燃石医学
Burning Rock Dx

Burning Rock Biotech Limited

4Q20 Updates

BNR US Equity

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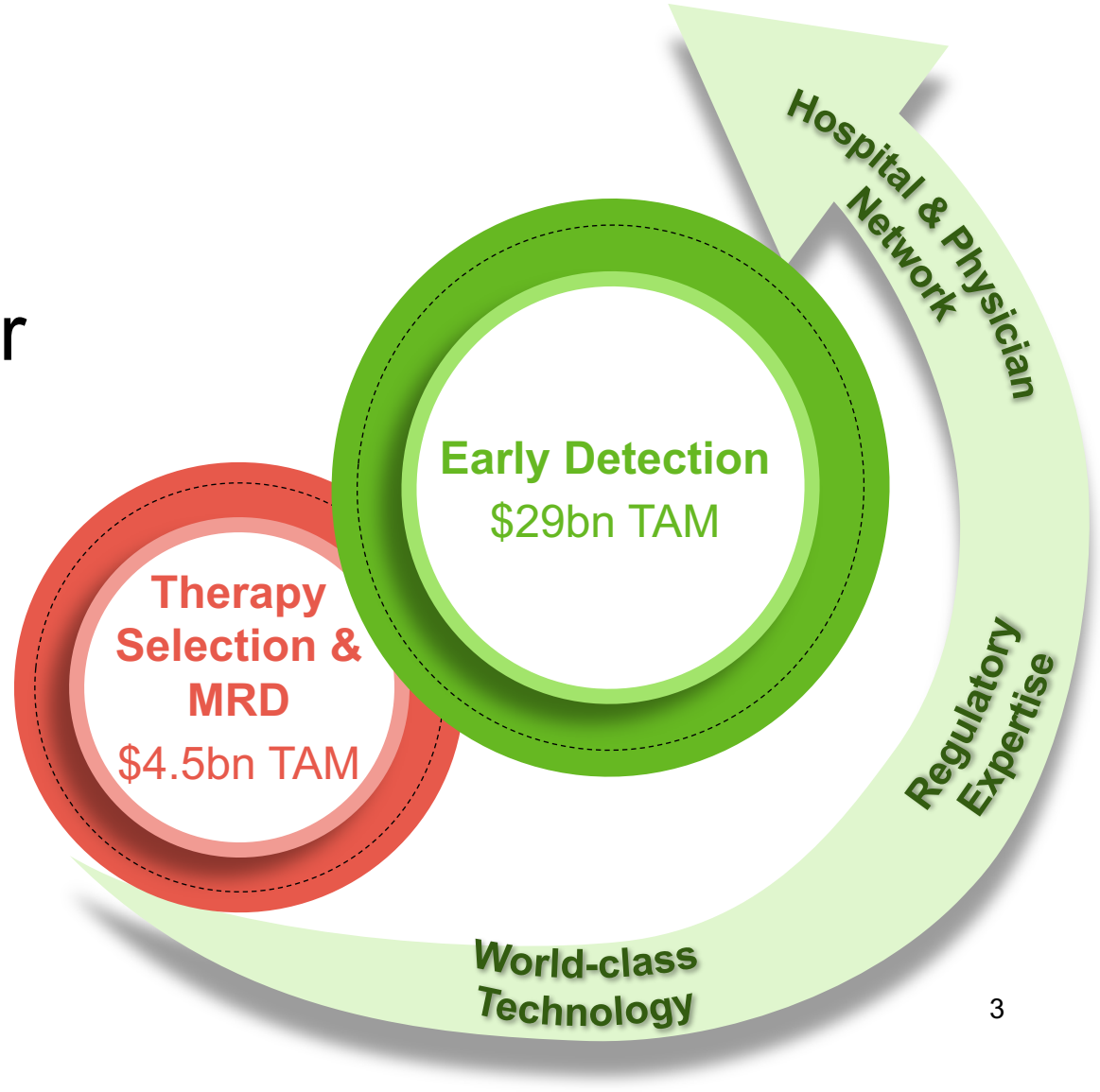
What we do

China's **molecular diagnostics** leader for **precision oncology**



Notes:
Total addressable market size estimated per China Insights Consultancy industry report

Today's topics

- 2020 recap
- Blood-based multi-cancer early detection – from lab to commercialization
- Liquid biopsy therapy selection testing – strengthening our position for long-term success
- 2021 priorities
- Financials

2020 recap

Therapy Selection

Leader in China's NGS-based precision oncology diagnostics market

- **273k** cumulative tests completed. **72k** tests completed in-hospital[1]
- **+33%** YoY revenue growth in 2H20, **+43%** gross profit growth
  - **+26%** central-lab revenue in 2H20**.** 44% tests were blood-based during 2020
  - **+63%** in-hospital revenue in 2H20. 29 contracted hospitals for reagent kits[2], +10 during 2020
- Strong performance in the FDA-led SEQC2 study, results pending publication
- Leadership in NMPA's NGS approval programs in ctDNA, large tissue-based panels and CDx[3]

Early Detection

At the forefront of blood-based, multi-cancer early detection

- Progressed from internal R&D into large-scale clinical programs, building off our proprietary methylation-based assay
- Strong product development execution
  - 6-cancer product development completed
  - 9-cancer test development with performance improvement in progress
  - Preparation under way for further product development
- Accelerating commercialization

Notes:
[1] As of 31 Dec 2020, cumulative number of tests completed since inception, including multiple testing for a single patient
[2] As of 31 Dec 2020, excluding pipeline hospitals that are still in the process of completing contracts, excluding hospitals with only instrument sales
[3] Companion diagnostics development, working alongside pharmaceutical partners

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Bringing multi-cancer early detection from lab to the real world

6-cancer test product development completed, early access initiated

	Product development	Intended-use validation	Commercial roll-out
BR 6-cancer test	✓ Training and case-controlled validation (completed) ➢ Capacity ramp-up ongoing	➢ Early access in progress ➢ Prospective validation	• Revenue generation targeted for 2022, subject to early-access feedback

BR competitive advantages

1 Best multi-cancer product in China

Through highly-sensitive methylation assay and large training dataset

2 Strong validation dataset

Through research collaboration with leading physicians and real-world data

3 First mover advantage

Increasing volume / data enables improved product performance and unit cost reduction

Path to commercialization

Positive feedback from commercial insurers and hospitals

	Commercial insurers	Hospitals
Commercial channels	Payor market with commercial insurers	High-end self-pay market with top comprehensive hospitals, leveraging existing commercial relationships built as part of the therapy selection business
Value propositions to commercial partners	• Cost savings by discovering and treating cancers early • Addressing unmet end-customer needs on cancer screening, with a unique multi-cancer product	• Physical check-up revenue generation, meeting unmet end-customer needs for multi-cancer screening • Downstream revenue generation out of follow-up diagnostics and treatment • Meeting top hospitals' demand for innovative products, leading the forefront of oncology research

