

# **Individualized cancer care through molecular diagnostics**

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Weill Cornell Medical College**

Confidential, October 2011

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**Our technology will guide physician decision  
in cancer prevention, early detection, and  
therapy based on the molecular signatures of  
the individual patient, rather than the average  
population.**

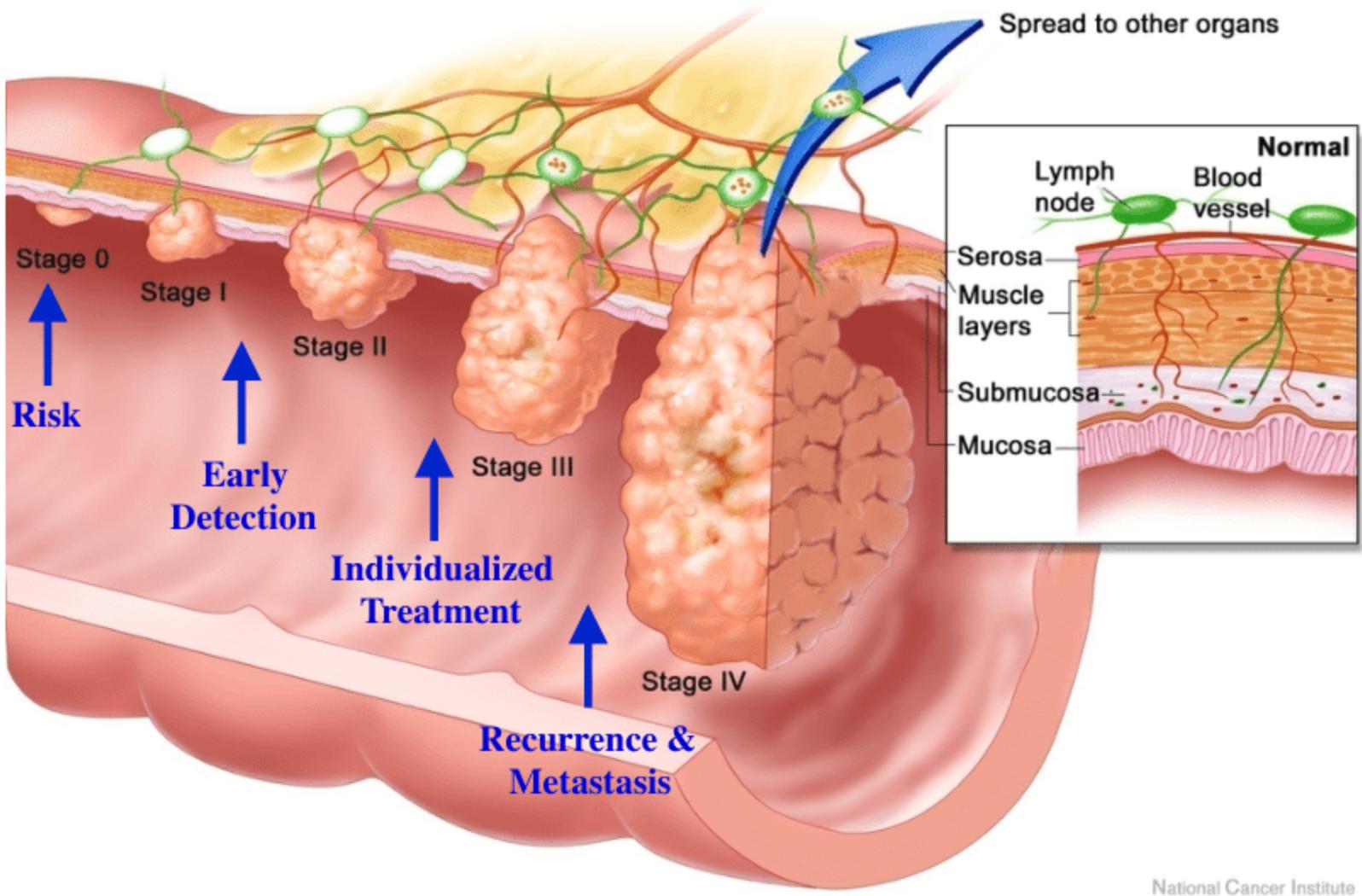
# Cancer concerns

- Are you or your family at risk of getting cancer?
- Do you already have a hidden cancer growing within you?
- What kind of treatment will you get?
- Will your cancer return, and will you survive?

