

# VolitionRx

EPIC 2014



Dr Mark Eccleston (MBA)

Nucleosomics®

Revolutionizing Cancer Diagnostics

***A VolitionRx Company***

20A

Rue Du  
Seminaire

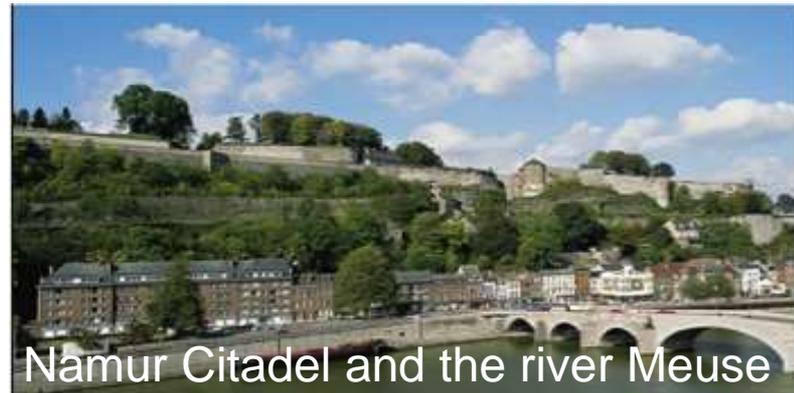
B-5000 Namur

Belgium

[www.volitionrx.com](http://www.volitionrx.com)

# Origins and Current Status

- Belgian R&D facility, US OTC listed
- Nucleosomics® Core Technology Platform
- \$11M equity funding and €1.47M DG06 (regional) funding
- Experienced management team
- Core team of 7 scientists
- Chief Operations Officer
- Sales and Marketing Director
- Kit production
- Former Eppendorf lab



# Epigenetics - Definitions

- *“Heritable changes in gene expression without changes in DNA sequence”*
  - Non sequence based changes in phenotype and gene expression
  - Environmentally modulated
  - Reversible
  - Heritable
- *“Structural Adaptation of Chromosomal Regions so as to register, signal or perpetuate altered activity states”*
- *What turns genes on and off and under what circumstances*
  - '09 Silver Jubilee of groundbreaking work by Surani, Solter and Cattanaach
  - Global epigenetic market **\$1.7 billion in '09** with **CAGR of 60% to '12**

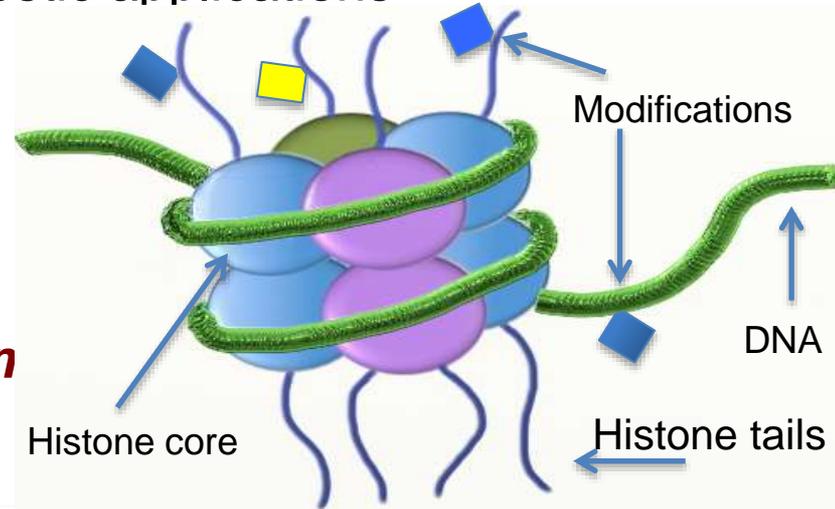
# Epigenetics meets oncology

- Epimutations provide a second hit in two-hit cancer initiation model
- These events can take place **years** before symptoms present\*
- Gradual ramp up to (often) high nucleosome levels on diagnosis
- Histone variants can distinguish nucleosomes of tumour origin
- Altered histone modification profiles in cancer derived nucleosomes
- Applications
  - Low cost screening and early diagnosis
  - Patient stratification e.g. Neoadjuvant therapy selection
  - Prognosis

