



Brussel, 25 maart 2008

Beste Collega,

Betreft : De PROGENSA PCA3 test

Zoals gevraagd, vindt U hierbij het aanvraagformulier voor de PROGENSA PCA3 analyse, de PCA3 protocol, de overeenkomstige brief, de informatie brochure, en een aantal tubes voor urineanalyse.

Zoals u in de protocol zult vaststellen, moet het urine monster (2.5 ml) binnen de 4 uur in de voorziene tube overgebracht worden (de vervoertube bevat een adequate beschermingsvloeistof en kan blijven aan kamertemperatuur). Deze moet vervolgens binnen de 5 dagen aan ons teruggestuurd worden.

Gezien de kosten van de reactieven, wordt deze analyse ten bedrage van 259 € aan de patiënt gefactureerd. Omdat deze momenteel volledig ten laste van de patiënt is, vragen wij u het aangehechte aanvraagformulier te willen gebruiken en ons ook de ondertekende toestemmingsbrief terug te sturen.

Met de meeste hoogachting,

Prof JL Gala

Adres van het laboratorium:

Prof. J.L. GALA  
Centre for Applied Molecular Technologies  
(1st Floor, A127 lokaal)  
Clos Chapelle-aux-Champs 30, Bus 30.46  
1200 Brussel



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## Aanvraag voor PROGENSA/PCA3 urine onderzoek

### **Datum van afname:**

### ***Patient :***

Naam :

Voornaam :

Geboortedatum :

Adres :

### ***Geneesheer:***

Naam :

Dienst-Adres :

Telefoon :

### **Handtekening**

**Opmerking:** Voor de uitvoering van dit onderzoek moet een door de patiënt getekend document aangehecht worden waarin duidelijk vermeld is dat de patiënt op de hoogte is van de volledige informatie betreffende de test en dat hij akkoord gaat met de financiële implicatie van de analyse.



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**Formulier akkoord van de patiënt.**

Ter attentie van de Heer Professor Jean-Luc Gala,

Ik, ondergetekende, verklaar,

- alle noodzakelijke uitleg over het nut van de ProgenSA-PCA3 test van mijn arts te hebben gekregen,
- op de hoogte te zijn dat die test tot nu toe alleen uitgevoerd wordt in CTMA (Centre for Applied Molecular Technologies, UCL, Brussel),
- op de hoogte te zijn dat die test tot nu toe niet door het RIZIV terugbetaald wordt, en dat ik dus akkoord ben om de kosten van de test (259 € ,twee honderd negenenvijftig €) zelf te betalen.

Te :

Op :

voor akkoord:

Naam, voornaam,.....,

Handtekening.....



## PROGENSA™ PCA3 Urine Specimen Kit

### Physician Instructions

For *in vitro* diagnostic use.

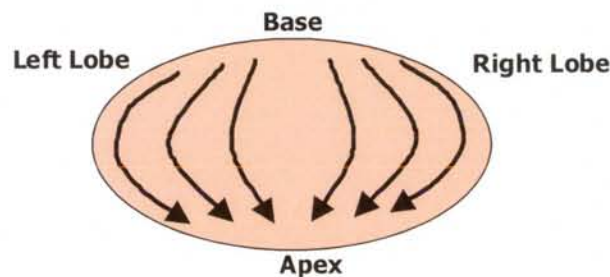
For U.S. export only.

### Intended Use

These physician instructions are intended to direct the physician how to properly collect urine from male patients following a digital rectal exam (DRE) procedure consisting of three strokes per lobe. The collected urine will be processed according to the *Specimen Handling Instructions* and tested with the GEN-PROBE® PCA3 Assay.

### Instructions

1. It may be helpful to request that the patient consume a large volume of water (approximately 500 mL) to ensure sufficient urine for collection.
2. Conduct a DRE as described below immediately prior to urine collection. Apply pressure on the prostate, enough to depress the surface approximately 1 cm, from the base to the apex and from the lateral to the median line for each lobe as shown in the figure below. **Perform exactly three strokes for each lobe. This is not intended to be a prostatic massage.**



3. Following the DRE, direct the patient to provide first catch urine (approximately 20 to 30 mL of the initial urine stream) in an appropriately labeled urine collection cup. This must be the first voided urine specimen following the DRE. Use a collection cup free of any preservatives. If a patient cannot stop his urine flow and provides more urine than the requested 20 to 30 mL, keep the entire volume. If the patient is unable to provide the requested volume, at least 2.5 mL is required to run the PCA3 Assay.
4. Unprocessed urine specimens, if not immediately processed, must be maintained at 2°C to 8°C or kept on ice. The chilled, unprocessed urine specimen must be transferred into the urine specimen transport tube within four hours of collection (see *Specimen Handling Instructions* for further instructions). **Do not freeze unprocessed urine specimens.**

### Warnings and Precautions

- A. For *in vitro* diagnostic use.
- B. For U.S. export only.
- C. See the *Specimen Handling Instructions* for further warnings and precautions.



