"Development of a novel blood-based diagnostic test for colorectal cancer"

ColoDetect

SME instrument – phase 2

Grant Agreement number: 666540

Deliverable 7.5

COLODETECT® brochure

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Dissemination Level		
PU	Public, fully open, e.g. web	**X**
CI	Classified, information as referred to in Commission Decision 2001/844/EC	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, restricted under conditions set out in Model Grant Agreement	

DISTRIBUTION LIST

Partner nº	INSTITUTION	PERSON IN CHARGE
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1. About the deliverable

The present deliverable **D7.5 – COLODETECT® factsheet** is part of the Task 7.2 named *"Production of dissemination materials and means"* in Work Package number 7 (WP7) of ColoDetect project, and is aimed at achieving the following objectives for the Dissemination & Communication of results [Months: 1-36]:

- dissemination and communication action to ensure a high impact and knowledge of the technology developed in COLODETECT® colorectal cancer diagnostic test.
- to allow the general public to know about the advantages of COLODETECT® test compared to currently used technologies.
- to allow the target final users of the *in vitro* diagnostic (IVD) kit to know about the specifications and application of the test.
- to allow the medical community in Europe about how the assay works and its application.
- to promote COLODETECT® product in specific events aimed at the end-users.

2. About the brochure

This informational brochure was intended to provide elementary information on COLODETECT® test:

i. Description

The brochure consist of six-pages. It has been designed with color patterns in harmony with the project website (http://colodetect.com) in blue basis colors to preserve a uniform graphical design. It also shows a central picture in the cover which refers to the target population for COLODETECT® test, that is the group of people ranging from 50 to 75 years old who will benefit from the results of the product in terms of better diagnosis, increased patient's survival and improved life quality.

From a structural point of view, the document does not contain columns nor tables since the design was aimed to allow certain continuity while reading, avoiding visual obstacles and allowing the development of ideas 'from the problem to the solution' in a hierarchical way. The brochure begins with the epidemiological data on colorectal cancer and the limitations of current diagnostic methods, emphasizing the importance of early diagnosis and its direct relationship with the prognosis and mortality of patients.

The first page contains an introductory information about COLODETECT® diagnostic test and highlights the key features of the product in an eye-catching image. Second page underscores those distinctive aspects of the test that represent competitive advantages compared to other technologies or tests currently in use.

The reader can also find within the second page the references on the target population for COLODETECT® test, the probable results and the recommendations on how to proceed on a case-by-case basis.

Up to this point in the brochure, the product COLODETECT® is presented in colloquial language, concise and easy to understand for the general public.

From this point, the document focuses on the technical aspects of the product, introducing more specific or scientific terminology, whose purpose is to explain clinician and end users (diagnostic laboratories) the test workflow and the technology used to obtain the result from a patient's serum/plasma sample.

The description of technical features of the product includes:

- COLODETECT® technology overview
- COLODETECT® indirect (serological) immunoassay
- Reaction detection using Luminex® instruments, including the operation mode
- Integrated software for data acquisition and analysis

With this information, the end user can have a clear idea about COLODETECT® utility and the equipment necessary to carry out the assay.

ii. Dissemination

COLODETECT® brochure is intended to target a wide variety of stakeholders, mainly people from the healthcare sector, private-health insurance companies, patients and health-care administration among others.

COLODETECT® brochure has been designed to be distributed. It also can be downloaded from the ColoDetect webpage. The leaflet will be disseminated throughout the term of the project and a number of 2.000 COLODETECT® brochures has been printed as was indicated in task 7.2 of ColoDetect project.

Event for its distribution will be:

- AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics (October 26 - 30, 2017 Pennsylvania, US).
- MEDICA 2017 (13th & 14th of November, 2017 Düsseldorf, Germany)
- BioSpain 2018 (Autumn, Spain)
- BIO International Convention 2018 (June 4-7, 2018 Boston, MA, US)

- Others…

This brochure will be also handed out at all events and meetings where PROALT will participate presenting COLODETECT® product, including potential investors or commercialization partners.