\*Aotake 1999, Holdenrieder 2009

# Nucleosomes - Diagnostic Potential

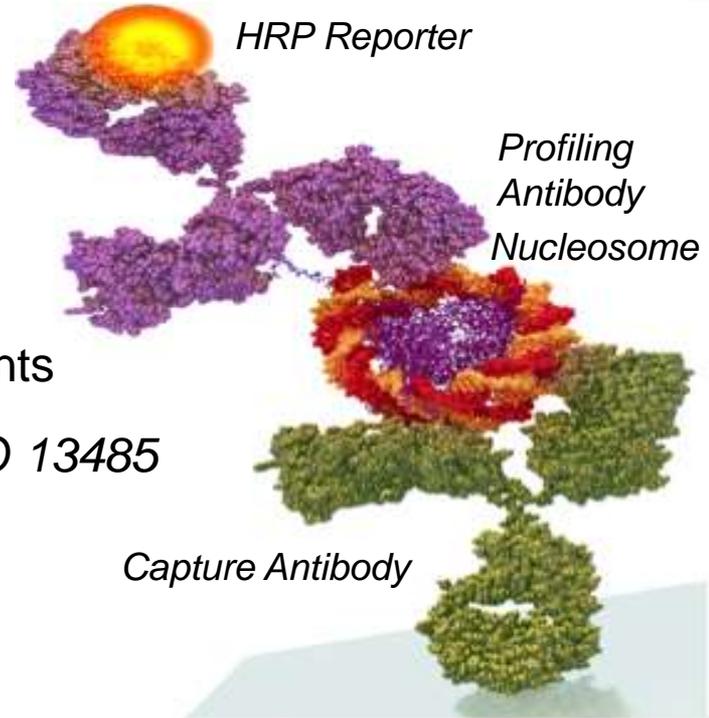
- Nucleosomes are a basic structural unit for genes
- Elevated cell turnover increases blood nucleosome levels
  - Cancer, heart attack, surgery, severe auto-immune disease
- This has previously limited diagnostic applications
  - Therapy response
  - Relapse
- ***Volition has solved this problem***



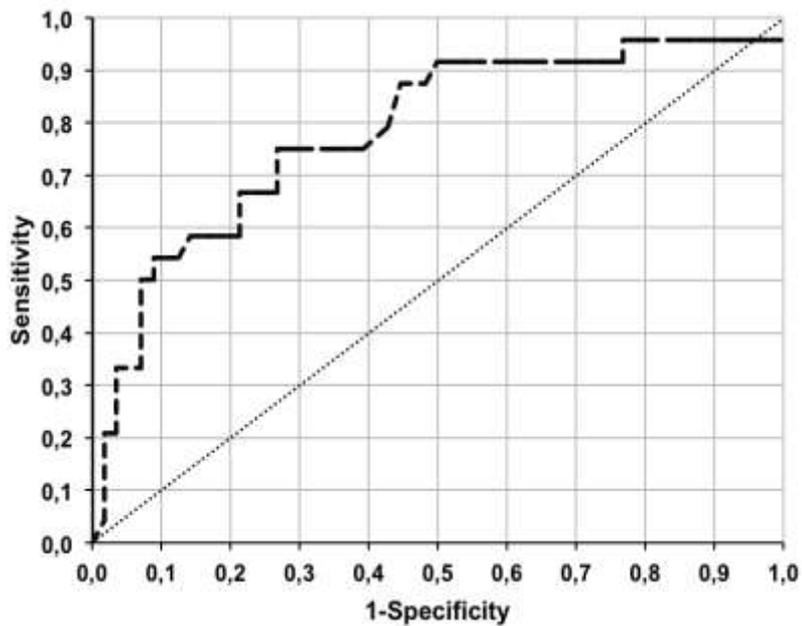
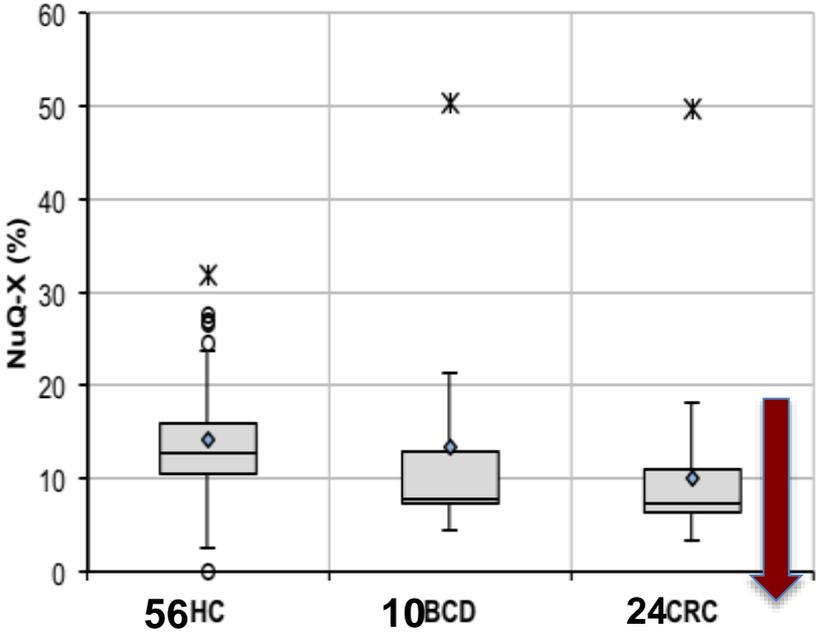
# Nucleosomics<sup>®</sup> - Accessing the Epigenome

