



NovioGendix

Winnaar van
**Mercator Award 2009 for
Knowledge-Based Entrepreneurship**

Een spin-off van UMC St Radboud



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CSO

hoogleraar experimentele urologie

UMC St Radboud, Nijmegen

Presentation Overview

- **NOVIOGENDIX SNAPSHOT**
- **PCA3 – STARTING POINT AND LEARNING CASE**
- **PCA3 – TOWARDS REIMBURSEMENT**
- **NGDX R&D – APPROACH**
- **NGDX R&D – PIPELINE**
- **NGDX R&D – 2010 ACTIVITIES**

Noviogendix

- vision and ambition-



- Importance of diagnostics will grow
- Understand the positioning of the test (i.e. the disease area)
 - Predisposition
 - **Diagnose disease**
 - **Prognostic; Predict natural course of disease**
 - **Companion diagnostics; Predict response to treatment**
 - **Surrogate end point (clinical trials); measure response to treatment, predict therapeutic effect**
- Capitalize on experiences with PCA3

NOVIOGENDIX SNAPSHOT

“**Molecular Diagnostics for Genito-Urinary Tumors**”

Spin-off from UMC St Radboud Nijmegen

Founded November 2006

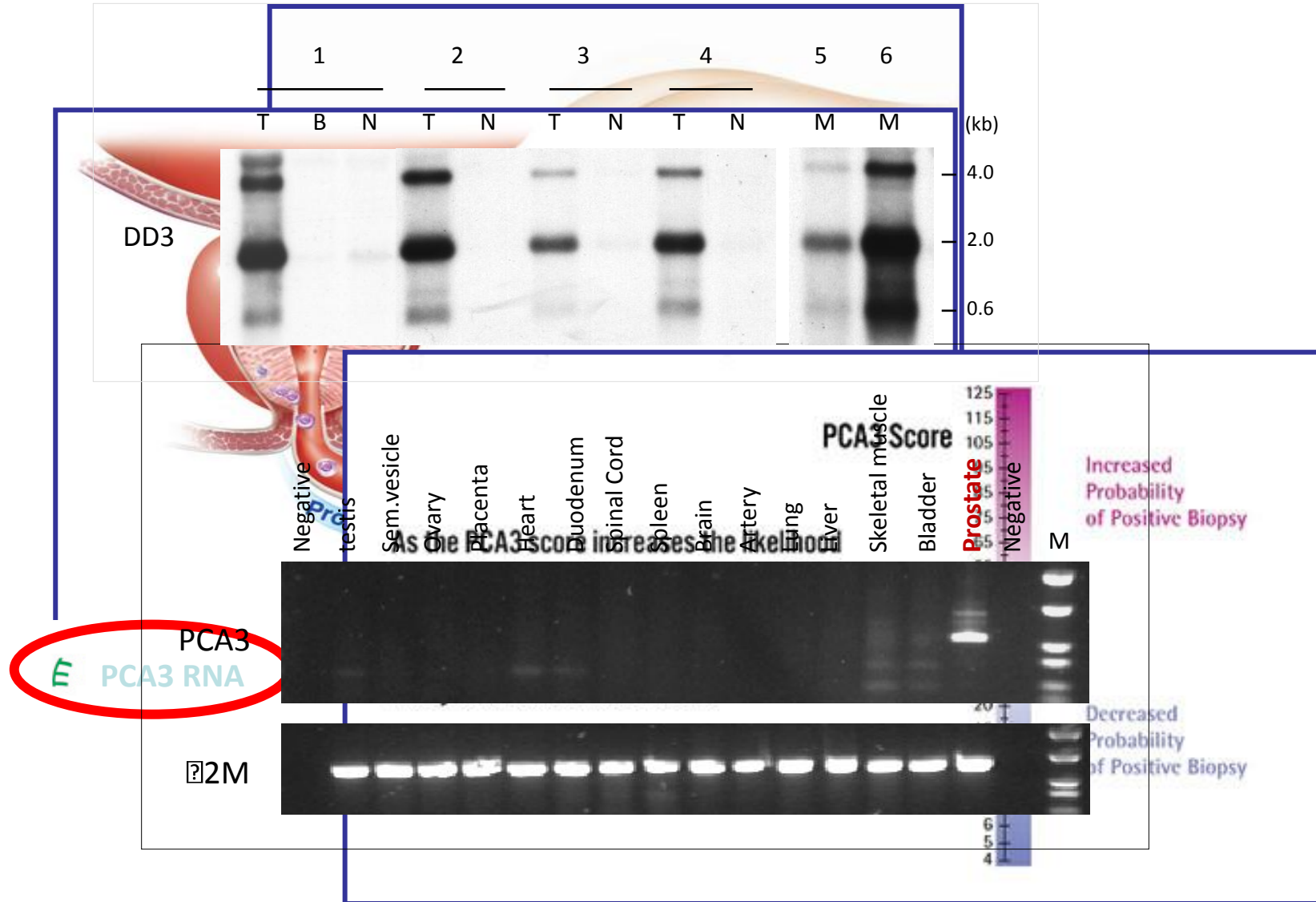
14 employess (11 FTE)

