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Sienna Cancer Diagnostics

Results – Financial Year ending 30 June 2017

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Financial Results and Commentary

Financial Overview

Profit And Loss Statement ($'000s)	FY16	FY17
Product Revenue	**641**	**804**
Total Revenue (including product, r&d tax refund & interest)	1,344	1,457
Cost of Sales	(102)	(45)
Gross Profit	**1,242**	**1,412**
Administration Expenses	(706)	(883)
Employee Expenses	(1,487)	(1,380)
Direct R&D Expenses	(406)	(500)
Capitalised R&D	881	656
Net Profit/(Loss) Before Tax	**(477)**	**(695)**

- +25%. StatLab sales efforts started March 2017

- 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)	30 June 2017
Cash	720
Other Current Assets	353
Non-current Assets	2,303
Total Assets	3,376
Liabilities	732
Net Assets	**2,644**

- The balance of cash at 31 August 2017 was approximately $4.2 million.

Revenue Commenced

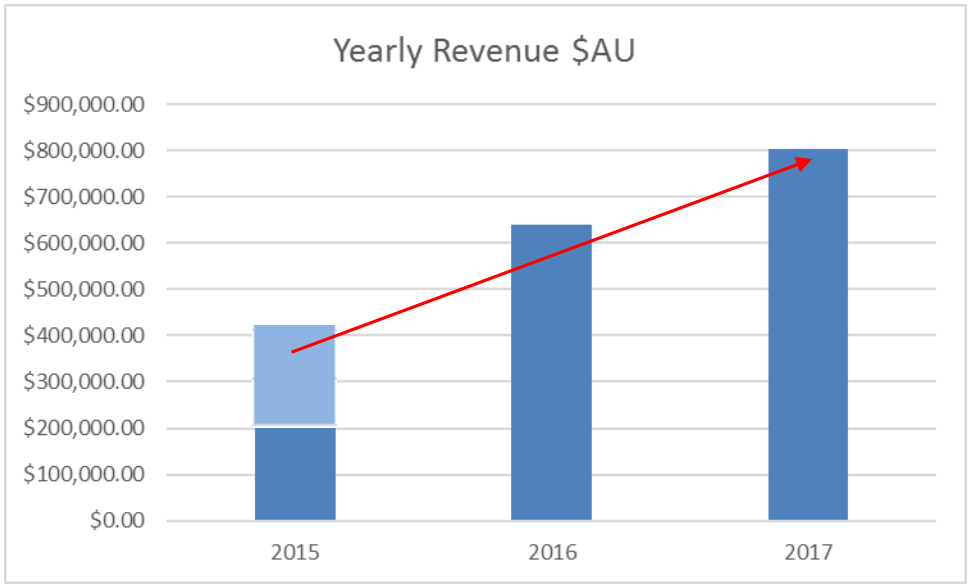
Initial Sales Growth:

Revenue FY 15 = $213K (half year only) Reported as $304K including an up-front

Revenue FY 16 = $641K (first full year, 1 lab only)

Revenue FY 17 = $804K (+25% growth over prior year)

StatLab sales force commenced selling March 2017



"We've already generated initial sales and we are still only a few months after launch. I expect significant growth over the next couple of years as the market awareness and acceptance of this new and clinically useful test increases."

- Dr Mark Rees, VP StatLab Medical Products

Sienna's Largest Market – The USA

Prior to the commercial launch of the IVD product, Sienna had derived product income from a single strategic laboratory partner using a pre-IVD version of the test in the USA.

In the last 4 months of FY2017 Sienna's US distribution partner, StatLab Medical Products, began selling the IVD registered product, targeting pathology laboratories who perform urine cytology testing.

- priority targets are large volume private pathology labs & leading academic institutions performing urine cytology

> "As well as delivering real value to our customers and patients, this product is a significant growth opportunity for our advanced diagnostics business."
>
> - Dr Mark Rees, VP StatLab Medical Products

The sales process involves:

- Educating pathologists in target labs about the new test
- The customer agreeing to evaluate the test in their lab
- Acquiring samples, optimising the test on customer equipment, and reviewing results with the pathologists
- Commercial agreement reached between StatLab & the customer
- The pathology laboratory marketing the new service (test) to urologists

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Company & Technology 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	~$4.2m
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 & Merrilyn 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

Geoffrey Cumming (BSc (Hons), BAppSc, MAICD, MBA, PhD)		Non-Executive Chairman	- Geoff has held senior roles in the global healthcare and biotechnology sector for more than 20 years - 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) - Currently a NED of Anteo Diagnostics Ltd and Medical Australia Ltd (ASX: MLA)
Matthew Hoskin (BAppSc)		Chief Executive Officer	- 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 - 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)
David Earp (JD PhD)		Non-Executive Director	- Originally a partner in an IP law firm, advising life science clients - 1999 - 2012 served in various roles at Geron Corporation (California, NASDAQ- listed), including chief patent counsel, chief legal officer and senior VP - Former NED of TA Therapeutics Ltd (HK), ViaGen Corporation (Texas) as Executive Chairman, currently President & CEO of Circle Pharma.