ANNEX I

COLODETECT® brochure

COLODETECT

BLOOD-BASED TEST FOR EARLY DIAGNOSIS OF **COLORECTAL CANCER**

PROALT
PROTEIN ALTERNATIVES

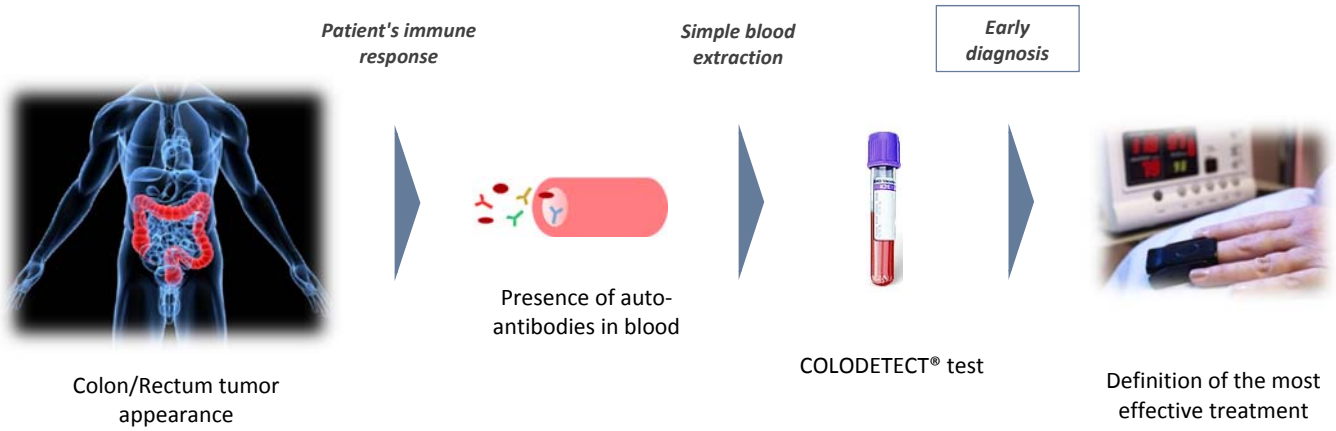
Colorectal cancer (CRC) is the second most frequent and most deadly neoplasia worldwide that affects men and women between the ages of 50 and 75, indistinctly. There are about 41,000 new cases per year in Spain and more than one million worldwide. CRC is the second leading cause of cancer death in men and women, surpassed only by lung cancer in men and breast cancer in women.

Early diagnosis is esential since survival rate is highly related to cancer stage at diagnosis. At present, only 30-40% of colon cancer cases are diagnosed in early stages, resulting in 5-year mortality rates of around 50%. Such survival rates can be increased significantly up to 90-95% when patients are diagnosed at early stages, where symptoms have not yet revealed (bleeding, abdominal pain, intestinal occlusion, among others).

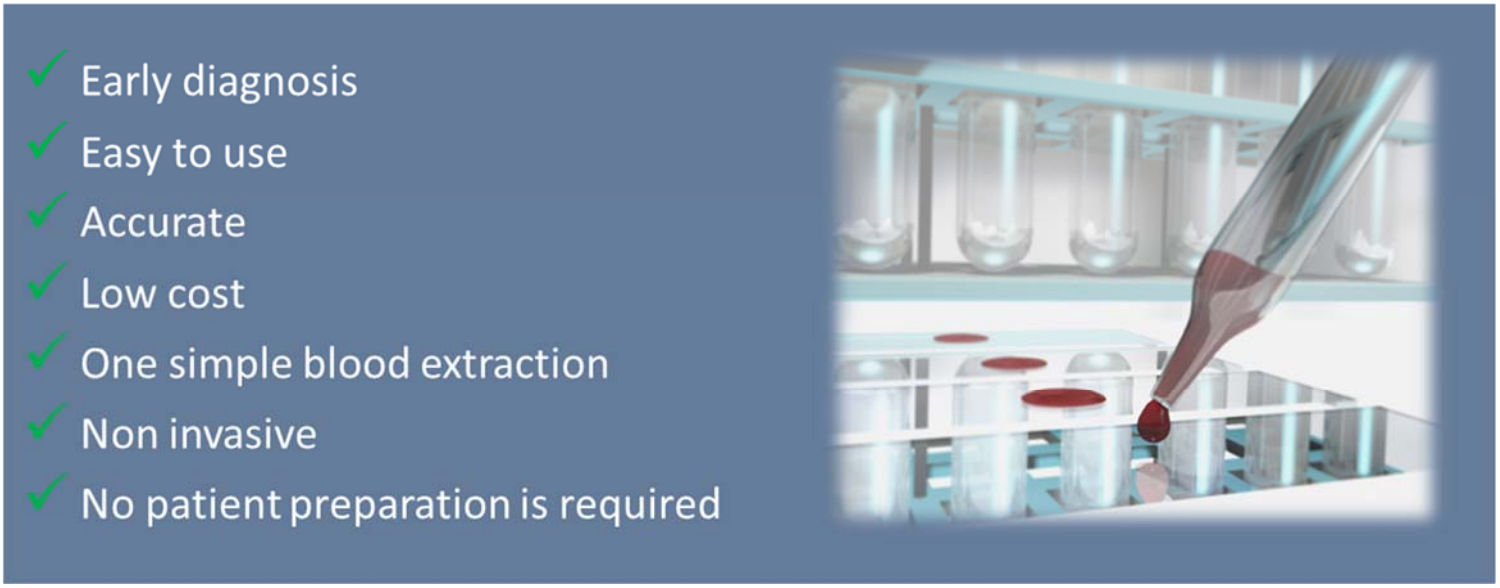
Current diagnostic methods have serious limitations in detecting the disease at early stages, resulting in low adherence rates to the CRC screening programs for population at risk already implemented by the governments in developed countries. Other more reliable methods, such as colonoscopy, are invasive, costly and techically more compex, preventing them from being used for this purpose.

