HistoCyte Laboratories

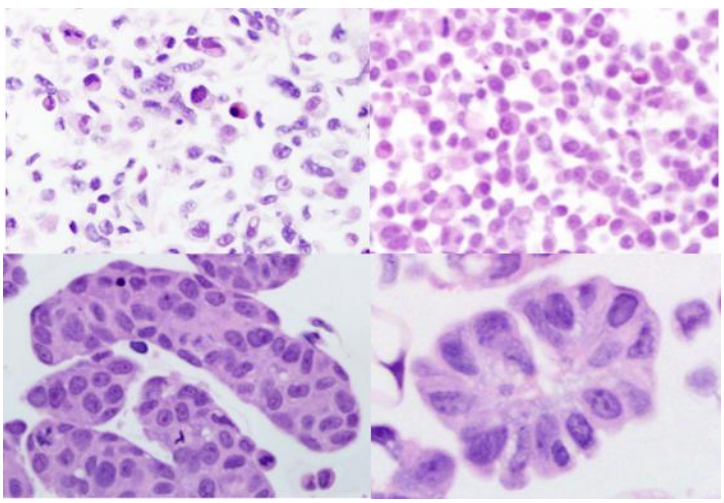
Quality in Control

Anti-hTERT Antibody (SCD-A7)

Product Code: HCL025

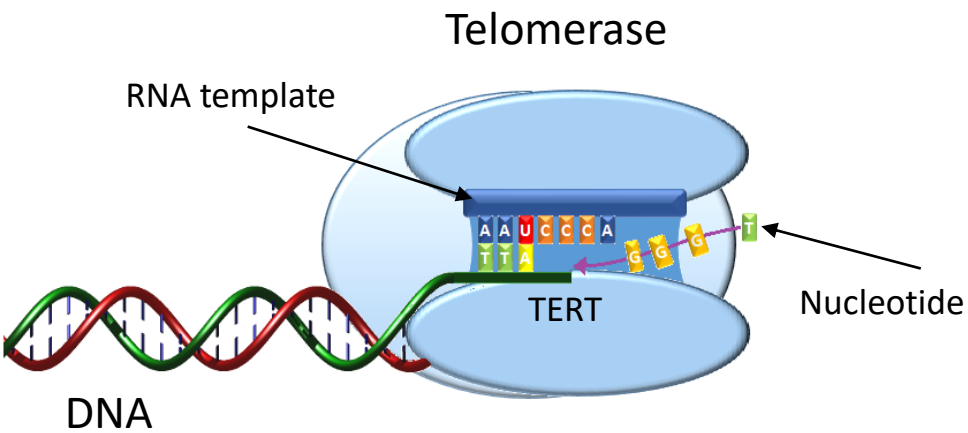
Contents

HistoCyte Laboratories Ltd is based in the heart of the Newcastle University campus. Started in 2014 by scientists with a combined experience of over 30 years in the development of reagents for immunohistochemistry and in-situ hybridization. Collaborating with pathologists locally and globally, HistoCyte Laboratories Ltd develops and supplies a range of cost effective products designed to help scientists to maintain and develop the quality of assays within their laboratory.



hTERT and Telomerase

Telomerase is a ribonucleoprotein that adds repeats (TTAGGG) to the telomere ends thus maintaining their integrity. The catalytic component of telomerase is known as the human telomerase reverse transcriptase (hTERT). By continually adding repetitive DNA sequences the natural degradation of the chromosomal ends is prevented thus enabling replication to carry on unchecked. It has been reported that in almost 90% of human cancers telomerase can be observed and therefore considered a critical step in carcinogenesis.[1]