Product development roadmap

Multi-year effort, high entry barriers. Real-world use provides feedback loop for product development

Single-cancer
2016 – 2019

- Results released at AACR 2019
- Lung cancer, proof of concept on assay and bioinformatics methodology
- Manuscript on methodology under peer review

3-cancer
2017 – Jan 2020

- Results released at AACR Special Conference on Liquid Biopsy, Jan 2020
- Lung, CRC, HCC
- 95.1% specificity and 80.8% sensitivity[1]

Product development completed, capacity ramp-up, building validation dataset

6-cancer
2018 – Nov 2020

- Results released at ESMO Asia, Nov 2020
- Lung, CRC, HCC, Ovarian, Pancreatic, Esophageal
- 98.3% specificity and 80.6% sensitivity[2]
- Tissue-of-origin (TOO) result in 98.6% cases; among those 81.0% were correct

Product development in progress

9-cancer
2019 – Ongoing

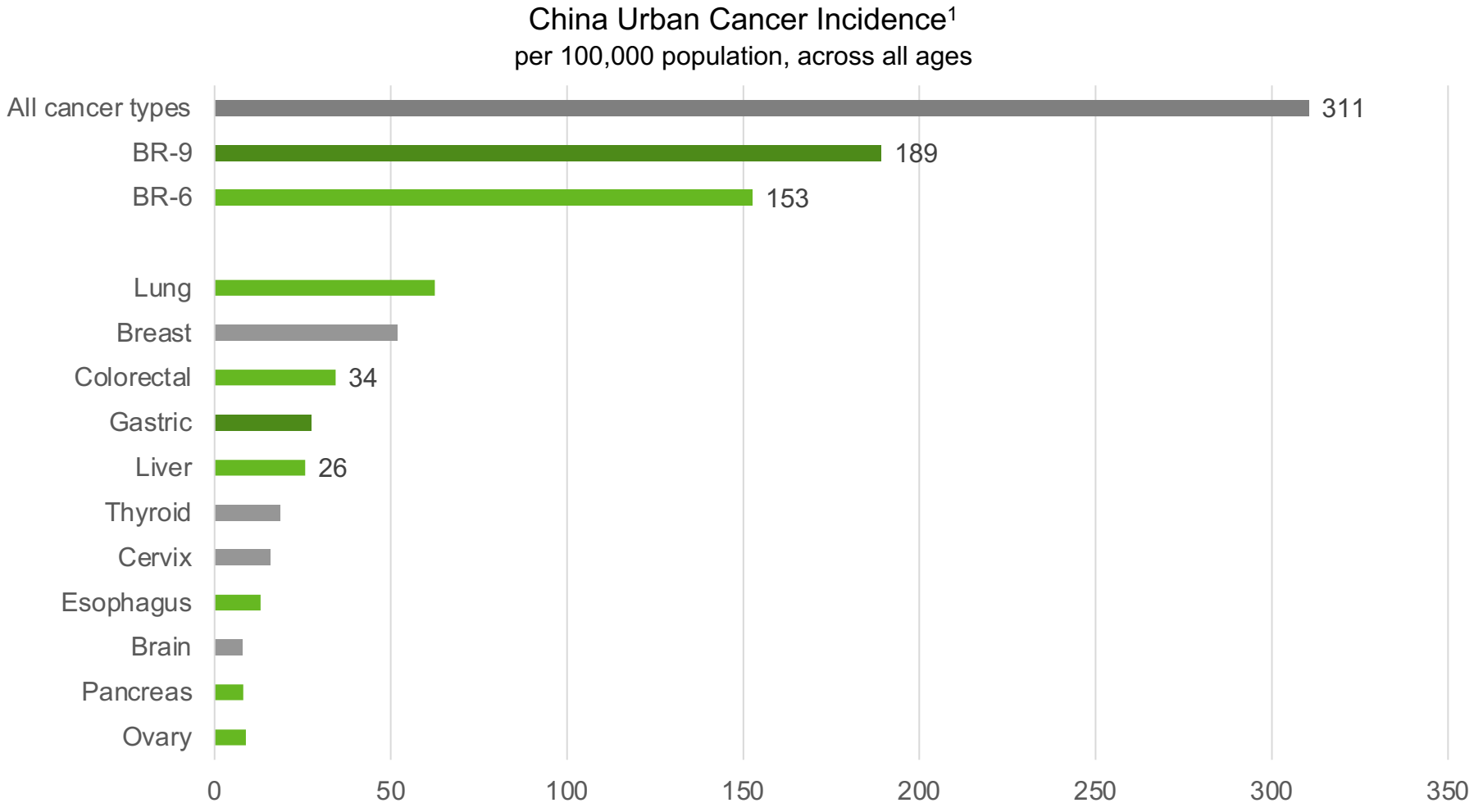
- Assay under development; training and validation to follow
- Lung, CRC, HCC, Ovarian, Pancreatic, Esophageal, Gastric, Cholangio, Head & Neck

Future product
To be announced

Notes:
[1] Training and validation cohorts combined, 490 cancer samples, 226 control samples. Sample size is aggregated through a series of case-control studies. 95.1% specificity (95% CI 91.2-97.4) and 80.8% sensitivity (95% CI 77.0-84.1)
[2] Validation cohort, 351 cancer samples, 288 control samples. Sample size is aggregated through a series of case-control studies. 98.3% specificity (95% CI 95.8-99.4) and 80.6% sensitivity (95% CI 76.0-84.6). Further details in Appendix.

Multi vs. single cancer early detection in China

Multiple times larger TAM



BR-6 covers 49% of China's urban incidence by cancer type

Note:

[1] Incidence data per "2018 China Cancer Registry Annual Report ", J. He et al., ISBN 978-7-117-28585-8

Multi vs. single cancer early detection in China

Significantly higher technology barrier

Single-cancer test

- Established technology, typically PCR based, with readily available products
  - US – First FDA approved product in 2014 (first submission in 2012)
  - China – NMPA approved products (class-III, including tissue and blood-based) in 2017, 2018, 2019, 2020, 2021, etc
- Small panel, low cost
- Relatively simple genomic data analytics

Multi-cancer test

- Biologically, blood-based tests are multi-cancer in nature
- Highly complex technology with product risk
  - Globally, only a small number of innovators have locked-down products going under intended-use validation
- Data as a key factor for development and validation
  - Evolving dataset leads to continuous product improvement and greater validation
- Unprecedented commercial potential
  - Possibility to fundamentally shift oncology landscape from late-stage therapeutics to earlier stage intervention