Board and Management Team (cont'd)

Personnel Overview

John Chiplin (BPharm PhD)		Non-Executive Director	- Former CEO of Polynoma LLC, a US based cancer immunotherapy company - Former founding CEO of ASX-listed Arana Therapeutics Ltd (now Teva) - Former head of the UK's $300m ITI Life Science investment fund - 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)
Carl Stubbings (BSc)		Non-Executive Director	- Considerable experience commercialising diagnostic products, both locally and globally - Based in USA, served as VP of Sales & Marketing for Focus Diagnostics (subsidiary of Quest Diagnostics) - Held roles at Benitec Biopharma Ltd (ASX-listed) as Chief Business Officer, Head of Commercialisation at BCAL Diagnostics (blood test for breast cancer developer). - NED of Analytica Medical Ltd (ASX) and Otakaro Pathways (NZ) developing a diagnostic test for Crohn's disease
Tony Di Pietro (B.Com, CPA, AGIA)		Chief Financial Officer and Company Secretary	- CPA accredited accountant with over 15 years of corporate accounting experience, gained both in Australia and the United Kingdom - Holds a Graduate Diploma of Applied Corporate Governance from the Governance Institute of Australia - 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

Sienna's Technology Platform

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

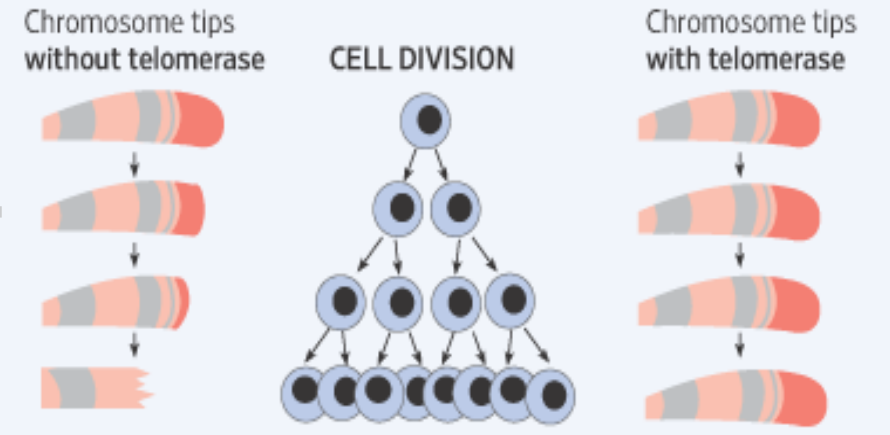


Image source: The Nobel Committee for Physiology or Medicine

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

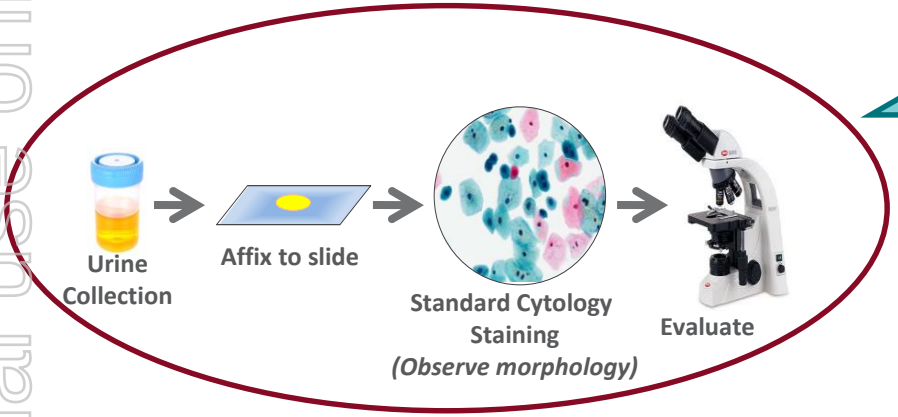
Sienna's test to identify hTERT in urothelial cells; used in conjunction with urine cytology

