

# BlueStain® GLOBAL

**Cytology applied to diagnosis**

# BlueStain® GLOBAL

BlueStain Global Ltd is a company established in London, UK between CESPU Diagnóstico (Portugal) and IKAR Arabia (United Kingdom).



# CESPU Diagnóstico, S.A.



CESPU Diagnóstico, is part of Portuguese CESPU Group, which is a Higher Education Institution that has been training highly qualified health professionals for over 40 years.

CESPU Diagnóstico, is a company created as a startup within the scope of the innovation developed in the IUCS research centers (initially called Targetalent) for the transfer of innovation. It resulted from a scientific research project, through which a new methodology for cytological diagnosis was developed, based on cytology and applied to telepathology.

The mission of CESPU Diagnóstico is to develop, implement, manufacture, and make available to the market medical devices in the diagnostic area based on cytological and molecular studies. The vision is to be a reference company, in the area of research, providing products and services that meet the requirements of manufacturing, clinical and laboratory diagnosis. Each partnership/business relationship is assured by commitment, rigor and quality, which are an integral part of the company.

# IKAR Holdings



KAR Arabia Investment Group is one of the vertical operating groups, belonging to IKAR Holdings, which is a multi-tiered group headquartered in London, encompassing more than 40 companies – spanning across 14 different sectors and geographical regions.

IKAR Holdings is a distinguished ecosystem of entrepreneurs, innovators, and investors from around the world that spans across a wide variety of industries and sectors. Our mission revolves around the commitment to empower growing business and emerging leaders globally.

IKAR Holdings is a multi-tiered group headquartered in London, encompassing more than 40 companies – spanning across diverse sectors and geographical regions. Its structure is reinforced by a network of external global partnerships and steered by a leadership team composed of accomplished business executives with established track records of success, united with the insights and expertise of senior figures from the political and public sectors.

## *Leadership*

### Board of Directors



**Prof. Fernando Ferreira**  
Independent Member – CEO, CESPU Diagnóstico



**Mario Diel**  
Independent Member – Chairman, IKAR Arabia Investment Group



**Sertan Ayçiçek**  
Independent Member – Deputy Chairman, IKAR Arabia Investment Group

### Executive Board



**Prof. Manuel Freire-Garabal y Núñez**  
Chairman, BlueStain Global



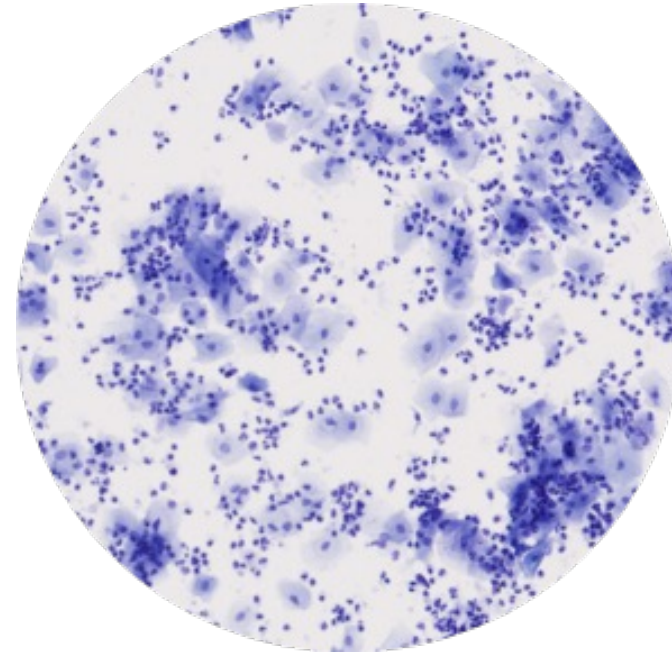
**Semih Ayçiçek**  
CEO, BlueStain Global



**Prof. Paula Melo**  
Chief Operating Officer, BlueStain Global

# Point of care solution

- Fast
- No lab
- Simple
- Everyone
- Logistic free
- Best executive cost



# Advantages

- Fewer repetitions – Better accuracy
- Less anxiety – Faster results
- Simplified Diagnostic – No logistic
- Better hope of life – Quick start of treatment
- Save lives – Early diagnosis





A breakthrough in  
cytological staining.