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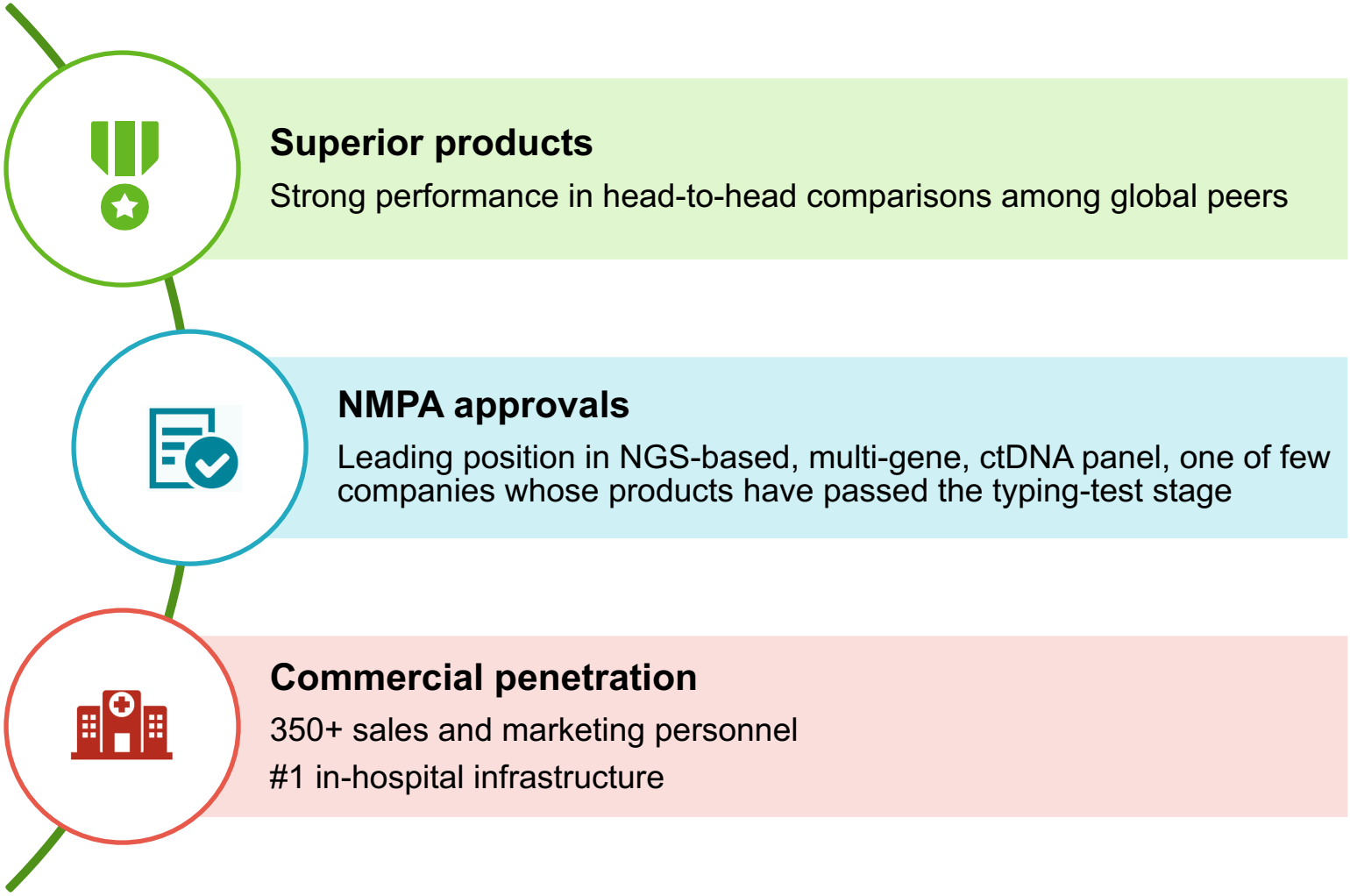
Factors for long-term success

Product as the core factor. NMPA approvals enable competitive differentiation



Superior products

Strong performance in head-to-head comparisons among global peers

NMPA approvals

Leading position in NGS-based, multi-gene, ctDNA panel, one of few companies whose products have passed the typing-test stage

Commercial penetration

350+ sales and marketing personnel

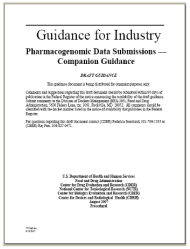
#1 in-hospital infrastructure

FDA-led SEQC2 (sequencing quality control) consortium study

SEQC2 Study Overview

MAQC/SEQC Consortium Projects – An Overview

- An FDA-led community-wide consortium effort to assess technical performance and application of emerging technologies (e.g., genomics).
- Accomplishments (2005 – 2014):
  - Evaluated 3 genomics technologies: microarrays (MAQC1-2), GWAS (MAQC2) and RNA-seq (MAQC3/SEQC1)
  - Best practice recommendation papers published at Nat Biotech
  - Supported the FDA development of the guidance document
- SEQC2 (2016 – 2021):
  - 4 Working Groups – Somatic Mutations, Oncopanel Sequencing, Germline WGS, Epigenetics QC
  - Over 20 manuscripts, five of them have been accepted by Nat Biotech


Guidance for Industry

Pharmacogenomic Data Submissions — Companion Guidance

Issues and Study Objectives

- FDA approved several NGS tests with sensitivity for AF ~5%
- Hundreds lab developed tests (LDT): sensitivity ~ 2-10%
- FDA approved ctDNA tests with sensitivity for AF ~0.3%
- Publications claimed detection sensitivity for deep NGS tests (of ctDNA through UMI) could reach lower AF and even 0.01%
  - Lack of concordance reported b/w liquid biopsy test labs
  - Key concerns for LBx: concordance with tissue sequencing, concordance across labs, concordance across LBx panels/tests

Comprehensive QC with Reference Samples is crucial for translating oncopanels from lab dev to clinical application !!!