# Cancer concerns

- **Risk:** Are you or your family at risk of getting cancer?
- **Early Detection:** Do you already have a hidden cancer growing within you?
- **Individualized treatment:** What kind of treatment will you get?
- **Recurrence and Metastasis:** Will your cancer return, and will you survive?

# Colorectal Cancer Progression



National Cancer Institute

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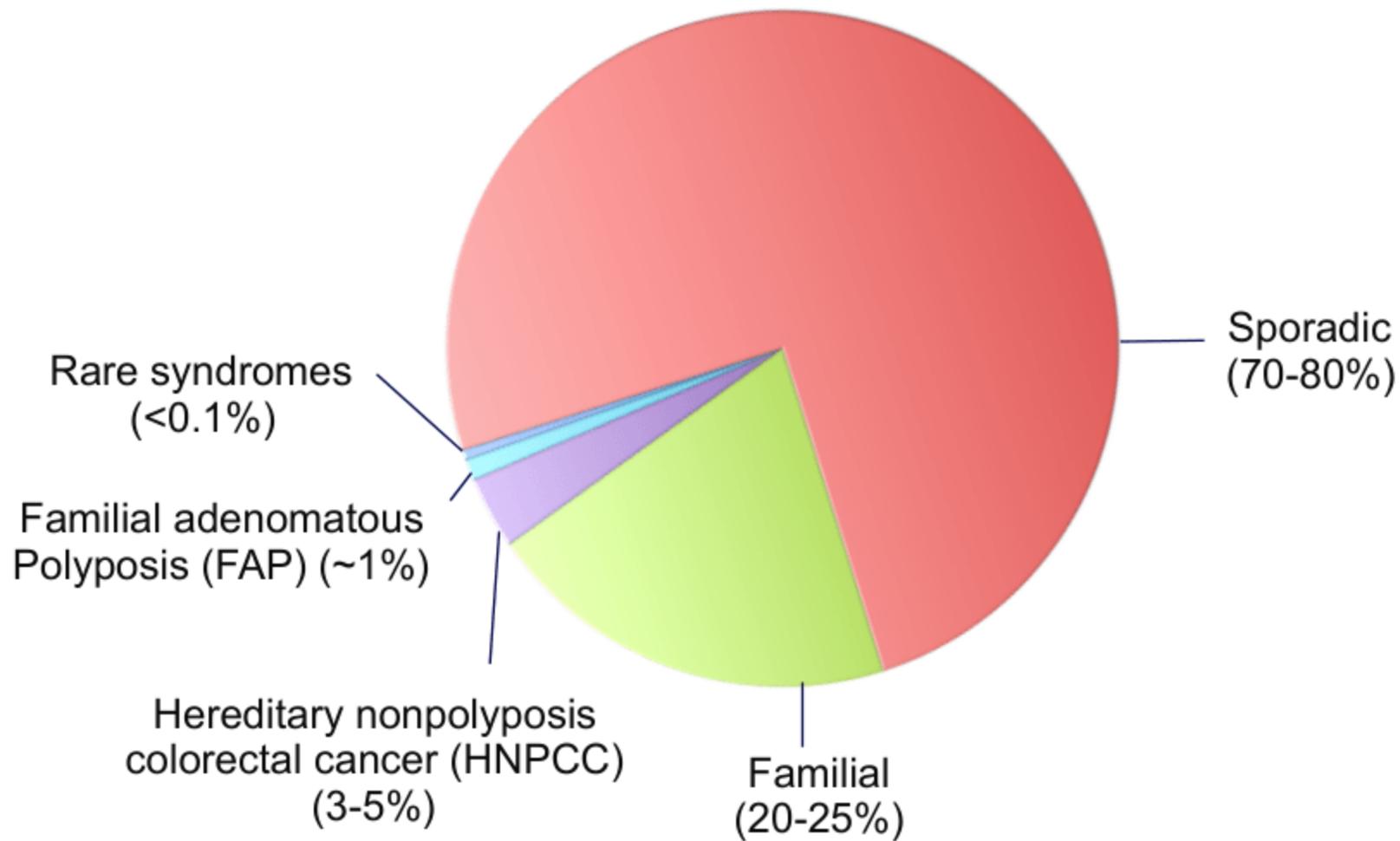
# Major problems with current cancer prevention and treatment:

- Individuals who will get cancer are not identified, losing the opportunity for prevention.
- Those with early “hidden” cancers often find out too late for more effective treatment.
- Individuals with cancer are given the *average* treatment for the *average* tumor with less than *average* results.
- Chemotherapy rarely cures, but is very toxic.

# Addressing Cancer concerns

- **Risk:** Identify individuals at risk of getting cancer by developing screens for changes in their DNA.
- **Early Detection:** Identify molecular markers of cancer, and develop tools to detect them at an earlier and more treatable stage.
- **Individualized treatment:** Identify tumor markers that predict outcome and guide treatment.
- **Recurrence and Metastasis:** Develop cancer drugs to prevent recurrence and treat metastasis.

# The Distribution of Colorectal Cancer

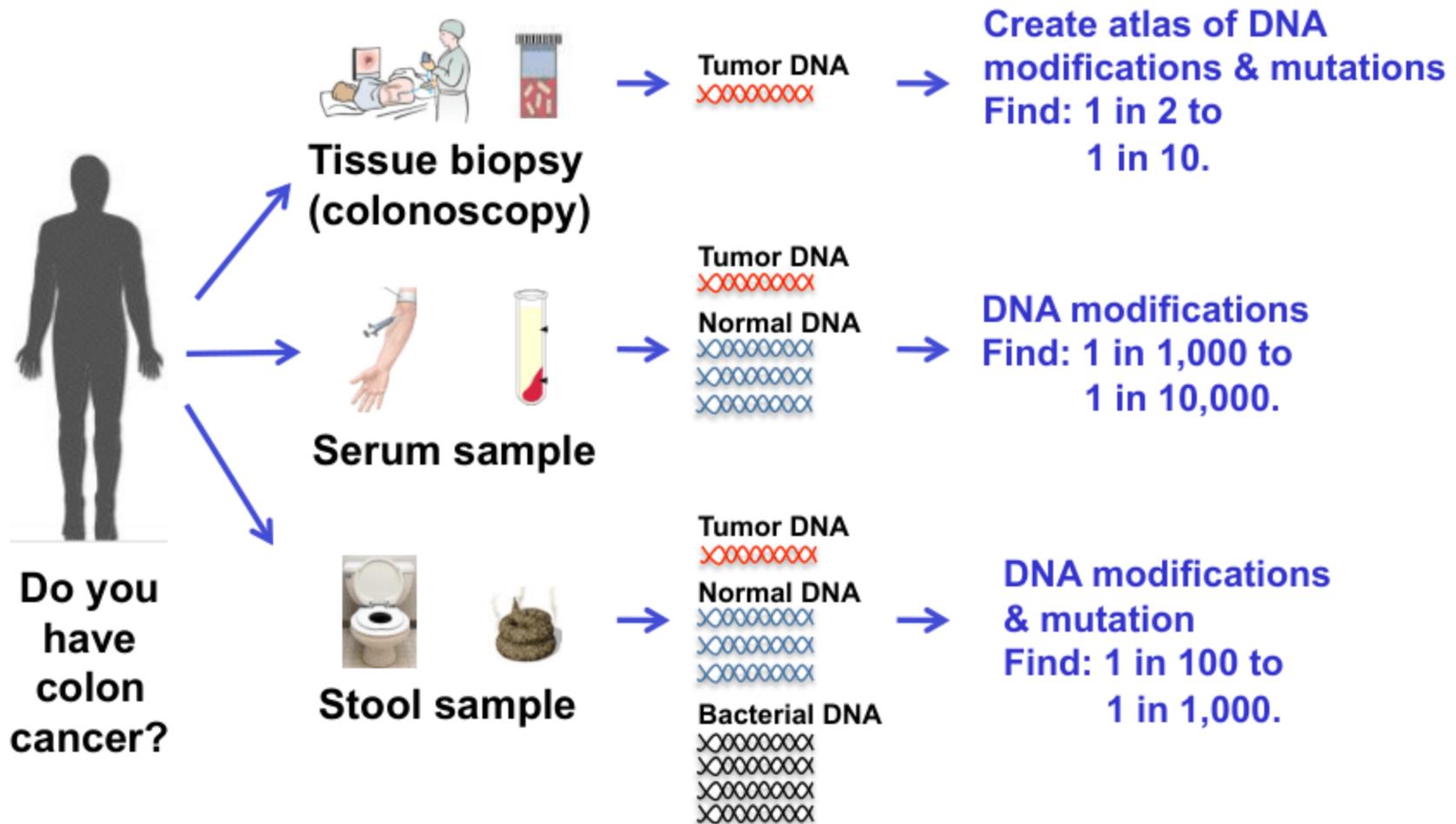


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# Early Detection: Do you already have a hidden cancer within you?

- Identify molecular markers of early cancers.
- Develop tests for these changes to identify if you have hidden cancer.

