



OaCP

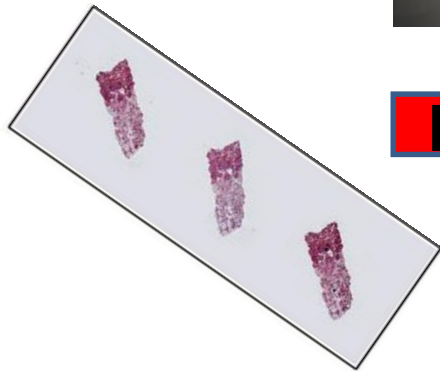
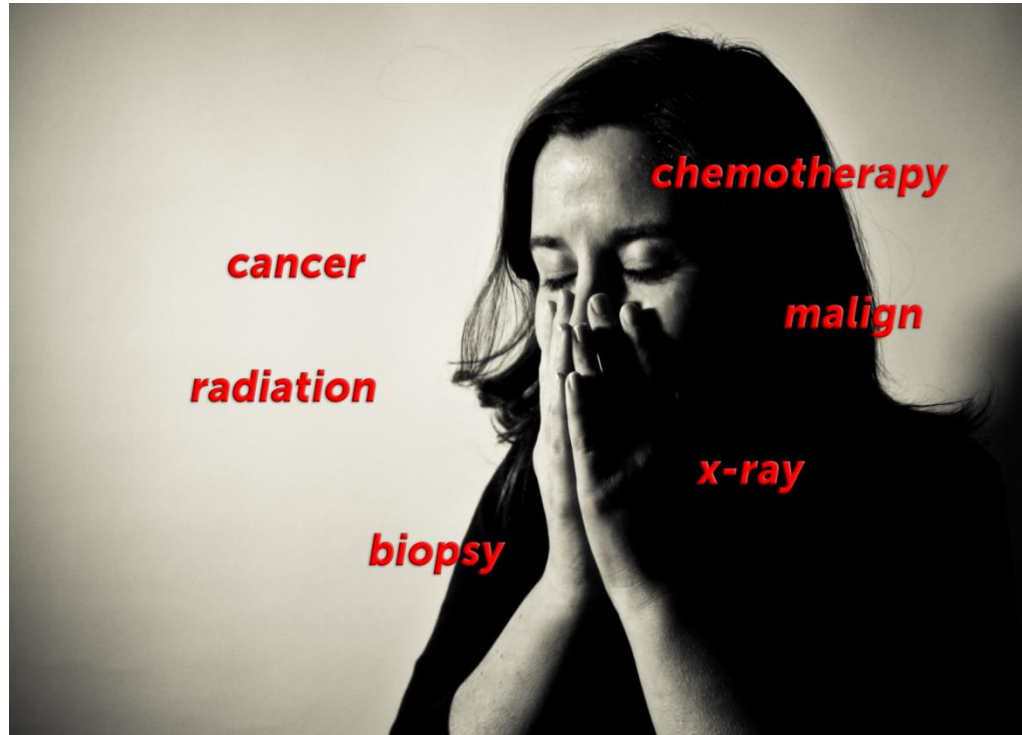
ONCOLOGY AND CYTOGENETIC PRODUTCS