Fast, simple, sustainable and economical.

- In vitro diagnostic medical device
- Stain all types of cytology specimens in just 2 minutes!

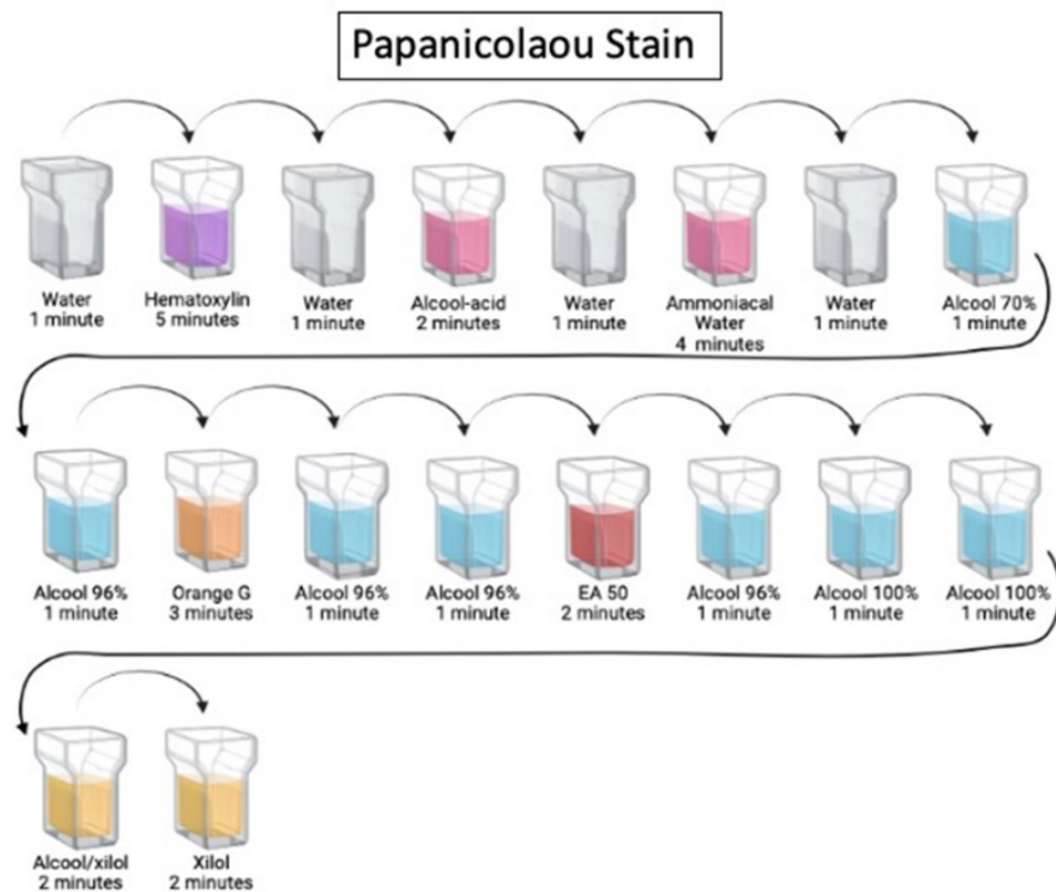
This provides a fully scalable and logistics-free turn-key solution for point-of-care cancer screening in a population scale.



# Protocol stain



VS



# Blue Stain<sup>®</sup>

Blue Stain<sup>®</sup> uses a specialized cytopathology stain combined with an advanced technology to rapidly issue results



Each kit is used by the Dentist to sample one oral lesion in each patient

- After performing the test the cytology is digitized and sent to our certified pathology expert center

- Results are supplied back to the Dental professional within the time frame of the appointment (less than 1/2h) in a report format

