

Emerging and disruptive technology

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“Disruptive technology” is a technology that could unexpectedly displace an established technology



amazon



amazonkindle

Old practices disrupted by new technology



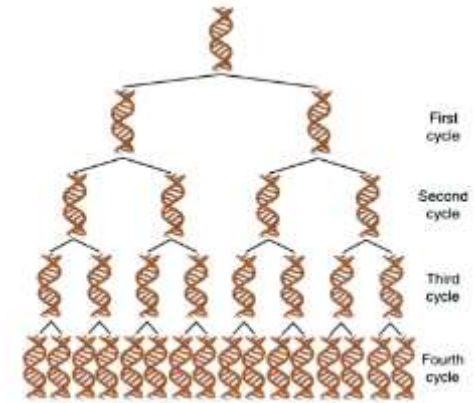
RAPID CHANGE FUELED BY TECHNOLOGY - cell phone disrupts the camera



So far



Immunoassay
PCR
Automation
Computing
McAbs



What is next?



1905



1932



1998



2016

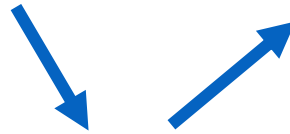


2050

1. Robots
2. Supply
3. Technology
4. Technology convergence
5. POCT
6. New specimens
7. Big biology/data
8. FDA

The tunnel of time

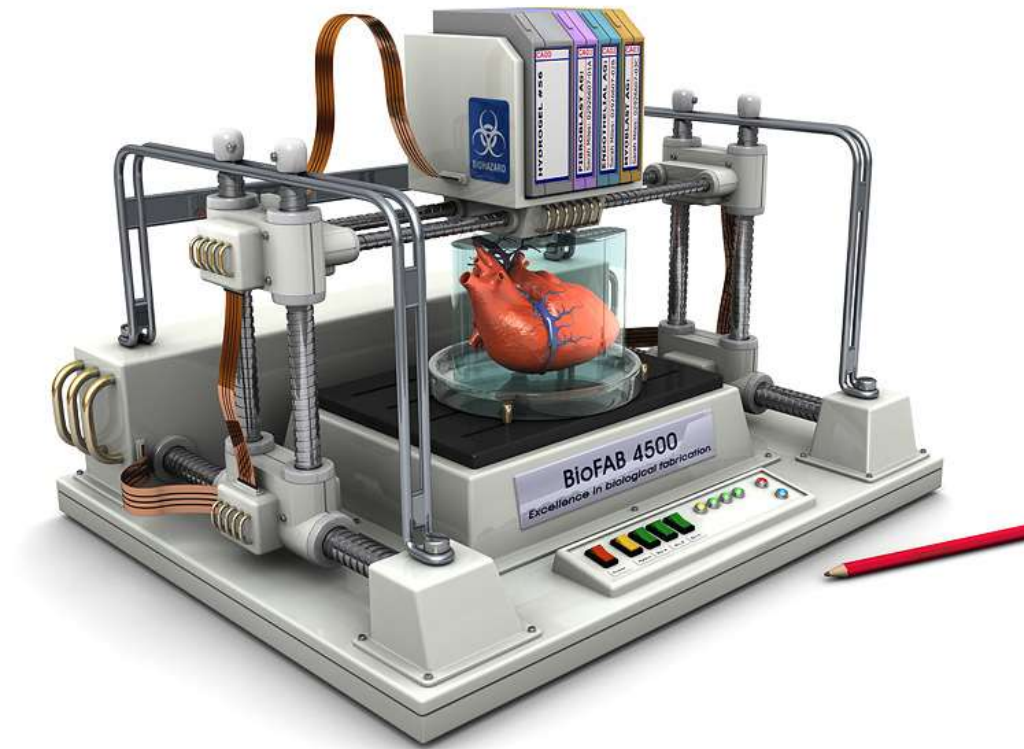
1. ROBOTS - Humanoid Robots – the next step in automation