FAST LABORATORY DIAGNOSTICS

Enrico Di Oto, founder

enrico.dioto@live.it

RITARDO NELLA DIAGNOSI



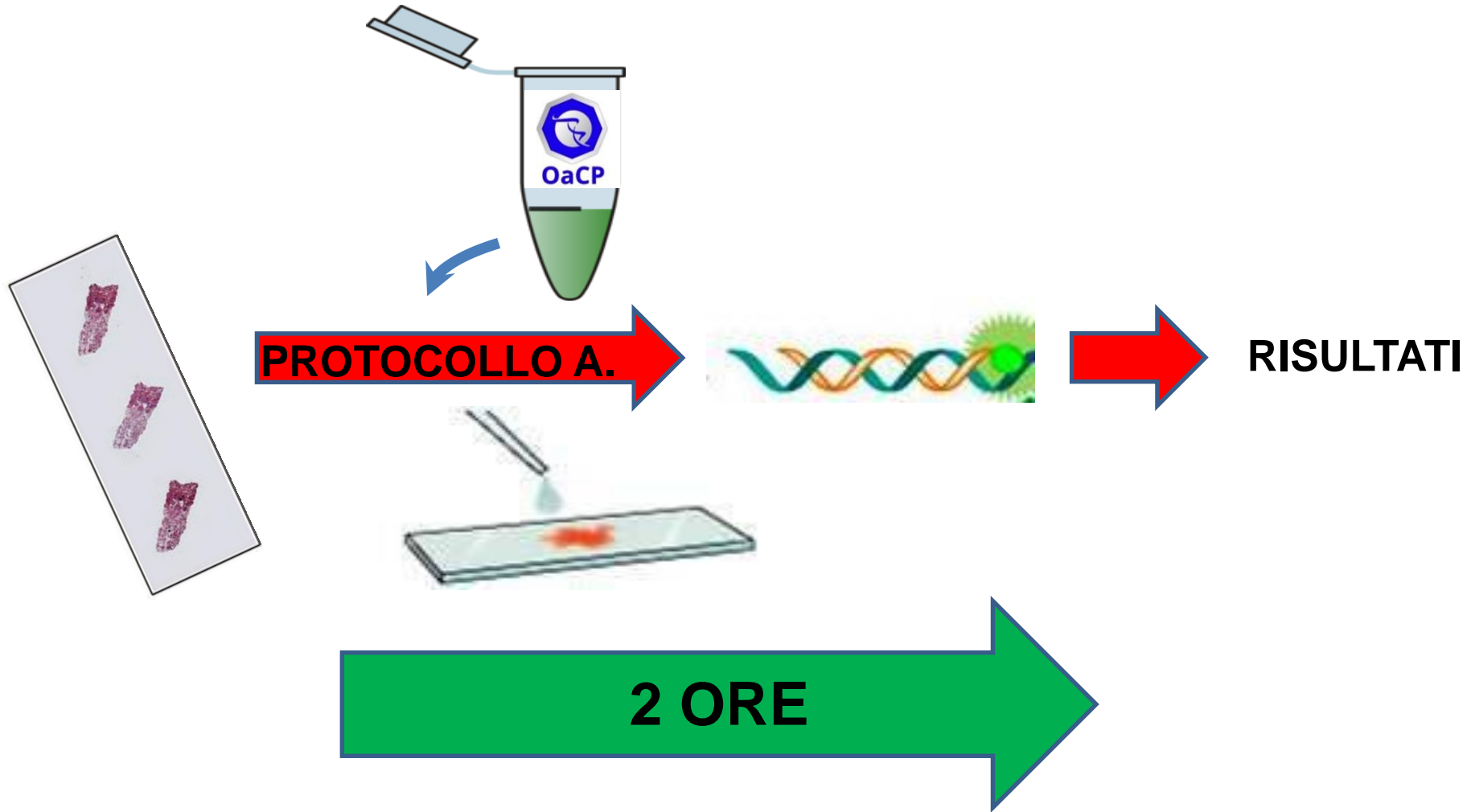
PROTOCOLLO ATTUALE →



RISULTATO

3 GIORNI →

SOLUZIONE





VELOCE



EFFICIENTE



**FACILE DA
USARE**





**Enrico Di Oto, PhD,
CEO**



**Francesco Villa
CBDO**



**Andrea Faviere
CMO**



**Matteo Allegro
CCO**



enrico.dioto@live.it

VALIDAZIONE

> 100

**Test
completati**

> 5

Applicazioni

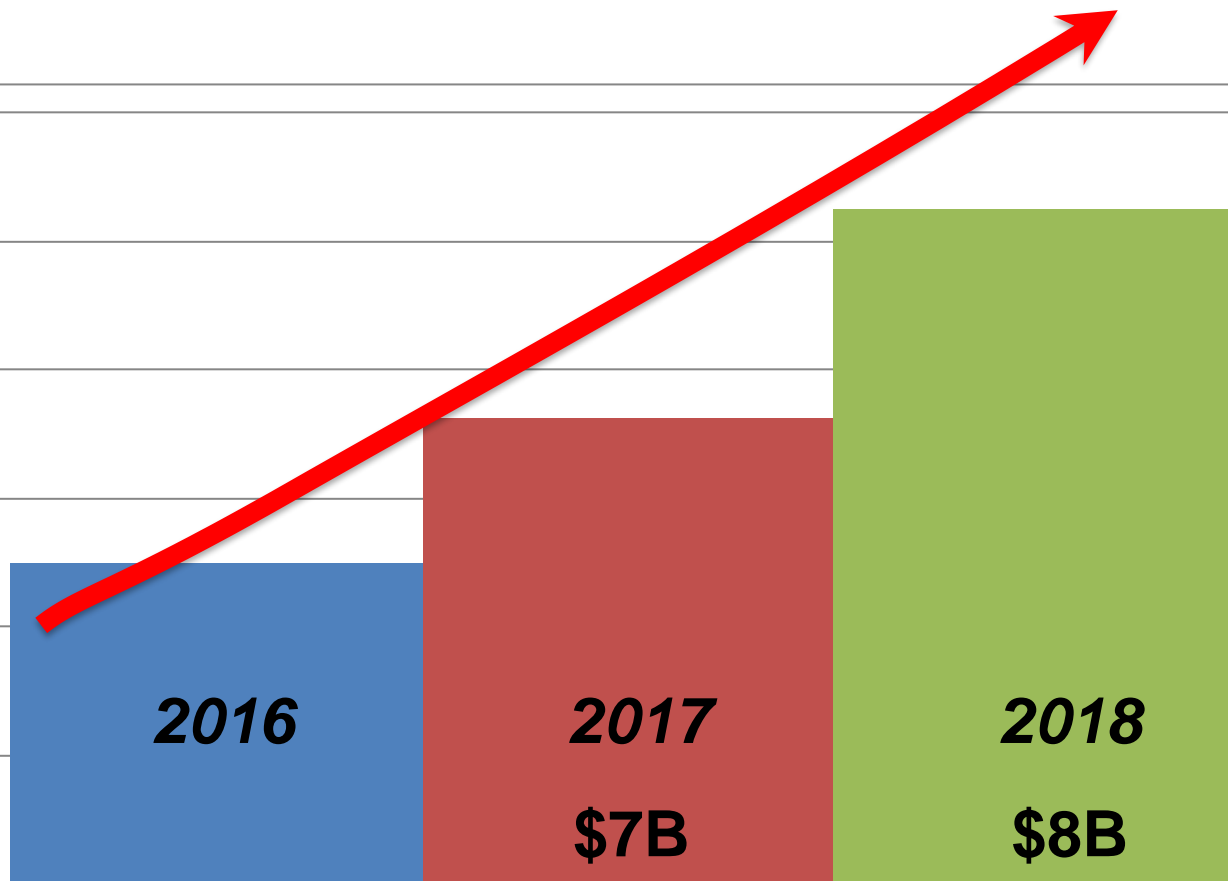
>99%

**RISULTATI
CORRETTI**

**Mammella
Polmone
Cervello
Tiroide
Cute**

MERCATO GLOBALE

\$6B in 2016





DIAGNOSI IN 2 ORE



POCO COSTOSO



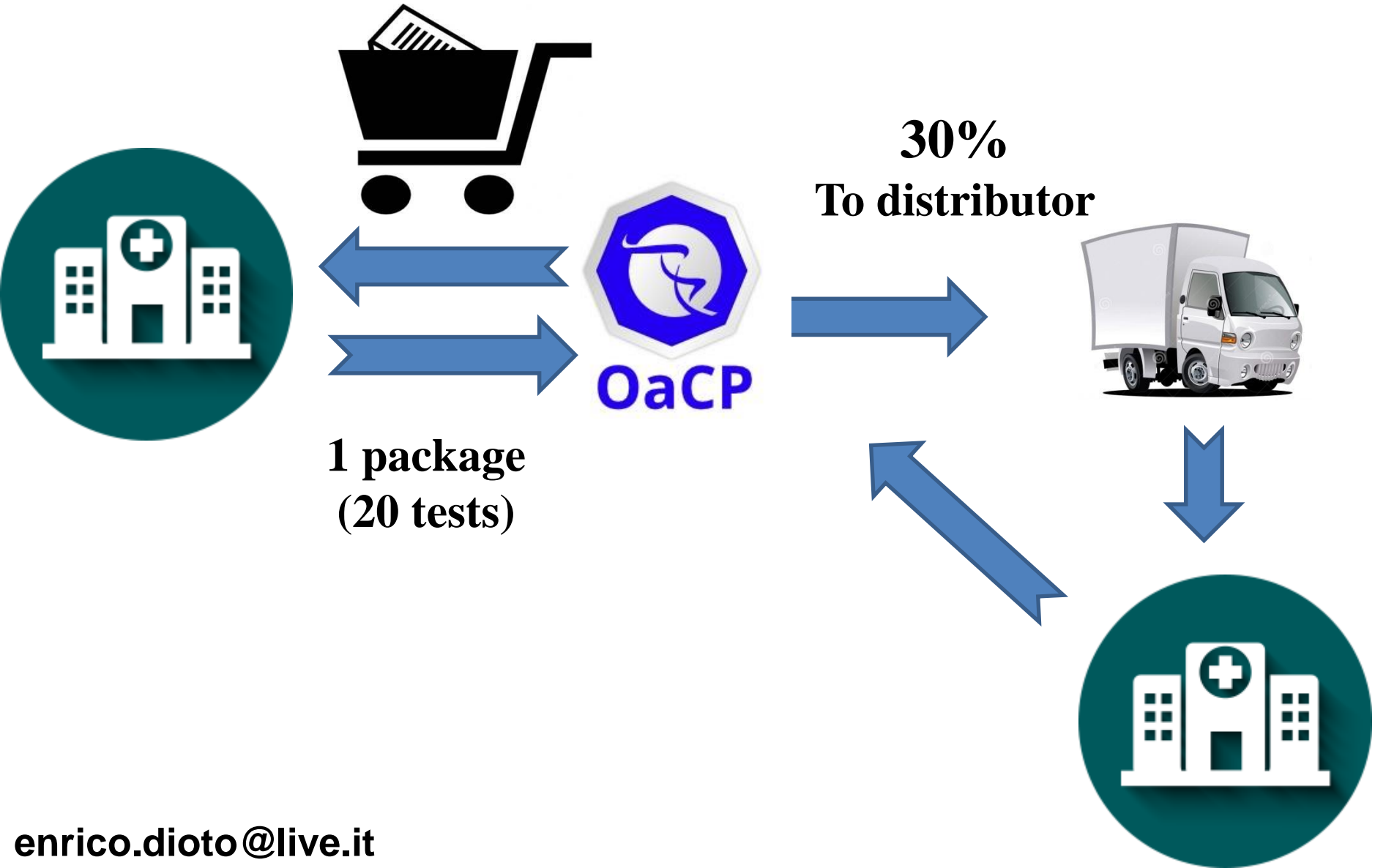
**MANTENIMENTO DEL
PROTOCOLLO IN USO**



**NESSUNO
STRUMENTO
DEDICATO**



BUSINESS MODEL



COSA CI SERVE:

Phase I: € 250K



**Test di
validazione
aggiuntivi**



**Registrazione
internazionale**



Go to Market

enrico.dioto@live.it



OaCP

ONCOLOGY AND CYTOGENETIC PRODUTCS

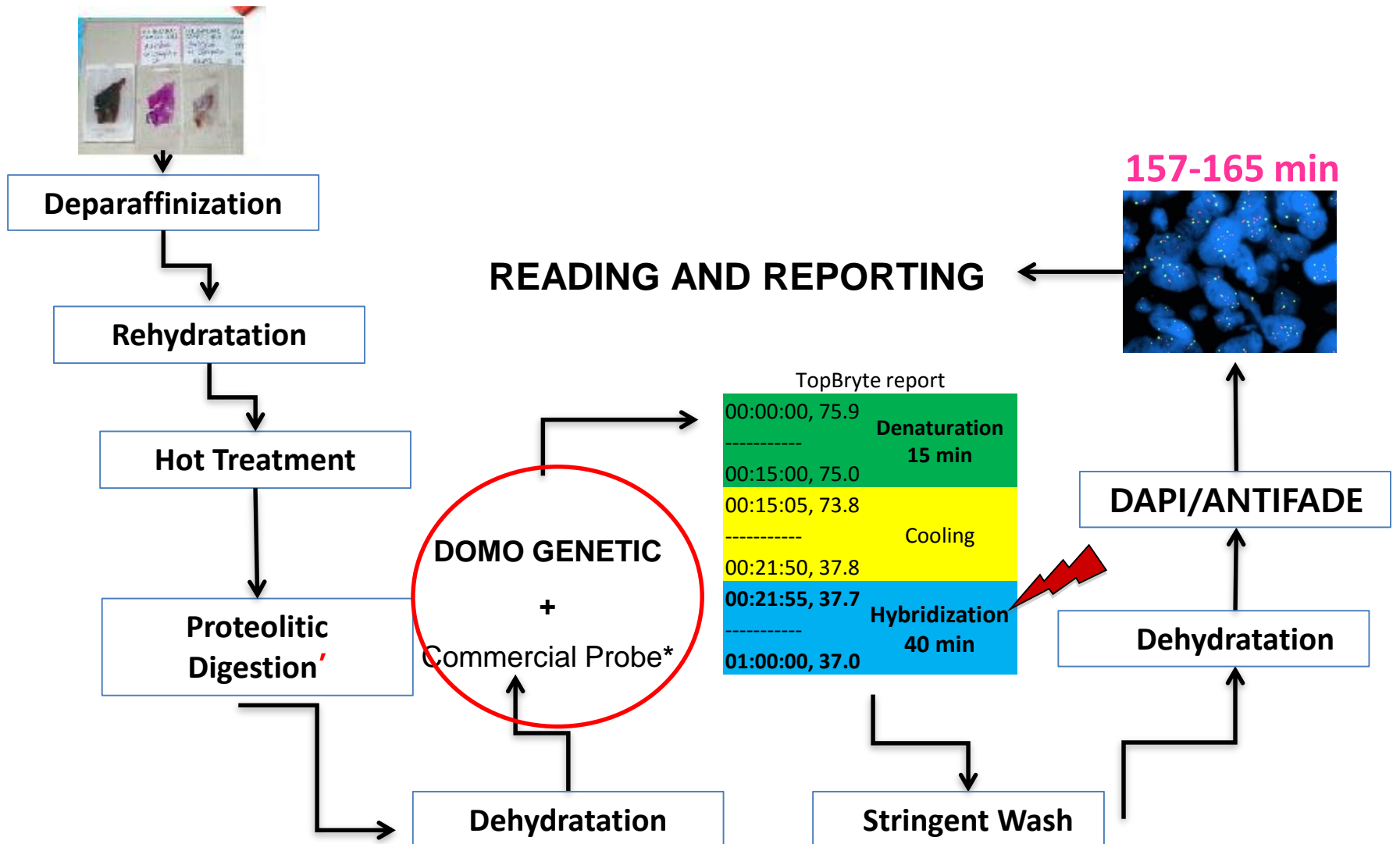
FAST LABORATORY DIAGNOSTICS

Enrico Di Oto, founder

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APPENDIX

Solution



* Commercial Probes from Vysis- Kreatech- ZytoVison -CytoCell ecc..

PRODUCT

RAW MATERIALS:

EASY TO FIND (ONLINE SELLERS)

INEXPENSIVE

NON TOXIC

EASLY STORED AND DELIVERED:

STABLE AT ROOM TEMPERATURE

SMALL AND LIGHT PACKAGE

EASY TO USE:

APPLICABLE UPON DIFFERENT PROTOCOL

APPLICABLE WITH DIFFERENT REAGENTS

NO TRAINING IS NEEDED

PRODUCT

READY FOR MARKET (RUO) PRODUCTION **MARKET (CEIVD)** **MARKET (FDA)**

2016

2017

2018

**EXTERNAL
VALIDATION**

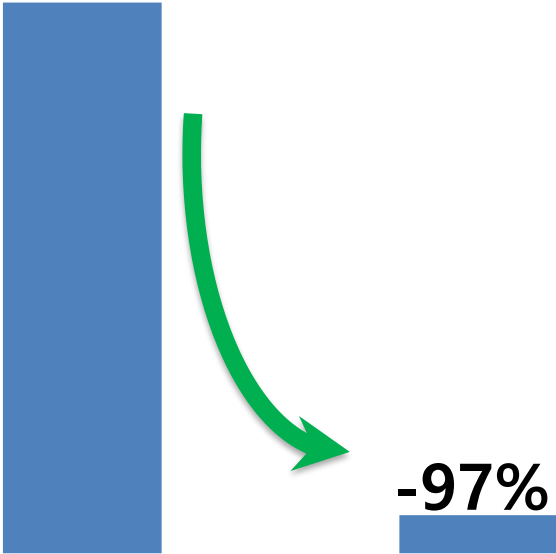
**CEIVD
APPLICATION**

**FDA
APPLICATION**

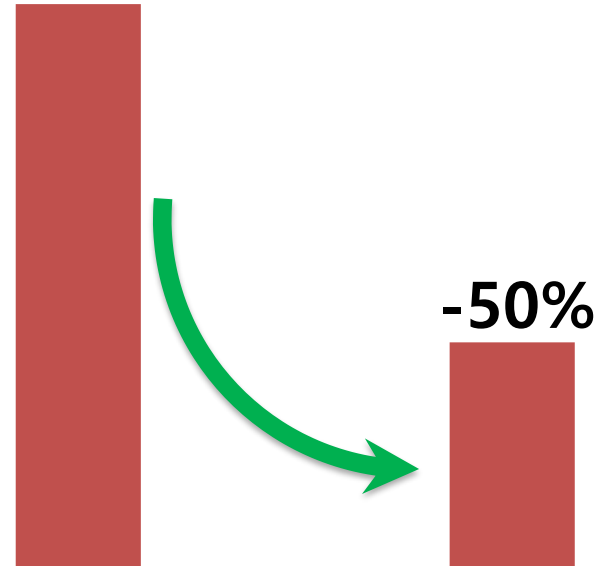
CONTINUOUS DEVELOPMENT

BENEFIT

TIME



TEST COST



“Patients may have feelings of anxiety and distress while waiting for the results of tests”

Adjustment to Cancer: Anxiety and Distress NIH 2015

“Standard incubation it is long and it would be useful to reduce”