<b><u>BlueStain®</u></b>	<b>Papanicolaou Stain</b>
<ul style="list-style-type: none"> <li>• Point-of-care</li> <li>• Simpler (1 reagent and tap water)</li> <li>• Doesn't need a lab</li> <li>• Stain rejection is lower because is only 1 reagent and tap water (less money spend)</li> <li>• Lower environmental footprint</li> <li>• Not carcinogenic</li> <li>• Quick (2 <u>minutos</u>)</li> <li>• Doesn't need logistic</li> <li>• No need for qualified professional</li> </ul>	<ul style="list-style-type: none"> <li>• No point-of-care</li> <li>• Complex with multiple steps (10 reagents)</li> <li>• Needs a lab</li> <li>• Stain rejection is higher because are 10 reagents and tap water (16 times more money spend)</li> <li>• Higher environmental footprint</li> <li>• Carcinogenic (because of <u>Xilol</u>)</li> <li>• Long protocol (±30 minutes)</li> <li>• Needs logistic</li> <li>• Need qualified professional</li> </ul>

# Value proposition

- Time to results

BlueStain®

30 min.

vs

Competitors

3 weeks

- Laboratory needs

No

vs

Yes

- Executive Cost

Cheap

vs

3 X

- Sustainability

Yes

vs

No



# Point of care solution

solution could provide immediate feedback within the same visit. Thus, there is a strong need for technology-driven solutions that can precisely and rapidly diagnose the entire spectrum of oral epithelial dysplasia (OED) and oral squamous cell carcinoma (OSCC) using minimally invasive sampling at the POC.

[Cancer Cytopathol.](#) 2020 Mar; 128(3): 207–220. Published online 2020 Feb 7. doi: [10.1002/cncy.22236](https://doi.org/10.1002/cncy.22236)

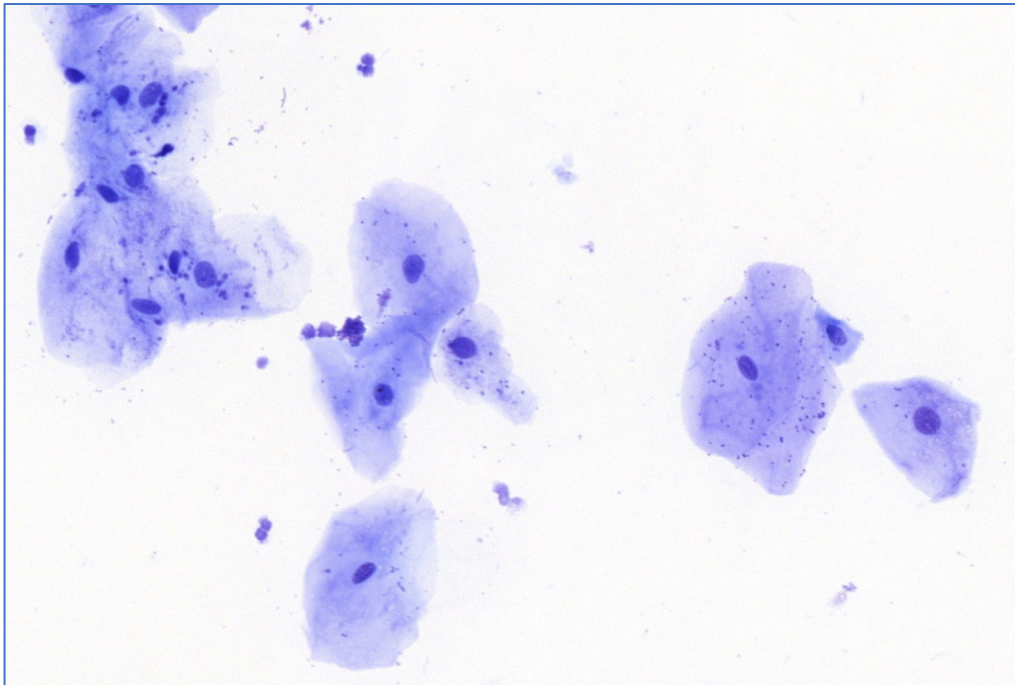
PMCID: PMC7078980 | PMID: [32032477](https://pubmed.ncbi.nlm.nih.gov/32032477/)

Point-of-care oral cytology tool for the screening and assessment of potentially malignant oral lesions

