# Gold nanoparticle-enabled blood test for the early diagnosis of pancreatic ductal adenocarcinoma.


**KEYWORDS**

- ❑ EARLY DIAGNOSIS
- ❑ SCREENING PROGRAM
- ❑ SEROLOGICAL TEST
- ❑ IN VITRO DIAGNOSTIC DEVICE
- ❑ PANCREATIC DUCTAL ADENOCARCINOMA (PDAC)

**AREA**

- ❑ BIOMEDICAL



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**Patent Type**
Patent for invention.

**Co-Ownership**
Sapienza Università di Roma 80%, Università Campus Bio-Medico di Roma 20%.

**Inventors**
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**Industrial & Commercial Reference**
Medical device sector targeted for 70% ca. to the National Health Service (www.confindustriadm.it).

**Time to Market**
Current state of development is TRL4. Prototyping is currently underway with the support of the startup FLIM Labs. We estimate to reach TRL7 within 8-12 months.

**Availability**
Cession, Licensing, Research, Development, Experimentation, Collaboration and Spin-Off.

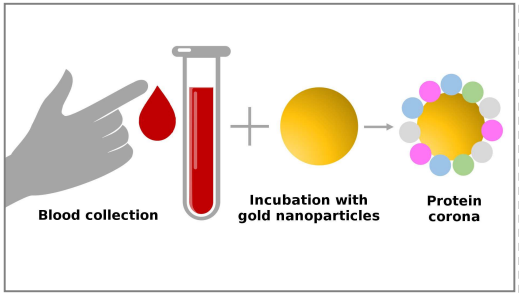



**Fig. 1** Exposing gold nanoparticles to human plasma leads to formation of a protein corona at the particle surface.

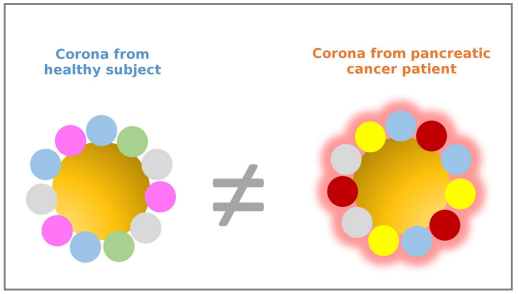
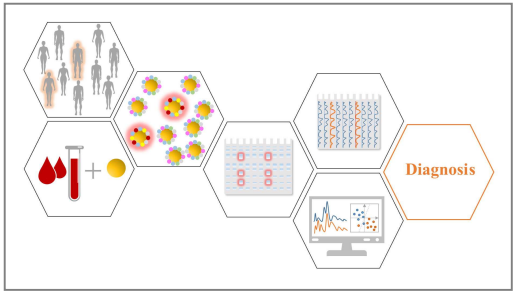



**Fig. 2** Composition of protein corona depends on the protein source; the corona formed in the plasma of healthy subjects differs from that formed in the plasma of cancer patients.





**Abstract**
The present invention relates to a new rapid, effective and low-cost first-level method to perform: (i) screening of subjects at risk of developing pancreatic adenocarcinoma within specific target populations (i.e. at least two first-level relatives diagnosed with pancreatic adenocarcinoma; hereditary forms of pancreatitis; genetic predisposition; presence of cystic lesions affecting the pancreas); (ii) identification of subjects for whom it is necessary and/or appropriate to carry out second level investigations; (iii) follow-up of pancreatic cancer patients treated with neo-adjuvant therapy.


**Pubblicazioni**


- ❖ The biomolecular corona of gold nanoparticles in a controlled microfluidic environment. Luca Digiacomo, Sara Palchetti, Francesca Giulimondi, Daniela Pozzi, Riccardo Zenezini Chiozzi, Anna Laura Capriotti, Aldo Laganà, Giulio Caracciolo. Lab on a Chip, 2019,19, 2557-2567.


**Fig. 3** Statistical analysis of the protein profiles obtained from the densitometric analysis of the electrophoretic profiles allows to identify subjects affected by pancreatic adenocarcinoma with high sensitivity and specificity

# Gold nanoparticle-enabled blood test for the early diagnosis of pancreatic ductal adenocarcinoma.

## Technical Description

The invention consists of an experimental procedure leading to the formation of a protein corona on the surface of gold nanoparticles following in vitro incubation in human plasma. The protein corona is subsequently isolated from the gold particles by means of a specific experimental protocol and then characterized by polyacrylamide gel electrophoresis (SDS-PAGE). The statistical analysis of the protein profiles obtained from the densitometric analysis of the electrophoretic profiles allows to identify subjects affected by pancreatic adenocarcinoma with sensitivity and specificity higher than 90%.

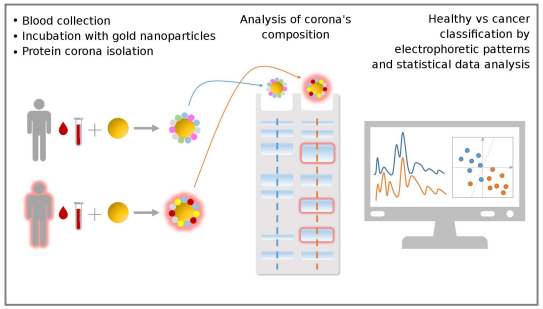



**Fig. 4** Steps of the experimental procedure.

## Technologies & Advantages

The development of screening tests for the early diagnosis of pancreatic adenocarcinoma have focused on serum biomarkers. To date, Ca 19.9 is the only marker approved by the Food and Drug Administration, but its use as a screening tool is unacceptable due to low sensitivity (median 79%) and specificity (median 82%). Different panels of biomarkers, which combine different proteins with each other with or without Ca 19.9, have proven useful in discriminating subjects suffering from pancreatic adenocarcinoma compared to healthy controls or patients suffering from other pathologies.

However, these methods are not applicable in clinical practice as they do not meet the ASSURED (Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free and Deliverable to end-users) criteria established by the World Health Organization for the development of diagnosis and screening technologies. On the contrary, the developed technology is completely aligned with the ASSURED criteria.

In particular, it combines high performance in terms of sensitivity and specificity with reduced costs and ease of use by non-specialized personnel.

## Applications

The main application concerns the diagnosis and monitoring of pancreatic adenocarcinoma in clinical practice. Commercialization of a device for the diagnosis and monitoring of pancreatic adenocarcinoma is of interest to the "Biomedical and Instrumental" division of the Medical Devices Sector which consists of 700 companies distributed throughout the national territory and which represents 18% of the sector. It is a highly heterogeneous, highly innovative and specialized industrial environment, where small enterprises coexist with big companies. A further application of the invention consists in the design and carrying out of R&D activities aimed at the development of a point-of-care device for the screening of pancreatic adenocarcinoma.

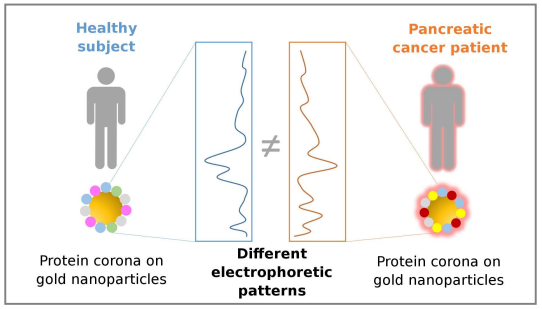



**Fig. 5** Schematics describing the developed technology.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