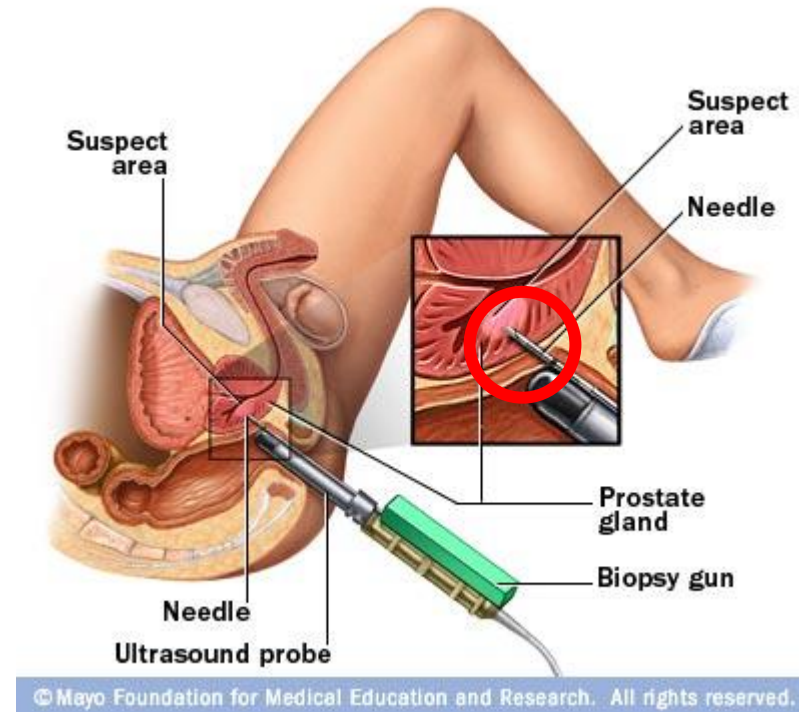
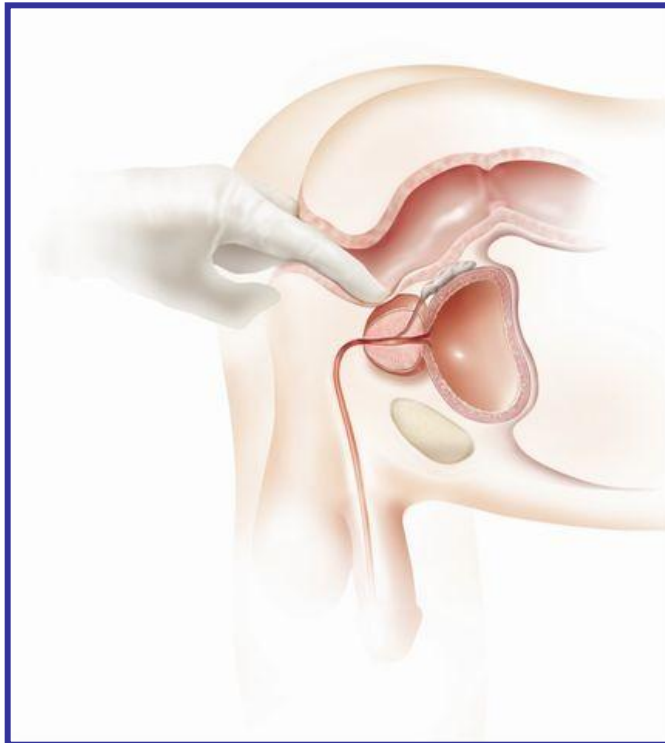
Operates in 2 business units:

- **NGDX ServiceLab (ISO certified)**
- **NGDX Research**
 - *Development of new biomarker based tests for genito-urinary cancers*

PCA3 – STARTING POINT

Ontdekking van PCA3 (= DD3)





PCA3 Pubmed; 1999-2010, 99 papers, 20+ studies all supporting this specific indication; many other indications are being studied