COLODETECT® TEST

This simple diagnostic test in blood allows the early detection of CRC even before symptoms appear. COLODETECT® detects several antibodies generated by the patient's immune system against its own tumor present in the colon or rectum. This subset of antibodies are usually referred to as auto-antibodies.



KEY COLODETECT® FEATURES



ADVANTAGES

The advantages of auto-antibodies when compared to other type of biomarkers like proteins, RNA, DNA, metabolites,… is that they appear early at detectable levels in patient's blood, are structurally more stable, have a long half-life and they are not affected by circadian rithms, making them suitable for early detection of the disease.

The simplicity, accuracy and afordable cost of COLODETECT® test makes it ideal for CRC screening in the large population at risk (men and woman from 50-75 years old), avoiding the obvious limitations offered by the invasive colonoscopy and providing a great advantage compared to traditional screening methods, which are based in the detection of blood in feces, have diet restrictions and require the patient preparation.

USAGE RECOMMENDATIONS

- Men and women over 50 years old.

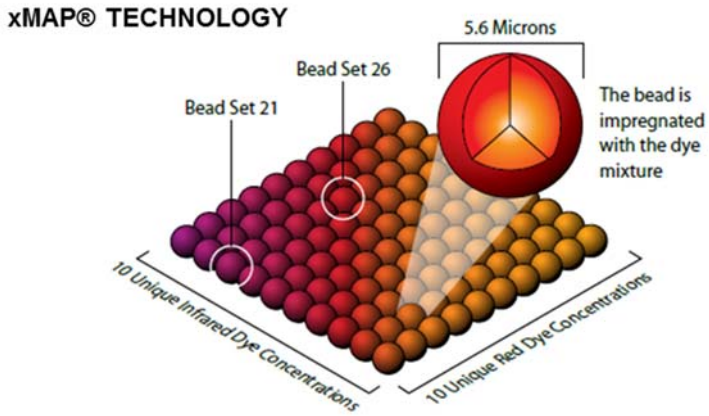
- Carry out the analysis every year or every two years after a negative result.

- In case of positive result, there is a high probability of having colorectal cancer. It is required to consult the specialist of digestive pathology. It is also advisable to perform a confirmatory colonoscopy, following the recommendations of the clinician.

COLODETECT® TECHNOLOGY OVERVIEW

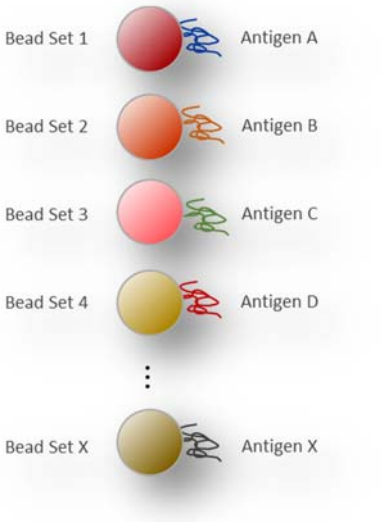
A High-throughput Multiplex Bead-based Assay for Colorectal Cancer Diagnosis

COLODETECT® assay was developed using the xMAP® technology from Luminex® Corporation. It is built on demonstrated existing technology as flow cytometry, microspheres, lasers or leds, digital signal processing and traditional chemistry, that were combined in a unique way. The technology uses 5.6 micron polystyrene microspheres which are internally dyed with red and infrared fluorophores. Using different amounts of the two dyes for different batches of microspheres, up to 100 different microsphere sets can be created. Each bead is unique with a spectral signature determined by its red/ infrared dye mixture. The bead is filled with a specific known ratio of the two dyes. As each microsphere carries a unique signature, the detection system can identify to which set it belongs.