- ✓ 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 exiting reimbursement

Enhancing Current Clinical Practice

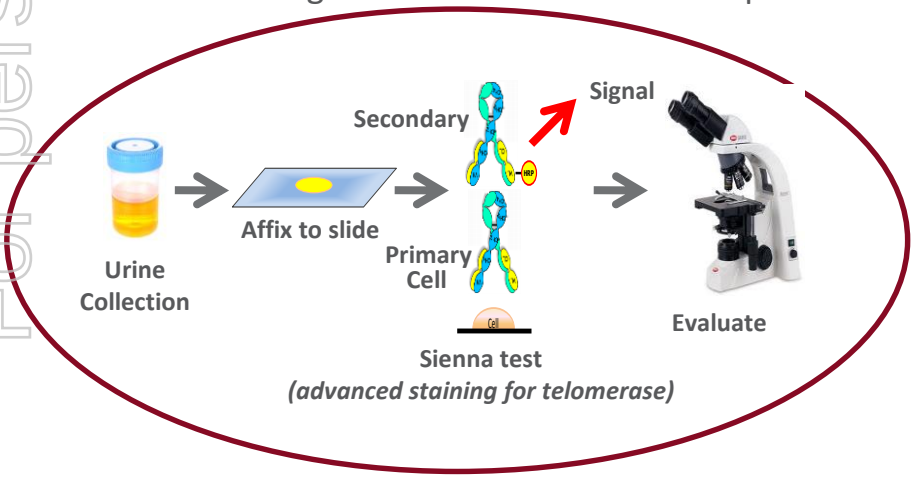
Urine Cytology

Observing for cancer cells from urine sample

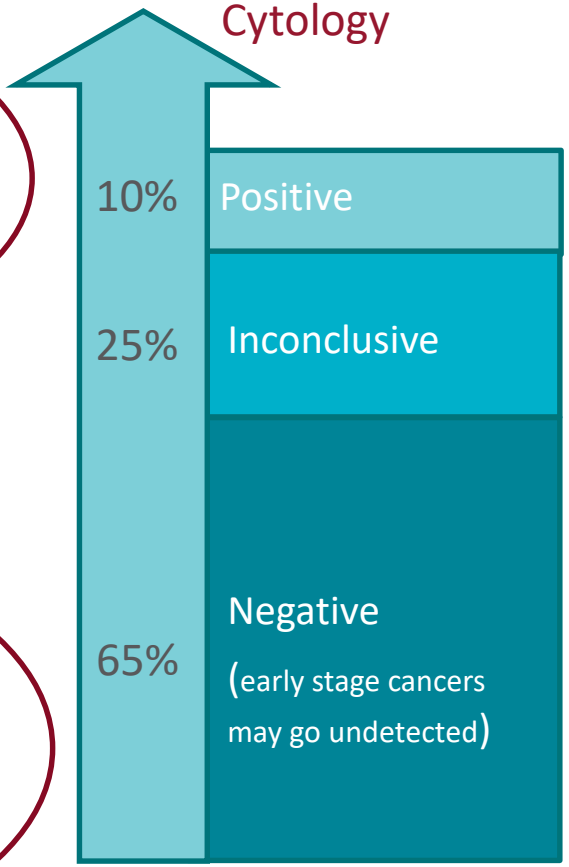


Urine Cytology + Sienna ICC Stain

Observing telomerase from urine sample



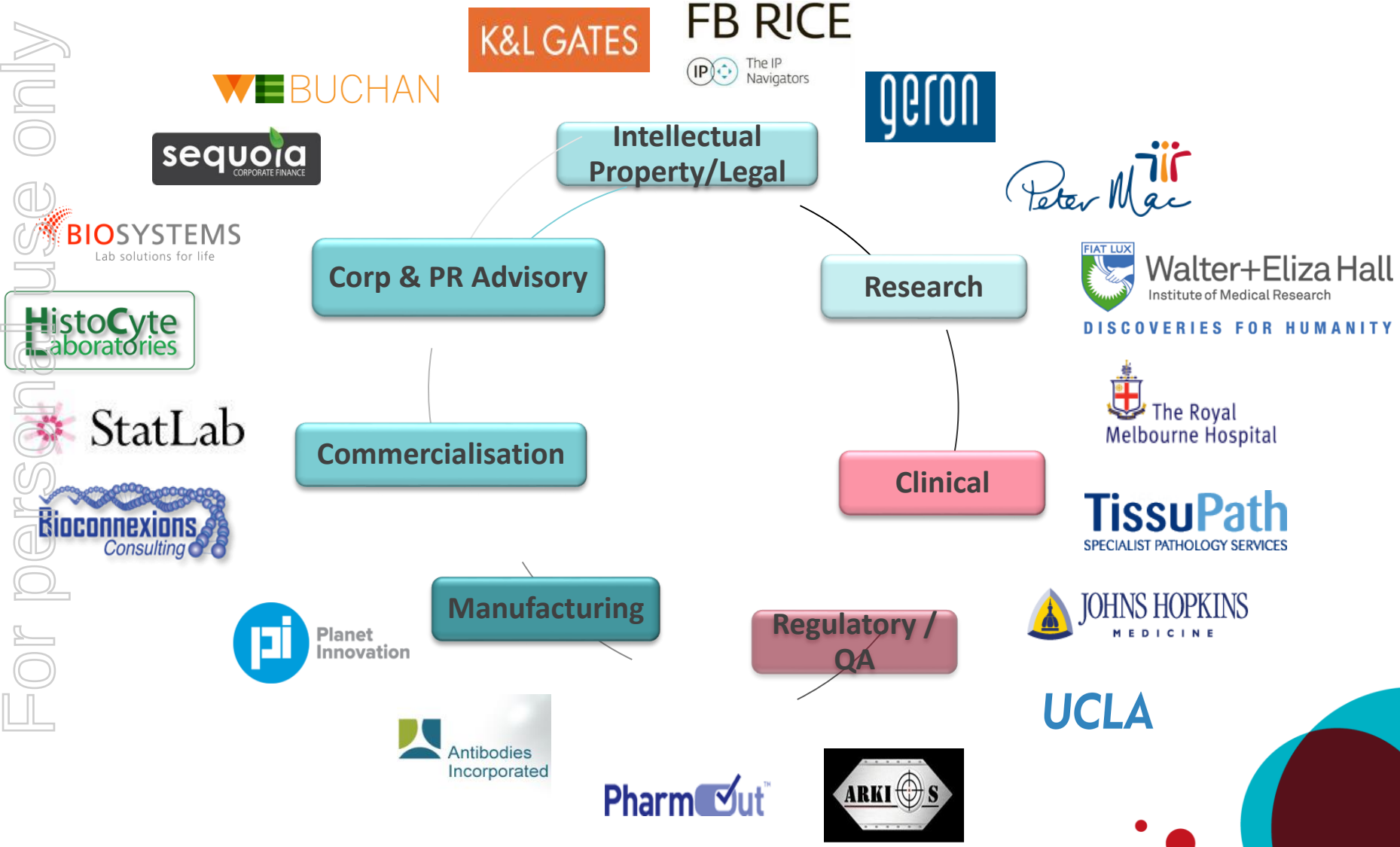
Bladder Cancer Detection From Standard Urine Cytology



Potential Benefits of Sienna Test

- Match
- Resolve
- Improve

Sienna's Partner Network



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Market Opportunity

Addressable Market

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

"The hTERT assay is a unique test which is now a key growth driver for the StatLab advanced staining business in the US."