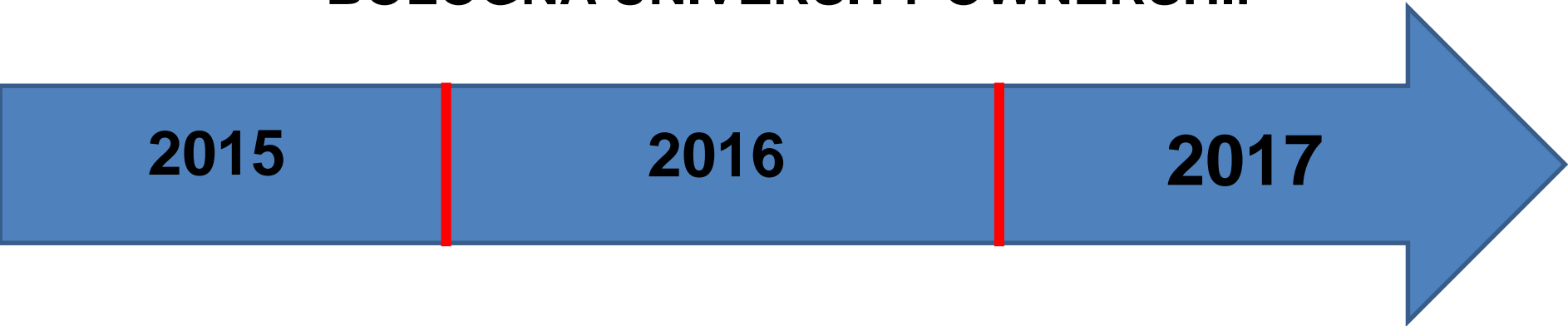
Head of Lab at Istituto cantonale di Patologia, Locarno (CH)

“your invention has great potential to penetrate the market and will find broad application”

CTO at Bachem

IP

BOLOGNA UNIVERSITY OWNERSHIP



2015

2016

2017

04 Feb '15

03 Feb '16

Feb '17

Italian application

PCT extention

Countries

Claims:

Reagents composition

Method

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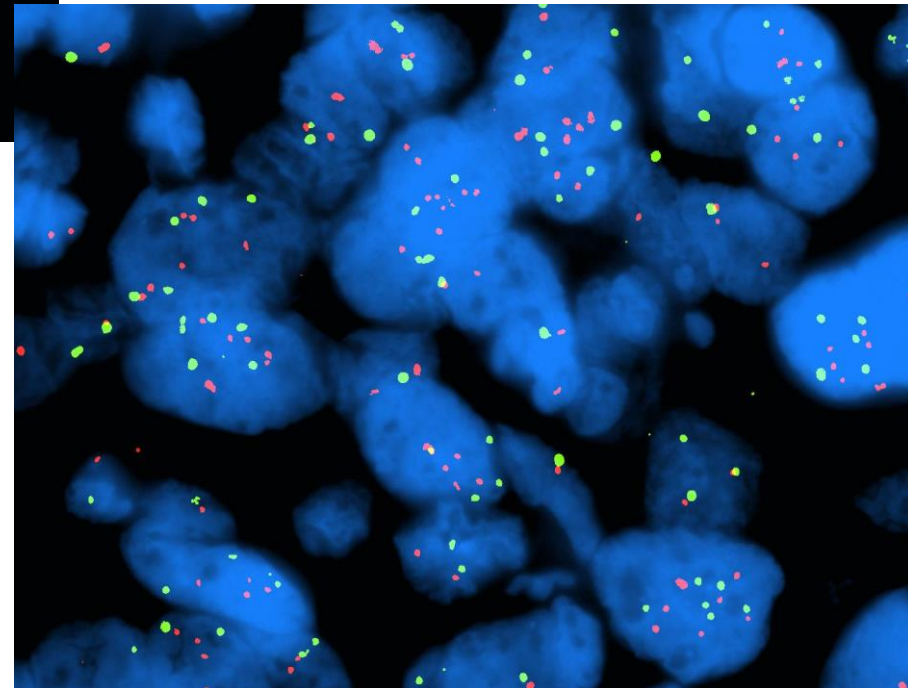
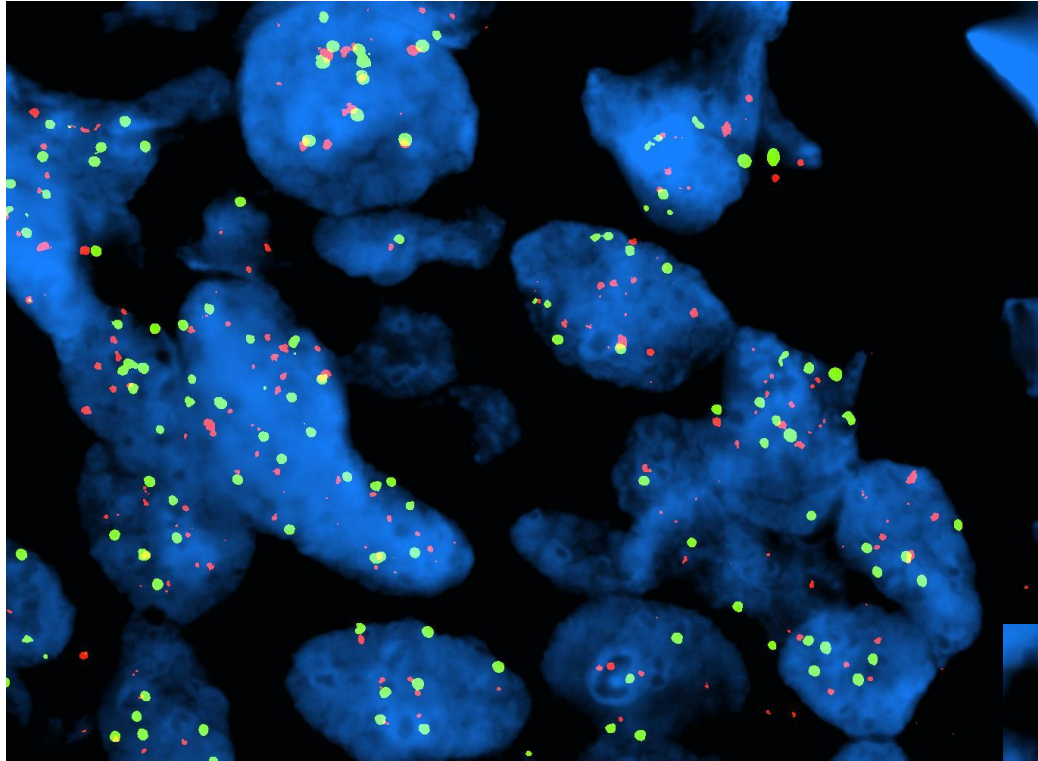
Validation Data and Images

DoMo Genetics

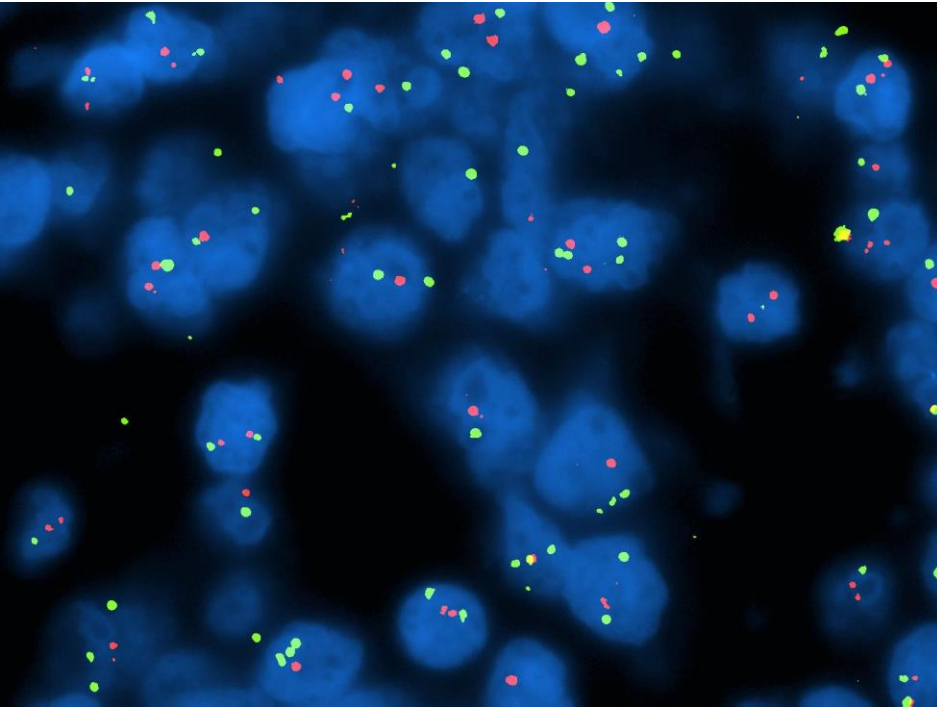
Breast carcinoma (FFPE)
stained with *HER2* FISH:

Tumor cells show *HER2* gene
polysomy (CEP7 ≥ 3).

STANDARD



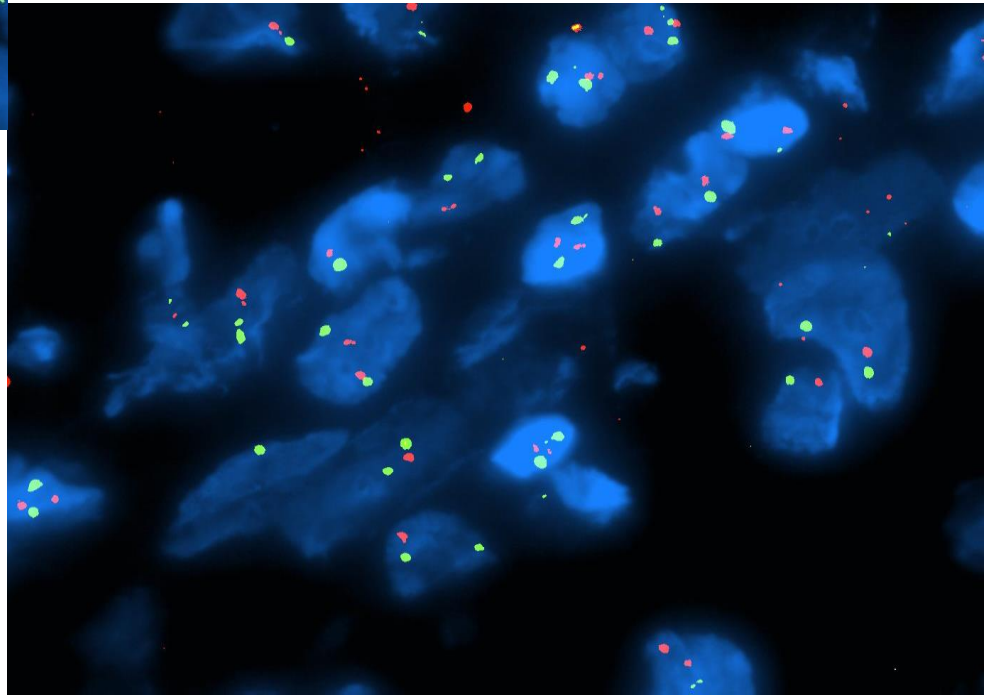
DoMo Genetics



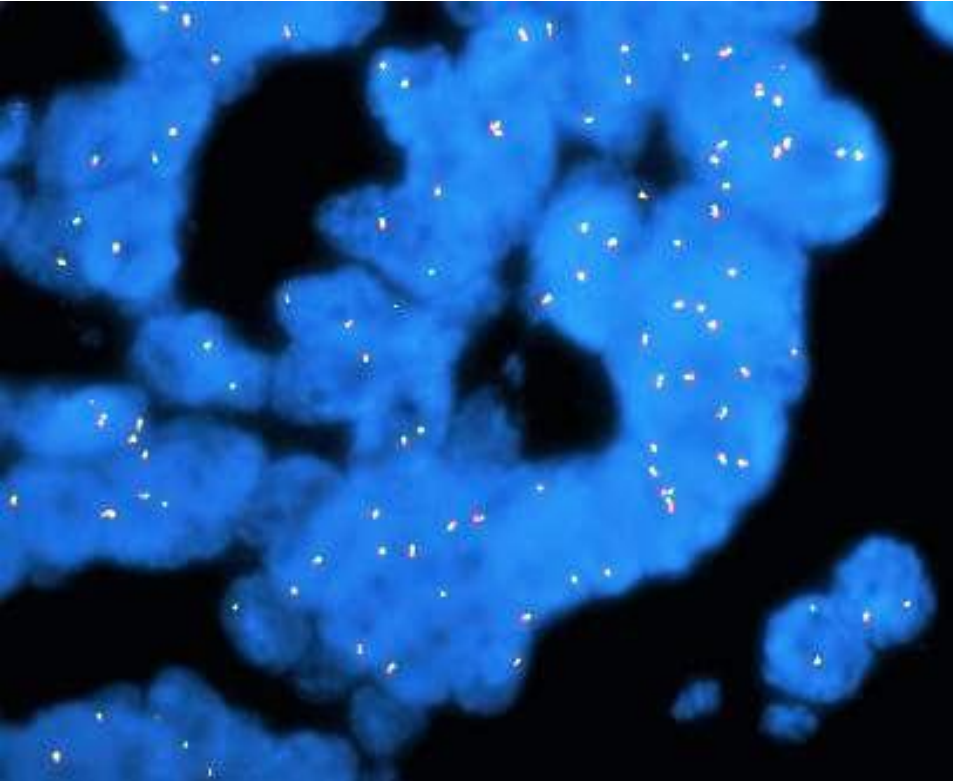
**Breast carcinoma (FFPE)
stained with HER2 FISH:**