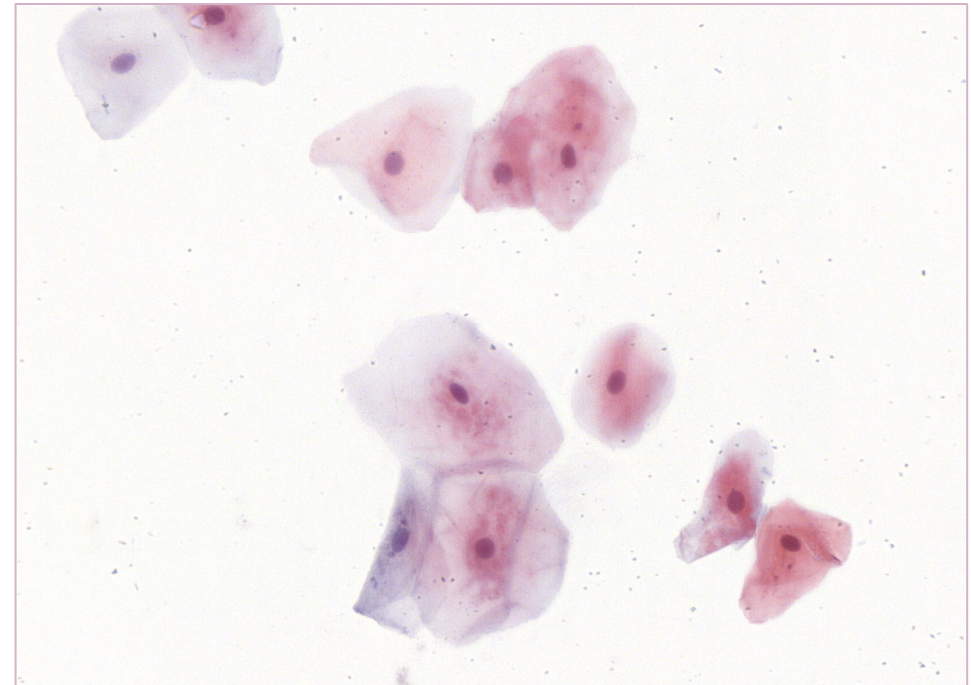
[Michael P. McRae](#), PhD, <sup>1</sup> [Sayli S. Modak](#), MS, <sup>1</sup> [Glennon W. Simmons](#), BS, <sup>1</sup> [Denise A. Trocheset](#), DDS, <sup>2</sup>  
[A. Ross Kerr](#), DDS, MSD, <sup>2</sup> [Martin H. Thornhill](#), MBBS, BDS, PhD, <sup>3</sup> [Spencer W. Redding](#), DDS, MEd, <sup>4</sup>  
[Nadarajah Vigneswaran](#), BDS, DrMedDent, DMD, <sup>5</sup> [Stella K. Kang](#), MD, MS, <sup>6, 7</sup> [Nicolaos J. Christodoulides](#), PhD, <sup>1</sup>  
[Craig Murdoch](#), PhD, <sup>3</sup> [Steven J. Dietl](#), MEng, <sup>8</sup> [Roger Markham](#), PhD, <sup>8</sup> and [John T. McDevitt](#), PhD<sup>1</sup>