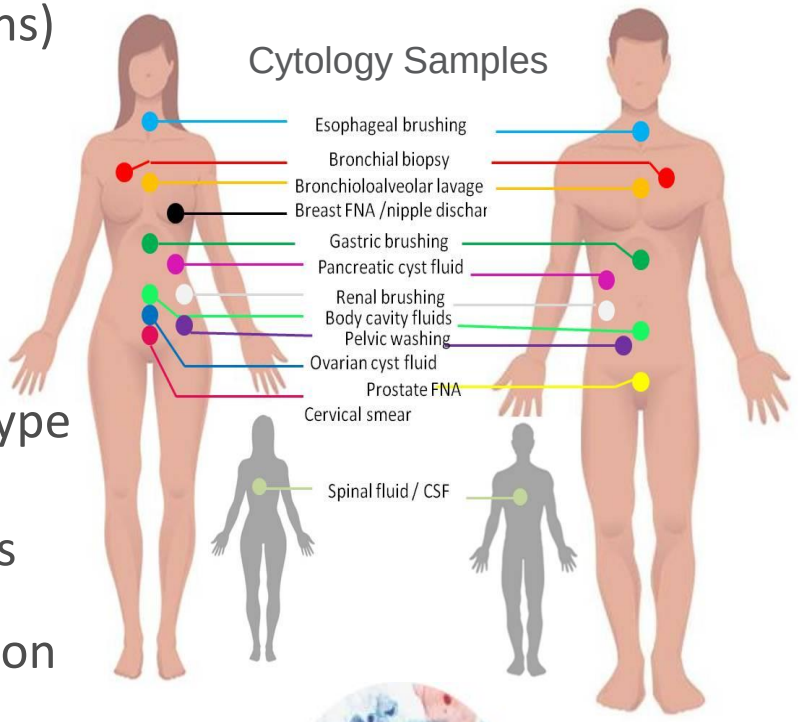
- Dr Mark Rees, VP StatLab Medical Products

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
Completed Jan 2015	**Q4 2016**	**Q4 2016 & onwards**	**2017 & onwards**	**2017 & onwards**
• Entry to targeted lab for market validation ✓	• Class 1 IVD listed in USA ✓	• Distributors signed for USA, UK & Switzerland ✓	• Clinical data driving further uptake in bladder cancer application	• Additional diagnostic biomarkers for Sienna pipeline
• Generated revenue & product demand ✓	• CE marked IVD registered in EU ✓	• Further distributors to be appointed for sales and marketing in rest of EU	• Validate utility in other cytology samples / cancer types	• Leverage existing expertise & infrastructure
• Clinical & business validation ✓	• IVD product provides access to all labs ✓	• Further expansion into Asia & other markets planned	• Investigate utility in histology with internal R&D plus external clinical collaboration	• Potential for strategic alliances with large Diagnostics companies
• Fast, cost effective market entry ✓	• Study data to support uptake of IVD in bladder cancer market ✓			
	• Leverage CE mark for TGA registration in Aus. ✓			

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
Total	**(4.6)**

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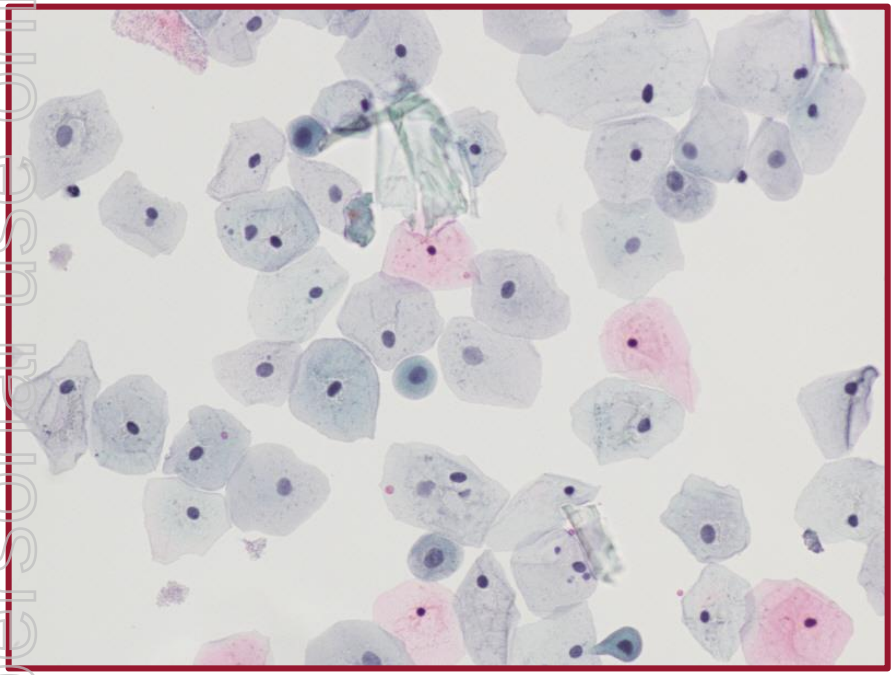
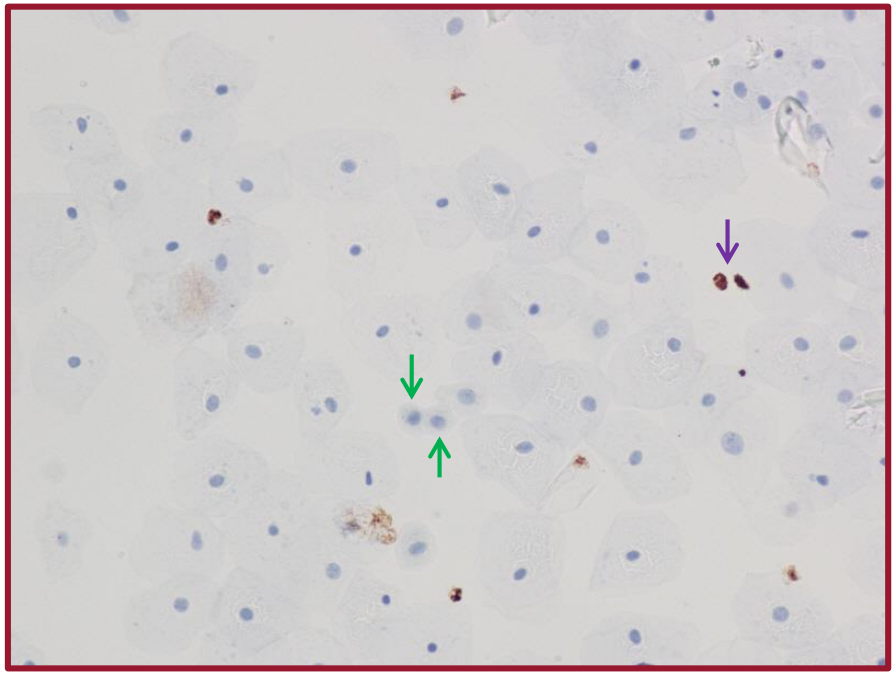
Appendix 1

