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# Sienna Cancer Diagnostics Limited

Investor Presentation – August 2017

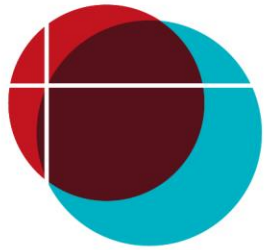
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# Company Overview

# Overview

Sienna is the developer of a new diagnostic technology with potential utility in numerous cancer indications. It is the first company to develop an In-Vitro Diagnostic product (IVD) for the detection of hTERT, a component of telomerase, in human clinical samples.

Sienna has registered its product as a **Class 1 IVD in the USA**, a CE marked / **General Class IVD in the EU**, and a **Class 2 IVD in Australia** for clinical diagnostic use.



## Developed a novel diagnostic technology

- Identification of a unique cancer biomarker (hTERT, a component of Telomerase)



## Commercially available - revenue commenced

- First customer adaptation – adjunct test to urine cytology for assisting bladder cancer diagnosis
- Addresses a clinical unmet need



## Multiple drivers for uptake

- Uses same patient sample already collected
- Additional information for urologist making diagnosis
- Delivering added value to labs through existing reimbursement



## Clear strategy for growth

- Drive revenue growth - first product already launched
- Global market expansion opportunity with potential to develop further clinical utility for the same product
- De-risked platform with multiple upside opportunities

# Corporate Snapshot

Company particulars	
Listed on ASX	August 2017
ASX ticker code	SDX
Cash at bank	~\$5.0m
Total shares on issue	180,262,327
Market Cap. at listing @ \$0.20	~\$36m



Major Shareholders	%
David Neate	9.4%
Traoj Pty Ltd	7.7%
Geron Corporation	7.7%
Board of Regents (Texas Uni)	2.6%
Barry & Marilyn Laws	1.9%

## Corporate details

- Located in the Small Technologies Cluster, Scoresby, Victoria – a specialist R&D laboratory facility and corporate office
- 10 staff including R&D, Quality, Commercial, Management and Administration
- To date, the Company has raised approximately \$22m in equity and \$6m in grants and R&D Tax Incentive refunds and concessions
- >5 years' Audited accounts




# Board and Management Team

## Personnel Overview

<b>Geoffrey Cumming</b> (BSc (Hons), BAppSc, MAICD, MBA, PhD)		Non-Executive Chairman	<ul style="list-style-type: none"> <li>- Geoff has held senior roles in the global healthcare and biotechnology sector for more than 20 years</li> <li>- Former MD of Roche Diagnostic Systems (Oceania), transforming the loss-making entity into the fastest growing and most profitable affiliate in the Roche group. Former CEO of Biosceptre International Ltd, successfully designing and securing key funding arrangements. Former MD of Anteo Diagnostics Ltd (ASX: ADO)</li> <li>- Currently a NED of Anteo Diagnostics Ltd and Medical Australia Ltd (ASX: MLA)</li> </ul>
<b>Matthew Hoskin</b> (BAppSc)		Chief Executive Officer	<ul style="list-style-type: none"> <li>- 20 years' experience in the biotech and healthcare sectors, specialising in antibodies and reagent detection systems, automated IHC / ICC stainers, tissue processors, pathology capital equipment as well as consumables and oncology pharmaceuticals</li> <li>- Prior roles at Siemens Medical, Leica Biosystems and Hospira (played a key role in driving the growth at Vision Biosystems which became one of Australia's most profitable biotechs and ultimately sold for ~AUD\$800 million)</li> </ul>
<b>David Earp</b> (JD PhD)		Non-Executive Director	<ul style="list-style-type: none"> <li>- Originally a partner in an IP law firm, advising life science clients</li> <li>- 1999 - 2012 served in various roles at Geron Corporation (California, NASDAQ- listed), including chief patent counsel, chief legal officer and senior VP</li> <li>- Former NED of TA Therapeutics Ltd (HK), ViaGen Corporation (Texas) as Executive Chairman, currently President &amp; CEO of Circle Pharma.</li> </ul>

# Board and Management Team (cont'd)

## Personnel Overview

<b>John Chiplin</b> (BPharm PhD)		Non-Executive Director	<ul style="list-style-type: none"> <li>- Former CEO of Polynoma LLC, a US based cancer immunotherapy company</li> <li>- Former founding CEO of ASX-listed Arana Therapeutics Ltd (now Teva)</li> <li>- Former head of the UK's \$300m ITI Life Science investment fund</li> <li>- Currently NED of Benitec Biopharma (ASX:BLT), Cynata Therapeutics (ASX:CYP), Adalta Ltd (ASX:1AD) and Chairman of AIM-listed Scancell Holdings Plc (AIM:SCLP)</li> </ul>
<b>Carl Stubbings</b> (BSc)		Non-Executive Director	<ul style="list-style-type: none"> <li>- Considerable experience commercialising diagnostic products, both locally and globally</li> <li>- Based in USA, served as VP of Sales &amp; Marketing for Focus Diagnostics (subsidiary of Quest Diagnostics)</li> <li>- Held roles at Benitec Biopharma Ltd (ASX-listed) as Chief Business Officer, Head of Commercialisation at BCAL Diagnostics (blood test for breast cancer developer).</li> <li>- NED of Analytica Medical Ltd (ASX) and Otakaro Pathways (NZ) developing a diagnostic test for Crohn's disease</li> </ul>
<b>Tony Di Pietro</b> (B.Com, CPA, AGIA)		Chief Financial Officer and Company Secretary	<ul style="list-style-type: none"> <li>- CPA accredited accountant with over 15 years of corporate accounting experience, gained both in Australia and the United Kingdom</li> <li>- Holds a Graduate Diploma of Applied Corporate Governance from the Governance Institute of Australia</li> <li>- Was previously at Acrux Limited, where he was a key member of management for more than 10 years. During this period, Acrux transitioned from a small loss-making public company to an ASX listed company generating significant profits</li> </ul>

Telomerase is a naturally occurring enzyme which maintains “protective caps” called telomeres on chromosomes during cell division.