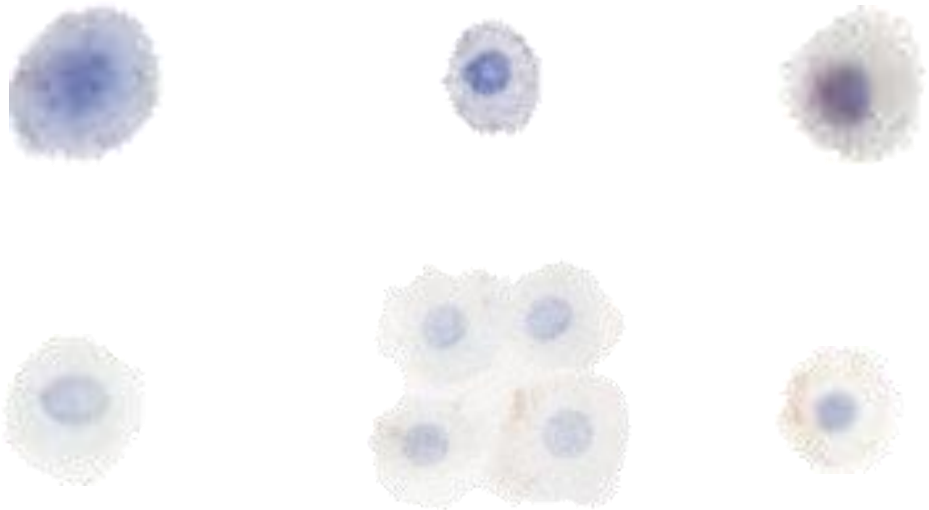
Sienna Cancer Diagnostics have developed an assay to hTERT using the clone SCD-A7. This is the only IVD antibody for the detection of hTERT using immunocytochemistry. Available in 1ml concentrates this provides approximately 100 tests (at 1/10) on the Ventana Benchmark applied to Cytospin preps.