Case Study A

Cytology



hTERT ICC



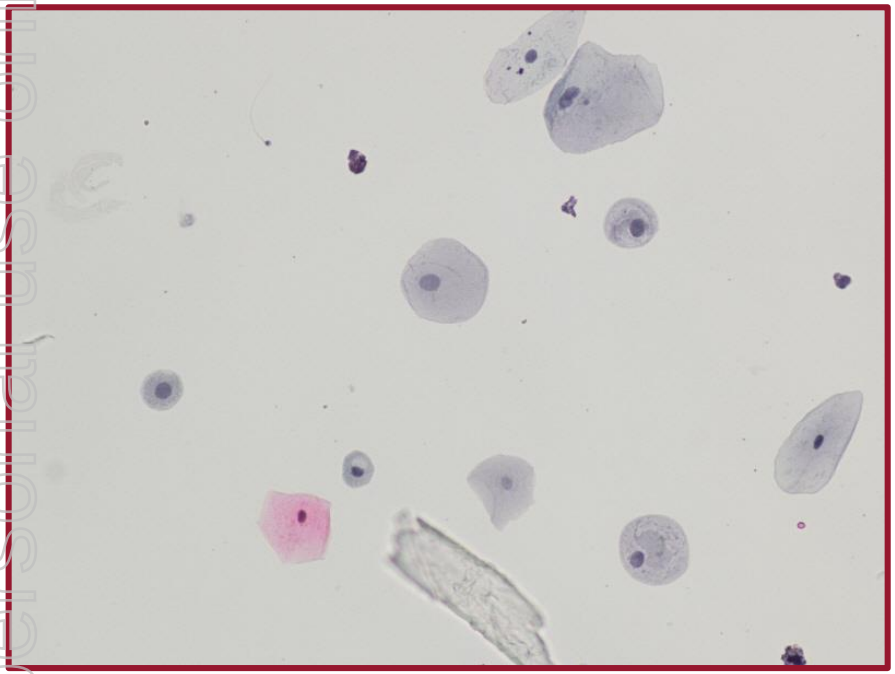
hTERT detected in infiltrating lymphocytes (**purple** arrow). No hTERT was detected in urothelial cells (**green** arrow).

Breakdown of diagnosis

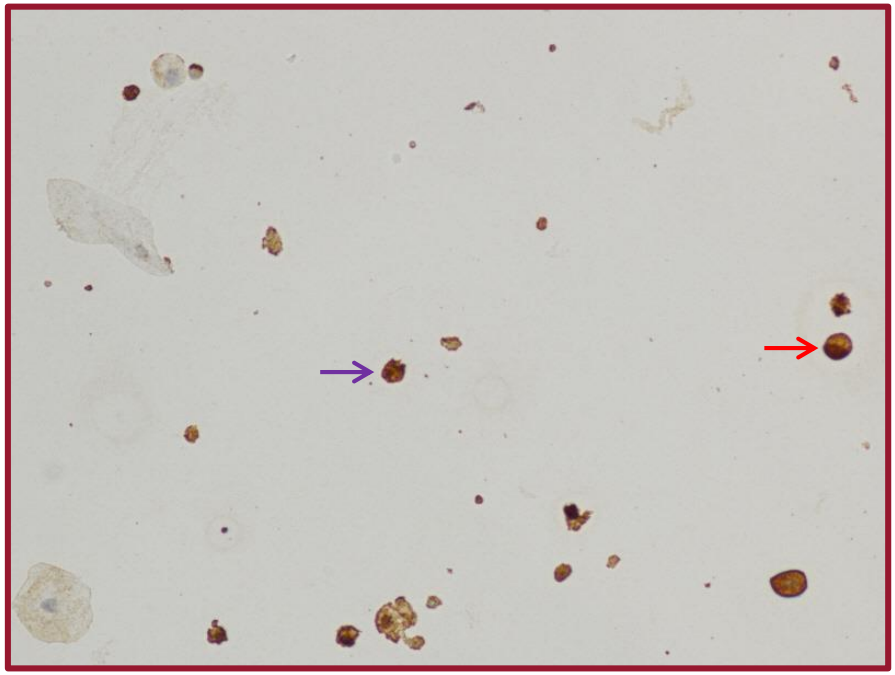
Cytology: Negative
hTERT ICC: Negative
Clinical Diagnosis: Negative