- Without telomerase, chromosomes fray over time leading to cell death
- Cancerous cells use telomerase to maintain chromosomal integrity resulting in cellular immortality
- Sienna has developed a novel reagent for the detection of telomerase in cells
- **The test uses existing patient samples and is run on existing lab IHC / ICC equipment**

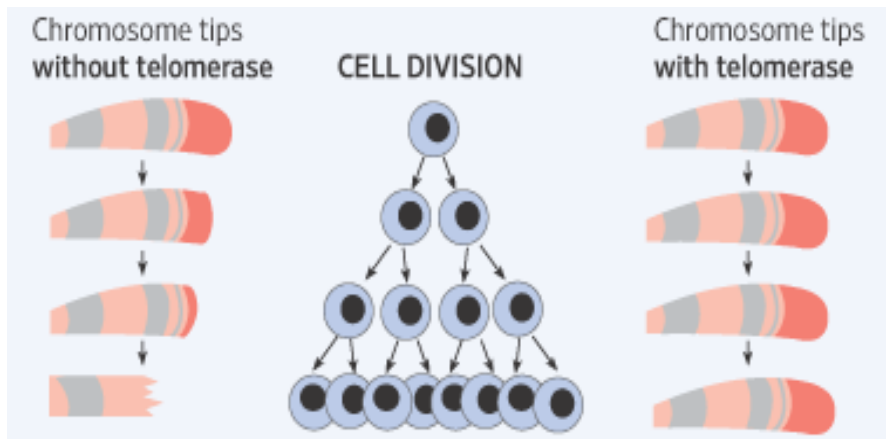


Image source: The Nobel Committee for Physiology or Medicine



**85%**

of all tumours express telomerase which makes telomerase a unique cancer biomarker.



# Addressing an Unmet Need in Bladder Cancer Detection

First commercial utility: Bladder Cancer (as adjunct to urine cytology)

## The Unmet Need

- Current routine test – urine cytology, has low sensitivity, particularly for early stage cancer
- Approx. 25% of urine cytology tests are inconclusive
- Other tests are invasive or very expensive



## The Sienna Solution

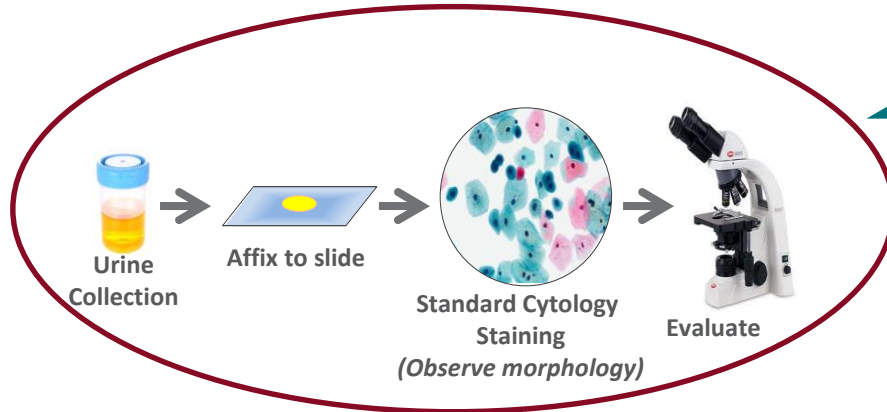
Sienna's test to identify hTERT in urothelial cells; used in conjunction with urine cytology

- ✓ Provides urologists with useful clinical information to assist in their diagnostic assessment
- ✓ Utilises the same sample already sent to the lab for urine cytology analysis
- ✓ Requires no further equipment beyond regular ICC/ IHC equipment
- ✓ Provides profitable revenue for diagnostic labs (USA) through existing reimbursement