**Tumor cells show HER2 gene
disomy (HER2/CEP7 ratio < 2).**

STANDARD



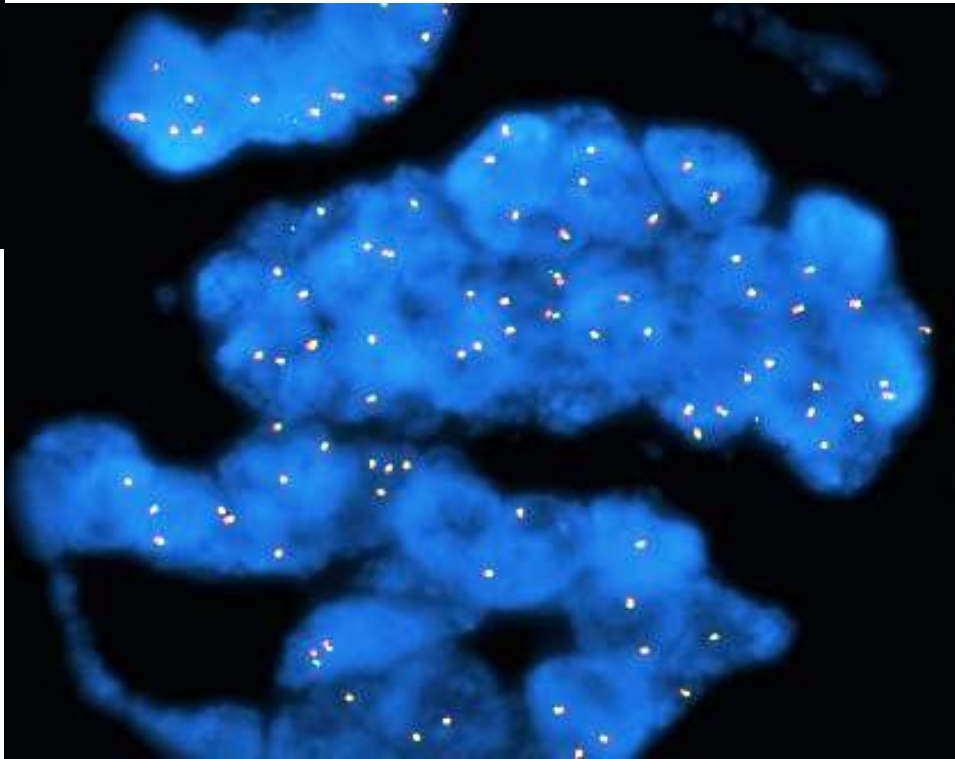
DoMo Genetics



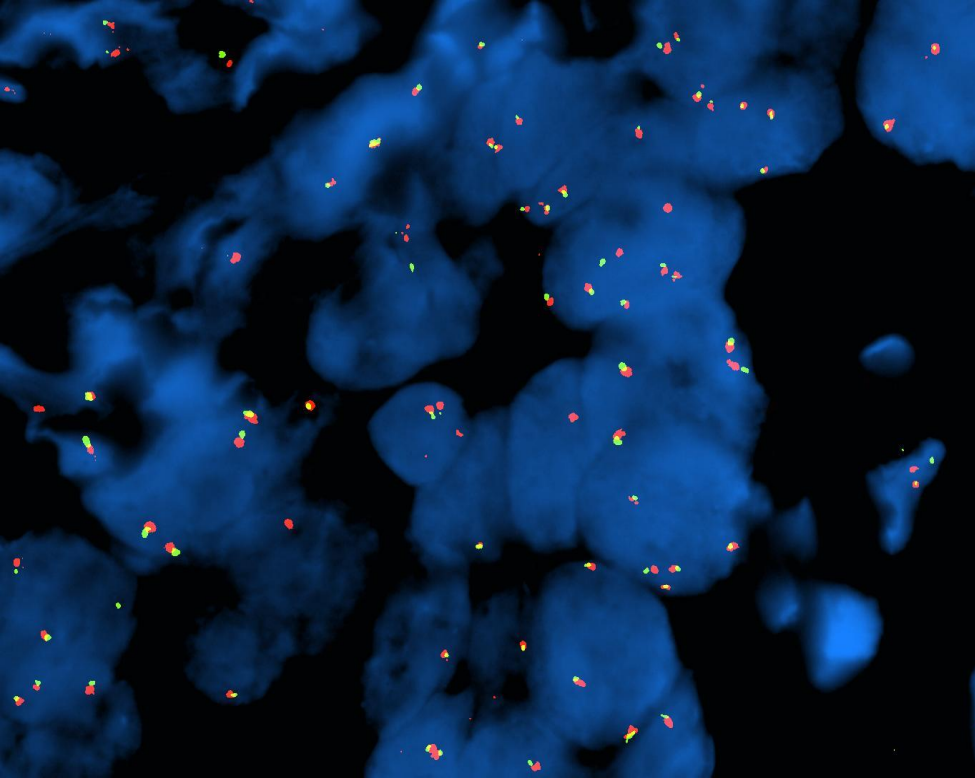
**Lung carcinoma (FFPE) stained
with ALK FISH:**

Negative for ALK rearrangement

STANDARD



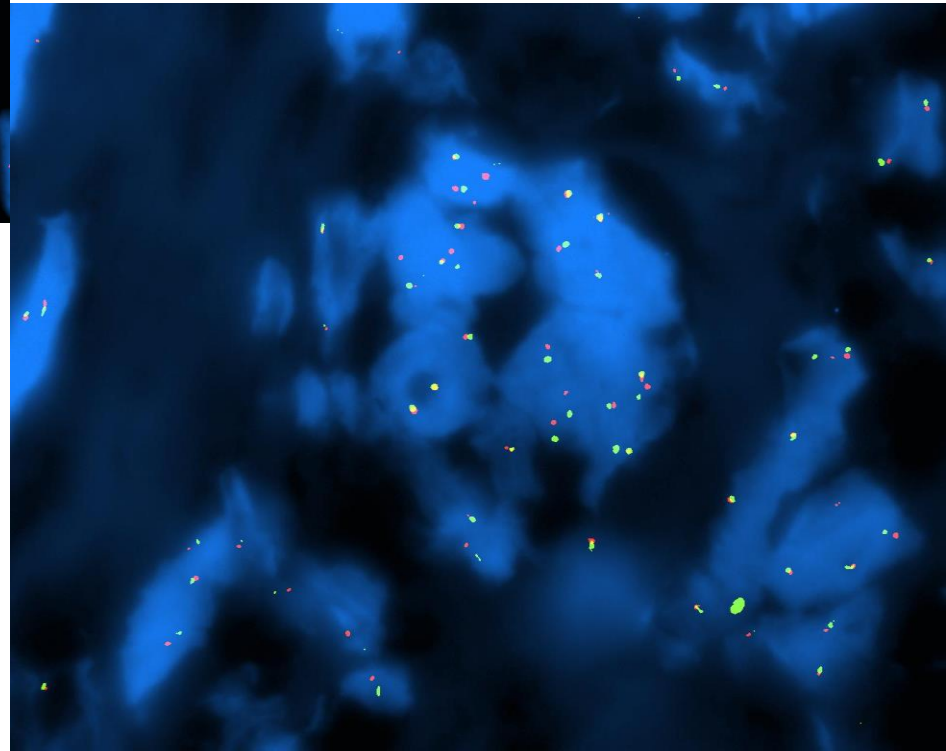
DoMo Genetics



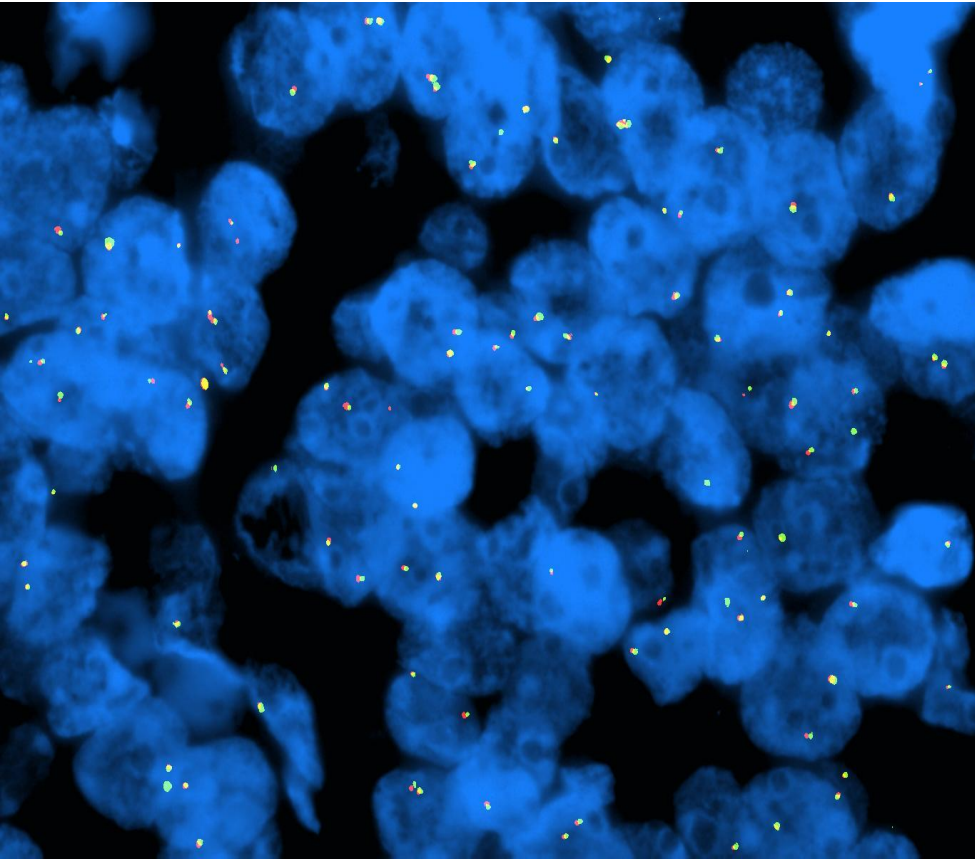
**Lung carcinoma (FFPE)
stained with ALK FISH:**