# Oral Cytology

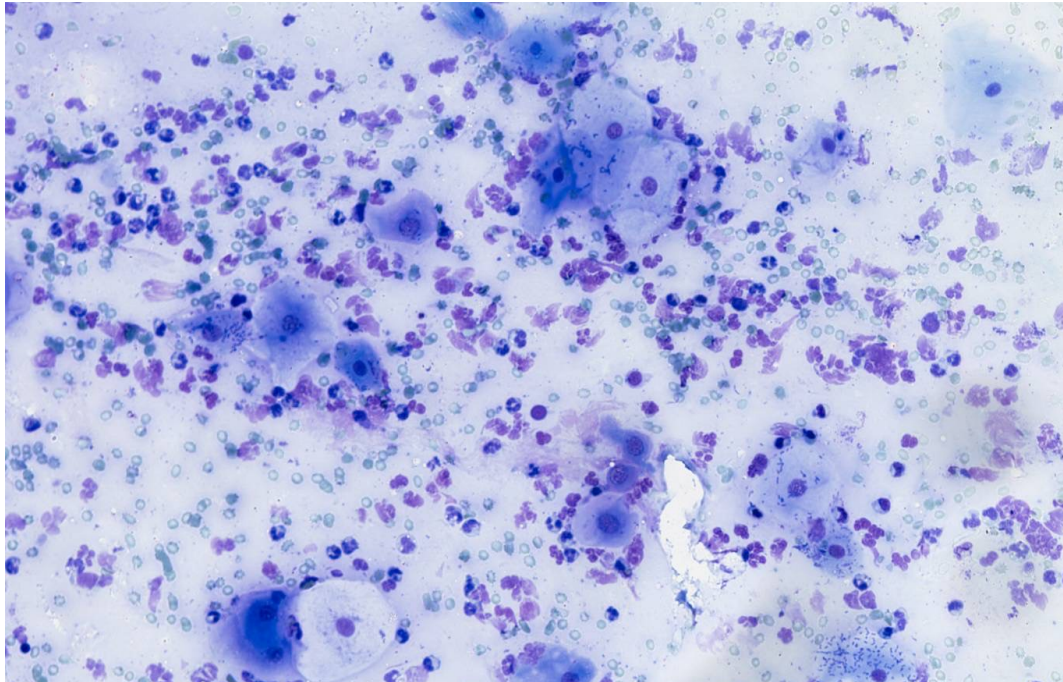


**Fig. 1 – Exfoliative cytology of the normal oral mucosa stained with the BlueStain® method (400x)**

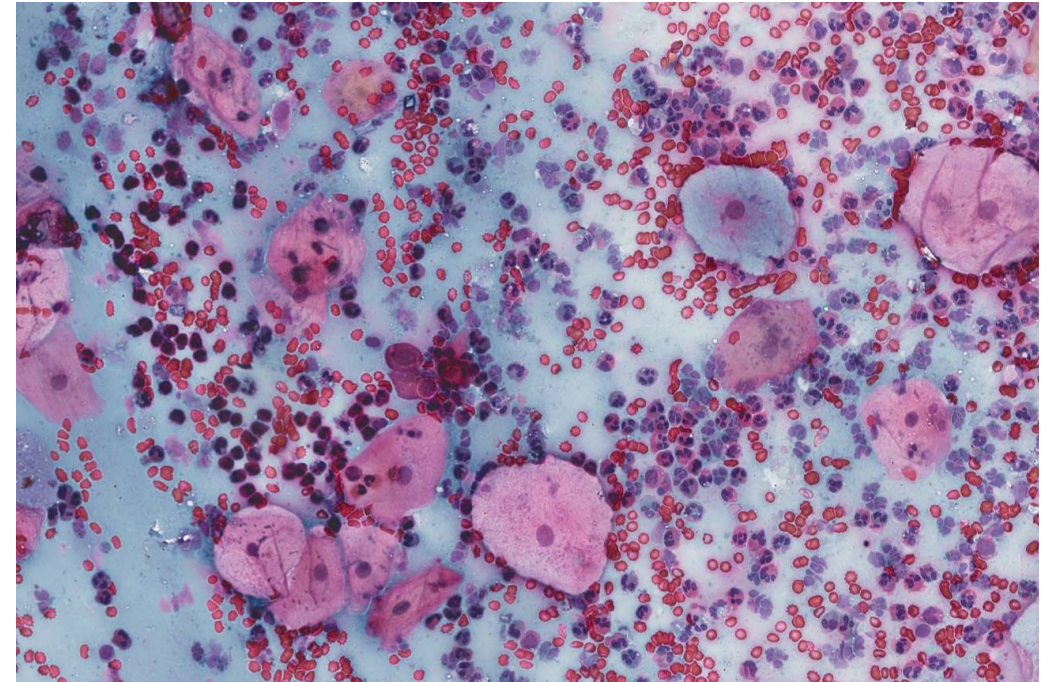