Case Study B

Cytology



hTERT ICC



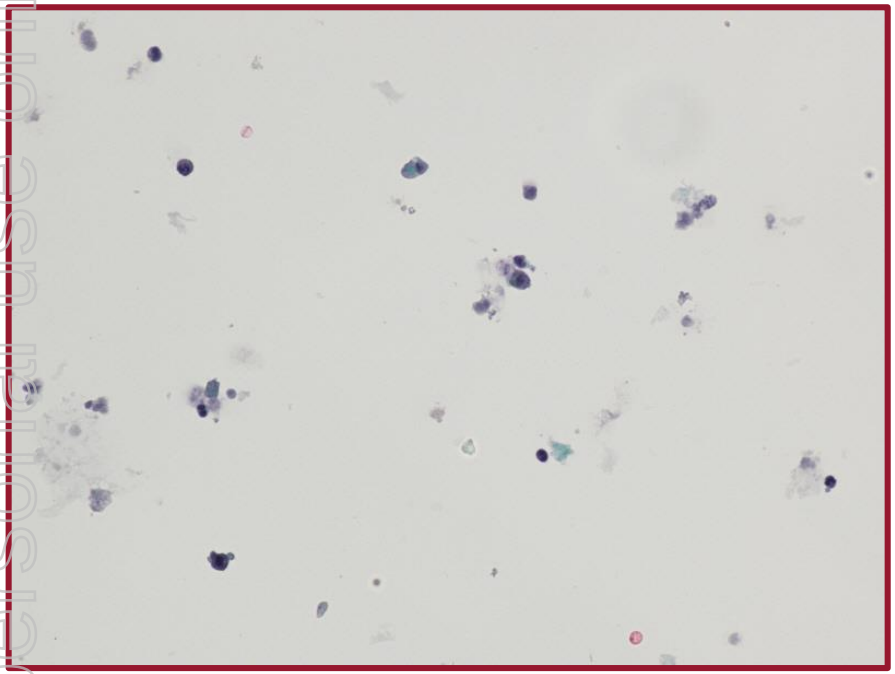
hTERT detected in abnormal urothelial cells (**red** arrow) and infiltrating lymphocytes (**purple** arrow).

Breakdown of diagnosis

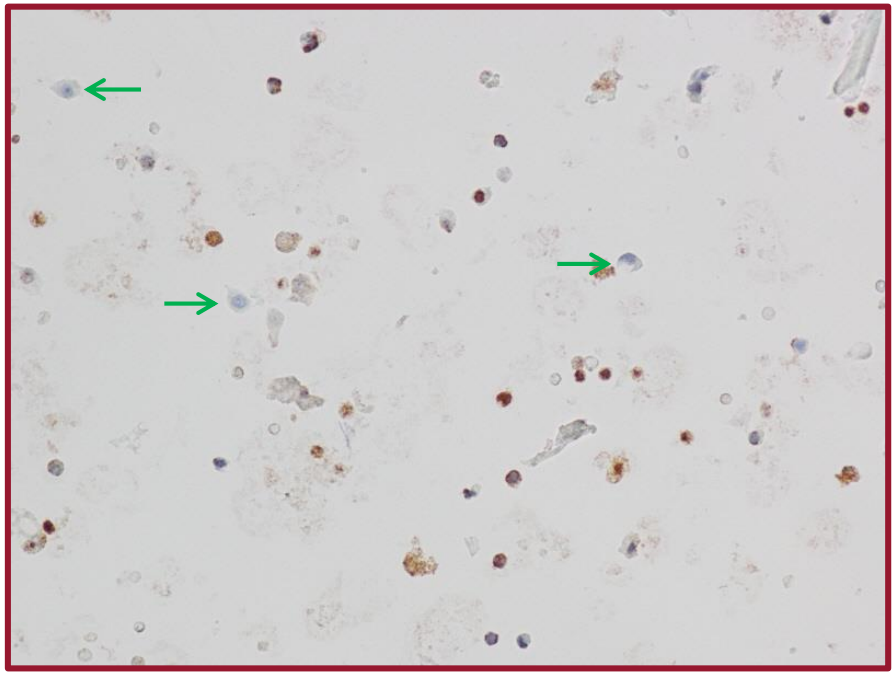
Cytology: Negative
hTERT ICC: Positive
Clinical Diagnosis: Cystoscopy Positive

Case Study C

Cytology



hTERT ICC



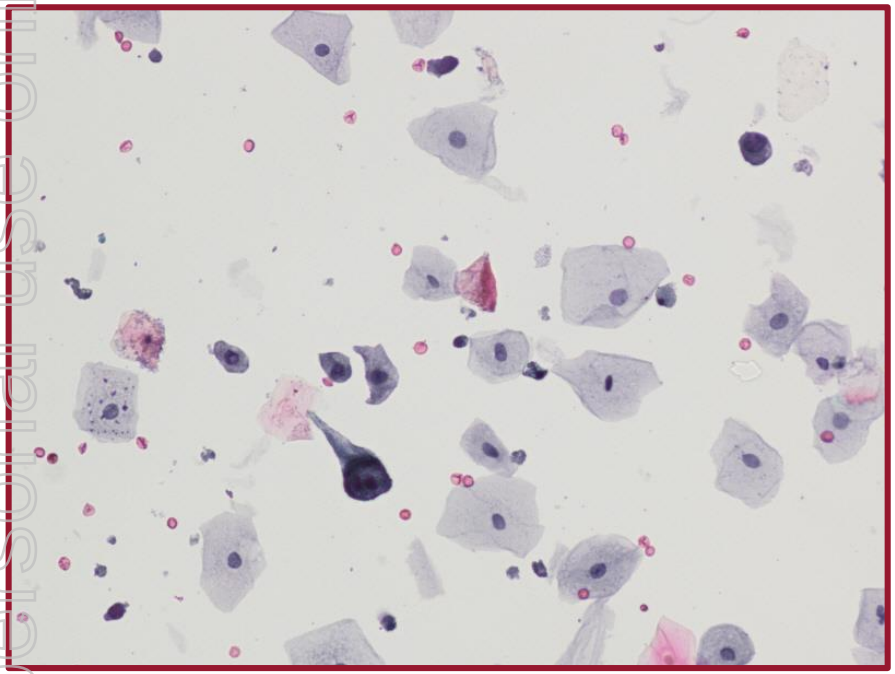
Urothelial cells remain hTERT negative (**green** arrow)