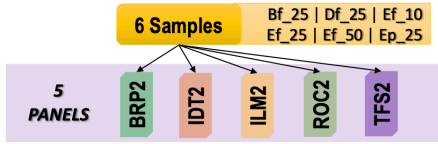
Liquid Biopsy Section

Objectives for Liquid Biopsy Core Study

- Aim to evaluate
  - Reproducibility
  - Sensitivity of Known Positives
  - False positive rate estimate through Known Negatives
  - All of them by VAF ranges:
    - 0.1 - 0.5%, 0.5 - 2.5%, >2.5%
    - Finer VAF ranges for sensitivity: 0.1 - 0.2%, 0.2 - 0.3%, 0.3 - 0.5%
- Evaluate the impact of DNA input amount
  - Three levels of input for Ef: 10ng, 25ng, 50ng
- Evaluate the impact of synthetic plasma (DNA extraction)
  - Qubit HS calibration and quantification
  - Calculate extraction yield

Samples for Liquid Biopsy Panels

- Centralized sample preparation
  - Enzymatic fragmentation -> better ligation efficiency
  - Gel-based size selection (160bp-180bp) to mimic cfDNA
  - 1ng/ul to mimic concentration after DNA extraction from plasma
  - Ep: 40ng/ml Ef in synthetic plasma



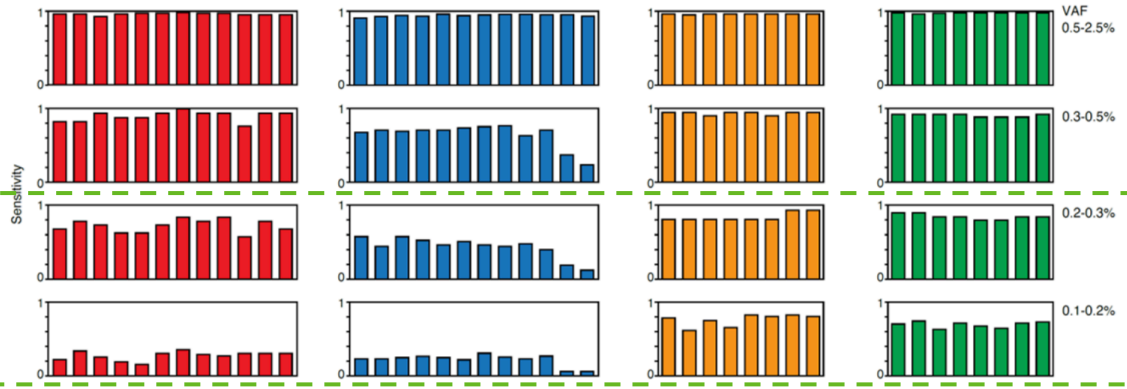
BRP2: Burning Rock Dx LungPlasma v4
IDT2: IDT xGen Non-Small Cell Lung Cancer
ILM2: Illumina TruSight 170 with UMI
ROC2: Roche AVENIO ctDNA Expanded Kit
TFS2: Thermo Fisher Oncomine Lung cfDNA Assay

Source:
"Establishing the analytical validity of circulating tumor DNA sequencing for precision oncology", 5th Annual Liquid Biopsy for Precision Oncology Summit, Feb 2021

Liquid biopsy results

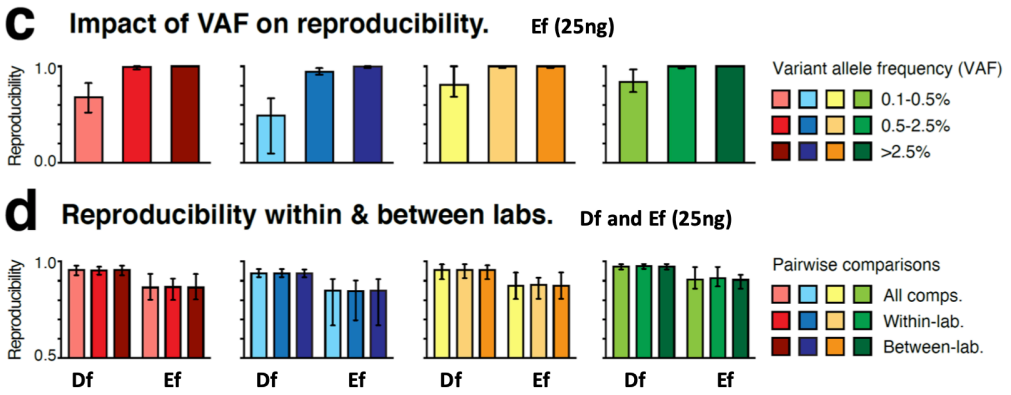
Full results pending publication of manuscript, which has been accepted by Nature Biotech

Sensitivity of Detecting ctDNA mutations in Ef (25ng) by four capture-based assays



High sensitivity for variants with VAF above 0.5%.

Reproducibility for Detecting ctDNA mutations by 4 capture-based assays



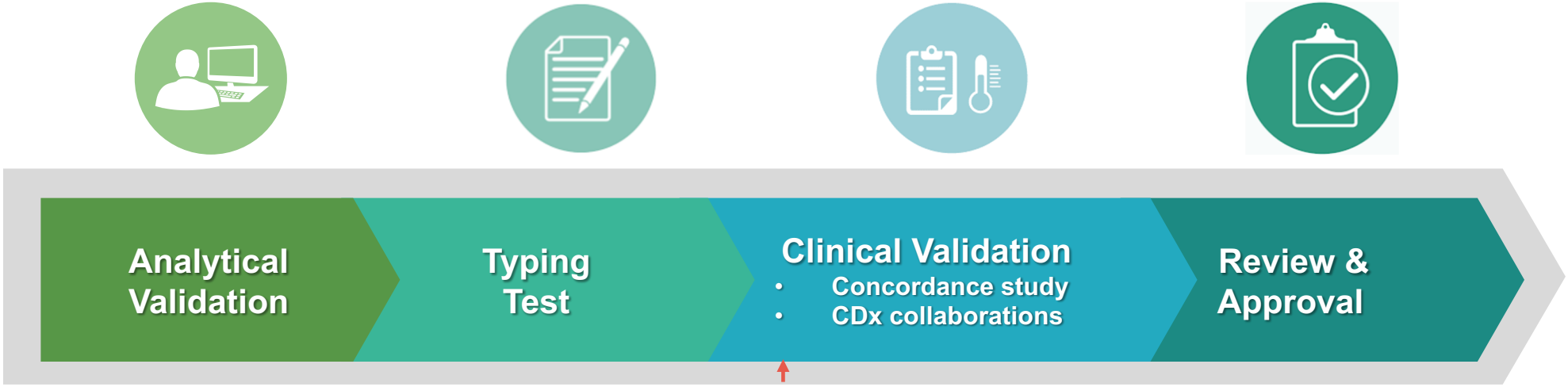
High reproducibility for variants with VAF above 0.5%.