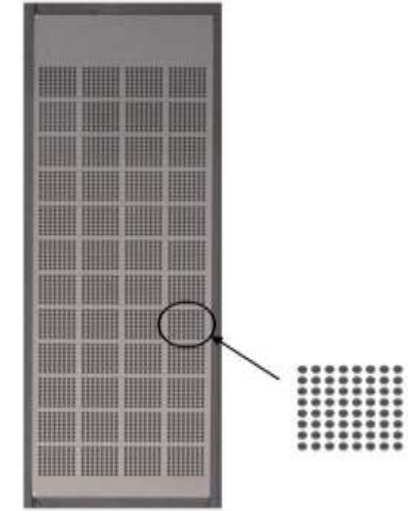
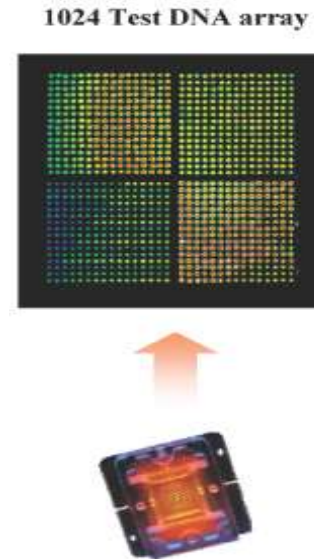
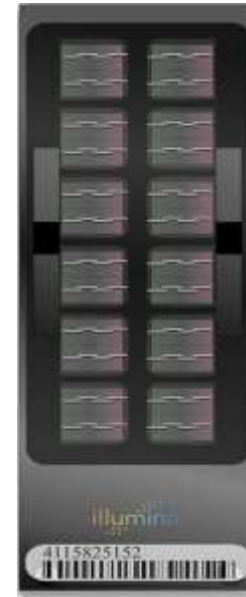
Humanoid robots – a better model!



2. SUPPLY - Replicators (3D printing) - disrupting supplies and service



3. TECHNOLOGY - "Array" domination - disrupting analytical methods



Thousands to multiple millions of simultaneous assays

3. TECHNOLOGY - Mass spectrometry in ascendance - disruption?

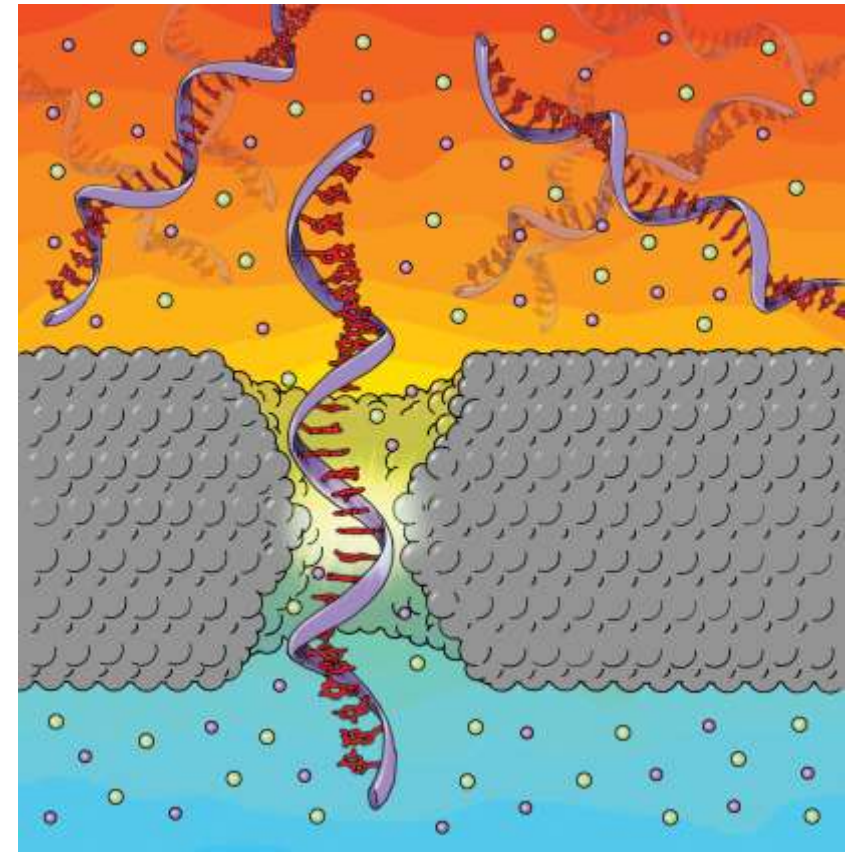
- Neonatal screening (amino acids, fatty acids,..)
- Confirmation testing (drugs of abuse)
- TDM
- Vitamin D
- Microbial ID
- Steroid analysis/profiles
- Protein analysis (thyroglobulin)
- Nucleic acid analysis (Cyp testing)