Breakdown of diagnosis

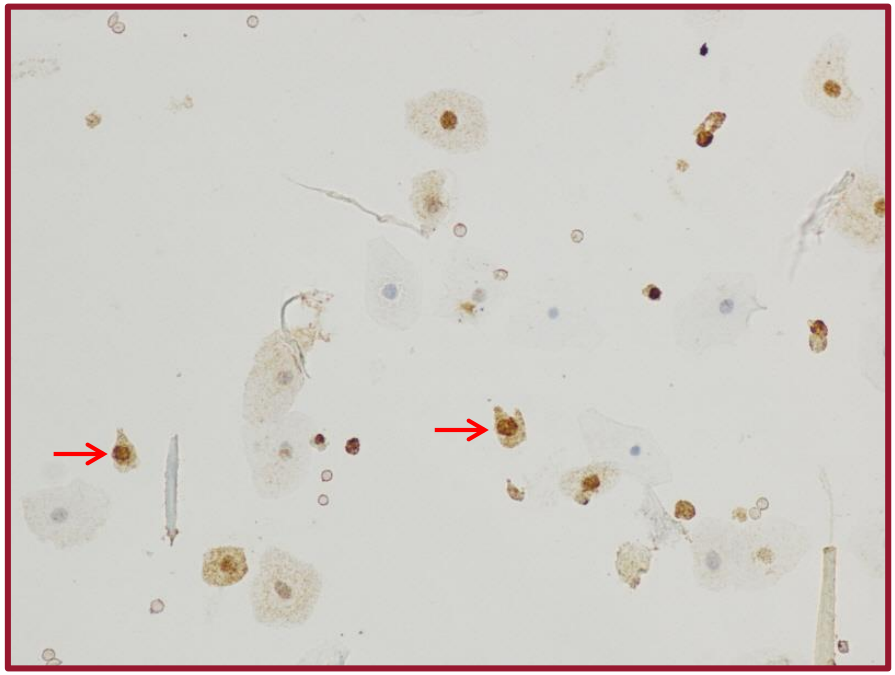
Cytology: Atypical Urothelial Cells (AUC)
hTERT ICC: Negative
Clinical Diagnosis: Negative

Case Study D

Cytology



hTERT ICC



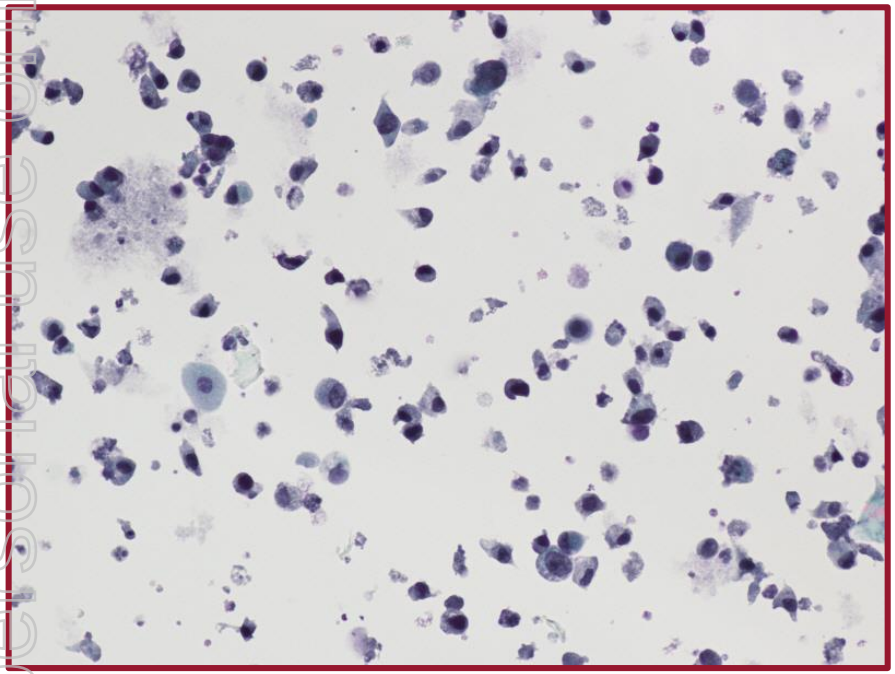
hTERT detected in abnormal urothelial cells (**red** arrow).