Source:
"Establishing the analytical validity of circulating tumor DNA sequencing for precision oncology", 5th Annual Liquid Biopsy for Precision Oncology Summit, Feb 2021

Liquid biopsy NMPA progress update

BR OncoCompass Target in leading position for multi-gene ctDNA NMPA approval process

NMPA[1] diagnostics approval process overview



BR's OncoCompass™ Target kit & software

- ✓ 101 genes + bMSI
- ✓ Multiple CDx co-development collaborations
- ✓ Typing test passed in Oct 2020
- ✓ Concordance study planned for 2H2021

Notes:
[1] National Medical Products Administration of China

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2021 priorities

Therapy Selection

Driving increased penetration of NGS-based diagnostics through product and commercial strengths

- Expansion of product menu
  - Completing tech transfer and validation of in-licensed products (myChoice HRD testing[1], DetermaRx[2])
  - Additional products under R&D
- NMPA registration program execution, laying the foundation of long-term competitive barrier
- Further in-hospital penetration

Early Detection

Bringing multi-cancer early detection towards real-world use

- Ramping up 6-cancer test capacity, in preparation for commercialization
- Multi-channel commercial team build-out
- Ongoing NMPA dialogues
- Roll-out of additional large clinical programs for product development and validation
- Additional R&D on future products

Notes:

[1] Myriad myChoice CDx test enables physicians to identify patients with tumors that have lost the ability to repair double-stranded DNA breaks, resulting in potentially increased susceptibility to DNA-damaging drugs such as platinum drugs or PARP inhibitors. In May 2020, the FDA approved myChoice CDx for use as a companion diagnostic to identify patients with advanced ovarian cancer with HRD-positive status, who are eligible or may become eligible for first-line maintenance treatment with Lynparza (olaparib) in combination with bevacizumab.

[2] DetermaRx is a treatment stratification test that identifies stage I-IIA non-squamous NSCLC patients at high-risk of recurrence despite ostensibly curative surgery, who may benefit from the addition of chemotherapy.

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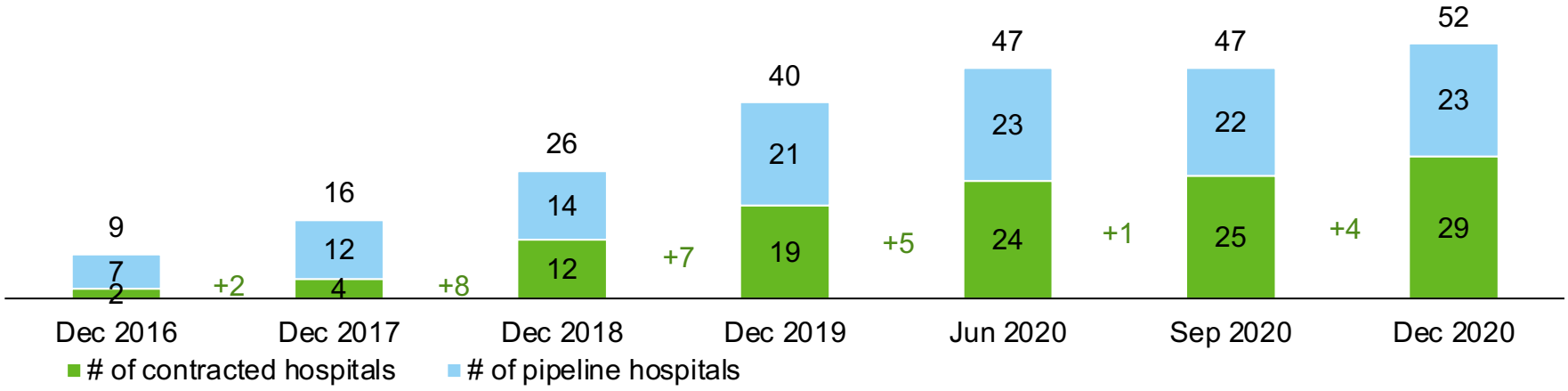
Operating metrics

Central-lab channel

	2018	2019	2020	1Q19	2Q19	3Q19	4Q19	1Q20	2Q20	3Q20	4Q20
# of ordering hospitals	263	335	312	249	265	281	304	232	284	289	294
# of ordering physicians	1,135	1,632	1,318	984	1,059	1,155	1,222	810	1,175	1,194	1,114
# of patients tested[1]	15,821	23,075	25,262	5,336	6,047	6,769	7,576	4,680	7,252	8,644	7,989
YoY	*67%*	*46%*	*9%*					*-12%*	*20%*	*28%*	*5%*
QoQ									*55%*	*19%*	*-8%*

In-hospital channel



Note:
(1) A patient who took multiple tests in different quarters of a given year is counted only once for that year

Financials

RMB millions	2019	2020	*18 YoY*	*19 YoY*	*20 YoY*	1Q19	2Q19	3Q19	4Q19	1Q20	2Q20	3Q20	4Q20	*2H20 YoY*	*4Q20 YoY*	*4Q20 QoQ*	2021 Guide
Revenue	**381.7**	**429.9**	***88%***	***83%***	***13%***	**104.5**	**84.8**	**103.7**	**88.7**	**67.3**	**107.0**	**123.9**	**131.7**	***33%***	***49%***	***6%***	**610**
Central lab	276.3	297.3	*83%*	*71%*	*8%*	72.8	63.4	69.3	70.8	46.1	74.6	89.9	86.7	*26%*	*23%*	*(4%)*	
In-hospital	87.7	117.9	*209%*	*164%*	*34%*	26.6	16.3	30.7	14.1	17.1	27.6	31.7	41.5	*63%*	*194%*	*31%*	
Pharma	17.7	14.7	*15%*	*25%*	*(17%)*	5.1	5.1	3.7	3.8	4.1	4.8	2.3	3.6	*(21%)*	*(7%)*	*57%*	
Gross profit	**273.3**	**313.9**	***88%***	***102%***	***15%***	**78.1**	**62.1**	**78.2**	**55.0**	**44.8**	**78.4**	**91.6**	**99.2**	***43%***	***80%***	***8%***	
Total opex	**442.4**	**726.3**	***54%***	***49%***	***64%***	**89.7**	**90.5**	**111.8**	**150.5**	**104.1**	**151.4**	**216.2**	**254.6**	***79%***	***69%***	***18%***	
R&D[1]	147.5	214.1	*114%*	*43%*	*45%*	30.7	34.3	36.8	45.7	37.9	45.9	58.7	71.6	*58%*	*57%*	*22%*	
S&M[1]	152.0	165.1	*52%*	*49%*	*9%*	26.3	34.4	42.1	49.3	29.6	37.5	43.9	54.2	*7%*	*10%*	*23%*	
G&A[1]	120.8	174.6	*18%*	*40%*	*44%*	31.2	20.0	29.8	39.8	32.6	40.6	44.9	56.5	*46%*	*42%*	*26%*	
SBC[2]	22.1	172.5				1.5	1.8	3.1	15.7	4.0	27.4	68.7	72.3				
Operating profit	(169.1)	(412.4)				(11.6)	(28.5)	(33.6)	(95.5)	(59.3)	(73.0)	(124.6)	(155.4)				
GP margin	**71.6%**	**73.0%**				**74.8%**	**73.2%**	**75.4%**	**62.0%**	**66.5%**	**73.3%**	**73.9%**	**75.3%**				
Opex / revenue	116%	169%				86%	107%	108%	170%	155%	142%	175%	193%				
S&M / revenue	40%	39%				26%	41%	41%	55%	44%	36%	36%	43%				