**Positive for ALK
rearrangement**

STANDARD



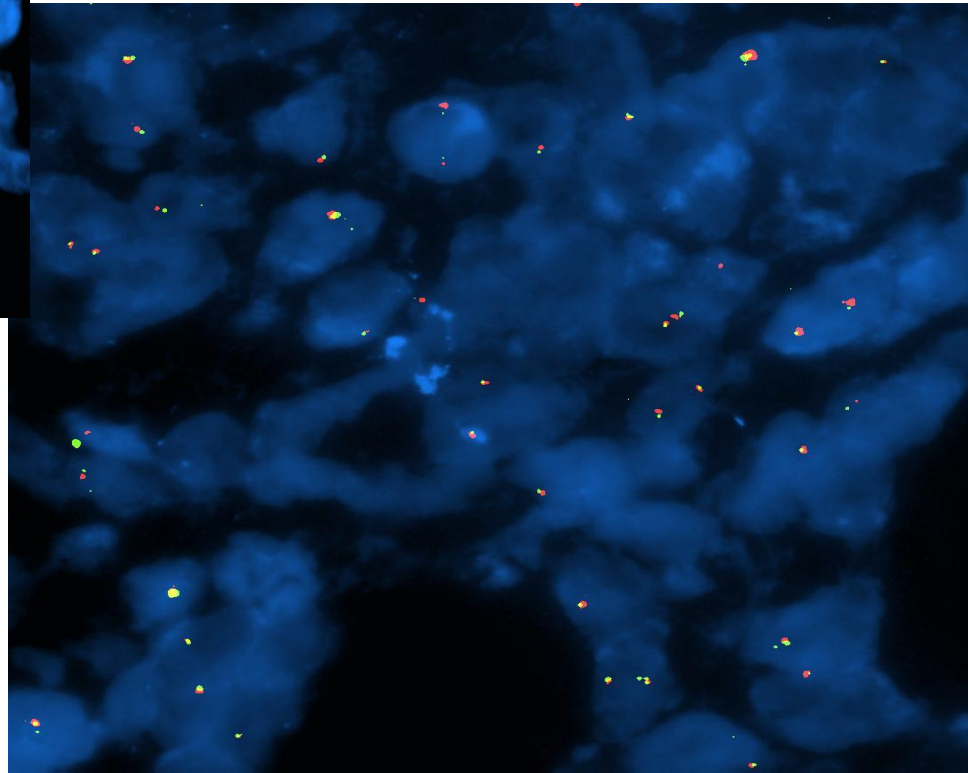
DoMo Genetics



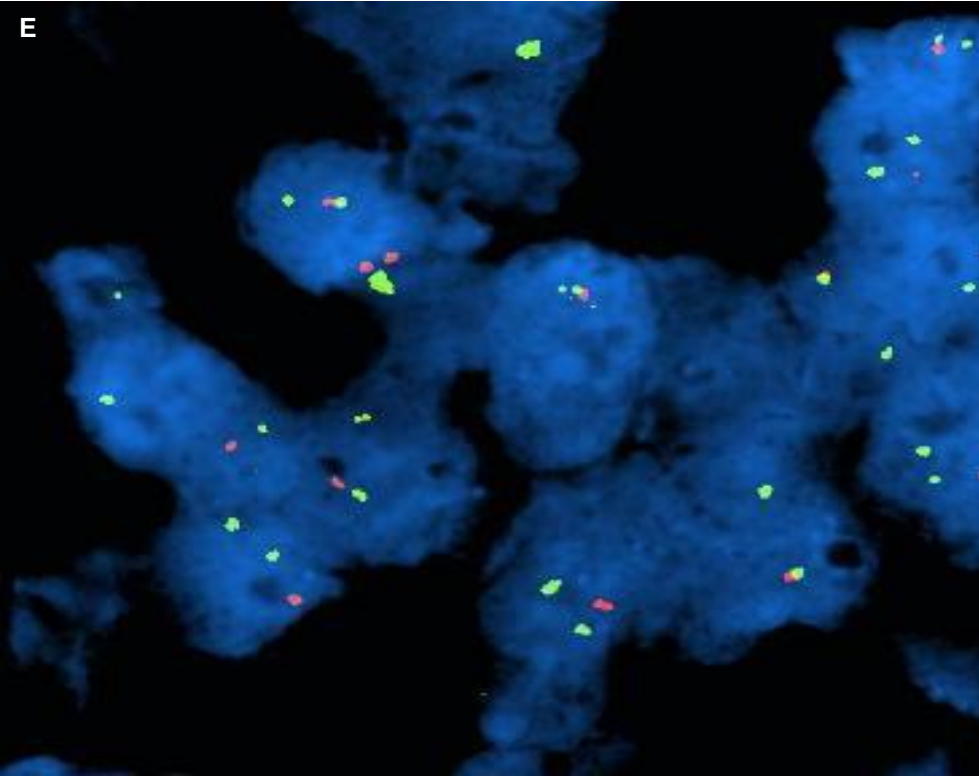
**Thyroid carcinoma (FFPE) stained
with ALK FISH:**

Negative for ALK rearrangement

STANDARD



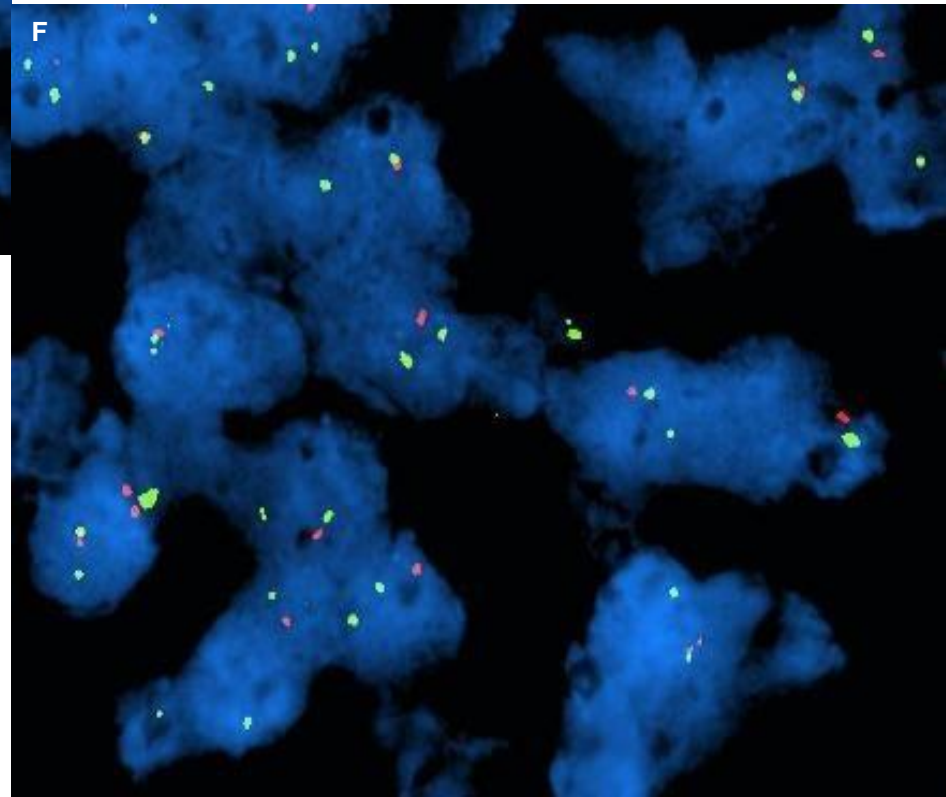
DoMo Genetics



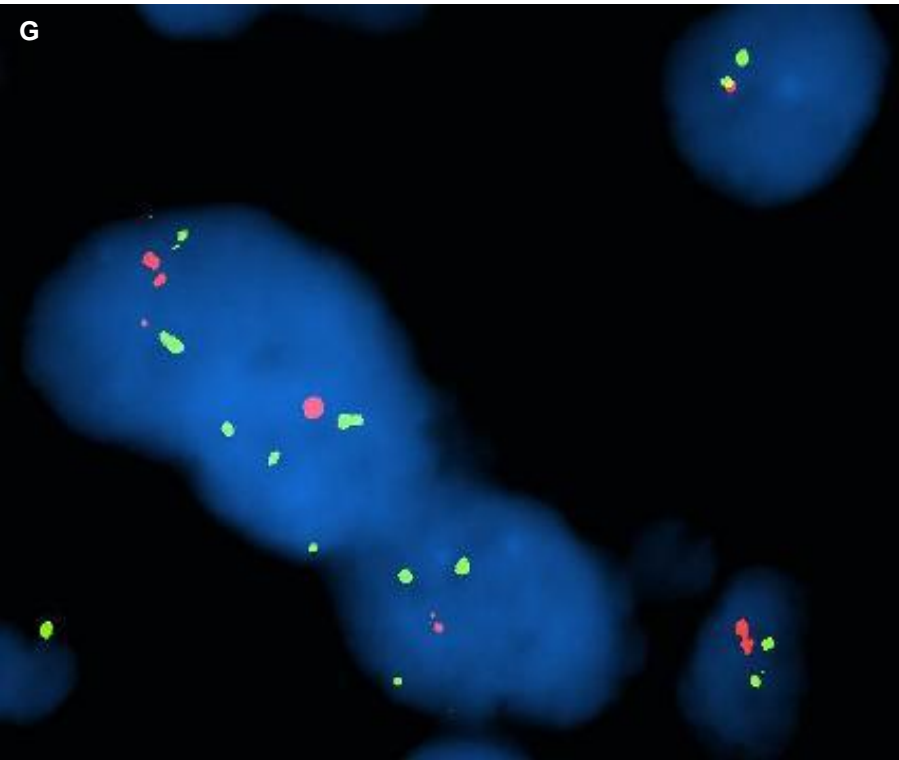
Brain cancer (FFPE) stained
with 1p36 FISH:

Deletion

STANDARD



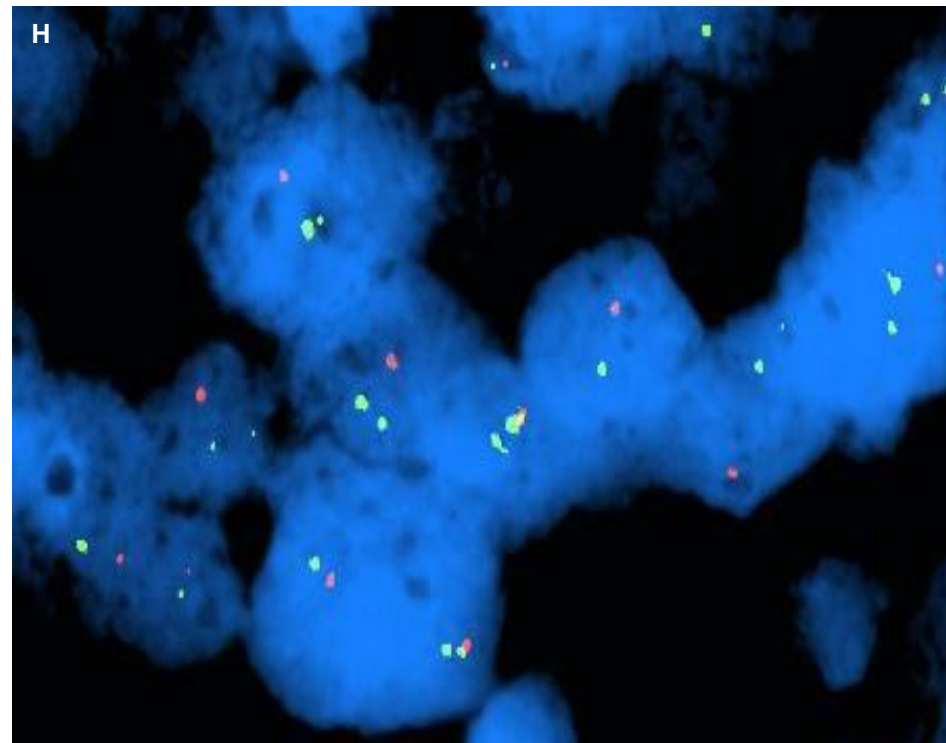
DoMo Genetics



Brain cancer (FFPE) stained with 19q13 FISH:

Deletion

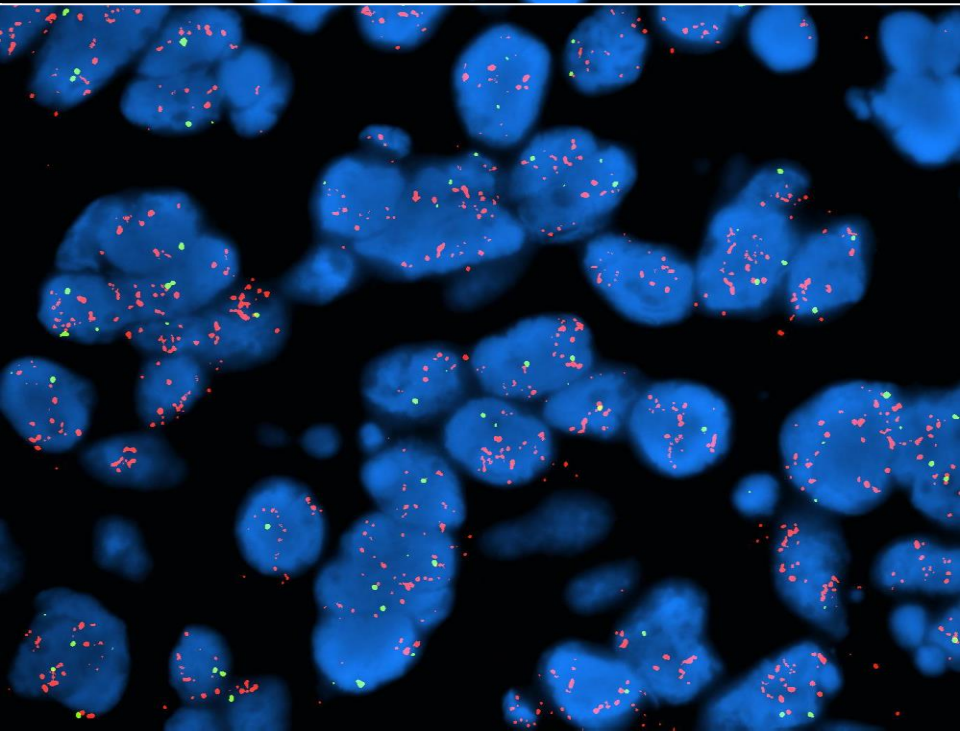
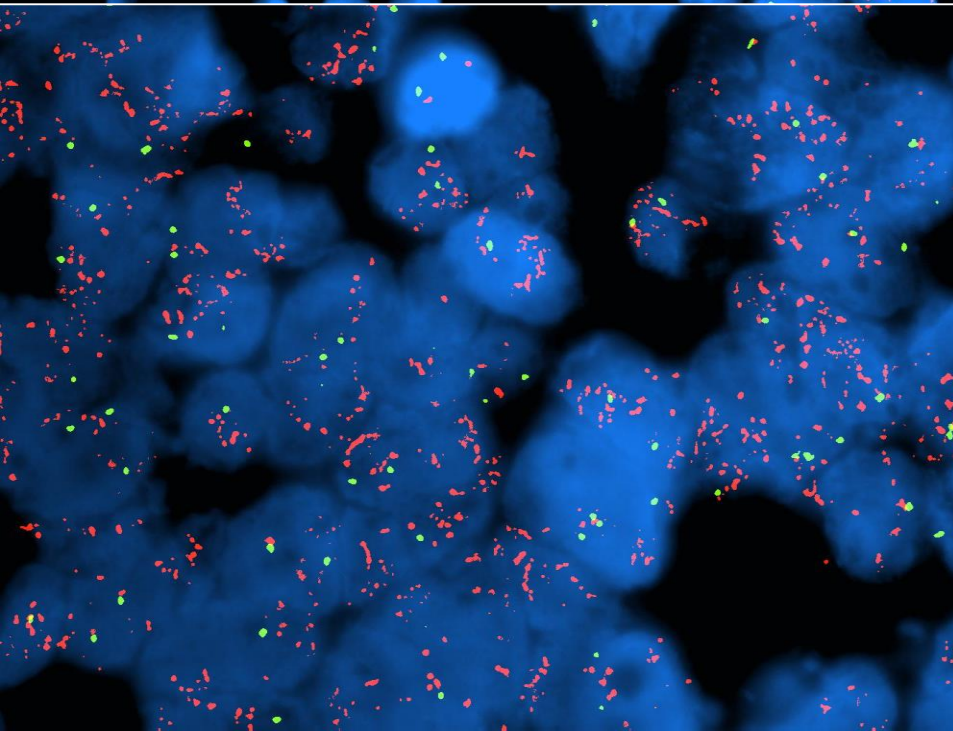
STANDARD



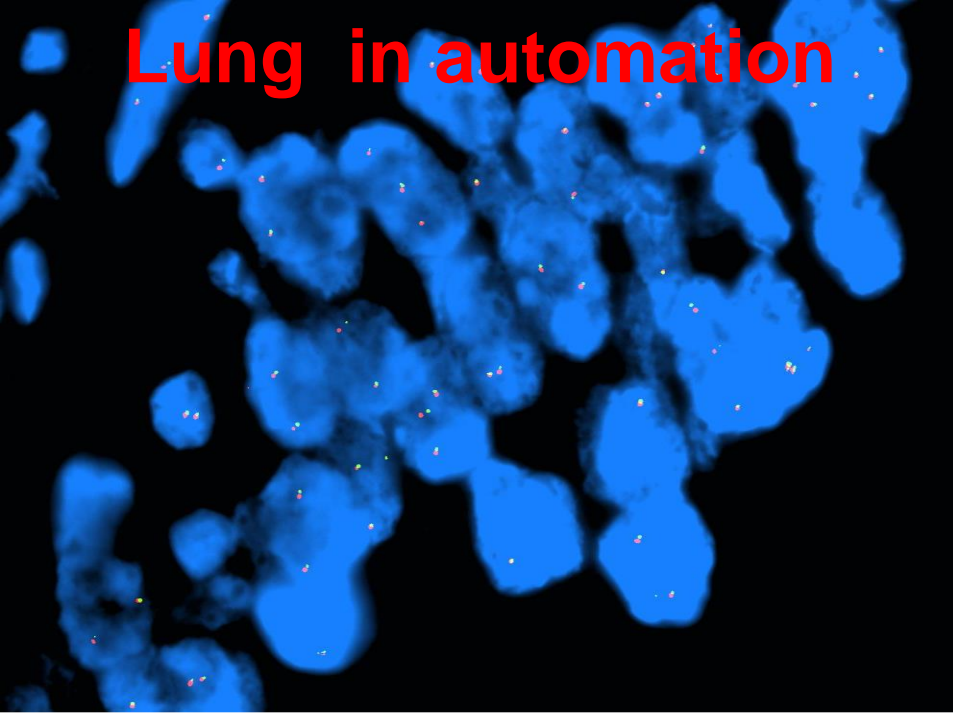
Breast in automation



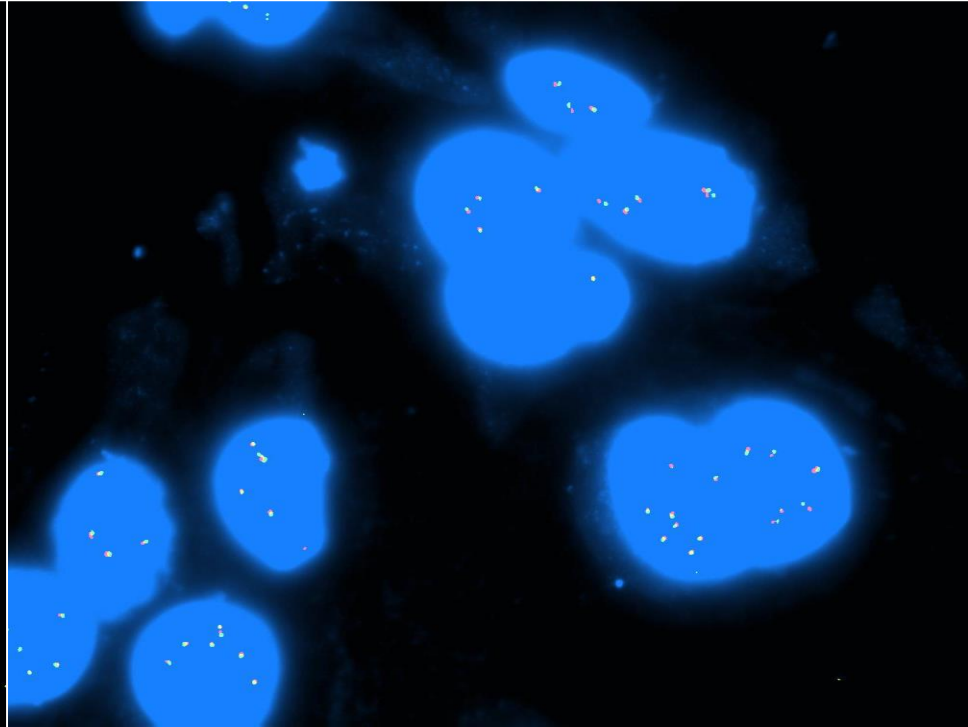
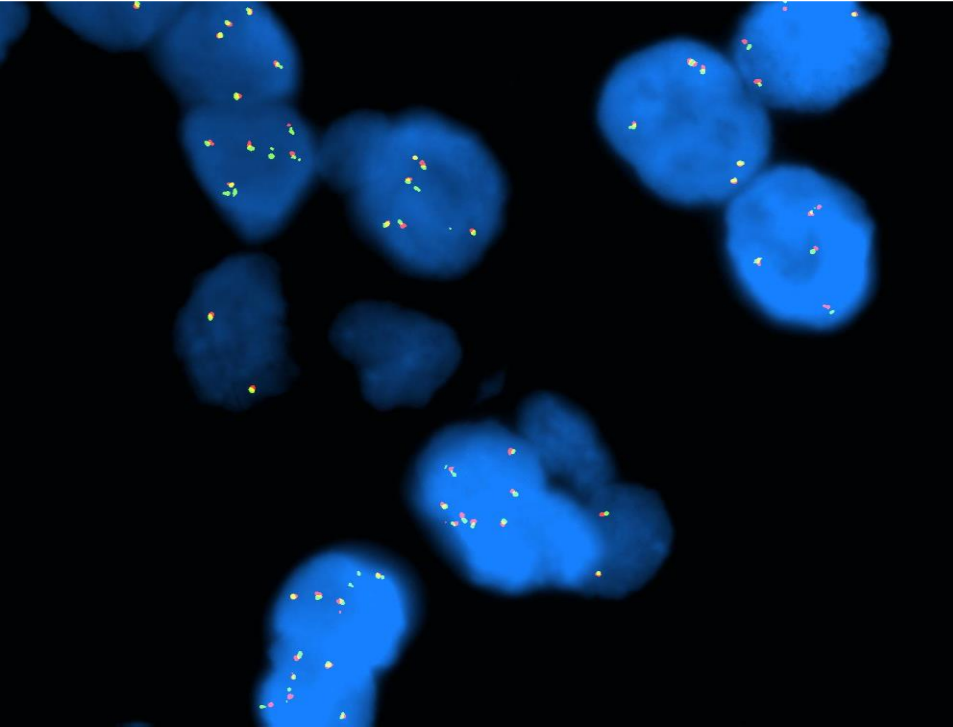
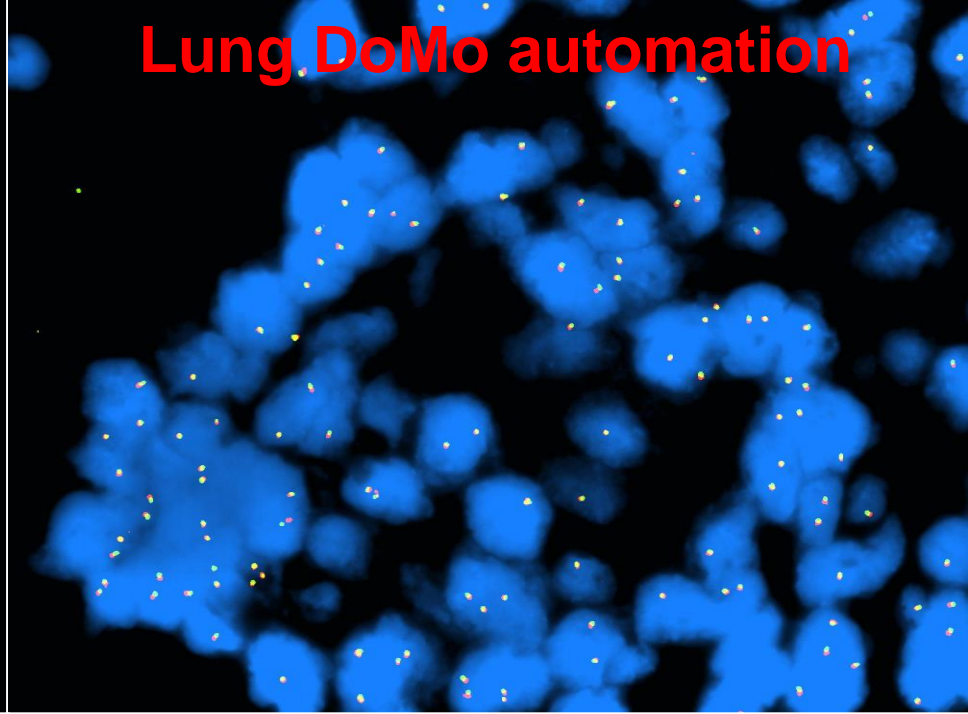
Breast DoMo automation