PCA3 – LEARNING CASE

2000

2003

2006 2007

2009

2012



PCA3 licentie van UMC St Radboud aan



IPR HISTORY

2000

2003

2006 2007

2009

2012



PCA3 license from UMC St Radboud to



PCA3 sub-license from

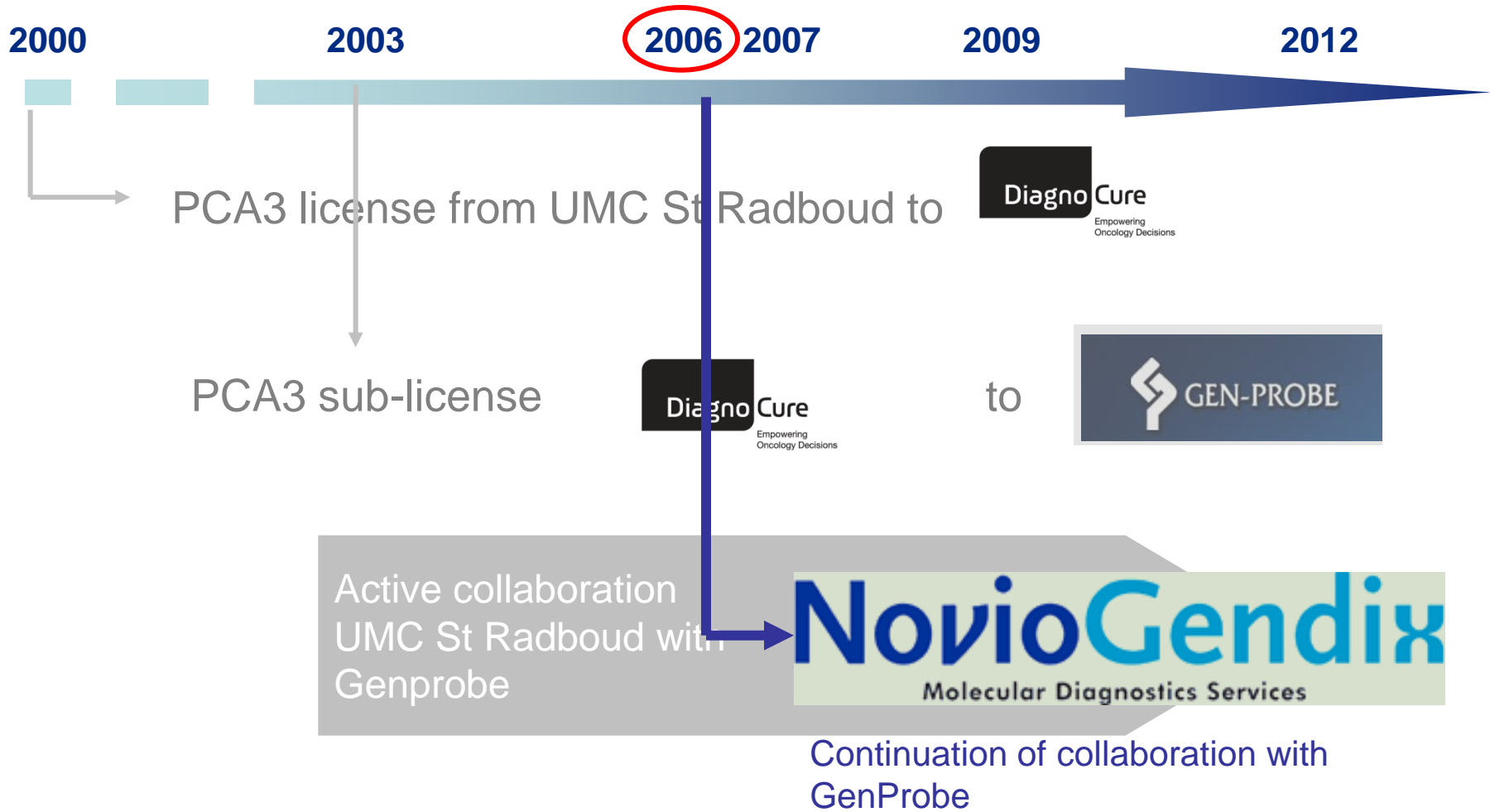


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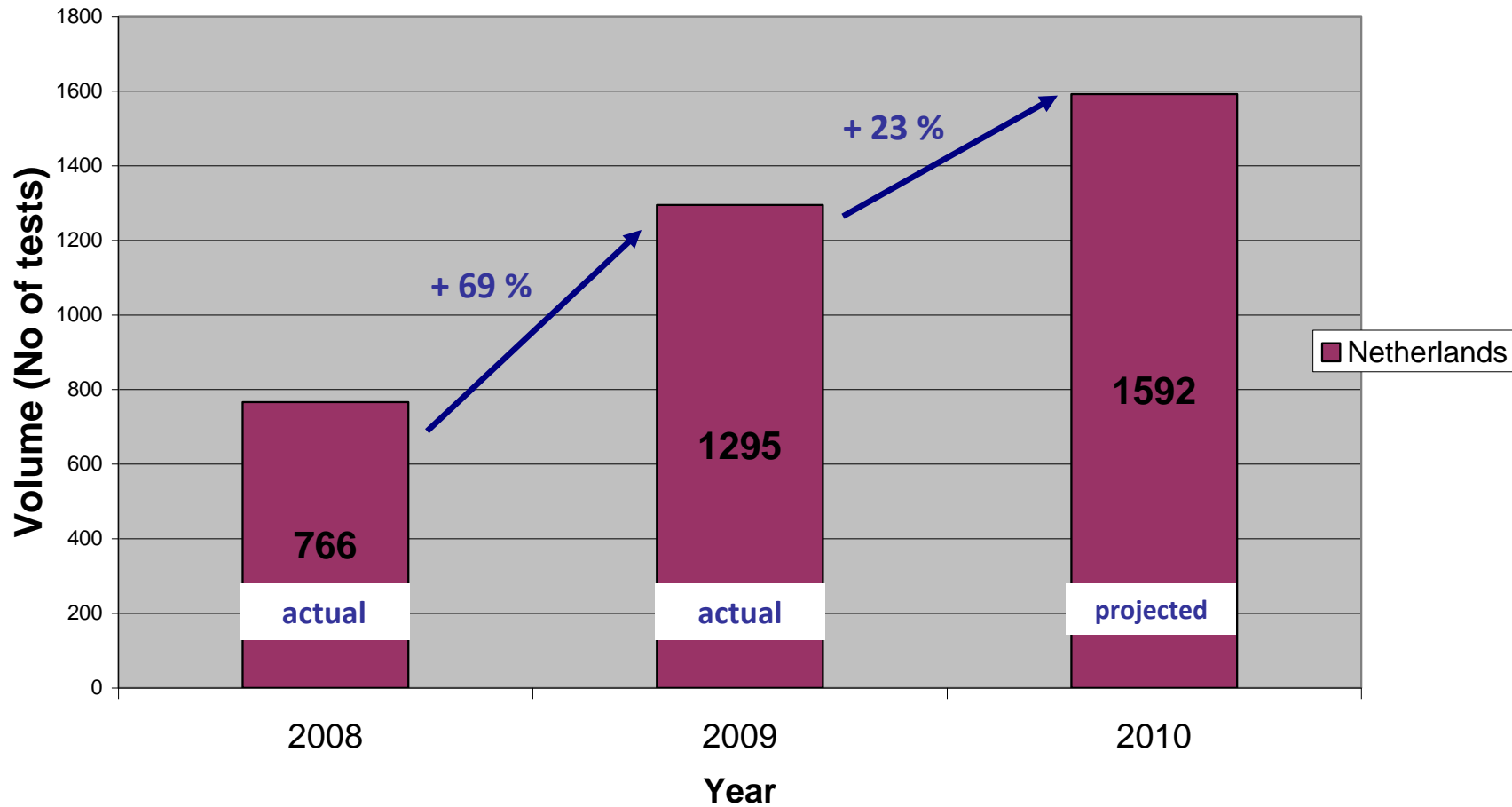


ACTIVE COLLABORATION
UMC St Radboud with
GenProbe

HISTORY of ACTIVITIES



PCA3 sales 2008-2010



PCA3 global sales are significant in ‘pre-FDA approval phase’

- GenProbe to service labs (2007-2010) -
approaching 10 M\$/year
- Service labs to end users (hospitals, patients)
- conservative estimate 30 M\$
- Conclusion
 - A biomarker can generate significant income as CE marked product, pre-FDA approval (probably to a lesser extend also for RUO products)
 - US market is the prime ‘launch market’
- File for PMA approval FDA submitted August 2010...

- During 2009 the effect of “non-reimbursed”-status of PCA3 became apparent (‘hurdle’)
- Discussion / lobby with urologist, insurance companies, patient groups etc.
- Aligned NVU, KOLs and GenProbe to prepare “reimbursement dossier”
- Dossier submitted on April 9th to DBC Onderhoud
- Fully supported by NVU and SCP