## Four patent-protected NuQ<sup>®</sup> suites of products:

1. NuQ<sup>®</sup>-X specific DNA modifications
  2. NuQ<sup>®</sup>-V histone variants
  3. NuQ<sup>®</sup>-M histone modifications
  4. NuQ<sup>®</sup>-A nucleosome-protein adducts
- Antibody supply and development agreements
  - In house manufacturing and outsourced *ISO 13485*
  - Research use only kits launched Q1 2014
  - 6 assays (retail €795-€995) and growing
  - Global distribution agreement



# Nucleosomics<sup>®</sup> - 5MC Single Biomarker



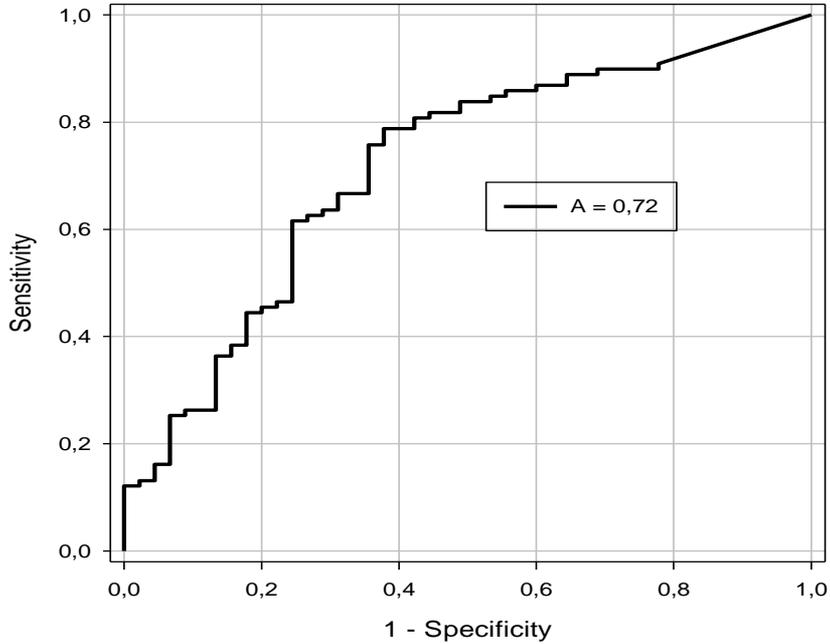
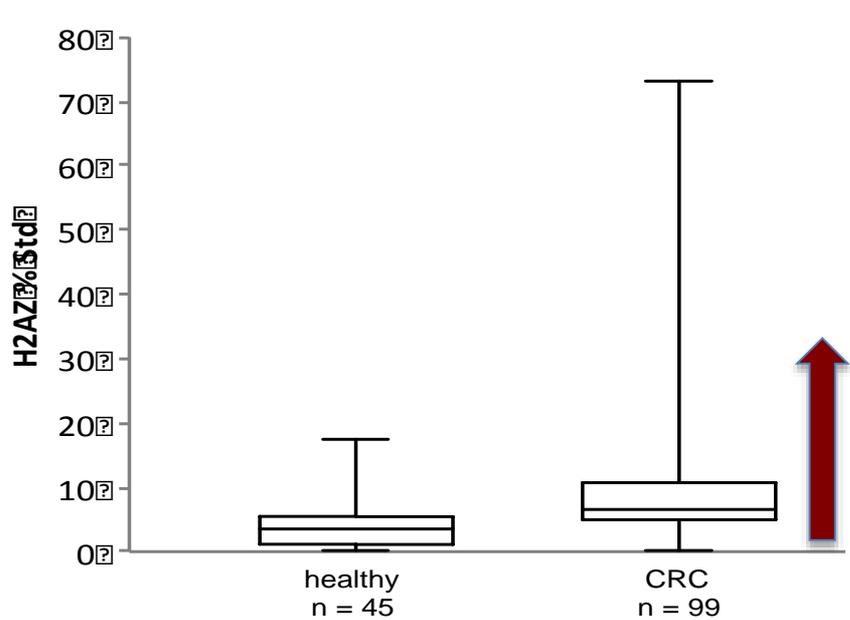
**75% Sensitivity / 72% Specificity**