**Fig. 2 – Exfoliative cytology of the normal oral mucosa stained with the Papanicolaou method (400x)**

# Oral Cytology



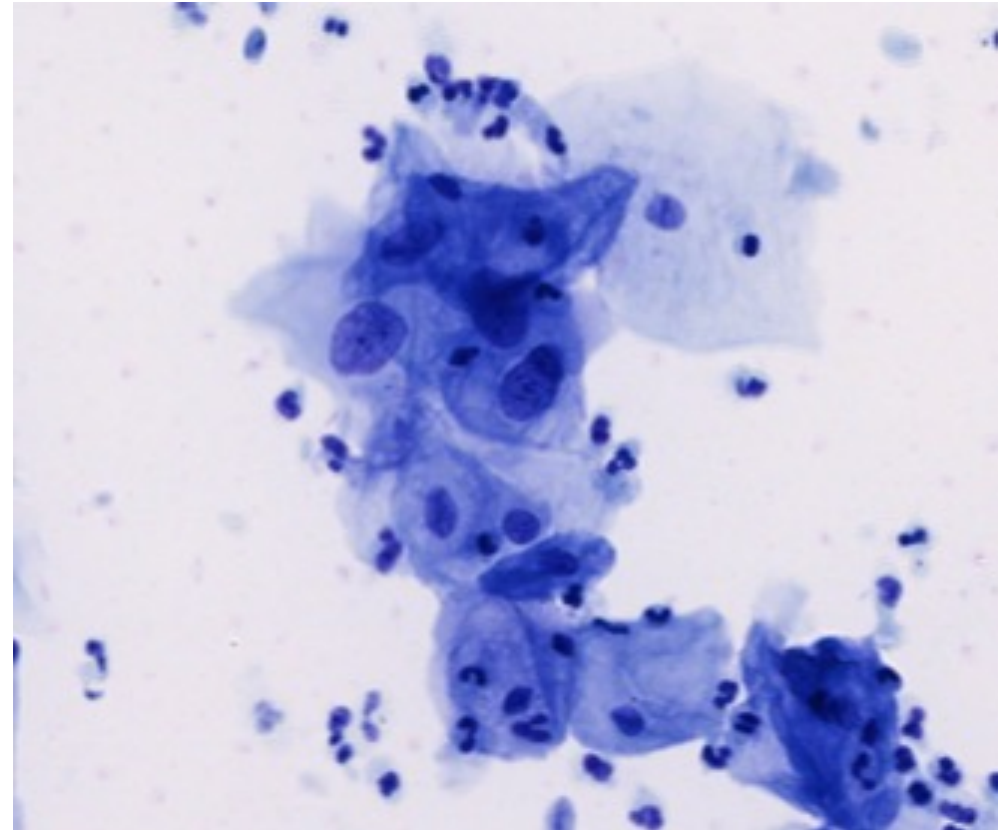
