

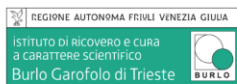


Smart Health: research for business innovation

BIOMEDICAL, IN VIVO AND IN VITRO DIAGNOSTIC

26-27 SEPTEMBER 2018
TRIESTE - ITALY

NATInFVG NIPT for traceable and digitalized Aneuploidies in Friuli Venezia Giulia



POR FESR
2014 2020
Friuli Venezia Giulia

OPPORTUNITÀ PER UNA CRESCITA SOSTENIBILE



Speaker:
Dr. Diego Boscarino



Area Science Park, Padriciano 99, 34149 – Trieste

www.abanalitica.it info@abanalitica.it

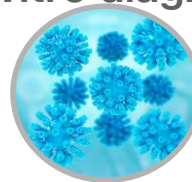
26 September 2018





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- AB ANALITICA, founded in 1990 in Padua, is a certified company according UNI EN ISO 9001 and UNI EN ISO 13485:2012 for design, development, production and commercialization of in-vitro diagnostic medical devices (IVD)
- IVD based on Molecular Biology methods for use in Infectious diseases, Hematology, Oncology, Genetic tests, Pharmacogenetics and Next-Generation Sequencing (NGS);
- Design, development, production management, commercialization and technical assistance regarding instruments for the preparation of samples for use in in-vitro diagnostics and commercialization and technical assistance for in-vitro diagnostic instruments





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NON INVASIVE PRENATAL TESTING OVERVIEW

- Enabled by new sequencing technologies and discovery of free circulating fetal DNA fragments in maternal plasma
- Ministerial guidelines: first or second choice test for the monitoring of the major autosomal aneuploidies
- Many IVD (In-vitro diagnostics) devices and LDTs (Laboratory Developed Tests) already exist
- € 40 millions Italian prenatal diagnostic market
- A screening method for fetal chromosomal abnormalities. Not a diagnostic method
- Critical clinical target

NIPT

Non invasive

Prenatal Test



NIPT tests should be integrated into a path that involves pre- and post-test counseling by Pediatric Hospitals, carried out in laboratories equipped with specialized staff in NGS techniques, supported by up-to-date IT tools and equipped with sample monitoring systems optimized for the process

OBJECTIVES

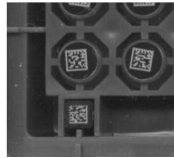
Overcome the current limits in the field of non-invasive prenatal testing through:

1. Complete traceability of the process and samples.
2. Creation of a biobank populated with recognized and accredited reference standards suitable for test validation.
3. Identification of a rapid and economic test to verify the percentage of the Fetal Fraction in the sample before the NIPT test.
4. Extension to other aneuploidies and some chromosomal micro-rearrangements through cross validated methods.
5. implementation of data management in the hospital electronic medical record system
6. Implementation of prediction algorithms and their integrated use through a Decision Support System (DSS) for operators and end users.
7. Development of a dedicated training platform that can be adapted to different