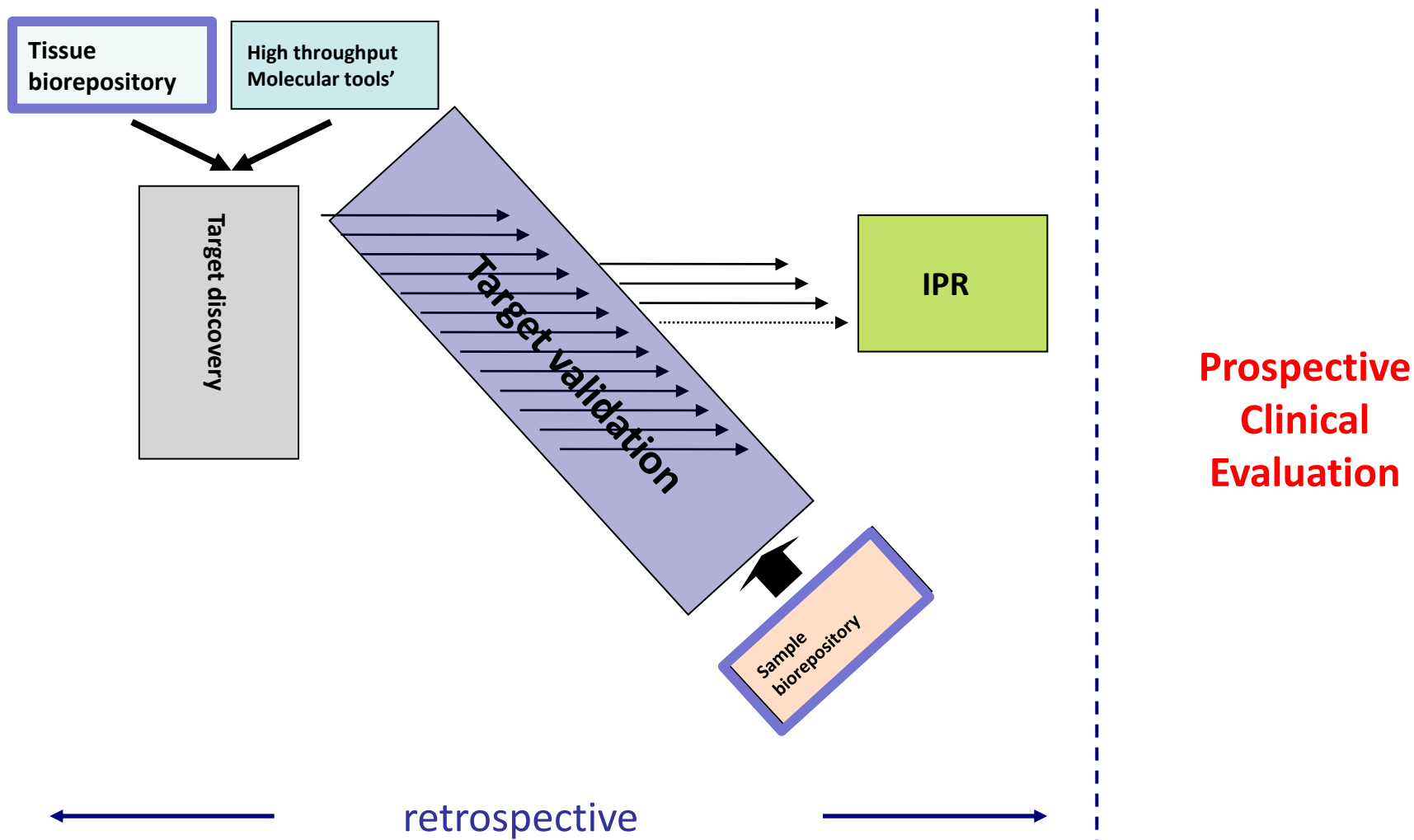


Quote (in Dutch) from concluding paragraph:

De indieners van dit dossier zijn van mening dat vergoeding van deze test terecht is, daar het voldoende tot de stand der wetenschap en praktijk behoort. De indieners van dit dossier, waaronder de voorzitter van de werkgroep prostaatkanker van de NVU en de voorzitter van de landelijke richtlijncommissie die de Nederlandse richtlijn heeft opgesteld Dr. Th.M. de Reijke, uroloog, Academisch Medisch Centrum ... zullen de PCA3 test aan de eerst volgende herziening van de richtlijn prostaatkanker toevoegen en zodanig omschrijven dat dit een diagnostische test is, die wordt aanbevolen, zoals beschreven is in dit dossier.

NGDX R&D - Approach

Noviogendix Research in-house capabilities to cover the spectrum from biomarker **discovery** through **validation** to **assay development** on state of the art technology platforms.



- 3 programmes in Genito-Urinary Oncology
- Diagnosis Prognosis and Staging of Prostate Cancer
- Diagnosis and Staging of Renal Cancer
- Aggresiveness and Recurrence Bladder Cancer