# Enhancing Current Clinical Practice

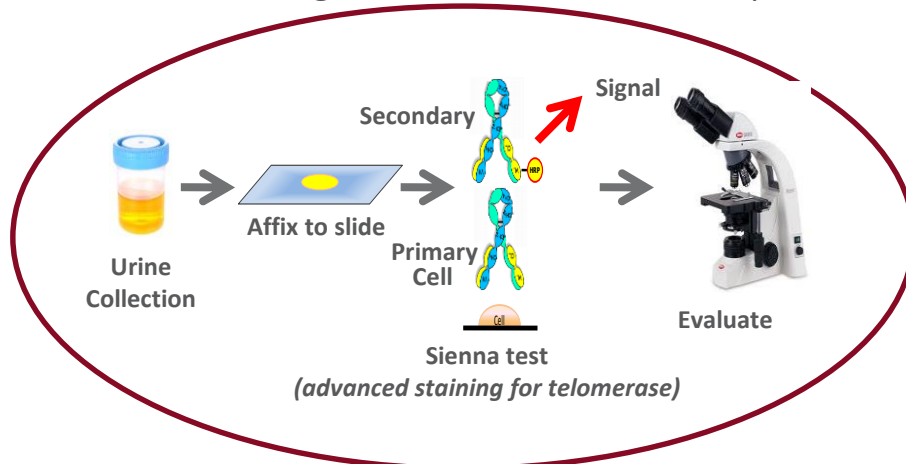
## Urine Cytology

Observing for cancer cells from urine sample

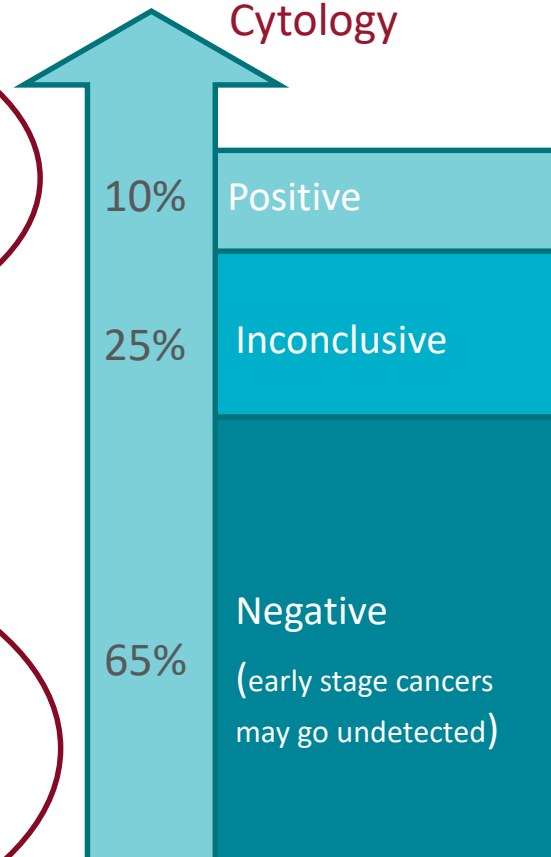


## Urine Cytology + Sienna ICC Stain

Observing telomerase from urine sample



## Bladder Cancer Detection From Standard Urine Cytology



## Potential Benefits of Sienna Test

Match

Resolve

Improve

# Financial Overview

## Profit And Loss Statement (\$'000s)

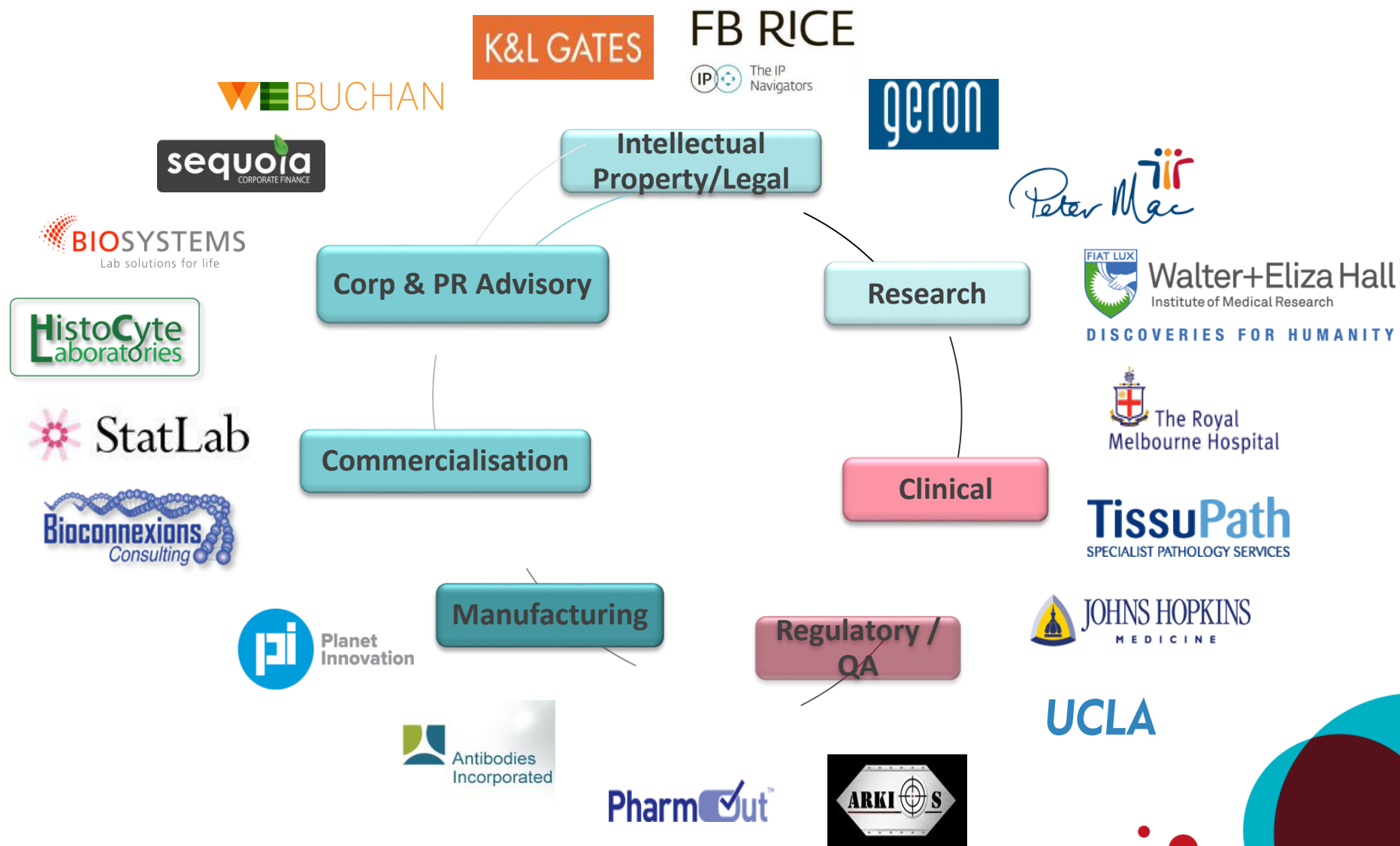
	FY16	FY17 YTD (1/2 yr as at Dec 31, 2016)
<b>Revenue</b>	<b>1,344</b>	<b>936</b>
Cost of Sales	(102)	(21)
<b>Gross Profit</b>	<b>1,242</b>	<b>915</b>
Administration Expenses	(706)	(228)
Employee Expenses	(1,487)	(601)
Direct R&D Expenses	(406)	(387)
Capitalised R&D	881	656
<b>Net Profit/(Loss) Before Tax</b>	<b>(477)</b>	<b>(355)</b>

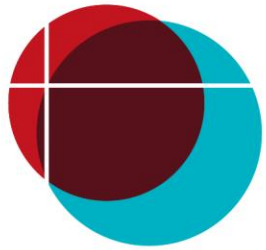
- Revenue includes product incomes, R&D Tax Incentive refunds and interest
- Capitalised R&D represents development expenditure for Sienna's IVD that was recently registered with regulatory bodies in the US, EU and Australia. No further expenditure will be required to be capitalised

## Balance Sheet (\$'000s) 31/03/2017

Cash	1,195
Other Current Assets	114
Non-current Assets	2,321
<b>Total Assets</b>	<b>3,630</b>
Liabilities	284
<b>Net Assets</b>	<b>3,346</b>