Notes:
1 Excluding share based compensation (SBC)
2 Share based compensation

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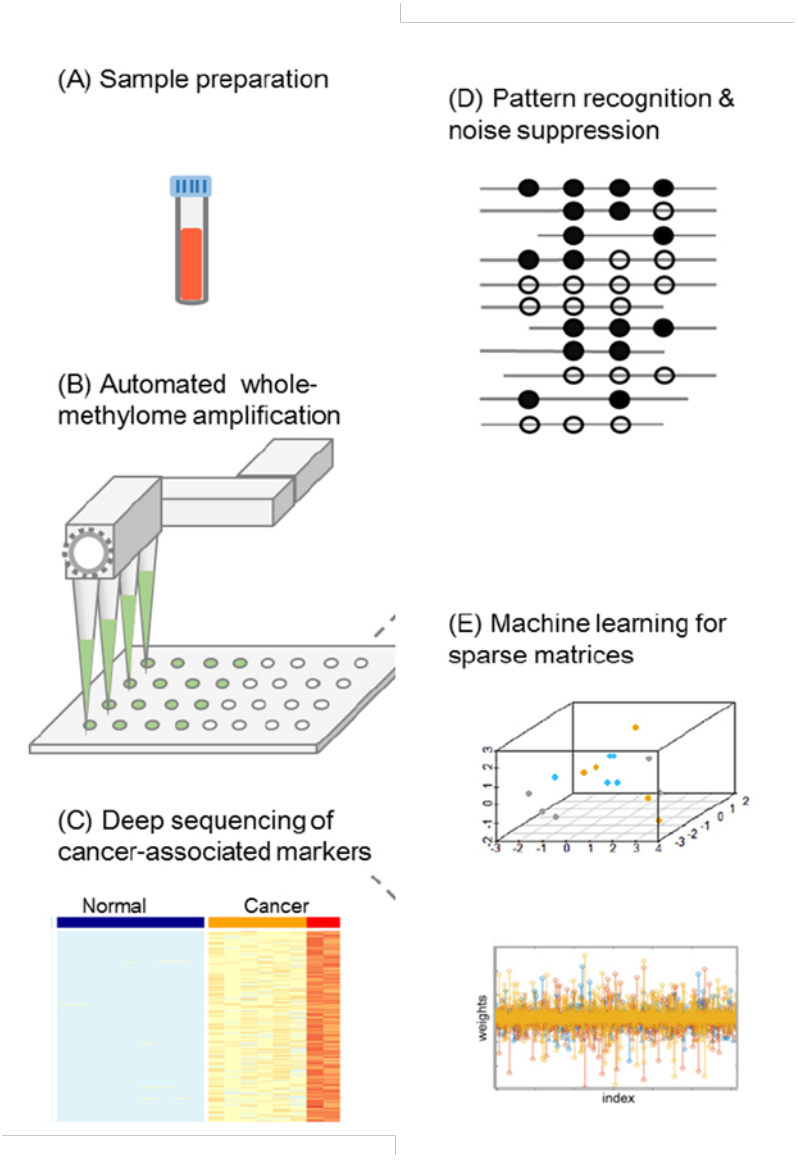
Appendix

6-Cancer early detection performance data released at ESMO Asia (Nov 2020)

Burning Rock early detection technology – ELSA-seq

R&D started in 2016; combination of targeted deep methylation sequencing and machine learning



Technology Highlights:

- ✓ Single-stranded library prep starts as low as 1ng cfDNA
- ✓ Bisulfite conversion or enzymatic conversion compatible
- ✓ Intelligent probe design to maintain the methylation level fidelity
- ✓ Multiple noise reduction and signal corrections before machine-learning model building

Clinical progress

Marker discovery (tissue)

~5.5 million CpG sites
LC/CRC/LIHC/OVCA/PAAD/ESCA

~450,000 CpG sites
TCGA & GEO database

Panel validation (tissue and blood)

~160,000 CpG sites
LC/CRC/LIHC/OVCA/PAAD/ESCA/Control

Assay validation (blood)