Format	Product Code
1ml	HCL025

sienna
CANCER DIAGNOSTICS

1. Oncogene (2002) **21,** 688-697

Negative hTERT

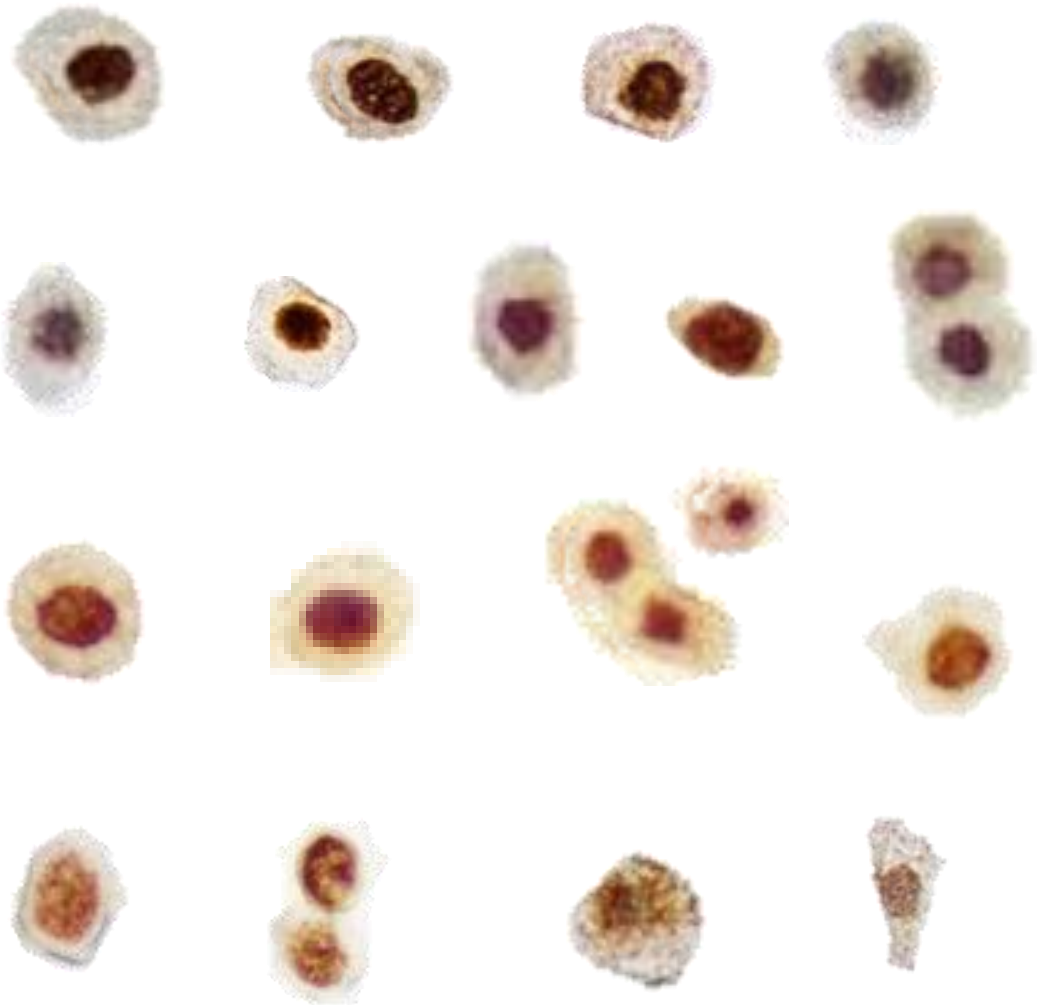


In these cells there is an absence of staining in the nuclei indicated by the blue colour. Therefore these are considered hTERT negative.

Sometimes there is cytoplasmic staining ranging from blushing through to punctate speckling.

This observation is considered negative relative to the hTERT status of the cell(s).

Positive hTERT



Positive hTERT staining covers a spectrum of staining intensities and patterns but the defining feature is localisation in the nucleus. From the examples above this can be intense, entire-nuclear staining through to diffuse punctate staining.

Guidance and additional data

It is important that assessment is conducted by a cytopathologist or equivalently qualified and experienced person. Optimisation and validation are critical to adoption and must be conducted by those personnel experienced in immunocytochemistry.

Adjunct with Cytology

Sienna Cancer Diagnostics have validated SCD-A7 for IVD use. Their data has demonstrated that when used as an adjunct with cytology, sensitivity of detection increased from 16%-74%. (Cases were confirmed for presence of cancer by cystoscopy). In addition used together with cytology it had a negative predictive value of 95% in the study

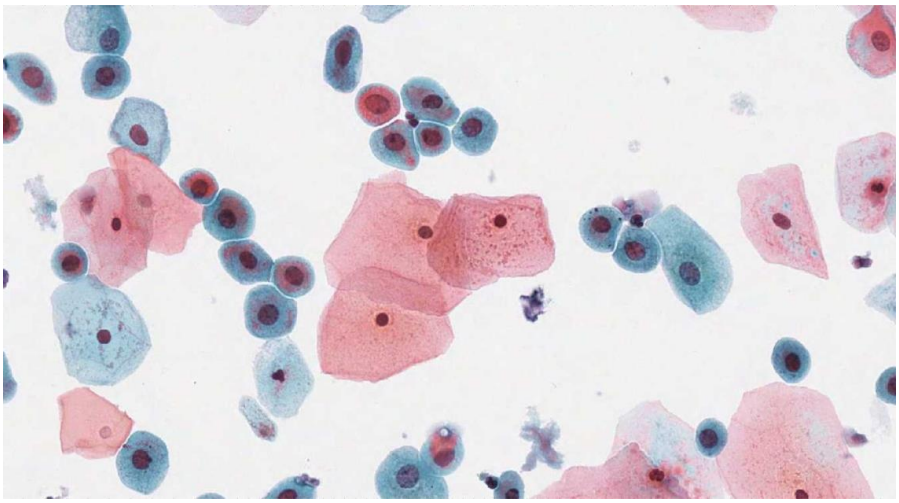
Identifying Potential Cancer

Identification of the presence of hTERT provides useful adjunct information to assist in making a diagnosis. hTERT is not expected to be detected in normal urothelial cells, so identification of this biomarker is very relevant. It is potentially useful in identifying increased potential for cancer when urine cytology is negative or atypical