AB ANALITICA: BIOBANKING SOLUTIONS



2D tubes and racks



Array barcode reading



Wired barcode reading



Mobile barcode reading



Wireless infrastructure



Wireless temperature monitoring



Lab Freezers equipped with dedicated Freezer Racks for 2D tube storage

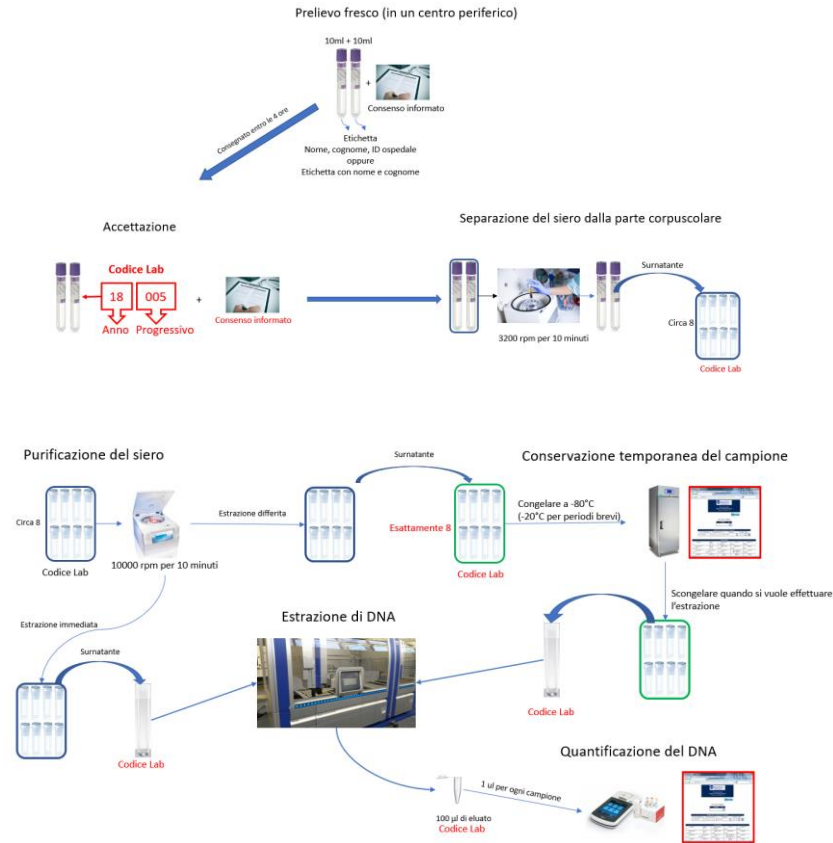


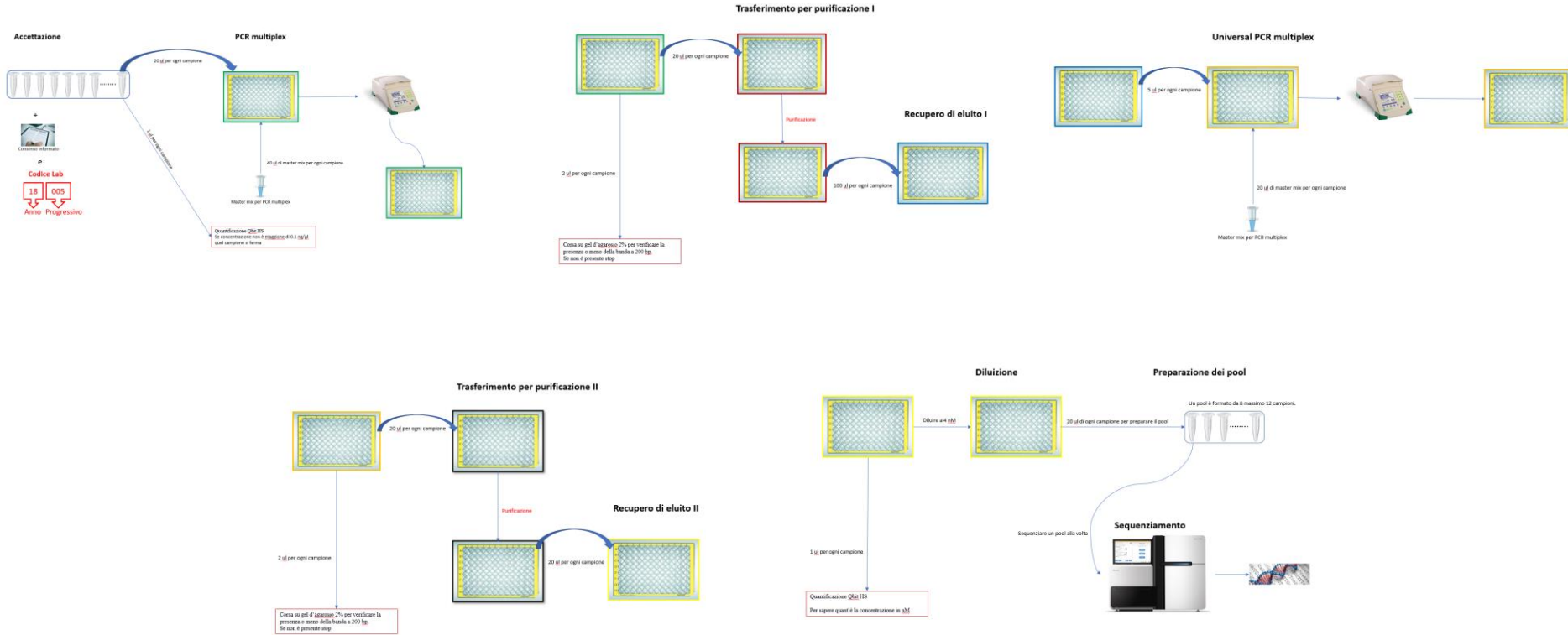
Storage data server and dedicated software



Cryogenic label printing and barcoding







PROGRESS STATUS

Traceability

1. Workflow analysis completed
2. Solutions based on Biobanker software and 3 different approaches designed: (1) tracking through entity IDs, (2) tracking through status flags, (3) barcoded physical constraints
3. Solutions based on approach (1) and (2) implemented and tested (tests ongoing at CBM)

Alternative to manual operation traceability under evaluation: full automation

Other project activities are on track



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CONCLUSIONS

NATlinFVG is on its way to achieve the expected results

For NIPT traceability, a foundation for a marketable solution has been established



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*Thank you for your kind
attention!*