# Sienna's Partner Network





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# Market Overview

## Sienna's Current Market

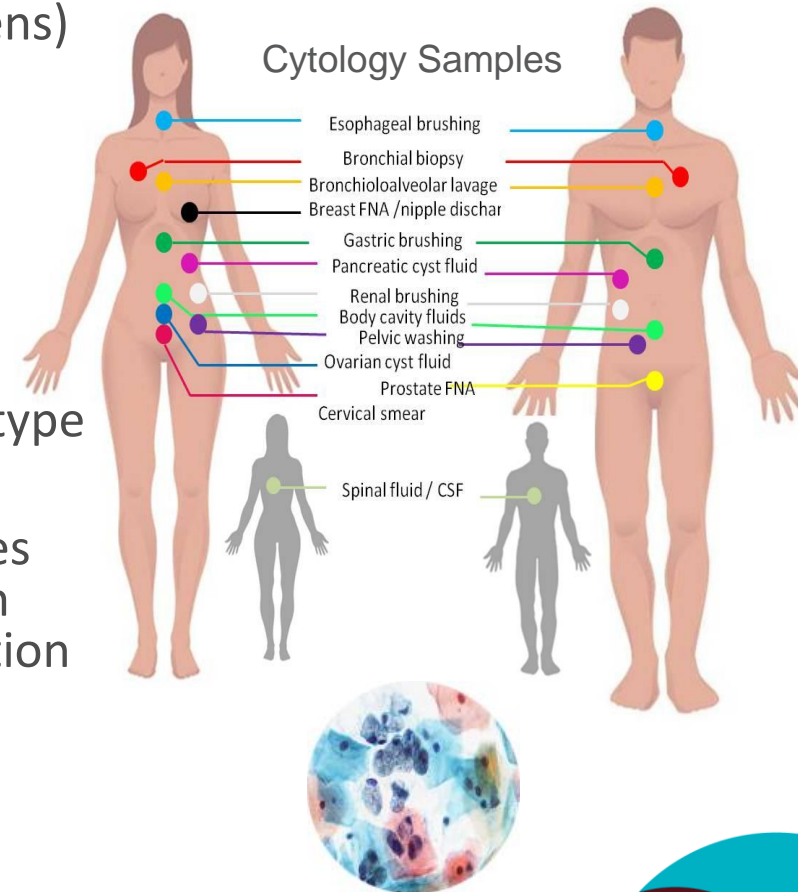
- There are an estimated 1.3m – 1.6m urine cytology tests performed each year in the USA alone for bladder cancer
- With a reimbursement of approximately US\$108.38 per test, Sienna has the ability to participate in a market valued over US\$140 million in the USA in the application of bladder cancer
- With the USA representing approximately 42% of the global cytology tests for bladder cancer Sienna estimates there are approximately 3.5m tests performed globally

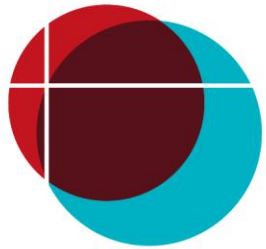
## Sienna's Future Market

- Sienna's products are developed for the global cancer IVD market which is expected to reach US\$8.3b by 2019 with a CAGR of approximately 8%
- Of the overall cancer diagnostics market, the immunoassay and histology/cytology segments are the ones in which Sienna's product is expected to be utilised - these segments represent approximately US\$5b per year
- If Sienna successfully develops and validates additional applications for its telomerase based product, the global market opportunity will expand significantly compared to the bladder cancer market alone

# Expansion Opportunity

- Cytology is a common diagnostic tool in numerous solid cancers (fluid/brush specimens)
- Sienna reagent can be applied to existing laboratory sample collection procedures and technology platforms
- Same reimbursement codes applied independent of cancer indication or sample type
- This will be dependent on which sample types Sienna and its partners determine there is an unmet clinical need addressable by the addition of telomerase ICC testing
- Additional market potential exists for use in histology (tissue samples), which is a larger market opportunity, and a target for future R&D





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# Growth & Investment Highlights



# Investment Highlights



## Path to initial profitability commenced

- Bladder Cancer Application
  - >\$22M Sienna market opportunity in USA alone
  - >\$54M Sienna market opportunity globally

## Potential application expansion for existing product

- Additional cytology applications
  - Bladder Cancer only one of many cancers (~85%) that use telomerase
  - R&D work required but ability to leverage existing regulatory / reimbursement status



## Target customers benefit

- Pathology labs:
  - Deliver better clinical information to referring physicians (globally)
  - Drive profitable revenue growth for their business (reimbursed markets including USA)
  - Become established customers through Bladder Cancer application, then increase utilisation if additional applications are validated



## Lower entry barriers

- USA national reimbursement is \$108 per test, generating revenue for pathology labs
- Sienna test is automation-system neutral, it creates revenue for big diagnostics in IHC / ICC
- Well established laboratory technique, non-disruptive



## Biotech investment with multiple growth opportunities

- Large opportunity for further revenue / profit growth exists through
  - Increased market penetration (# of labs)
  - Increased utilisation (# of urine cytology tests reflexed to Sienna test)
  - Geographical expansion (increased # of new countries entered)
  - Increased # of clinical applications (new cancer / sample types) for hTERT testing
  - Potential for further expansion into histology (tissue sample) applications
  - Technology expansion (additional in-licensed products launched)

# Revenue Growth Map

Initial ASR Launch (USA)	Regulatory (IVD) expansion	Geographical Expansion	Increase Utility	Bus Dev Activity
<p><b>Completed Jan 2015</b></p> <ul style="list-style-type: none"> <li>• Entry to targeted lab for market validation ✓</li> <li>• Generated revenue &amp; product demand ✓</li> <li>• Clinical &amp; business validation ✓</li> <li>• Fast, cost effective market entry ✓</li> </ul>	<p><b>Q4 2016</b></p> <ul style="list-style-type: none"> <li>• Class 1 IVD listed in USA ✓</li> <li>• CE marked IVD registered in EU ✓</li> <li>• IVD product provides access to all labs ✓</li> <li>• Study data to support uptake of IVD in bladder cancer market ✓</li> <li>• Leverage CE mark for TGA registration in Aus. ✓</li> </ul>	<p><b>Q4 2016 &amp; onwards</b></p> <ul style="list-style-type: none"> <li>• Distributors signed for USA, UK &amp; Switzerland ✓</li> <li>• Further distributors to be appointed for sales and marketing in rest of EU</li> <li>• Further expansion into Asia &amp; other markets planned</li> </ul>	<p><b>2017 &amp; onwards</b></p> <ul style="list-style-type: none"> <li>• Clinical data driving further uptake in bladder cancer application</li> <li>• Validate utility in other cytology samples / cancer types</li> <li>• Investigate utility in histology with internal R&amp;D plus external clinical collaboration</li> </ul>	<p><b>2017 &amp; onwards</b></p> <ul style="list-style-type: none"> <li>• Additional diagnostic biomarkers for Sienna pipeline</li> <li>• Leverage existing expertise &amp; infrastructure</li> <li>• Potential for strategic alliances with large Diagnostics companies</li> </ul>

# Recent IPO (ASX : SDX)

IPO Capital Structure	
Issuer	Sienna Cancer Diagnostics
# shares issued at listing	~23m
Funds Raised in IPO	~\$4.6m
Total shares on issue	~180m
Market Cap. at listing @ \$0.20	~\$36m