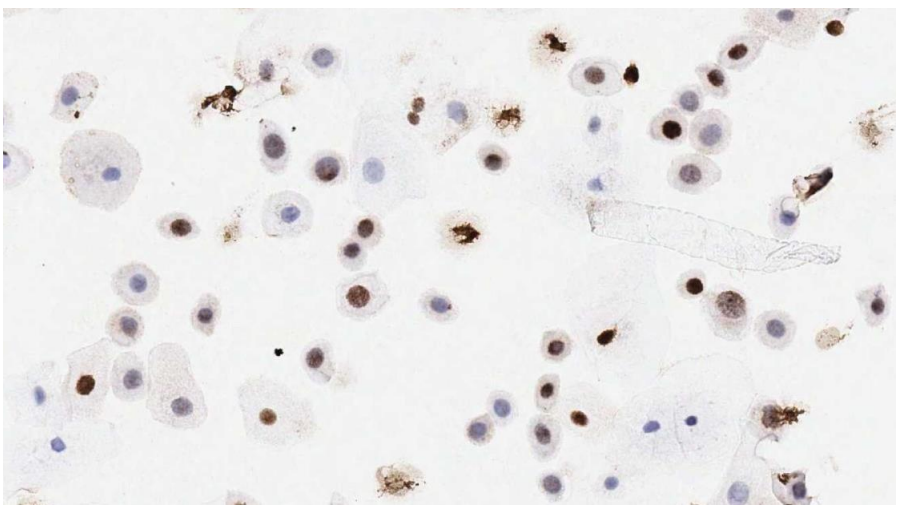
Case Study: RMH12-001

As part of the validation work case RMH12-001 (low grade disease) illustrated the utility of SCD-A7 over conventional cytology.

The initial cytology result was benign. However, the ICC with SCD-A7 was positive. Histological assessment of the biopsy was positive (Ta G1).



Cytology: Benign



Telomerase ICC positive

Cytologically normal urothelial cells stain nuclear positive by Telomerase ICC. Positive telomerase staining correlated to cystoscopy confirmed bladder cancer where cytology alone did not.

Also Available from HistoCyte Laboratories Ltd

For more information email: **info@histocyte.com**
For orders email: **sales@histocyte.com**
Telephone: +44 (0) 191 603 1007

Product Name	Format	Code
HPV/p16 Analyte Control[DR] (Four core with dynamic range of HPV gene copies)	Slide(2)	HCL001
	Slide(5)	HCL002
	Block	HCL003
HPV/p16 Analyte Control (Three core with standard range of HPV gene copies)	Slide(2)	HCL004
	Slide(5)	HCL005
	Block	HCL006
ALK-Lung Analyte Control (Two core positive and negative for the EML4-ALK translocation)	Slide(2)	HCL007
	Slide(5)	HCL008
	Block	HCL009
ALK-Lymphoma Analyte Control (Two core positive and negative for the NPM-ALK translocation)	Slide(2)	HCL010
	Slide(5)	HCL011
	Block	HCL012
Breast Analyte Control (Two cores, one positive for Her2, ER and PR. The other negative)	Slide(2)	HCL013
	Slide(5)	HCL014
	Block	HCL015
Breast Analyte Control[DR] (Five cores with a dynamic range of expression of Her2, ER and PR. Including negative control)	Slide(2)	HCL016
	Slide(5)	HCL017
	Block	HCL018
PD-L1 Analyte Control[DR] (4 core with a dynamic range of expression of PD-L1)	Slide(2)	HCL019
	Slide(5)	HCL020
	Block	HCL021
ROS1 Analyte Control (Two cores positive and negative for ROS1 translocation)	Slide(2)	HCL022
	Slide(5)	HCL023
	Block	HCL024
Sienna Cancer Diagnostics hTERT assay. 1ml of anti-hTERT mouse mAb.	1ml	HCL025

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REF 01-5002 CE

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