GENETRON 泛生子
ANSWERS FOR CANCER

Genetron Holdings Limited

(Nasdaq: GTH)

4Q & 2021 Financial Results

March 2022

Disclaimer

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Leading Precision Oncology Company in China

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TAM: Diagnosis & Monitoring

LDT + IVD

Diagnosis: $6.7B[1]
MRD: $14B[2]

LDT – Top player covering 500+ hospitals

IVD – 7 products approved;
S5 + Lung 8 NGS solution

MRD partnerships in blood and solid tumors

AstraZeneca FOSUN PHARMA 复星医药

Biopharma Services

Biotech Industry: $0.5B[1]

High growth Chinese biotech industry

#1 Ranking: 60 total biopharma partners

CDx demand is growing as NMPA increases focus on genomic testing for innovative drugs

基石药业 CSTONE PHARMACEUTICALS HUTCHMED

TAM: Early Screening

Liver cancer: $7.2B[1]
CRC cancer: $23.0B[1]
Lung cancer: $5.8B[1]

HCCscreen™ –
- FDA breakthrough device designation (NGS)
- Leading prospective data
- Commercialization roadmap

HCCscan™ –
- PCR-based assay expands market opportunity leveraging existing customer capabilities

Multi-cancer development with innovative technology in liquid biopsy

Our Proprietary Technology: One-step Seq, Mutation Capsules

1. Frost & Sullivan, Market potential in China as of 2023
2. Euromonitor, Globalcan, Company internal estimates market potential

Table of Contents

4Q & 2021 Events Recap

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Revenue growth with strong in-hospital sales momentum

- Total 2021 revenue **RMB 532.0 million, 25.3% annual revenue growth**
- **Gross margin improved to 63.5% in 2021** vs 61.3% in 2020
- IVD revenue increased by 64.4% in 2021 to RMB 154.5 million
- A total number of **58 hospital partnerships** in 2021, with **30 IVD hospitals contracts**

Early-screening business with first-mover advantage

- Successfully launched HCC early screening test in China, broadened registrational strategy –
  - **HCCscan™ (PCR assay)** – 5 clinical sites started patient enrollment
  - **HCCscreen™ (NGS assay)** – reported data from large-scale prospective study, enrollment to begin in late 2Q2022
- **Multi-omics blood-based CRC early screening** assay, preliminary data shows **>91% sensitivity and 95% specificity**

Leading position in MRD, CDx and others

MRD:

- Co-development with AstraZeneca R&D China for **personalized MRD tests for solid tumor**
- Gastric and LARC MRD data published, liver data has been accepted in a high impact journal
- Exclusive collaboration with Fosun Pharma to commercialize **Seq-MRD® for hematologic cancer** in China

CDx:

- HUTCHMED: ORPATHYS® in NSCLC in China
- Cstone: AYVAKIT® in China, which has entered the NMPA priority review process
- **Onco Panscan**, a CE-marked CGP assay to begin patient enrollment in late 2Q2022

Others:

- Ongoing registrational trial for **Thyroid Basic** at 4 clinical sites, expected to complete in 2022
- Mutation Capsule technology received invention patent

Liver cancer early screening tests development plan

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	Assay development	Clinical validation	Product launch
HCCscreen	• Multi-omics NGS assay powered by innovative and proprietary Mutation Capsule Technology • U.S. FDA Breakthrough Device Designation	• Mar 2019, China's first prospective (331 HBsAg+ patient cohort) and peer-reviewed study on HCC early screening PNAS • Mar 2021, investigational study (the "HIT" study) data readout: superior sensitivity and comparable specificity versus stand-of-care • Initiation of HCCscreen registrational trial in 2022 • Ongoing U.S confirmatory study	• LDT partnership with iKang Group to cover 100+ health check centers • Collaboration with local government for public health initiatives (Wuxi and Dafang) • Collaboration with digital health platforms and pharma partners • Lab co-development within hospitals
HCCscan	• PCR-based multi-methylation marker assay	• HCCscan registrational trial initiated in 4Q21 • 5 sites already started • Expect completion by 2022	

Solid-tumor MRD development plan

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	Assay development	Analytical validation	Clinical validation	Product launch
Tumor-informed	Completed prototype assay development using Mutation Capsule technology	***Journal of Hematology & Oncology 2021***: detect 0.001% tumor DNA from peritoneal lavage fluid samples (**gastric cancer**)	• Comparing personalized and fixed panel MRD strategies in **LARC**: published in ***EBioMedicine 2022*** • Comparing personalized and fixed panel based MRD strategies in **HCC**: **Publication accepted**	• Assay optimization with AstraZeneca ongoing, completion by end of 2022 • Pilot **LDT launch in Q2 2022** and official launch before year end 2022
Tumor-naïve	Evaluating the performance of different types of biomarkers for fixed panel MRD strategy, including mutation, fragmentation, methylation, etc, leveraging on Mutation Capsule's parallel profiling feature from one single sample			