Use of Funds	\$m
Complete additional clinical studies and undertake sales & marketing activity to increase the uptake of the IVD product in the bladder cancer applications	(1.58)
Internal and external research and development to validate additional clinical applications	(1.59)
Business development to expand the use of the IVD geographically	(0.28)
Introduce new technologies to Sienna's product pipeline	(1.02)
Expenses of the offer and capital purchases	(0.79)
Working capital	(1.78)
R&D Tax Incentive Refunds	1.71
Existing Cash	0.73
<b>Total</b>	<b>(4.6)</b>

# Contact Details

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## Sienna Cancer Diagnostics

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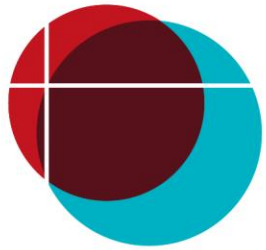
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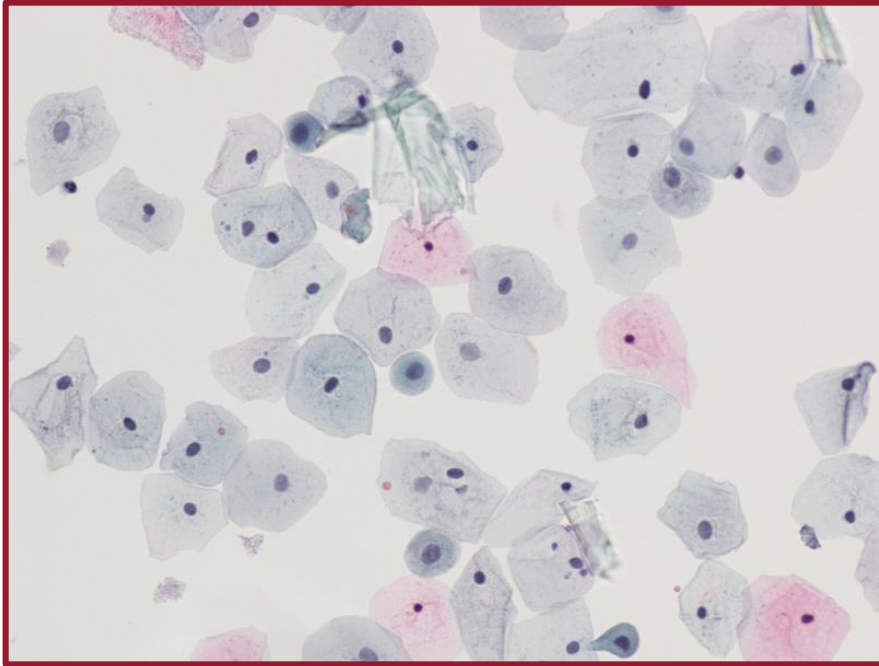


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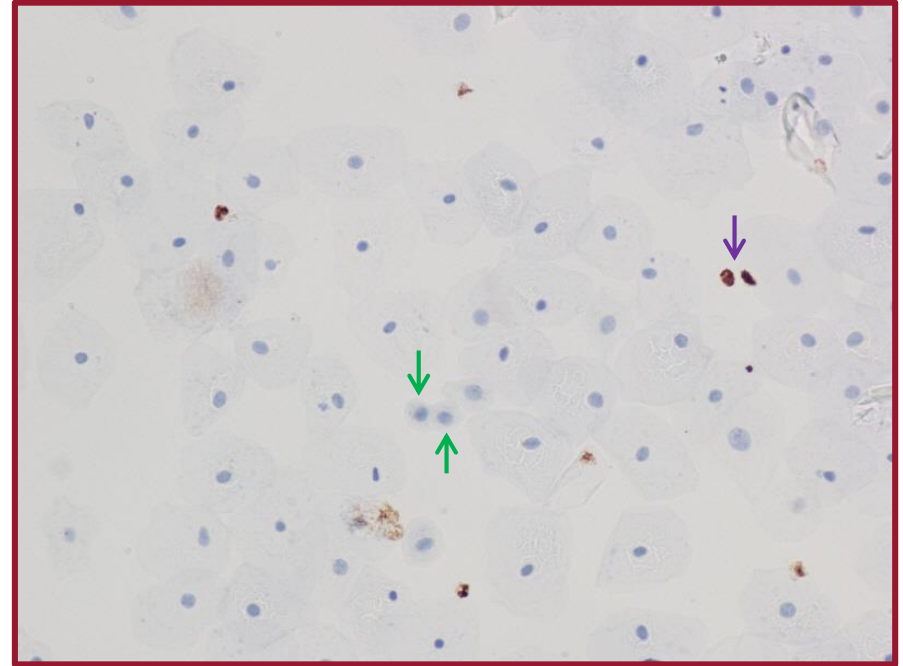
# Appendix 1