## PROGENSA™ PCA3 Urine Specimen Kit

### ► Specimen Handling Instructions

For *in vitro* diagnostic use.

For U.S. export only.

### Intended Use

The PROGENSA™ PCA3 Urine Specimen Kit is for the collection and transport of male urine specimens that will be tested with the GEN-PROBE® PCA3 Assay.

### Contents

**PROGENSA™ PCA3 Urine Specimen Kit, Cat. No. 302352**

Each kit consists of 50 Urine Specimen Transport Kits containing:

Component	Quantity	Description
PROGENSA™ PCA3 Urine Specimen Transport Tube	1 X 2.3 mL	GEN-PROBE® Urine Transport Medium.
Disposable Transfer Pipette	1	For the transfer of 2.5 mL of urine from the primary collection container to the PCA3 Urine Specimen Transport Tube.

### Warnings and Precautions

- For *in vitro* diagnostic use.
- For U.S. export only.
- Use this kit only with the PCA3 Assay. Performance has not been established with other products.
- Do not apply the urine transport medium directly to skin or mucous membranes or take internally.
- Use routine laboratory precautions. Do not eat, drink or smoke in designated work areas. Wear disposable, powderless gloves and laboratory coats when handling urine specimens and kit reagents. Wash hands thoroughly after handling urine specimens and kit reagents.
- Take care to avoid cross-contamination during the urine specimen handling steps. Urine specimens can contain high levels of mRNA target. Ensure that urine specimen containers do not contact one another, and discard used materials without passing over open containers. If gloves come in contact with urine specimen, change gloves to avoid cross-contamination.
- Do not use this kit after its expiration date.
- Maintain proper storage conditions during urine specimen shipping to ensure the integrity of the urine specimen. Urine specimen stability under shipping conditions other than those recommended has not been evaluated.

### Storage Requirements

Store the PCA3 Urine Specimen Kit at room temperature (15°C to 30°C).

### Urine Specimen Collection and Handling

- Obtain a post-digital rectal exam urine specimen in a urine collection cup (see *Physician Instructions* for detailed instructions). Unprocessed urine specimens, if not immediately processed, must be maintained at 2°C to 8°C or kept on ice. The chilled, unprocessed urine specimen must be transferred into the urine specimen transport tube within four hours of collection. **Do not freeze unprocessed urine specimens.**

- To process urine specimens, tightly cap and invert the unprocessed urine specimens five times to resuspend cells. Remove the cap of the urine specimen transport tube and transfer 2.5 mL of the collected urine into the tube using the disposable transfer pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on the urine specimen transport tube label.
- Re-cap the urine specimen transport tube tightly and invert the urine specimen five times to mix. This is now known as the processed urine specimen.
- Store as described in *Processed Urine Specimen Transport and Storage* below.

### Processed Urine Specimen Transport and Storage

Processed urine specimens must be transported to the laboratory in the urine specimen transport tube at or below 30°C (may be frozen).

**Shipping arrangements must be made to ensure processed urine specimens are received by the testing site within five days of collection.** Upon receipt of the shipment, the laboratory may store the specimen at 2°C to 8°C for up to 14 days before disposal is required. If longer time periods are needed, processed urine specimens can be stored at -20°C or below for up to 90 days. Refer to the table below for the allowable storage times at different temperatures.

Storage Temperature	Time*
8°C to 30°C	up to 7 days**
2°C to 8°C	up to 14 days
-20°C or below	up to 90 days

\*Time is from the point of urine specimen processing and the temperature listed (or lower) must have been maintained the entire time.  
\*\*Time allowed for shipment at 30°C or below.

Processed urine specimens may be subjected to up to five freeze-thaw cycles.

**Note:** Follow International Air Transportation Association (IATA) PI650 requirements for packaging when urine specimens are transported by common land and air carriers.

