facilitate commercial discussions with large scale SEA healthcare provider partners to grow Pacific Edge's SEA business.
- Publication of a white paper summarising the results from the completed user programs from five public hospitals in Singapore.





# STRONG GROWTH OUTLOOK FOR 2H21 AND BEYOND

- Momentum has continued into the second half of FY21 with U.S. cash receipts for October increasing 68% on pcp.
- Test use and revenue growth expected to continue to escalate in 2H21 and beyond.
- Expect increasing number of commercial tests from CMS and Kaiser Permanente to underpin strong revenue and operating cashflow growth.
- Identified opportunities for growth in all our targeted markets. US market remains our primary focus.
- Strengthened balance sheet provides additional growth capital allowing us to scale-up the business to meet the expected increase in demand for Cxbladder.
- More resources invested in the US, directed towards achieving commercial contracts with large institutional healthcare customers and growing sales to existing customers and private payer coverage inclusion.





### **Enquiries to:**

**David Darling** 

Chief Executive Officer

Pacific Edge Limited

Tel: +64 3 479 5802 Mobile: +64 21 797981

Email: david.darling@pelnz.com

www.pacificedge.co.nz www.cxbladder.com www.pacificedgedx.com



## CXBLADDER'S PIVOTAL COMMERCIAL CUSTOMERS





















### **GLOSSARY**



- **CMS:** Centres for Medicare and Medicaid in the US. Provide insurance coverage for healthcare of all US citizens over the age of 65 years. This is approximately 62 million patients.
- **Commercial Tests:** Tests that have been analysed by Pacific Edge, for a specific customer, including the User Programmes run by customers as part of their adoption process but excluding any tests run for clinical studies.
- Laboratory Throughput: Total commercial and non-commercial tests processed through Pacific Edge's laboratories in the USA and New Zealand, including tests for User Programmes.
- Local Coverage Determination (LCD): A decision by a Medicare Administrative Contractor (MAC) whether to cover a
  particular service. In the case of a Laboratory Developed Test, such as Cxbladder, this is a national decision as all national
  wide invoices are processed and signed off for coverage by Novitas (our MAC).
- Change in US revenue accounting from cash to accrual basis: Accrual accounting for US revenue (NZ IFRS 15): Since Cxbladder's inclusion in the LCD, the Group has been able to reliably estimate both the probability, timing and size of payment received from the CMS for each test. The inclusion within LCD combined with the growing support for the use of Cxbladder within the US has also allowed the Group to reliably estimate both the probability and size of payment received from customers covered by private insurance, or with no insurance cover. Therefore, an accrual has been included for tests which have been performed but for which payment had not been received by 30 September 2020. There has been no change to the revenue accounting policy for ROW which is on an accrual basis.



### **GLOSSARY**



- Rule-Out Tests: A relatively new form of diagnostic process requiring performance metrics of high sensitivity and a high Negative Predictive Value (NPV). High sensitivity and high NPV will provide an accurate ruling out of patients who do not have disease.
- Rule-In Tests: More conventional diagnostic process that identifies those people who have disease. The performance metrics are usually high sensitivity and high specificity.
- LDT: Laboratory Developed Tests are a class of medical tests that are regulated under CLIA c.f the FDA
- MAC: Medicare Accredited contractor. The CMS (see definition for CMS) have defined 9 regions across the US and appointed MAC's to administer their business for CMS patients. Pacific Edge's MAC is NOVITAS. NOVITAS is the MAC that administers the CMS business in the region where the Pacific Edge laboratory is located. All patient invoices for Cxbladder tests carried out on CMS patients across the US are administered by NOVITAS under the LCD (See definition of LCD)