# Case Study A

## Cytology



## hTERT ICC



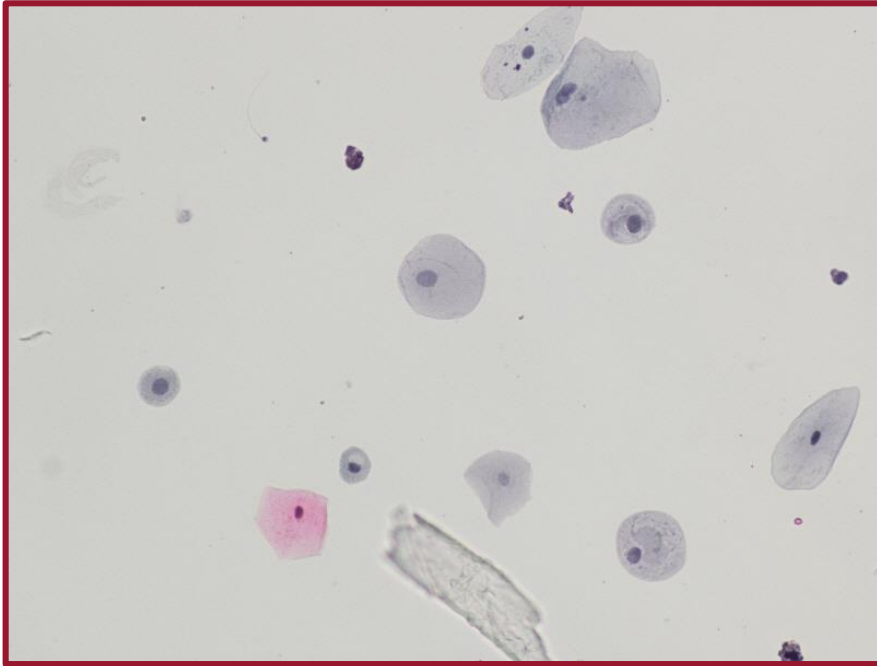
## Breakdown of diagnosis

Cytology: Negative  
hTERT ICC: Negative  
Clinical Diagnosis: Negative

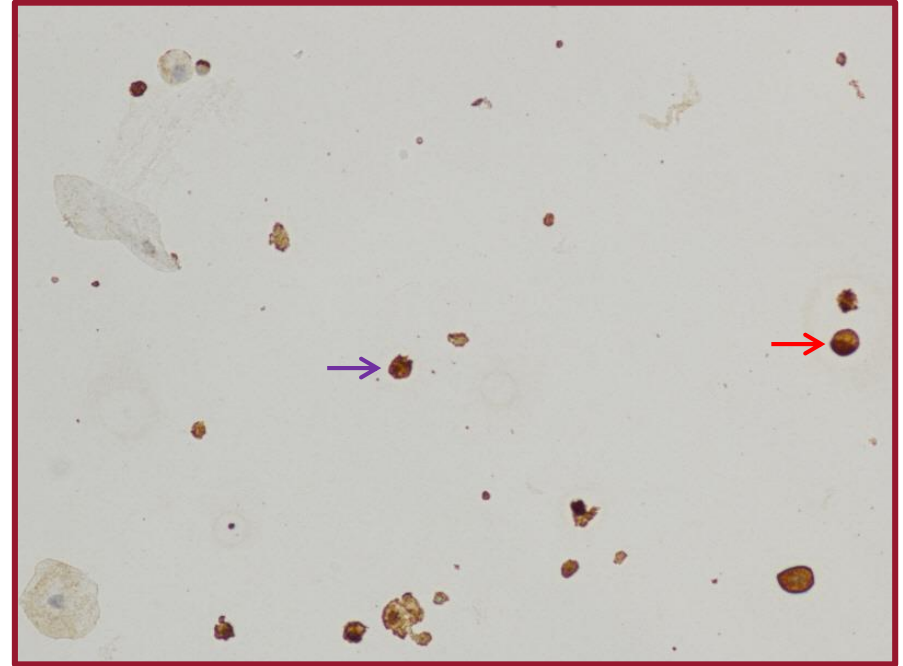
hTERT detected in infiltrating lymphocytes (purple arrow). No hTERT was detected in urothelial cells (green arrow).

# Case Study B

## Cytology



## hTERT ICC



## Breakdown of diagnosis

Cytology: Negative

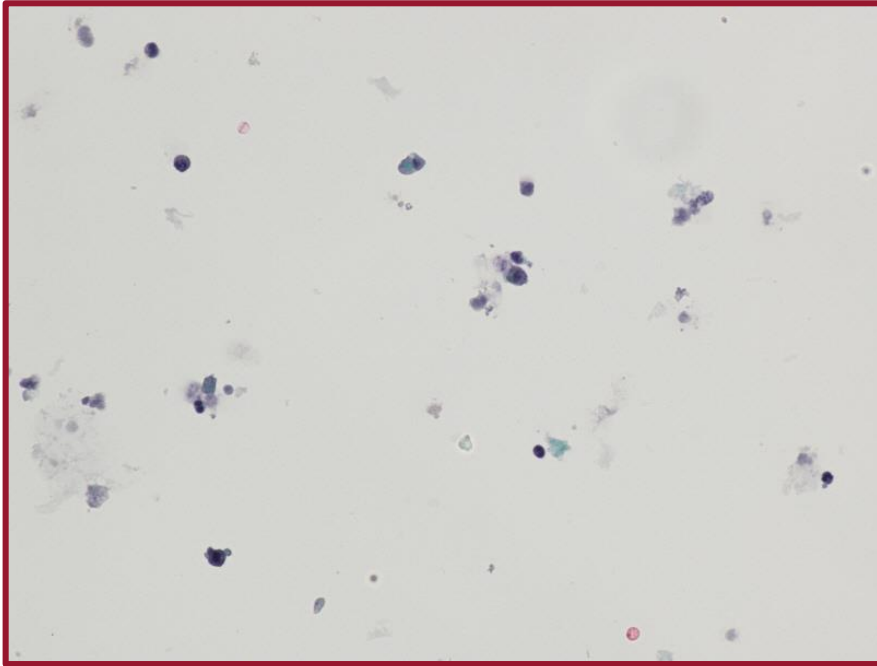
hTERT ICC: Positive

Clinical Diagnosis: Cystoscopy Positive

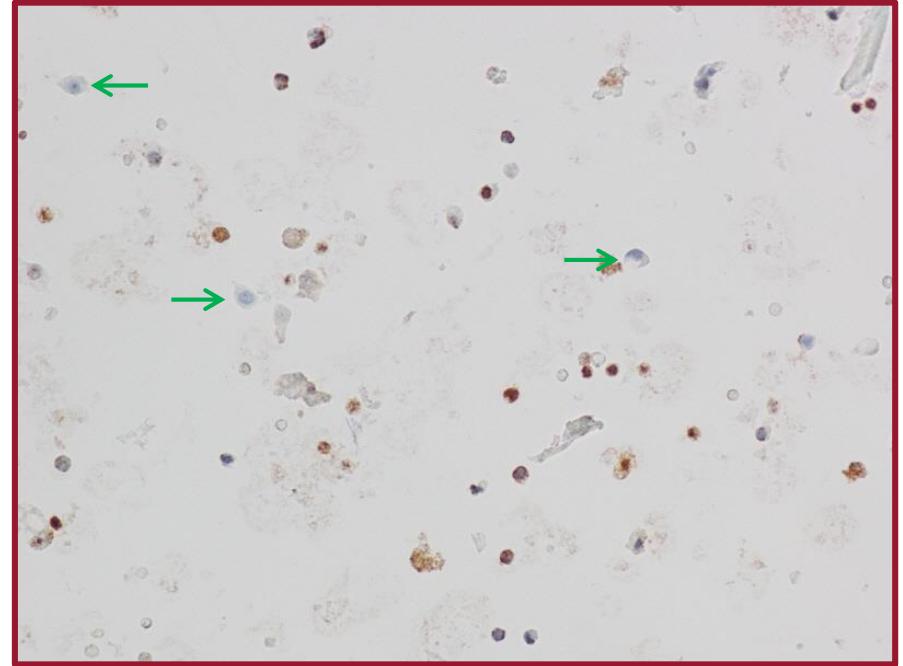
hTERT detected in abnormal urothelial cells (**red** arrow) and infiltrating lymphocytes (**purple** arrow).