3. TECHNOLOGY - Nanotechnology



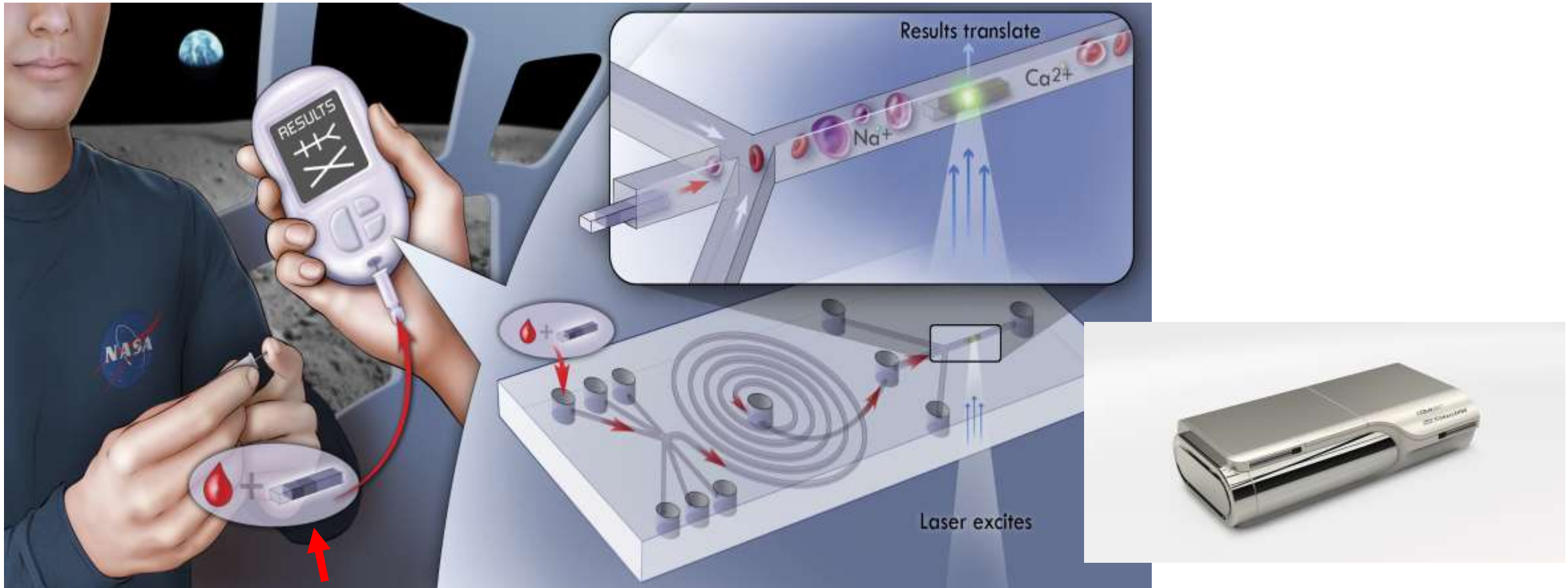
Nanopore sequencing



A NEW SOURCE OF DISRUPTIVE TECHNOLOGY - XPrize?



DMI



Nano dipsticks

4. TECHNOLOGY CONVERGENCE



Phone + PDA + GPS + MP3 + internet + texting + tv/video + **TESTING**

4. TECHNOLOGY CONVERGENCE - Memory sticks, thumb drives, dongles, ... disrupting glucose meters



GMATE SMART

5. POCT - Disposable electronics - removing the human from critical steps in the process



5. POCT - Nucleic acid testing - simple cartridges disrupt molecular testing



Alere
2015 CLIA Waiver

Influenza A&B



HSV 1 & 2



Influenza A&B

Spartan RX
CYP2C19

Sample to result. DNA on demand.



CYP2C19*2, *3 and *17

5. POCT - Direct access testing



Harmonyx - CYP testing



23andMe - carrier status

5. POCT - Home placement - A trend?



Connect With The New 2net Hub From Qualcomm Life.

By 2030, almost 1 out of every 5 Americans -- some 72 million people -- will be 65 years or older!



Phil

Vite

6. NEW SPECIMENS - cell free DNA, tfDNA, circulating tumor cells & exosomes



HarmonyTM
PRENATAL TEST

verifi[®]
prenatal test
your questions – answered

NO SPECIMEN?
non-invasive testing

Trisomy 21, 18, 13

Illumina and Microsoft - a \$100M disruption to cancer screening?

GRAIL

grailbio.com

Ultra-deep sequencing to detect circulating tumor DNA
early detection of cancer in asymptomatic individuals through a blood screen
Illumina next-generation sequencing technology



amazon.com

illumina®

BEZOS EXPEDITIONS SUTTER HILL
VENTURES

BILL GATES

ARCH Venture Partners

7. BIG BIOLOGY/DATA - Population-scale Genome Projects - accelerating molecular diagnostics

Million genome project (BGI)

Million genome project (NIH, USA)

Million Veterans Project (USA)

100,000 Genomes Project (UK)



华大基因
BGI



Genomics
england



8. FDA - disrupting LDTs

The Public Health Evidence for FDA Oversight of Laboratory Developed Tests: 20 Case Studies

iii. Target Now Cancer Biomarker Test

Category	LDT Characteristics
LDT Name	Target Now
Description	Molecular test to detect 20 cancer biomarkers for a range of tumor types
Purpose	Profile a cancer and suggest chemotherapy
Target Population	Patients with refractory or recurrent cancer
Alternatives	Follow standard chemotherapy regimens
LDT Problem 1	List of suggested treatments generated by the test have not necessarily been shown to have an impact for a patient's particular cancer
LDT Problem 2	List of suggested treatments generated by test have not been studied in combination
LDT Problem 3	Improper clinical trial design to validate test
Clinical Consequence	Patients may forego standard cancer therapy for unproven alternative therapy, with related risk of serious adverse events
Potential Impact of FDA Oversight	Assurance the test meets minimum performance standards; evaluation of manufacturer claims
Cost Impact of Inaccuracy	Not estimated