Lung in automation



Lung.DoMo automation



Breast cancer: Statistical data

* N: Indicates cases that have no HER2 gene amplification.

* A: Indicates cases that have amplification

FISH Standard		FISH RM2015000048		FISH Standard		FISH RM2015000048	
ID	HER2 Interpretation	HER2 Interpretation	ID	HER2 Interpretation	HER2	HER2 Interpretation	
1	N*	N	26	N		N	
2	N	N	27	N		N	
3	N	N	28	N		N	
4	A*	A	29	N		N	
5	A	A	30	N		N	
6	N	N	31	A		A	
7	N	N	32	N		N	
8	N	N	33	A		A	
9	N	N	34	A		A	
10	N	N	35	N		N	
11	N	N	36	N		N	
12	A	A	37	N		N	
13	N	A	38	N		N	
14	N	N	39	N		N	
15	N	N	40	N		N	
16	N	N	41	N		N	
17	N	N	42	N		N	
18	N	N	43	N		N	
19	N	N	44	N		N	
20	N	N	45	N		N	
21	N	N	46	N		N	
22	N	N	47	N		N	
23	A	N	48	N		N	
24	N	N	49	N		N	
25	N	N	50	N		N	
			51	N		N	
			52	N		N	
			53	N		N	
			54	N		N	
			55	N		N	
			56	A		A	
			57	N		N	
			58	N		N	
			59	A		A	
			60	A		A	

Concordance DoMo Genetics vs Standard

Lung statistical data

Lung statistical data	Comparison
<i>t</i>	0,2506
LD	58
P	0,8030

No significant differences for $p < 0.01$

Breast signals diameter measurement

	DoMo Genetics		Standard	
nuclei	Red	Green	Red	Green
1	10,3	14	10,2	10,3
2	11,7	12	6,03	12,4
3	7,6	15	4,1	15,2
4	12	11	10	17
5	10,6	14	10,8	8
6	12,4	18,4	10,8	9,1
7	12,4	12,4	6,4	10,8
8	9,2	12	7,6	15,3
9	12,3	15,5	13,6	12,2
10	12,3	11,4	10,3	9,1
Average	11,08	13,57	8,983	11,94

	red vs red	green vs green
t	2,0148	1,353512
LD	18	18
	No significant differences for p<0.01	No significant differences for p<0.01

Lung signals diameter measurement

	DoMo Genetics		Standard	
nuclei	Red	Green	Red	Green
1	8,6	7,3	10,4	7
2	8,5	6	9,4	6,5
3	6,2	7,6	8,1	6
4	9,1	5,1	7,1	7,4
5	9,2	7	8,2	8,1
6	7,8	6	7	5
7	7,8	8,1	6,3	7
8	11	7,1	8,2	6
9	7	8	5,8	5,1
10	7,8	5,1	6,4	8,5
average	8,3	6,73	7,69	6,66
t	0,982835	0,1370		
LD	18	18		
	No significant difference for p<0.01	No significant difference for p<0.01		

Brain signals diameter measurement

	DoMo Genetics		Standard	
nuclei	Red	Green	Red	Green
1	10	5,4	9,2	5,7
2	10	4	8,2	5,8
3	10	5,8	8,5	9,1
4	8	4	7,8	9
5	13	7,3	7,9	8,1
6	8	6,4	10,8	4
7	8,9	8,6	10,4	6,3
8	10	6,4	7,8	6,2
9	13	7,1	8,1	5,7
10	12,2	10,6	11	5,4
average	10,31	6,56	8,97	6,53

	red vs red	green vs green
t	1,8721	0,036343
LD	18	18
	No significant differences for p<0.01	No significativ e difference s for p<0.01

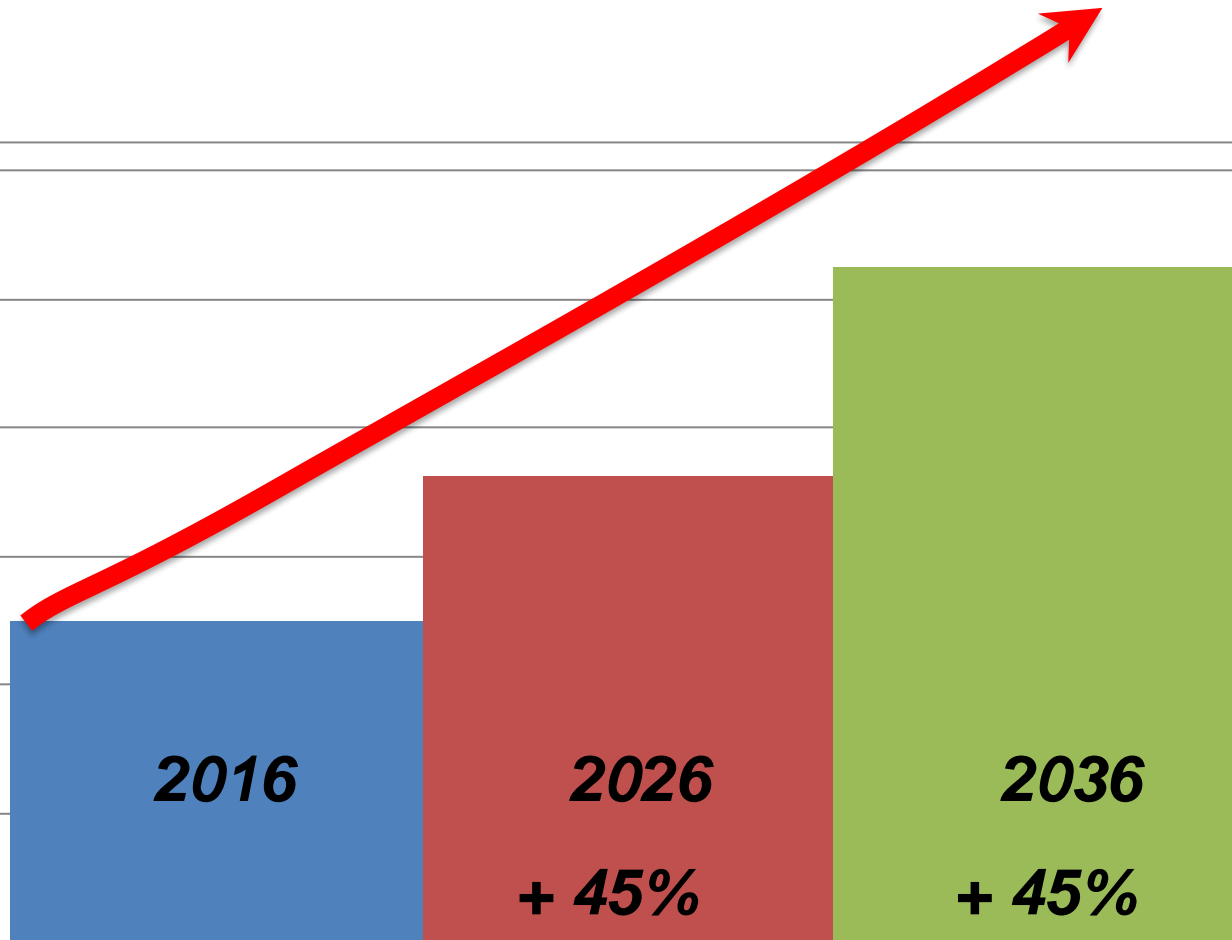
Brain signals diameter measurement

	DoMo Genetics		Standard	
nucleo	Red	Green	Red	Green
1	7,2	5,1	8,5	7,6
2	5	6,8	8,9	8,5
3	5,8	6,7	4,2	7,2
4	6,3	5,7	4,1	4
5	5	5	5,8	4,5
6	4,5	5,8	6,7	4,2
7	5,4	8	9	5,7
8	7,2	5	5,1	4,1
9	7	7	7	10
10	7,1	4,1	7,3	8,1
media	6,05	5,92	6,66	6,39

	red vs red	green vs green
t	0,9151	0,601527
LD	18	18
	No	No
	significativ e	significativ e
	differences for p<0.01	differences for p<0.01

Market

GLOBAL MARKET: \$6B in 2016



Milano, 17.12.2013

OGGETTO: Offerte. Vs. mail del 10.12.2013

Con la presente siamo lieti di sottoporre alla Vs. cortese attenzione la ns. migliore proposta economica per la fornitura di:

Status	Codice	Descrizione	Conf.	Prezzo/conf. offerto
IVD - CE	K573111-2	HER2 IQFISH pharmDxTM	20 test	2.720,00=

Condizioni Generali:

- L'I.V.A., pari al 22% sarà a Vs. carico;
- **Termine di consegna reattivi:** entro 7 gg. data ordine e secondo le Vs. indicazioni;
- **Pagamento:** Bonifico Bancario 90 gg.data ricevimento fattura;
- **Validità della presente offerta: 31/01/2013**

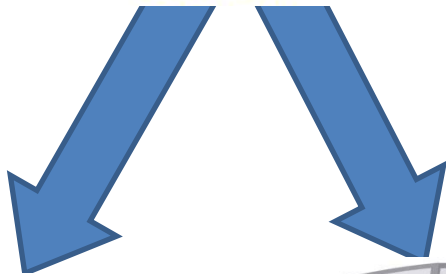
La informo inoltre, come da sua gentile richiesta, che il buffer di ibridazione non è vendibile separatamente.