# Challenges to Identify and Detect Early Cancer



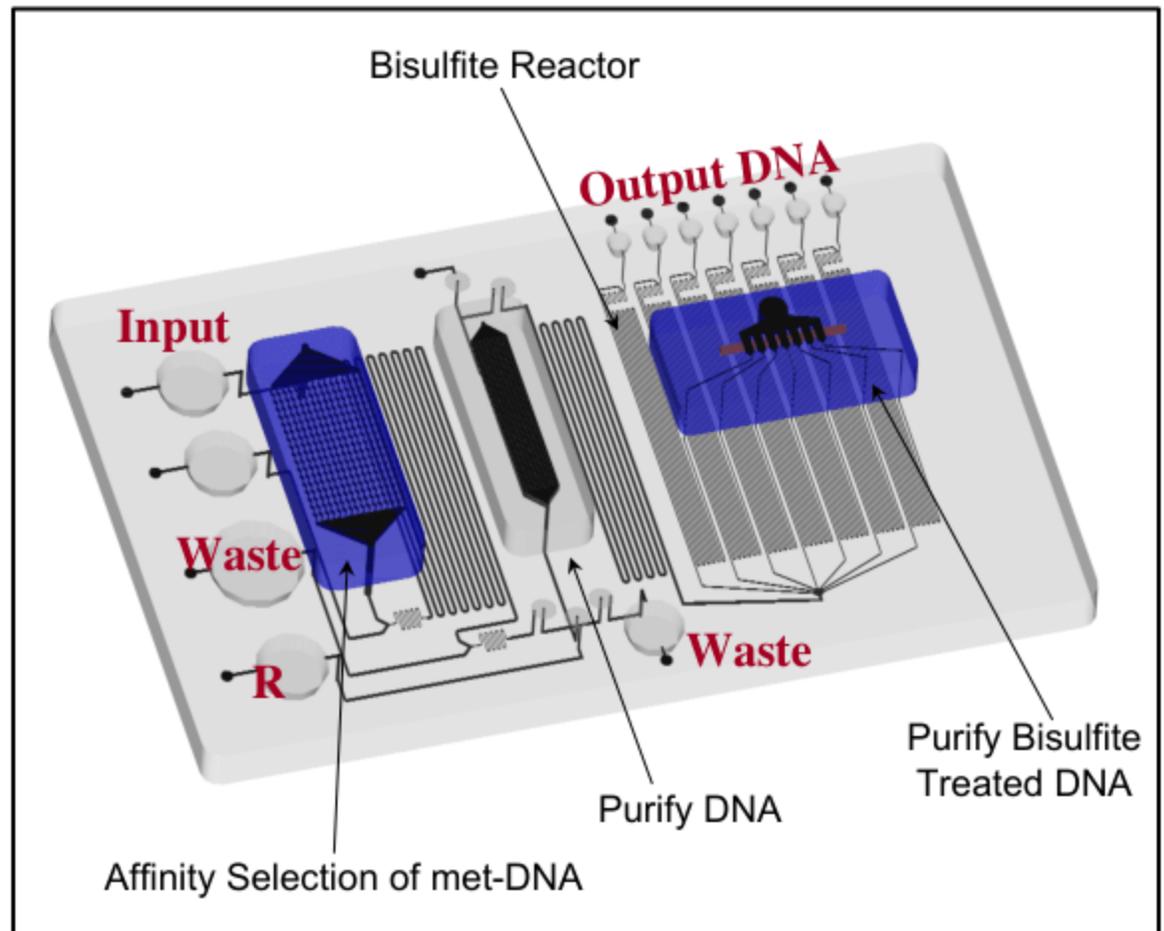