Breakdown of diagnosis

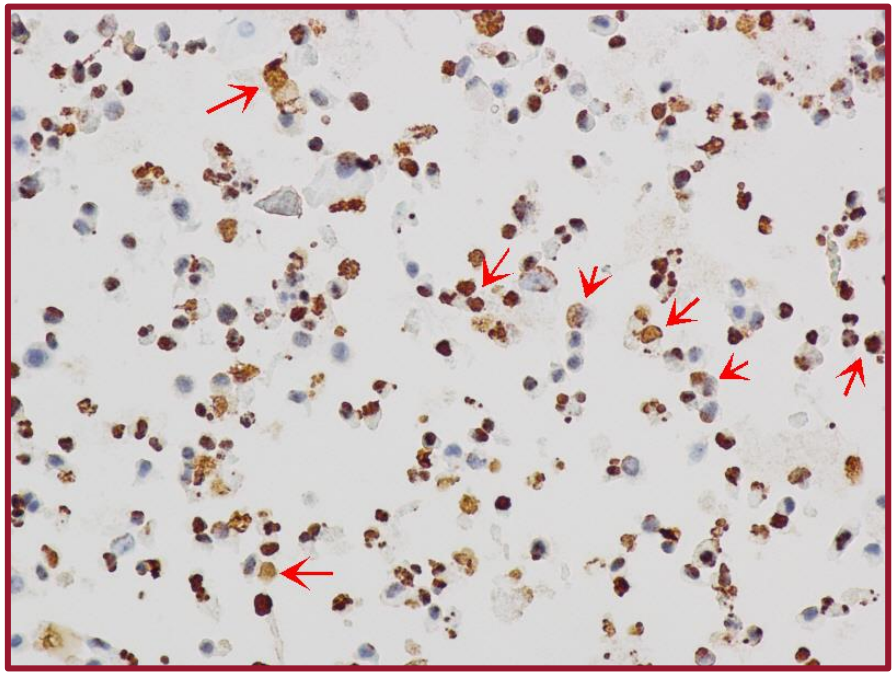
Cytology: Atypical Urothelial Cells (AUC)
hTERT ICC: Positive
Clinical Diagnosis: Biopsy Dx Positive

Case Study E

Cytology



hTERT ICC



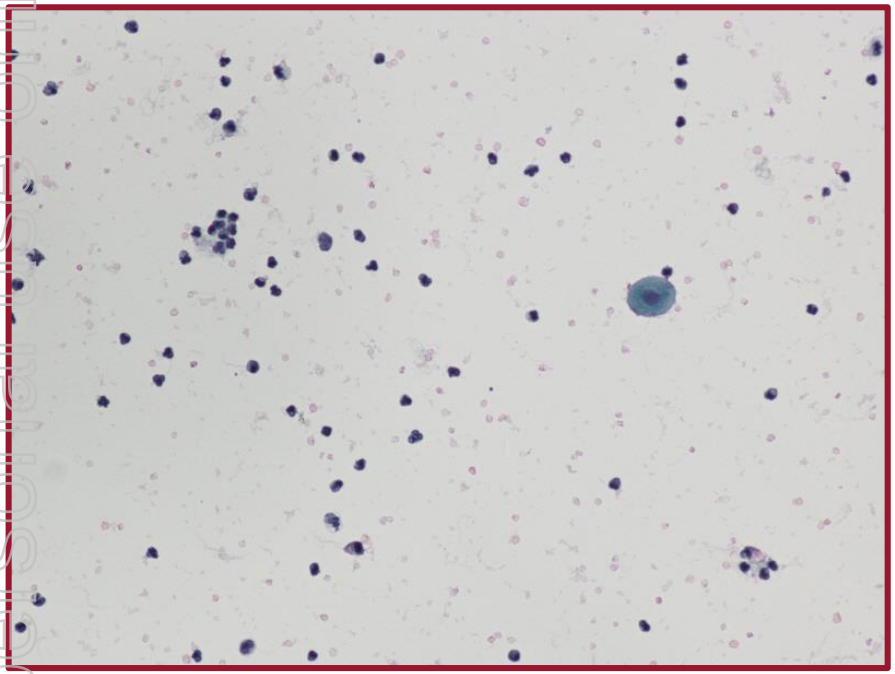
hTERT detected in abnormal urothelial cells (**red** arrow).

Breakdown of diagnosis

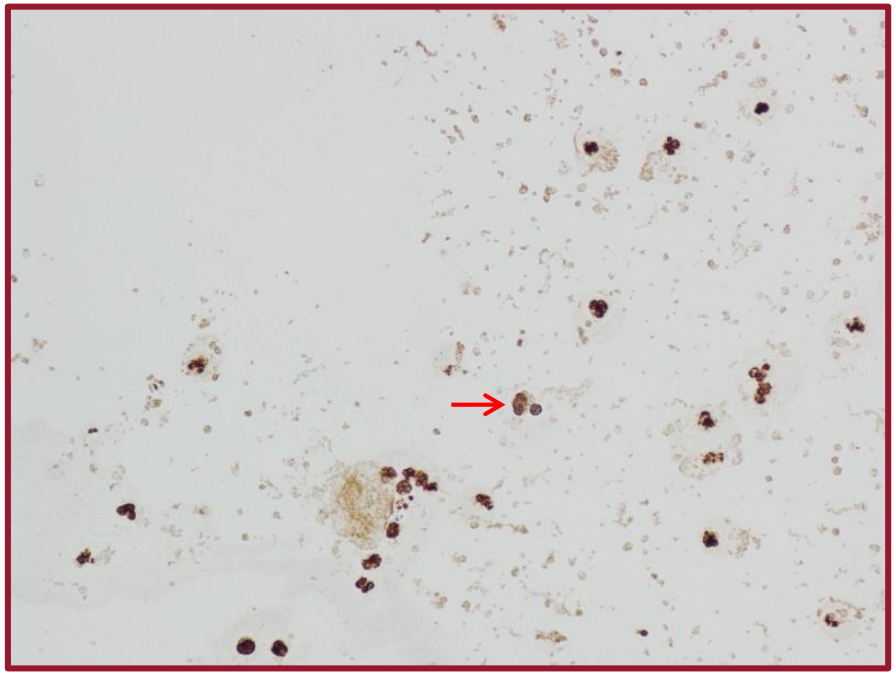
Cytology: High Grade Urothelial Carcinoma (HGUC)
hTERT ICC: Positive
Clinical Diagnosis: Biopsy Dx Positive followed by cystectomy

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)