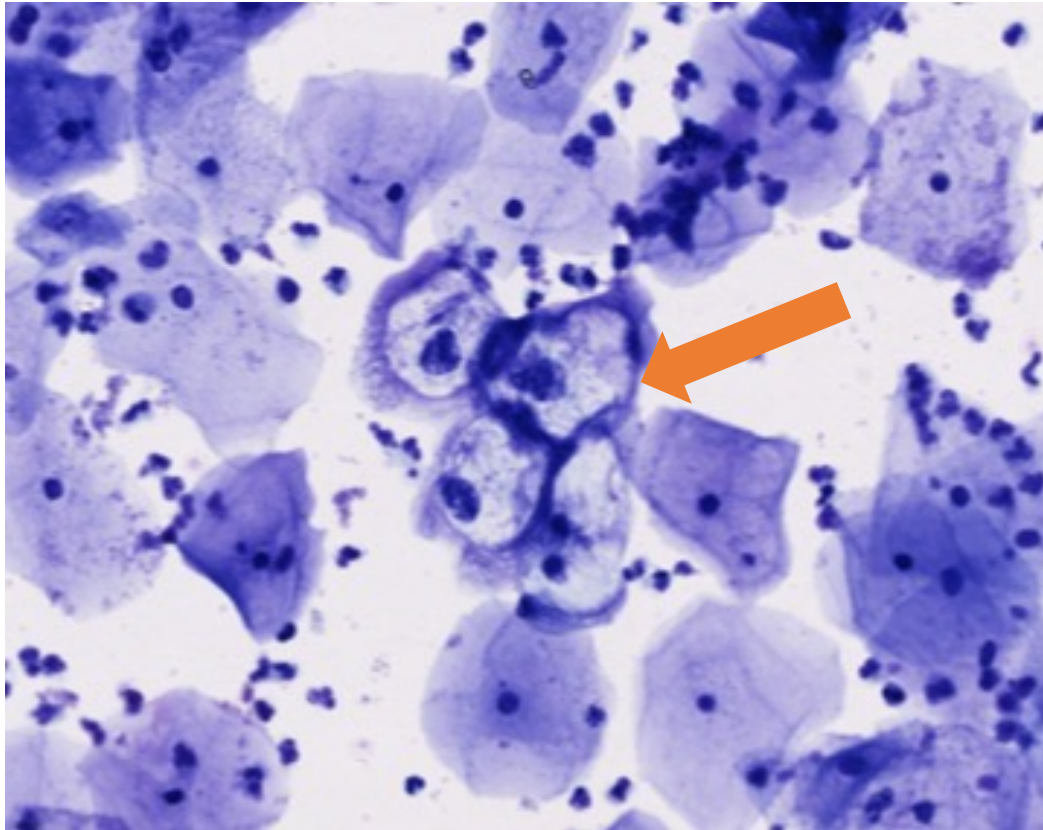
**Fig. 3 – Exfoliative cytology of the oral mucosa – squamous cell carcinoma - stained with the BlueStain® method (200x)**