Training Set		
LC	CRC	LIHC
OVCA	PDAC	ESCA
	CTRL	

Validation Set		
LC	CRC	LIHC
OVCA	PDAC	ESCA
	CTRL	

Additional Validation

Overview of training and validation sets

Comparable cancer and non-cancer groups

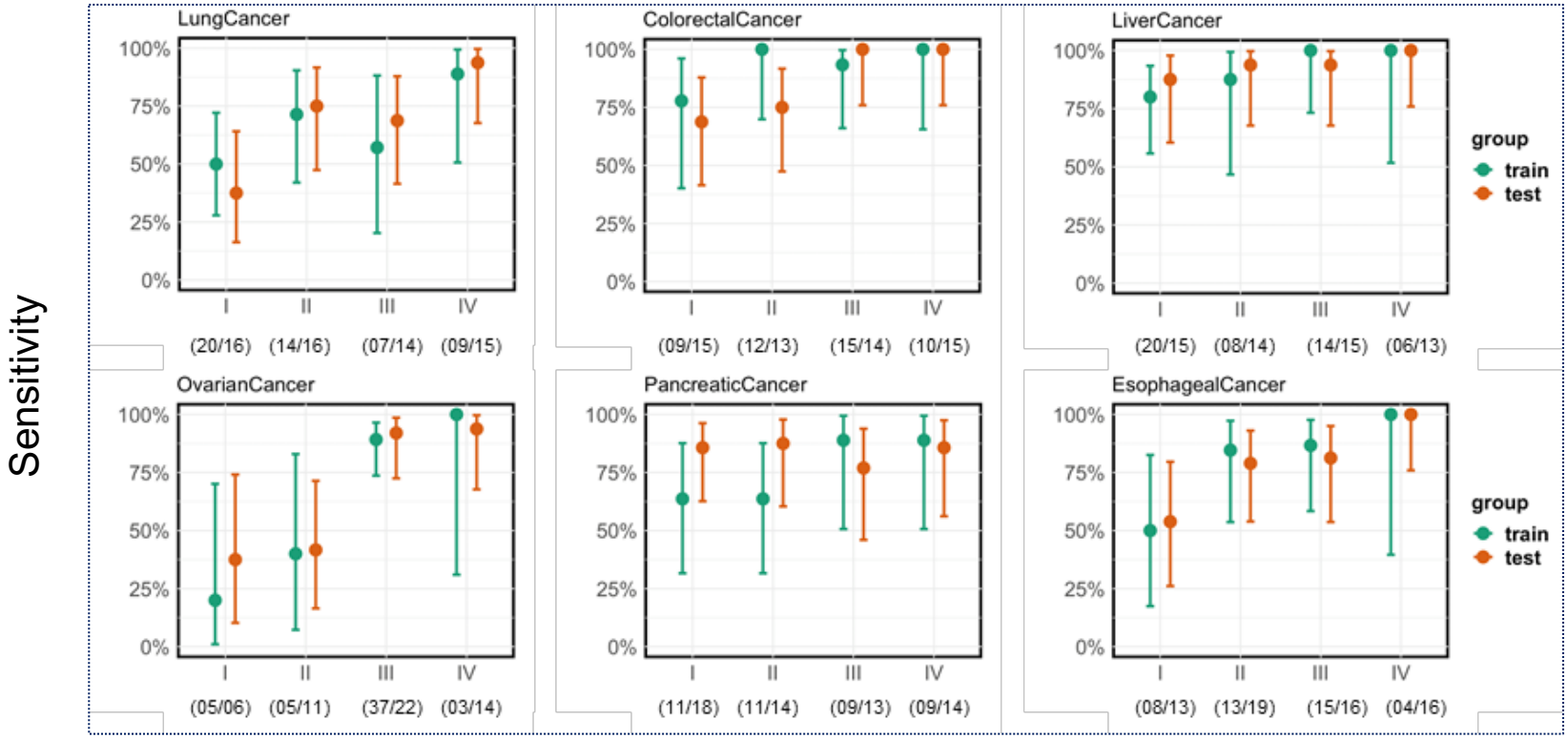
Training	Control	Cancer	LC	CRC	LIHC	OVCA	PAAD	ESCA
total	195	274	50	46	48	50	40	40
age, mean+/-SD	53+/-6	57+/-8	60+/-6	60+/-8	55+/-8	50+/-8	59+/-7	57+/-6
age, min/max	40/72	40/75	47/74	44/75	43/72	40/73	42/71	45/70
sex, female, n (%)	128 (70)	110 (40)	16 (32)	21 (46)	4 (8)	50 (100)	14 (35)	5 (13)
clinical stage, n (%)								
I		73 (27)	20 (40)	9 (20)	20 (41)	5 (10)	11 (27)	8 (20)
II		63 (23)	14 (28)	12 (26)	8 (17)	5 (10)	11 (27)	13 (33)
III		97 (35)	7 (14)	15 (32)	14 (29)	37 (74)	9 (23)	15 (37)
IV		41 (15)	9 (18)	10 (22)	6 (13)	3 (6)	9 (23)	4 (10)

Validation	Control	Cancer	LC	CRC	LIHC	OVCA	PAAD	ESCA
total	288	351	61	57	57	53	59	64
age, mean+/-SD	54+/-6	59+/-8	62+/-7	61+/-9	54+/-8	54+/-7	61+/-9	62+/-6
age, min/max	40/74	40/75	45/74	44/75	40/73	42/68	40/74	46/74
sex, female, n (%)	171 (59)	146 (42)	22 (36)	21 (37)	9 (16)	53 (100)	19 (32)	22 (34)
clinical stage, n (%)								
I		83 (23)	16 (26)	15 (26)	15 (26)	6 (11)	18 (30)	13 (20)
II		87 (25)	16 (26)	13 (23)	14 (25)	11 (21)	14 (24)	19 (30)
III		94 (27)	14 (23)	14 (25)	15 (26)	22 (42)	13 (22)	16 (25)
IV		87 (25)	15 (25)	15 (26)	13 (23)	14 (26)	14 (24)	16 (25)

1. Similar age distribution between cases and controls, and between training set and validation set
2. Balanced sample size among different stages and cancer types

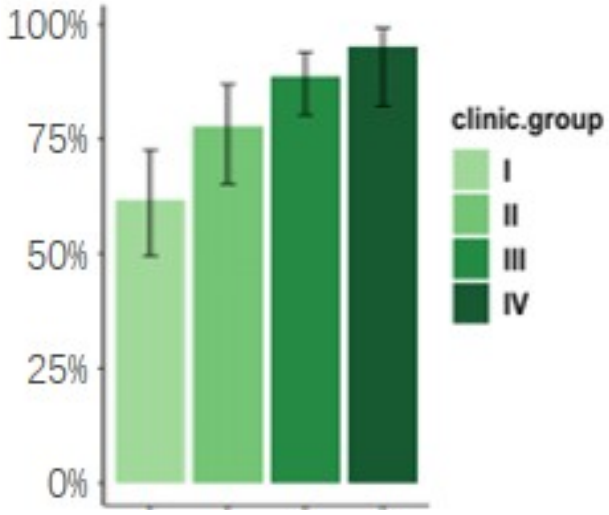
Note:
Sample size numbers are aggregated through a series of case-control studies.

Our test detects cancers at early stage with high specificity and high sensitivity

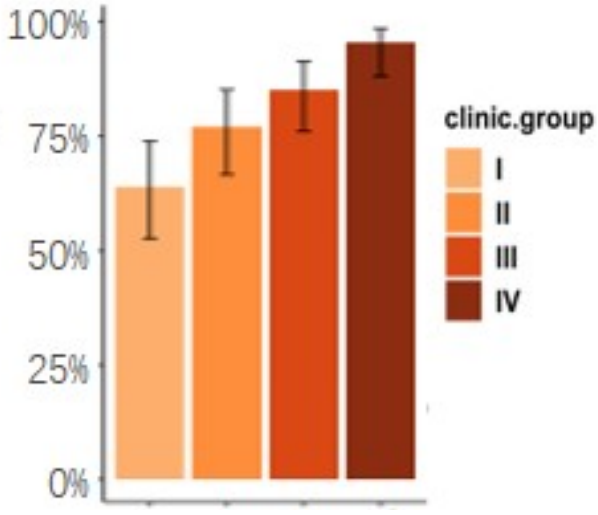


- The specificity was **99.5%** (95%CI: 96.7-100%; training) and **98.3%** (95%CI: 95.8-99.4%; validation)
- The sensitivity was **79.9%** (95%CI: 74.6-84.4%; training) and **80.6%** (95%CI: 76.0-84.4%; validation)