### Developed and manufactured by:

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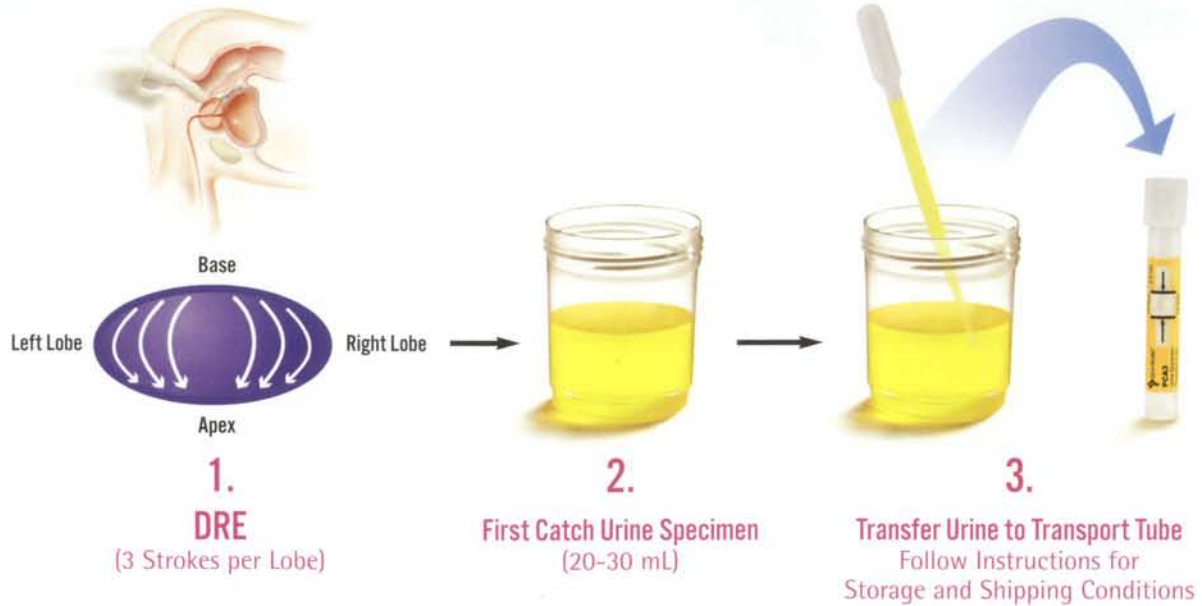
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## The PCA3 Urine Specimen Collection Procedure

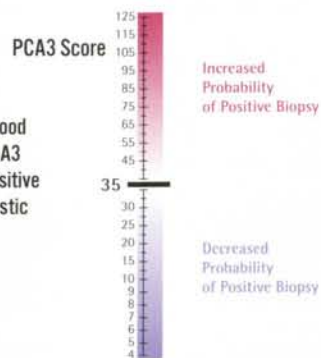


The PCA3 urine specimen collection procedure

DRE Instruction: apply pressure on the prostate, enough to depress the surface approximately 1 cm, from the base to the apex and from the lateral to the median line for each lobe and repeat this 3 times

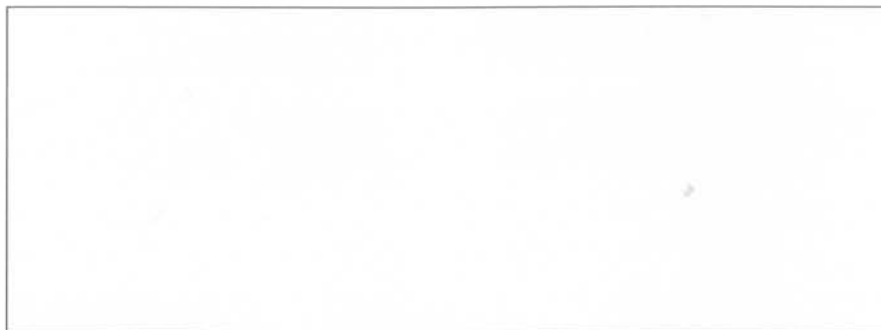
### Results Summary:

As the PCA3 score increases the likelihood for positive biopsy increases. As the PCA3 score decreases, the likelihood for a positive biopsy decreases. The greatest diagnostic utility occurs at a cut-off of 35.



References available upon request.

For More Information Contact:



10210 Genetic Center Drive San Diego, CA 92121 (800) 523-5001 WWW.GEN-PROBE.COM





# The first genetic test specific for prostate cancer, from a urine test

Prostate cancer (PCa) is the second most commonly diagnosed malignancy and a leading cause of cancer death in men across the globe. Current practices for detecting PCa utilize PSA and DRE as indications for biopsy and identify approximately 25% of patients with PCa. Unfortunately this means that 75% of biopsies are unnecessary, creating a considerable burden in terms of cost and patient discomfort.

PCA3 is a prostate-specific gene that is highly overexpressed in prostate tumors. Prostate cancer cells express 60 to 100 times more PCA3 mRNA than normal cells. The PROGENSA™ PCA3 test is highly specific and uses Transcription Mediated Amplification (TMA) to quantify the PCA3 mRNA in a patient sample. The resulting output is a highly useful PCA3 score that can be used in conjunction with other patient history to more accurately predict biopsy outcomes.

## Improves Biopsy Decisions

- ▶ PCA3 score adds useful information when PSA or DRE are inconclusive
- ▶ PCA3 score may support need for second biopsy, or watchful waiting
- ▶ PCA3 score provides additional information which may reduce patient anxiety

## Easy to use

- ▶ Uses first catch Urine Sample, post DRE (see illustration on back)
- ▶ Available in Labs throughout Europe

## Captures the Power of Molecular testing

- ▶ Detects PCA3 gene that is highly specific for Prostate Cancer
- ▶ Additional information improves the diagnosis of PCa, reducing the number of unnecessary biopsies



**PROGENSA™**  
**PCA3**

The test for better biopsy decisions.