# Case Study C

## Cytology



## hTERT ICC



Urothelial cells remain hTERT negative (green arrow)

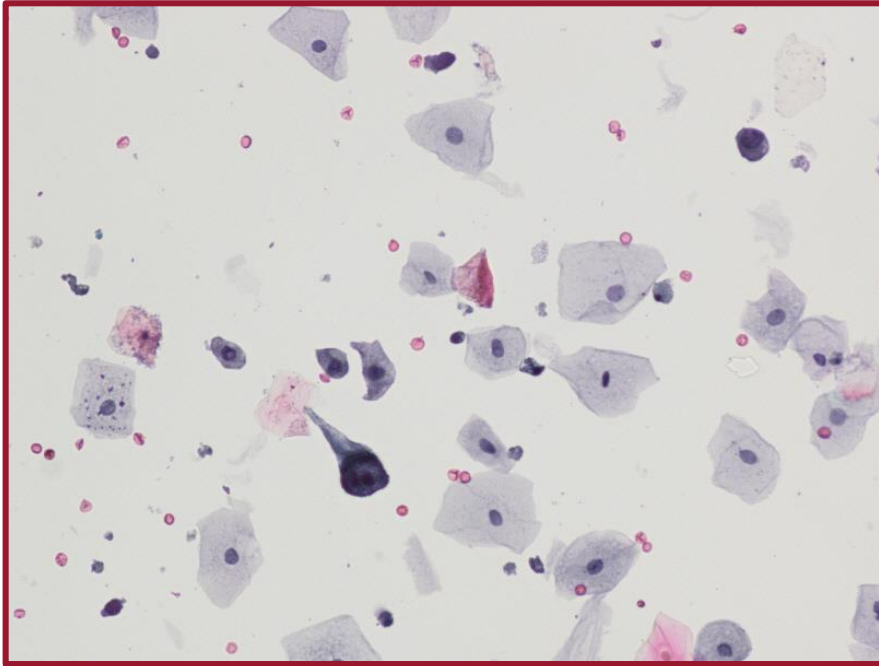
## Breakdown of diagnosis

Cytology: Atypical Urothelial Cells (AUC)  
hTERT ICC: Negative  
Clinical Diagnosis: Negative

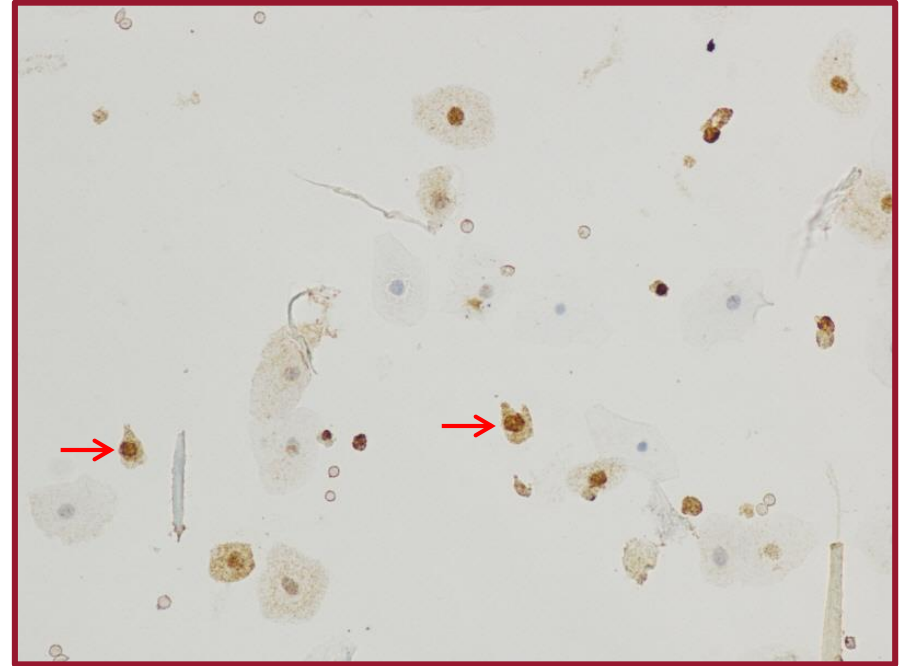


# Case Study D

## Cytology



## hTERT ICC



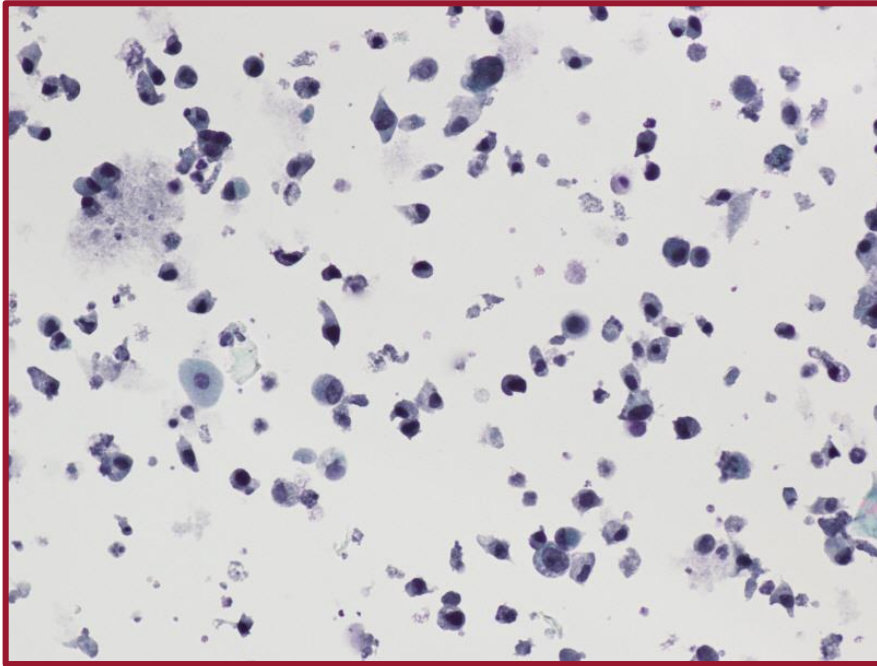
hTERT detected in abnormal urothelial cells (**red** arrow).