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DISRUPTORS

Robots

Supply

Technology

Technology convergence

POCT

New specimens

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FDA

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THE END

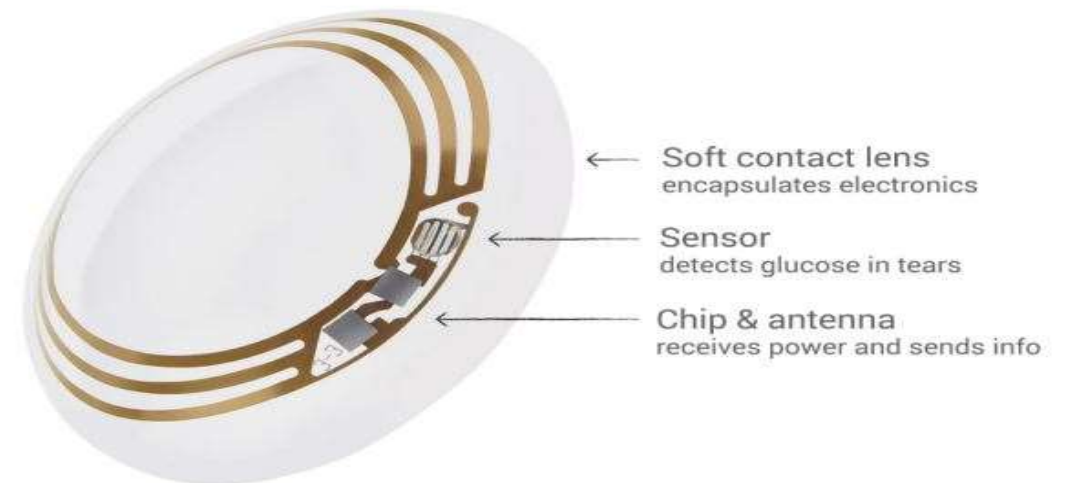
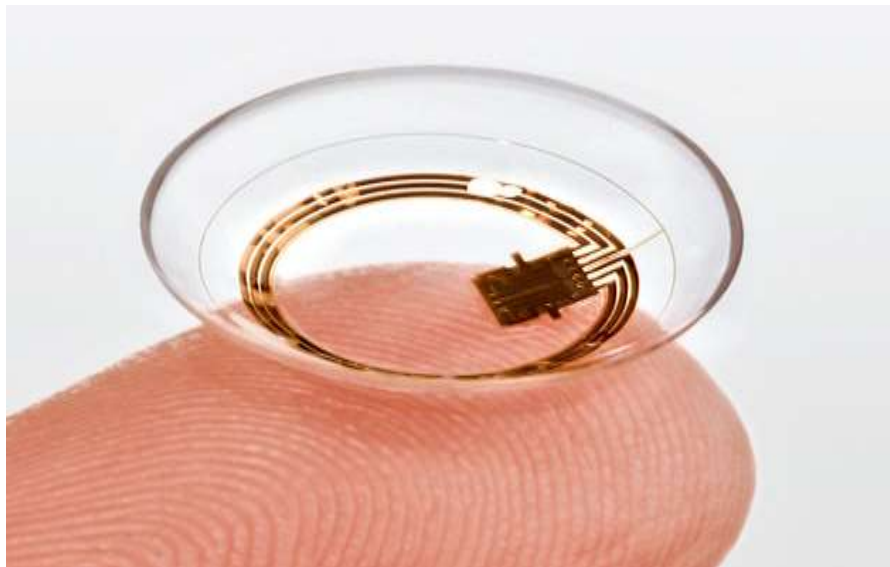
TECHNOLOGY CONVERGENCE - Contact lenses

Triggerfish® "Smart" Contact Lens for Glaucoma (SENSIMED – www.sensimed.ch/)

PDMS - silver wires continuously monitor pressure (via changes in the curvature of the cornea) and fluid flow within the eyes. Relay the data to a portable recorder worn by the patient

Google (clandestine Google X lab)

Glucose sensor - continuous monitoring + wireless (382 million diabetics)



TECHNOLOGY - Single molecule detection

Unimaginable at one time, now a reality.....impact?

DIGITAL ELISA

- ultrasensitive cancer markers - earlier detection of recurrence**

POCT - Theranos ?