Holdenrieder *et. al.* ANTICANCER RESEARCH 34: 2357-2362 (2014)



**Reproducible data sets**

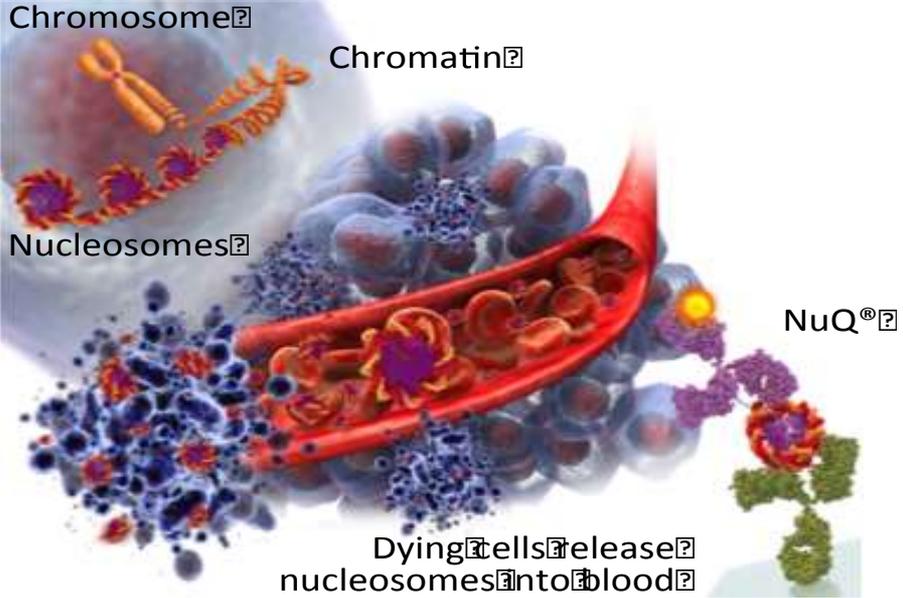
# Nucleosomics® - NuQ® V001 Single Biomarker