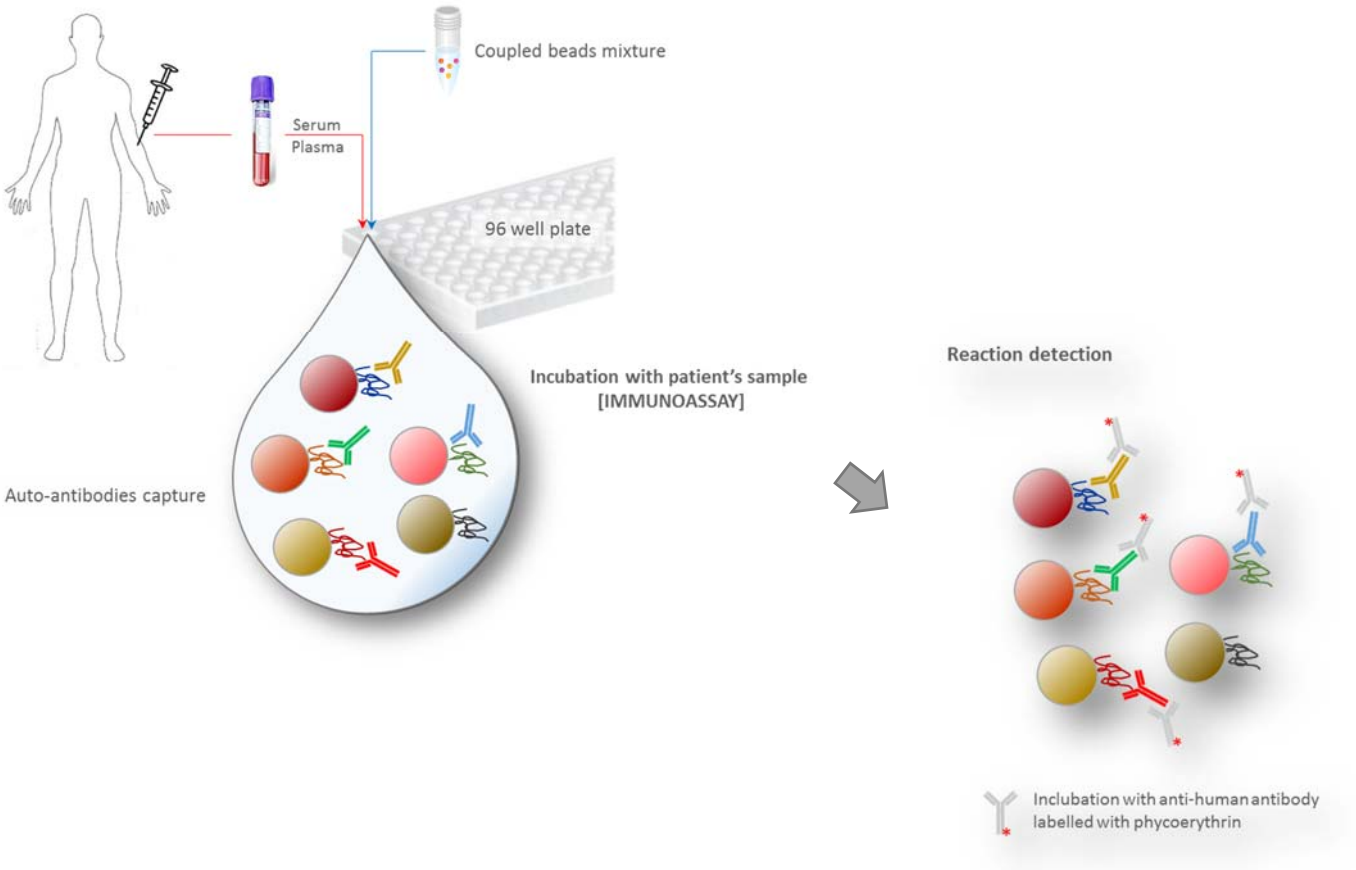
COLODETECT® INDIRECT (SEROLOGICAL) IMMUNOASSAY

COLODETECT® assay uses different color-coded tiny beads or microspheres manufactured by Luminex®. The selected colored beads that are part of COLODETECT® assay are each coated with a specific protein/antigen.