Per quanto riguarda la compatibilità la informo che i due filtri leggono lunghezze d'onda differenti. Inoltre l'Orange non è compatibile con le ns. sonde.

Restiamo a Vs. disposizione per quant'altro possa occorrerVi e, con l'occasione porgiamo distinti saluti.



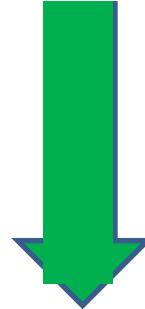
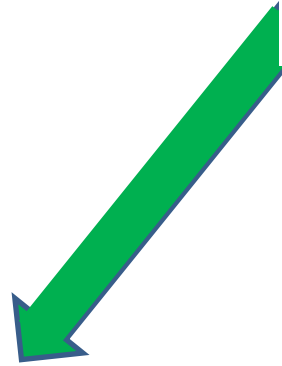
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EXTERNAL VALIDATION



OaCP



INSTITUTION 1



INSTITUTION 2



INSTITUTION 3

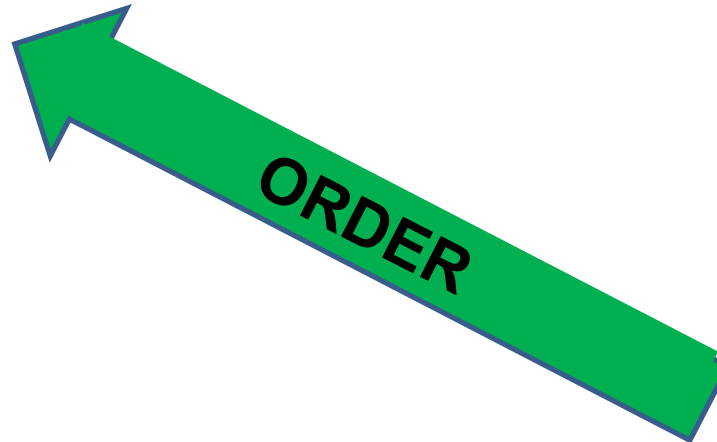
EU

CE

IVD



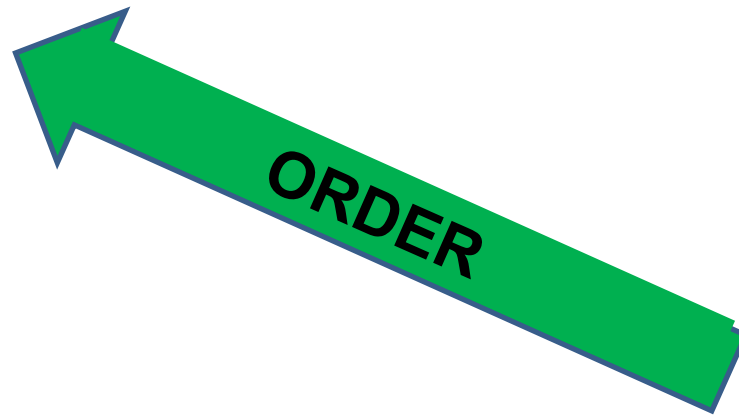
OaCP



USA



OaCP



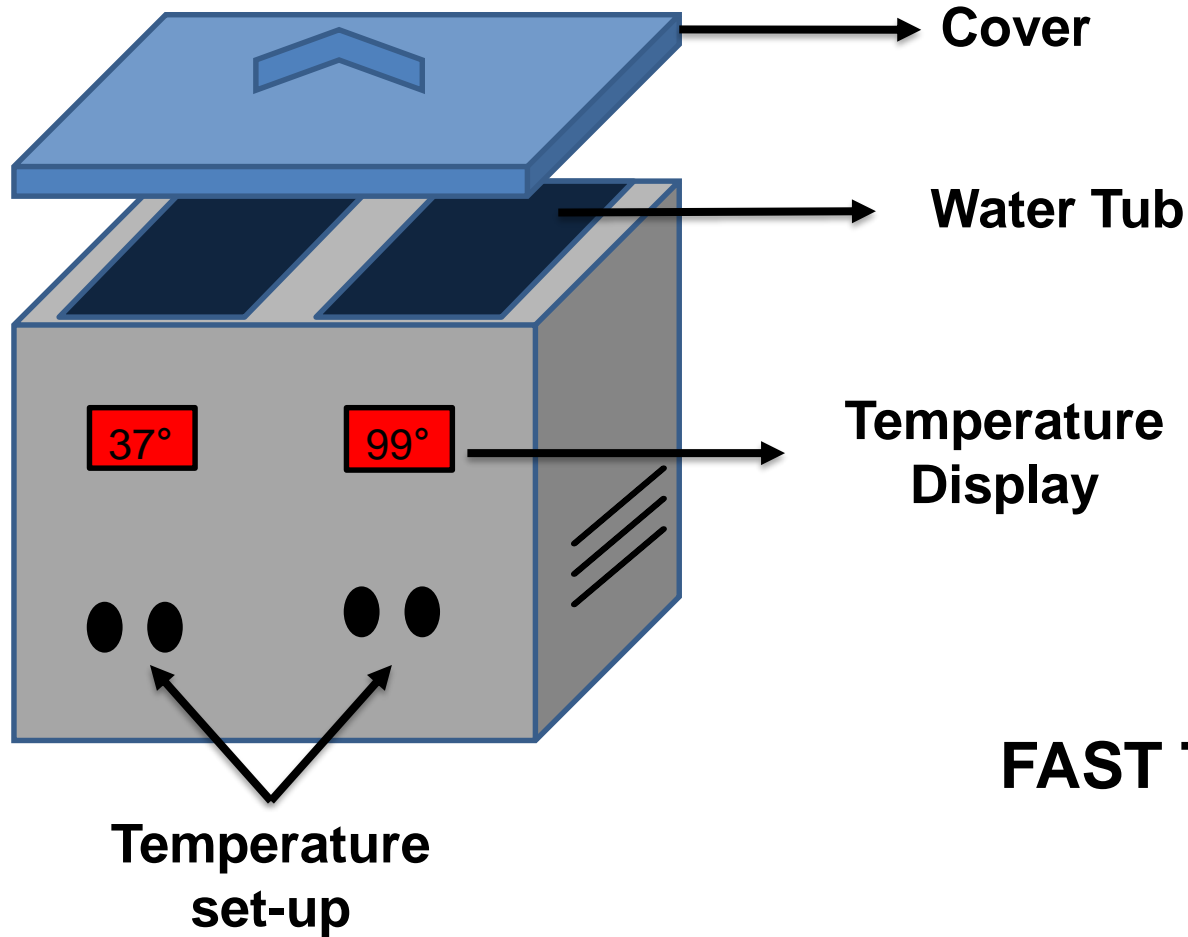
Institutional Review Board

Price strategy



Name	SOLVE	FAST	SUPER	SONIC
Test n°	20 test	20 test	20 test	20 test
Prize	850	900	930	950
Test Time	Standard	8 hrs	4 hrs	2hrs
Test Cost	-50%	-50%	-50%	-50%

New product



FAST THERMO-BATH

Finance

COMPARABLE EXITS

XVYSIS

REVENUES: 23.3M\$

**2001
(X15)**



ABBOTT

ACQUISITION: 355M\$



**REVENUES:
10.2M\$-17M\$**

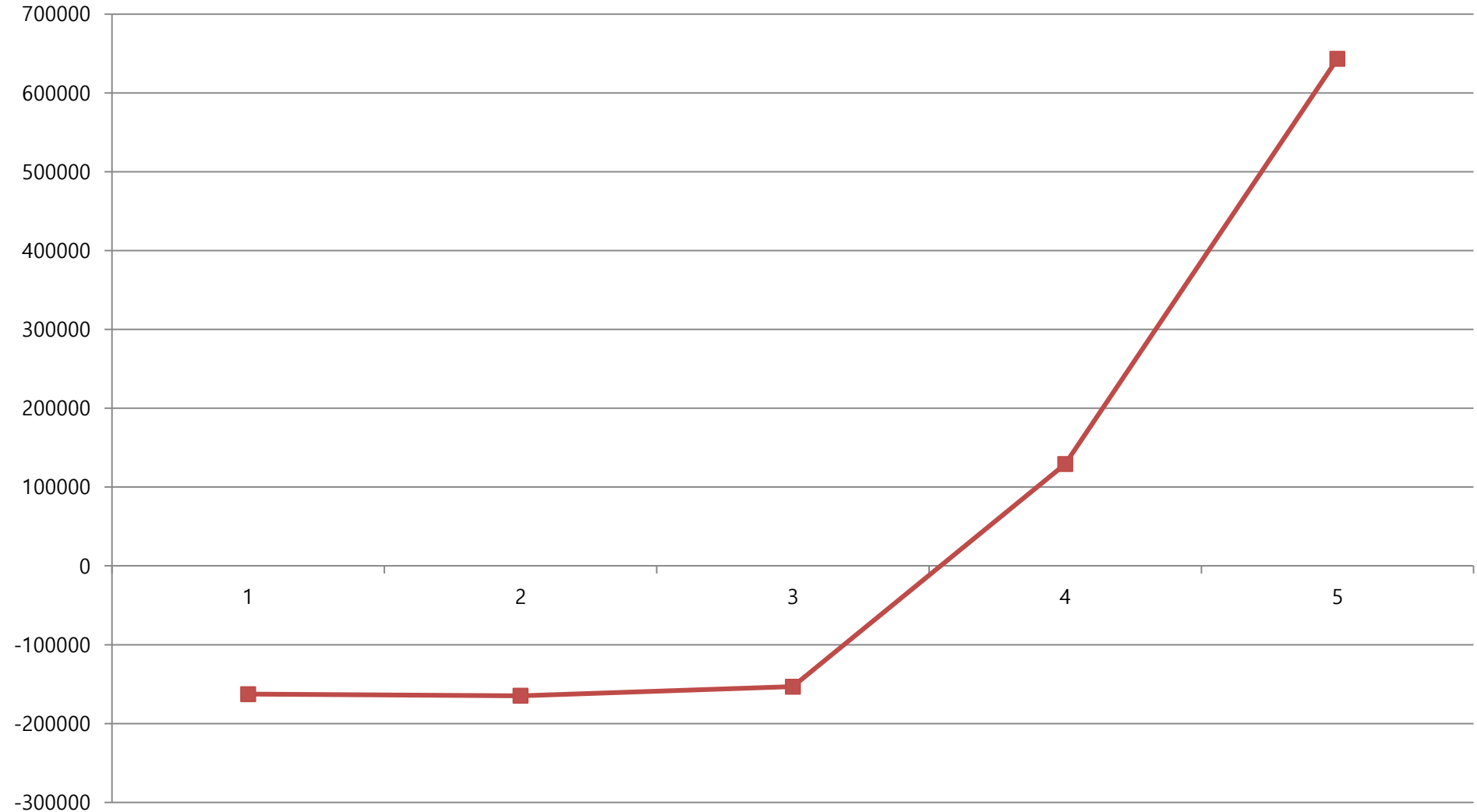
**2009
(X6)**



Agilent Technologies

**ACQUISITION: 66M\$-
110M\$**

CASH FLOW



enrico.dioto@live.it

BALANCE

	2017	2018	2019	2020	2021
Revenues	64.800	129.600	474.000	2.820.000	6.541.800
Expenditures	192.708	349.405	729.379	2.451.857	5.060.571
Net	(44.658)	(68.490)	18.067	914.088	1.829.224