## Breakdown of diagnosis

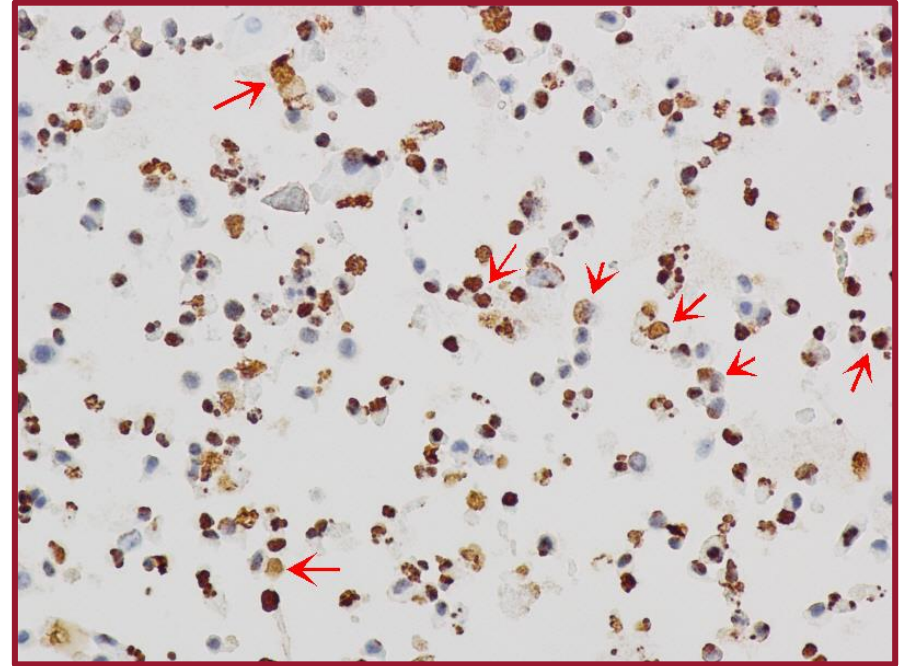
Cytology: Atypical Urothelial Cells (AUC)  
hTERT ICC: Positive  
Clinical Diagnosis: Biopsy Dx Positive

# Case Study E

## Cytology



## hTERT ICC



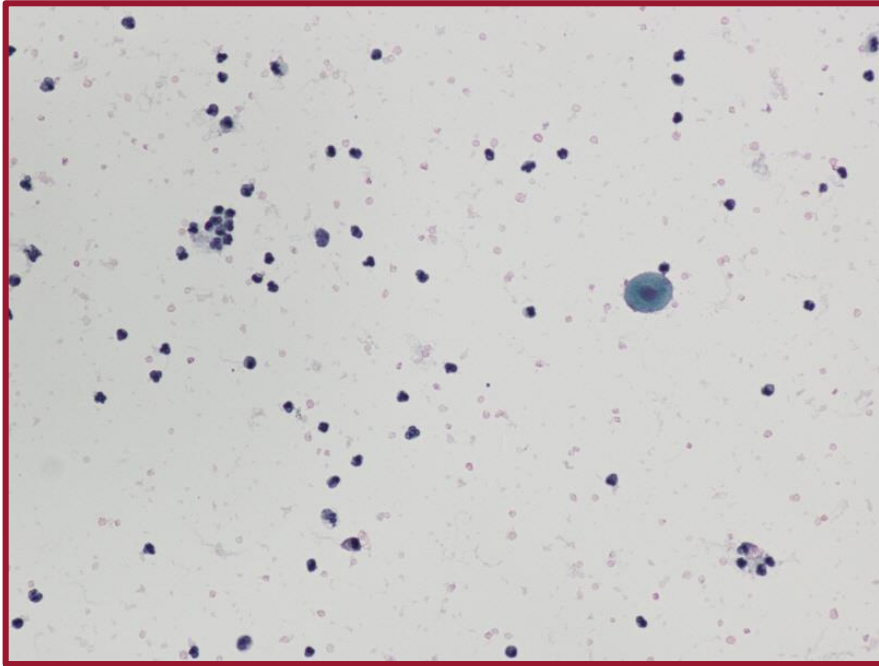
hTERT detected in abnormal urothelial cells (red arrow).

## Breakdown of diagnosis

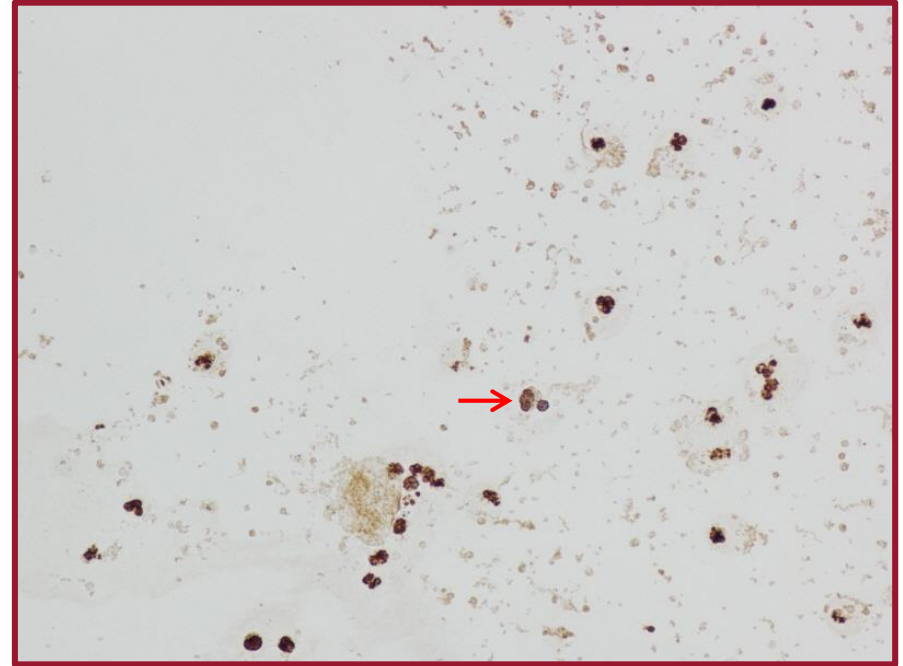
Cytology: High Grade Urothelial Carcinoma (HGUC)  
hTERT ICC: Positive  
Clinical Diagnosis: Biopsy Dx Positive followed by  
cystectomy

# Case Study G

## Cytology



## hTERT ICC



hTERT detected in abnormal urothelial cells (**red** arrow).

## Breakdown of diagnosis

Cytology: Atypical Urothelial Cells (AUC)

hTERT ICC: Positive

Clinical Diagnosis: Biopsy Dx Positive (Ta G3)