These combinations bead-antigen (covalently coupled) allows to simultaleously capture different specific auto-antibodies that are present in patient's blood sample, indicating thus the presence of the disease.

For the immunoassay development, a mixture of different colored-coated beads is prepared, which is then added to each well of a 96-well plate, allowing a flexible and open-architecture design that can be easily modified. Serum/plasma samples from patients are next added to each well, allowing the simultaneous capture and detection of specific auto-antibodies in a small blood volume of each individual.



ANTIGEN-ANTIBODY INTERACTION DETECTION USING LUMINEX® INSTRUMENTS

MAGPIX® reader system from Luminex® is used for auto-antibodies detection within the reaction. It is an affordable, compact fluorescent detection system suitable for medium-throughput multiplex immunoassays. This multiplexing unit performs up to 50 different tests in a single reaction volume and reads a 96-well-plate in just 60 minutes. The instrument features self-cleaning routines and magnetic bead compatibility, making it easy to learn and easy to use.

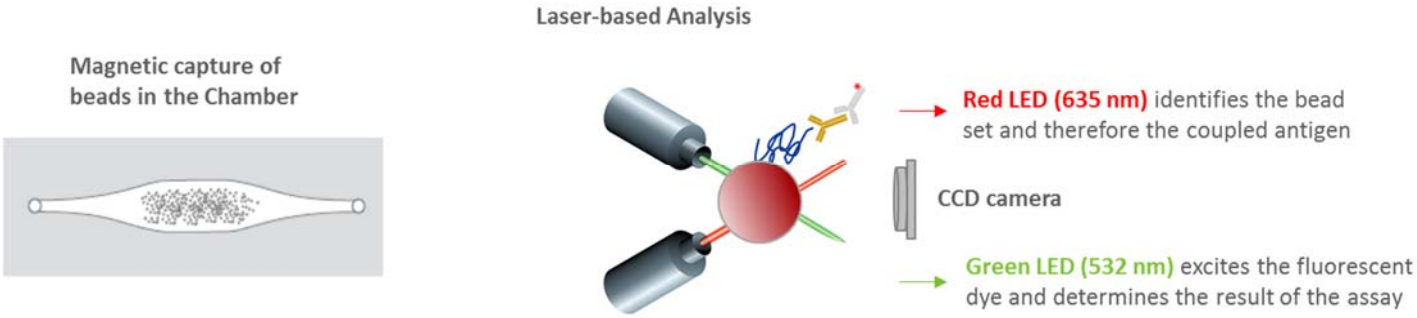
Key System Features

- Multiplexing: Up to 50 analytes per sample
- Sensitivity: Approximately single-digit picogram levels of protein
- Dynamic Range (Typical): ≥3.5 logs
- Read Time: 96-well plate in ≤ 60 min (up to 4,800 tests/hour)
- Daily Start-Up/Shut-Down: ≤ 15 min
- Foot Print: three ft linear bench space

LUMINEX® READER DESIGN

How it works?

Within the reader, fluidics allow the sample in study to reach the analysis chamber. Once within the chamber, a magnet retain the beeds and two different leds excite (i) the internal dyes that identify each microsphere particle, and also (ii) the reporter dye captured during the assay (anti-human antibody labelled with phycoerythrin in COLODETECT® assay). Many readings with a CCD camera are made on each bead set, further validating the results. In this way, the technology allows multiplexing of up to 50 unique assays within a single sample, both rapidly and precisely.



xPONENT® SOFTWARE FOR CLINICAL DIAGNOSTIC INSTRUMENTS

The MAGPIX® reader can be ordered with a laptop PC or a desktop PC. The system includes xPONENT®, a modular, flexible software package for controlling the equipment. The software's graphical user interface follows the typical assay workflow, but can be customized to meet the needs of a specific laboratory or assay like COLODETECT®. Navigation wizards and automated routine operations such as startup, shutdown, calibration, and performance verification further enhance system usability and result in increased walk-away time.

The software provides the user with enhanced data archiving, calibration and performance verification kits management, batch and protocol settings reports, automation connectivity, improved import/export functions to simplify data exchange, auto-launch of post acquisition analysis programs, range threshold analysis

capability, intra-well normalization analysis and real time regression and data analysis.

SCHEMATIC SUMMARY OF COLODETECT® IMMUNOASSAY PROTOCOL