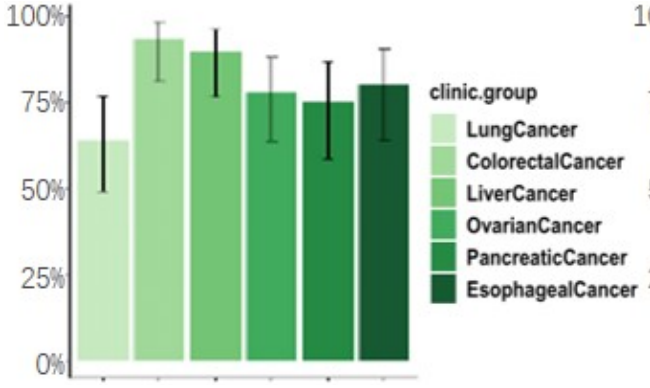
Our test detects cancers at early stage with high specificity and high sensitivity



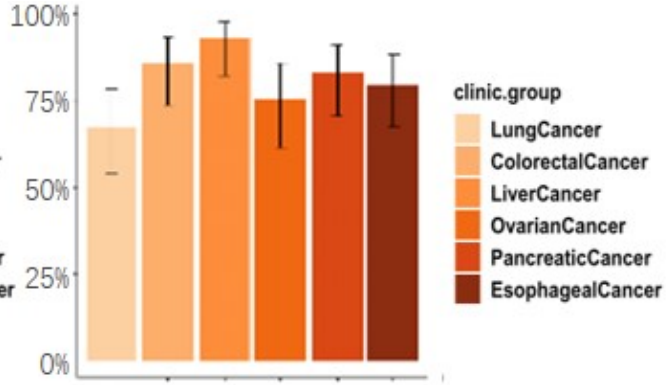
Training



Validation

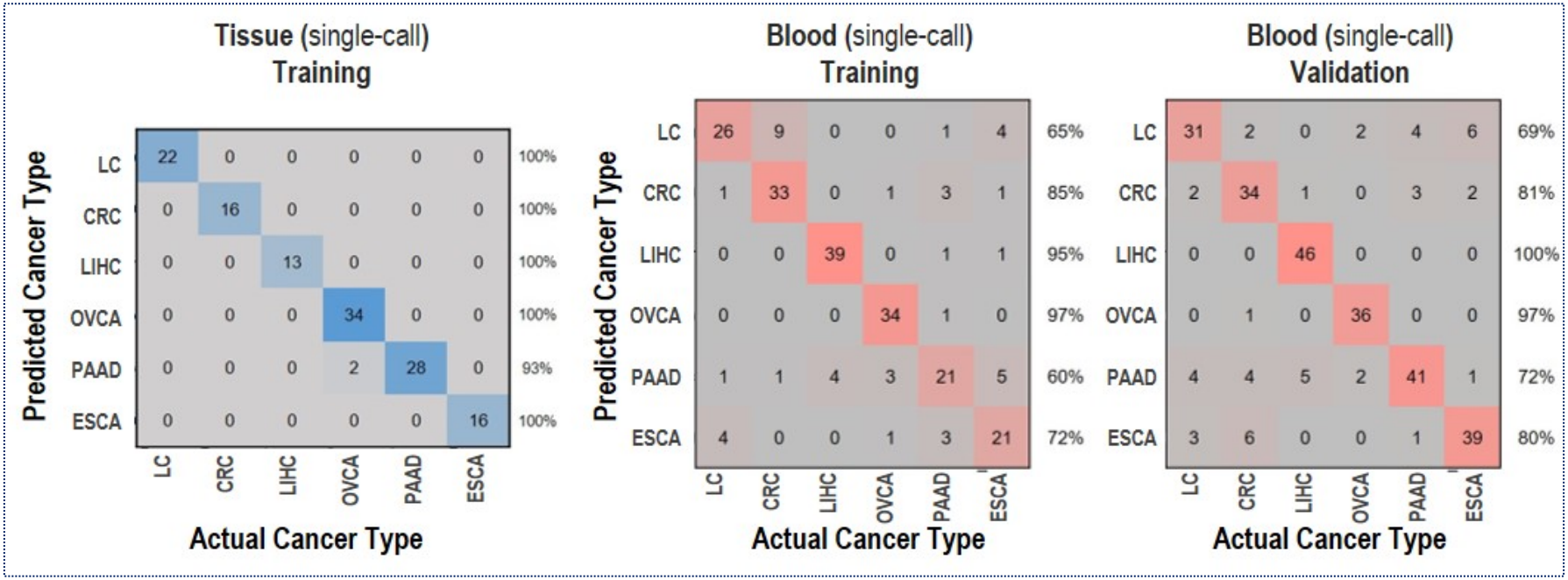


Training



Validation

Our test predicts the tissue of origin with high accuracy



- The classifier was able to distinguish different cancer tissue samples with exceptional accuracy **(129/131).**
- **98.6%** of detected cancer blood samples were assigned an organ-source in both training and validation sets:
  - For single organ calls, the predictive accuracy was **79%** (training) and **82%** (validation);
  - For top-two organ calls, the predictive accuracy was **89%** (training) and **87%** (validation).

6-cancer test sensitivity by cancer type and stage

Sensitivity and Specificity - Correct#/Total# (%)

Cancer	Group	I	II	III	IV	Overall
Lung	Train	10/20 (50.0)	10/14 (71.4)	4/7 (57.1)	8/9 (88.9)	32/50 (64.0)
	Test	6/16 (37.5)	12/16 (75.0)	9/14 (64.3)	14/15 (93.3)	41/61 (67.2)
Colorectal	Train	7/9 (77.8)	12/12 (100.0)	14/15 (93.3)	10/10 (100.0)	43/46 (93.5)
	Test	10/15 (66.7)	10/13 (76.9)	14/14 (100.0)	15/15 (100.0)	49/57 (86.0)
Liver	Train	16/20 (80.0)	7/8 (87.5)	14/14 (100.0)	6/6 (100.0)	43/48 (89.6)
	Test	13/15 (86.7)	13/14 (92.9)	14/15 (93.3)	13/13 (100.0)	53/57 (93.0)
Ovarian	Train	1/5 (20.0)	2/5 (40.0)	33/37 (89.2)	3/3 (100.0)	39/50 (78.0)
	Test	2/6 (33.3)	5/11 (45.5)	20/22 (90.9)	13/14 (92.9)	40/53 (75.5)
Pancreatic	Train	7/11 (63.6)	7/11 (63.6)	8/9 (88.9)	8/9 (88.9)	30/40 (75.0)
	Test	15/18 (83.3)	12/14 (85.7)	10/13 (76.9)	12/14 (85.7)	49/59 (83.1)
Esophageal	Train	4/8 (50.0)	11/13 (84.6)	13/15 (86.7)	4/4 (100.0)	32/40 (80.0)
	Test	7/13 (53.8)	15/19 (78.9)	13/16 (81.3)	16/16 (100.0)	51/64 (79.7)
Sensitivity	Train					219/274 (79.9)
	Test					283/351 (80.6)
Specificity	Train					194/195 (99.5)
	Test					283/288 (98.3)