**Fig. 4 – Exfoliative cytology of the oral mucosa – squamous cell carcinoma - stained with the Papanicolaou method (200x)**



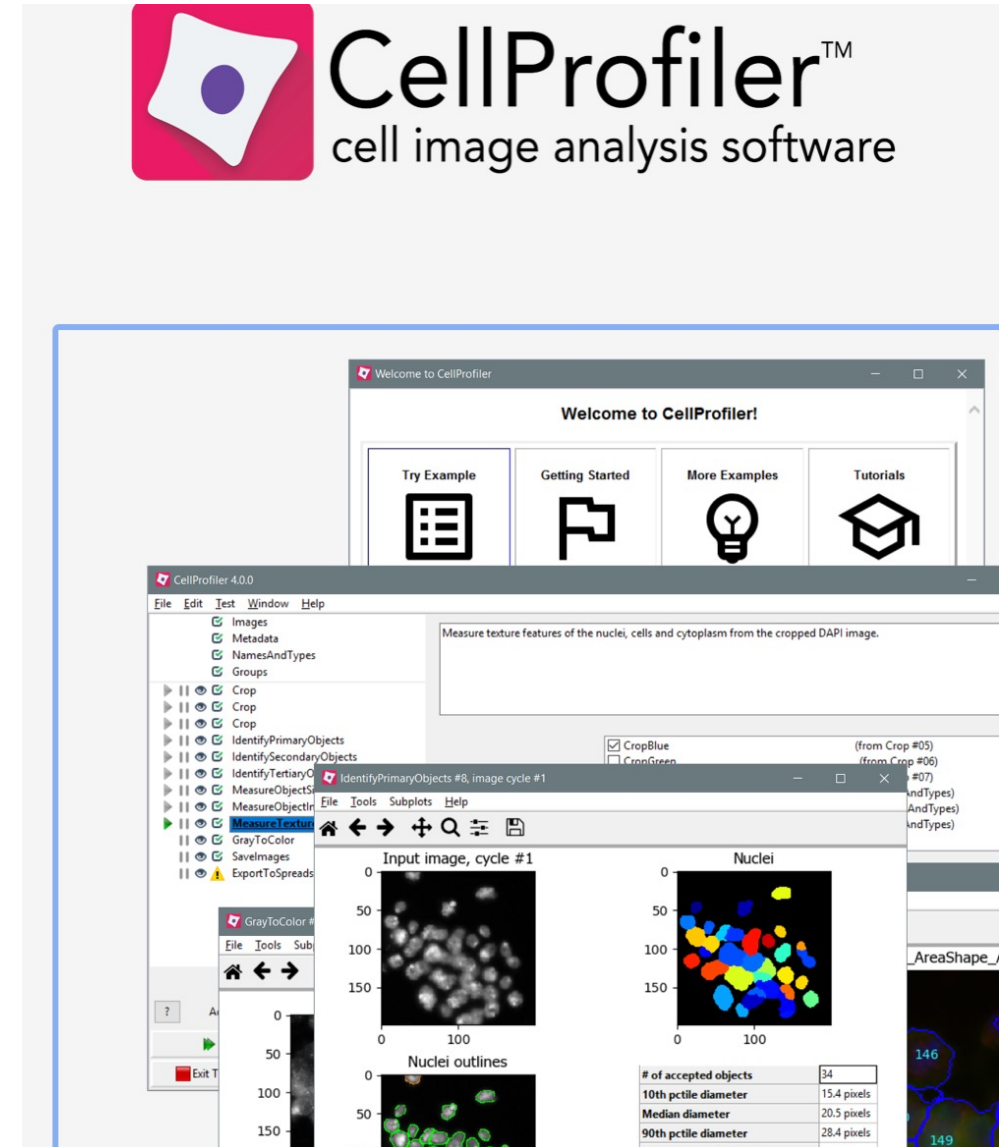
# Oral Cytology



**Fig. 5 – Gynecological cytology - stained with the BlueStain® method (400x)  
koilocytes suggestive of HPV**



# Digital pathology



# Intellectual property and quality

## Patent



National & European Patent applications submitted

## EU mark

EU

EU Declaration of Conformity

## ISO certification



NP 4457 (certified)

EN ISO 13485 and EN ISO 9001 (implemented)



# Scientific evidence

Acta Cytologica

## Techniques

Acta Cytologica  
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## A New Cytology Staining Method: A Fast Approach for Rapid On-Site Evaluation on Thyroid Fine-Needle Aspiration Cytology

Paula de Melo Alves<sup>a, b</sup> Fernando Ferreira<sup>c</sup> Telma Oliveira<sup>b</sup> Daniela Alves<sup>d</sup>  
Sule Canberk<sup>a, e, f</sup> Fernando C. Schmitt<sup>f, g, h</sup>

<sup>a</sup>PhD student in Pathology and Molecular Genetics, Institute of Biomedical Sciences Abel Salazar (ICBAS), University of Porto, Porto, Portugal; <sup>b</sup>Polytechnic Institute of Health of the North (IPSN), CESPU, Paredes, Portugal; <sup>c</sup>University Institute of Health Sciences (IUCS), CESPU, Paredes, Portugal; <sup>d</sup>Department of Pathology, Hospital Pedro Hispano, Matosinhos, Portugal; <sup>e</sup>I3S, Instituto de Investigação e Inovação em Saúde, University of Porto, Porto, Portugal; <sup>f</sup>PATIMUP, Institute of Molecular Pathology and Immunology of University of Porto, Porto, Portugal; <sup>g</sup>CINTESIS@RISE (Health Research Network), Porto, Portugal; <sup>h</sup>Department of Pathology, Faculty of Medicine, Porto University, Porto, Portugal

### Keywords

Thyroid fine-needle aspiration · Rapid stain · Rapid on-site evaluation · Diff-Quik · BlueStain®

scale from 1 to 3, representing poor, average, and good, respectively. **Results:** The quality index was slightly better for BlueStain® (53% vs. 47%) but not significantly different between the two stains. BlueStain® provides better details in

**Sensitivity: 94.4%**

**Specificity: 98.1%**

BlueStain® GLOBAL

# Blue Stain<sup>®</sup>

**Green** Solution

**We reduce 90% of pollutants**



## DIGITAL CYTOLOGY FOR CANCER DETECTION

### awards



Winner  
2014



2015



2015