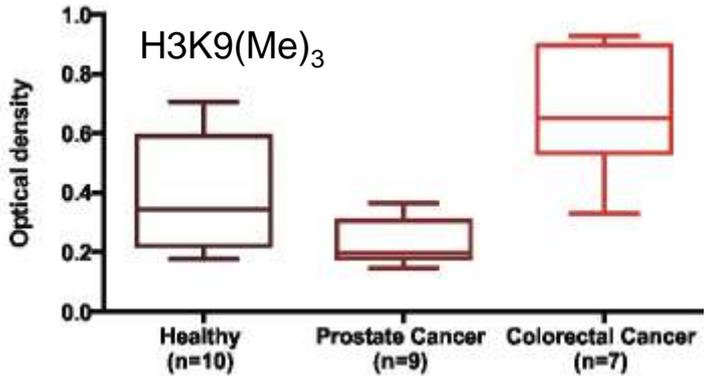
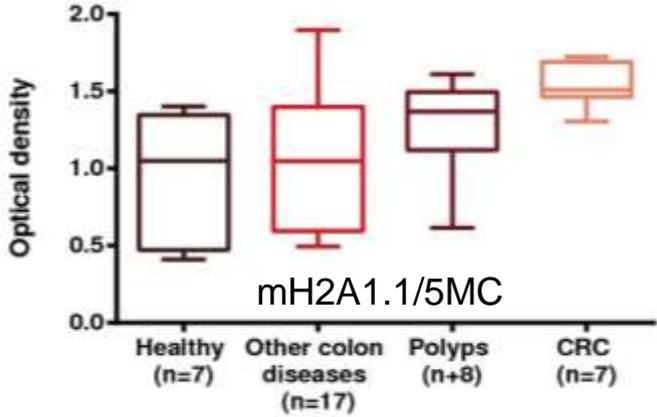
- CRC n = 99 (WACB)
- Healthy n = 45 (CTLS, Seralab, Liège, Imperial)

**75% Sensitivity / 64% Specificity**

# Nucleosomics®- Revolutionizing Cancer Diagnostics



- Clinical trials colon and prostate cancer
- CE mark application for lead indication
- Expand to US and pilot new indications



*Non invasive, affordable technology accessible by all*

# Nucleosomics® - CRC screening trial

- NuQ® CRC screening in representative 938 symptomatic cohort
- 3-assay test panel - 60µL of blood serum
  - 84% sensitivity (accurate detection) at 78% specificity
  - 60% detection of adenomas (polyps)
  - Similar Detection of early (I or II) and late-stage (III or IV)
- Completion of 4800 cohort Q1 2015
- Prospective 14000 cohort collection began April 2014

# Nucleosomics® - Commercial and Patient Impact

## The Market – our target

- “Blockbuster” population screening – \$4Bn for colorectal cancer
- Third most common cancer worldwide
  - 1 230 000 newly diagnosed and 609 000 deaths annually
- Second most common cancer in EU
  - 450 000 newly diagnosed and 230 000 deaths annually
- Mainly affects over 50s i.e. 175M citizens in Eu

## The Patient – our goal

- Earlier diagnosis of major cancers
- Stratification and treatment selection
- Monitoring for high risk groups e.g. genetically predisposed and relapse

# Nucleosomics®- Revolutionising Cancer Diagnostics



- Easily implemented
- Point of Care diagnosis



High Sensitivity  
(identifies patients with disease)

Rapid Specialist referral and treatment selection

High Specificity  
(identifies healthy)

Peace of mind



***Simple, affordable, accessible cancer diagnostics***

# VolitionRx - Current Trials

## Hvidovre Hospital, University of Copenhagen, *Denmark*

- Retrospective 5000 patient study – Colorectal population screening
- Prospective 14 000 patient study – Colorectal population screening

## Bonn University Hospital, *Germany*

Retrospective 800 patient study – various cancers (completed)

- Retrospective 1500 patient study - Lung cancer
- Prospective 4000 patient study - various cancers, healthy and disease controls
- Neo-adjuvant therapy stratification – breast cancer

## Mont-Godinne Hospital, *Belgium*

- 250 patient longitudinal study - early detection/prognosis of colorectal cancer.

# VolitionRx - Partnering opportunities

*Well-annotated blood or urine samples*

*Various stages of disease plus control materials for clinical studies*

*Therapeutic trials for patient stratification*

Hardware platform providers – research and diagnostic

CROs - epigenetic assays and generic efficacy/toxicity biomarkers

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***Seeking additional development partners***