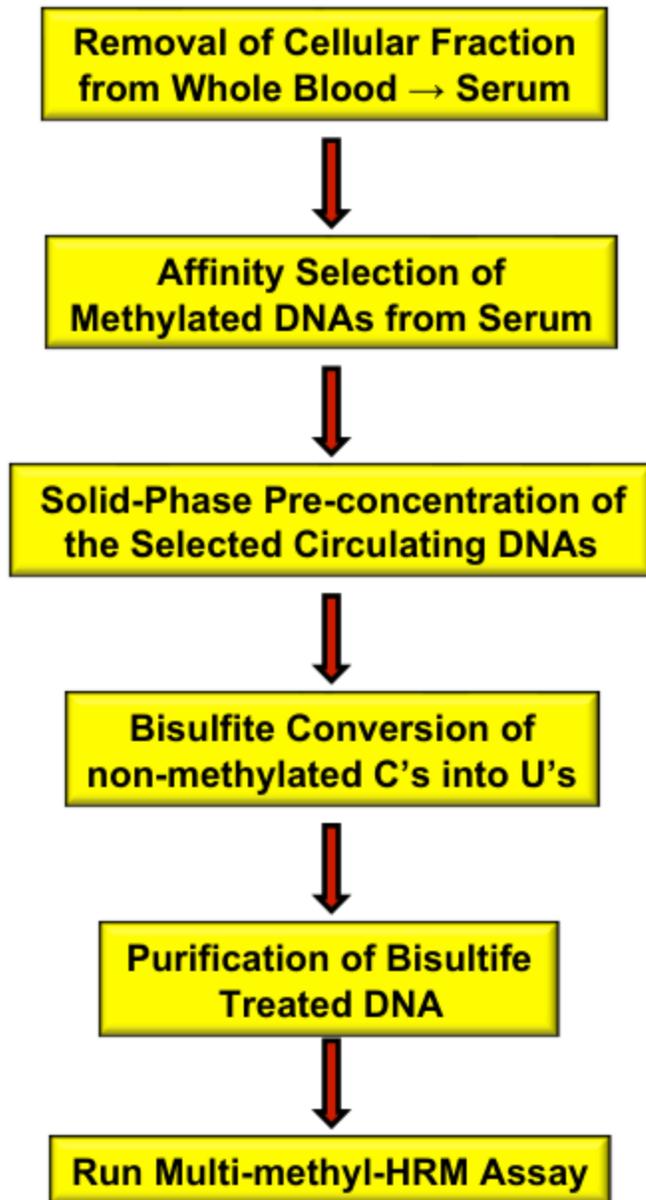
# Limitations of current colon cancer early detection tests:

- **Colonoscopy**: Compliance is less than 25%, cost is high, and 10%-20% of early lesions are missed.
- **Virtual colonoscopy**: Requires similar uncomfortable prep work, high cost, and no benefit in accuracy.
- **Fecal occult blood test**: Low cost, but misses too many colon cancers, and has mostly false results.
- **Epigenomics**: “Single-marker” serum test has high false-positive rate: Of every 1,000 tests, it give 110 “positives”, of which 1 will be a tumor, 109 will be erroneous and 1 tumor will be missed.

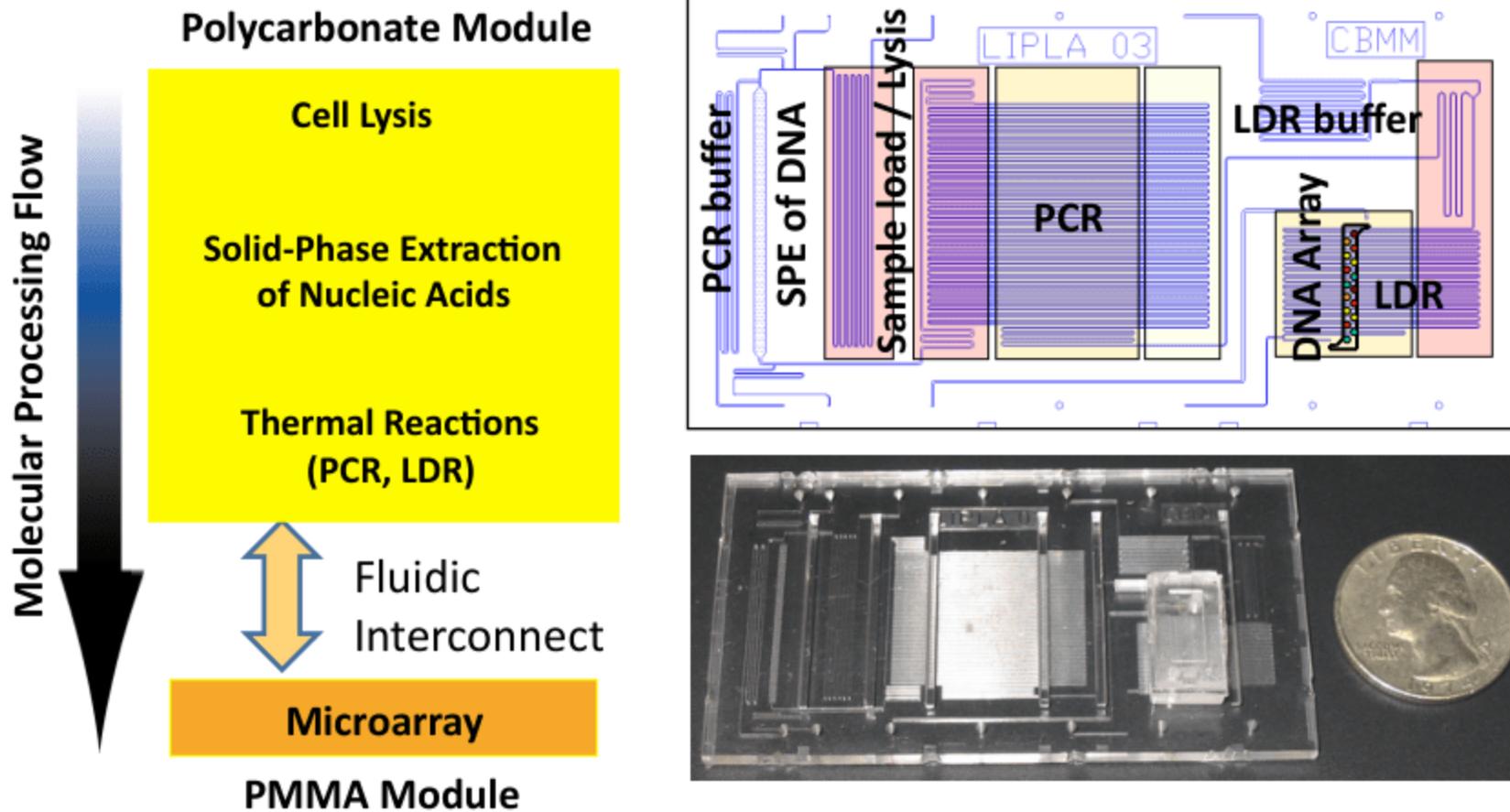
# Potential solution to colon cancer early detection test:

- Identify multiple markers of colon cancer, where each marker covers 50% - 70% of tumors.
- Develop novel microfabricated chip technology that would fully automate the assay, reducing cost and increasing accessibility of the test.
- Develop new “multiplexed real-time” assay to identify up to a dozen markers directly from DNA purified from serum.
- Low-cost test should achieve sensitivity and specificity that are significantly better than current approaches.

# The Fluidic Micro-processor for Analyzing Circulating DNA for Methylation Patterns



# Integrated Genotyping System using Modular Microfluidics



- **Modular approach – match material to application**
- **Continuous flow operation**

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# Strategic Advantage of iCareDx approach:

- **Multiplexed Assay format:** Allows for greater than 95% specificity, overcoming the unacceptably high false test results inherent to single marker assays.
- **Multidimensional Assay:** Allows for greater than 90% sensitivity, finding more individuals with hidden cancers than current one-dimensional assays.
- **Micro-fabricated devices:** Allows for automated high-throughput processing of multiplexed assay, which is essential in a clinical setting.

## Principle Investigator: Francis Barany, [REDACTED].

Dr. Francis Barany received his Ph.D. in Microbiology in 1981 at The Rockefeller University with Professor Alexander Tomasz. He was a Helen Hay Whitney postdoctoral fellow with Professor Hamilton O. Smith at the Johns Hopkins University School of Medicine from 1982-1985. Upon appointment as an Assistant Professor in Microbiology at Weill Cornell Medical College in 1985, he was named a Cornell Scholar in Biomedical Sciences, and in 1992 received a five year Hirsch/ Monique Weill-Caulier Career Scientist Award. He currently holds the rank of Full Professor in the Department of Microbiology and Program of Biochemistry and Structural Biology at Cornell/Sloan Kettering Institute. He held adjunct appointments at The Rockefeller University in the Dept. of Chemistry, Biochemistry, and Structural Biology, as well as Director of Mutation Research at the Strang Cancer Prevention Center. A prolific inventor with 36 issued US patents, he is best known for developing the ligase chain reaction (LCR) and ligase detection reaction (LDR) and Universal DNA arrays for detection of infectious diseases, genetic diseases, and cancer-associated mutations. The Barany Laboratory patents and intellectual property have generated over \$30 million in NIH Grants, NIST Grant, Industrial Sponsored Research Grants, over \$10 million in royalties to Weill-Cornell, and close to \$2 billion in sales to biotechnology companies. In 2009 he co-founded Coferon Inc., based on his invention of a new class of drugs that enter cells and self-assemble on the target. Dr. Barany was honored as Medical Diagnostics Research leader, Scientific American 50 in 2004, and the Ezra Innovation Award, Cornell University in 2011.

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