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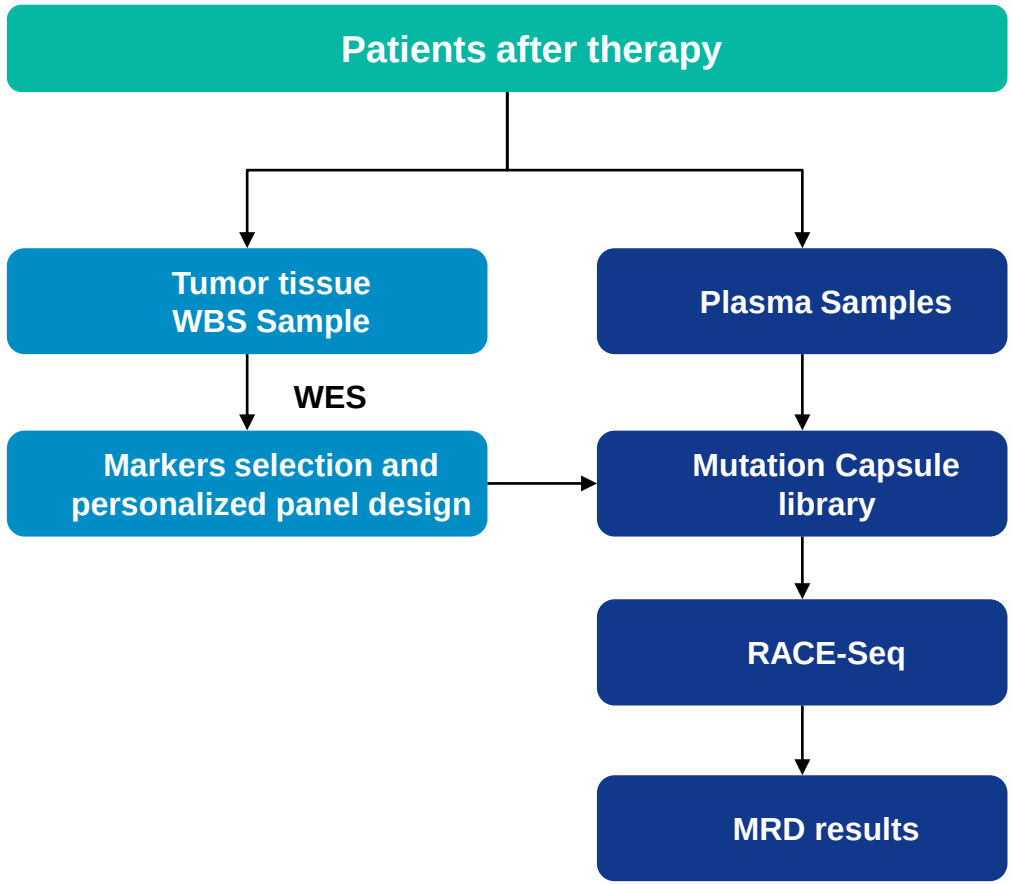
- Co-development for a personalized MRD assay for various solid tumor types in China
- This approach may help in the clinical management of patients far before metastatic lesions grow to significant size that detectable by conventional methods such as MRI and CT scanning
- AZ will incorporate the co-developed assay for China-specific studies.
- First step of a multi-year, exclusive LT partnership. Room to expand to IVD and commercialization

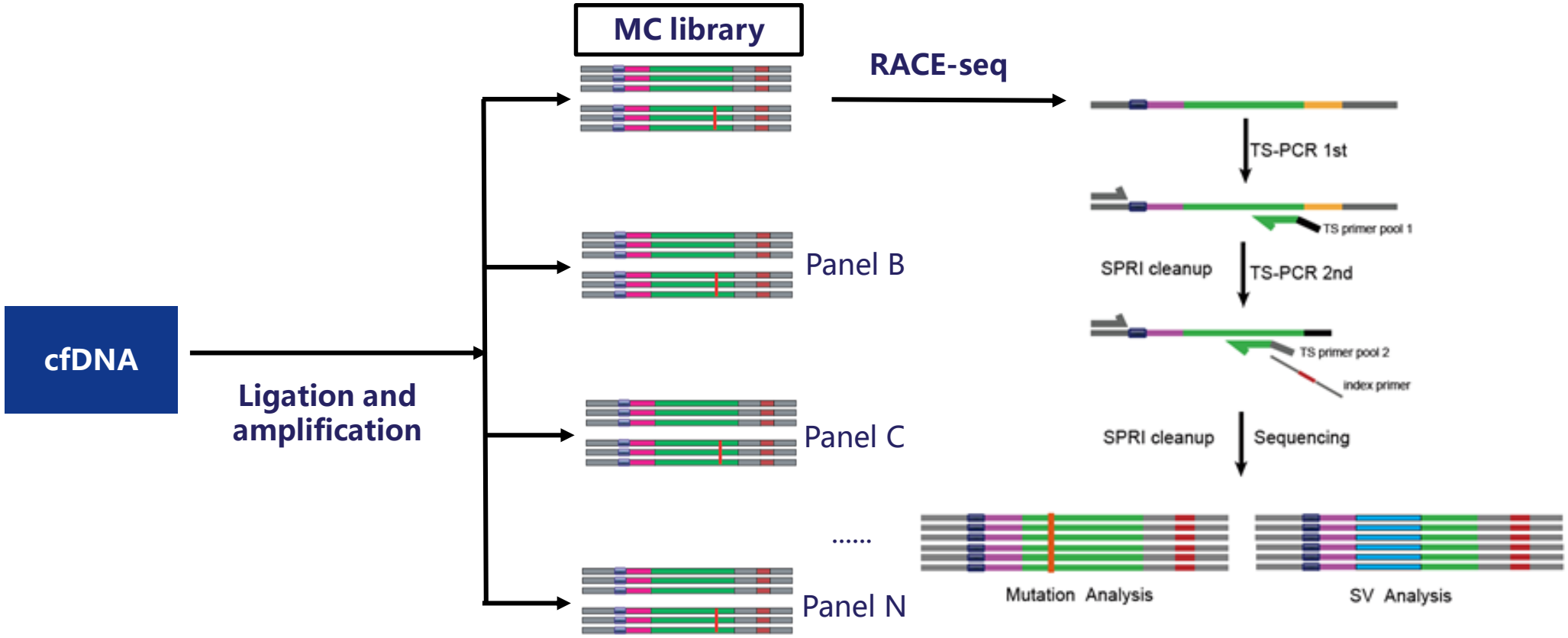
Tumor-informed MRD Workflow



Methodology:

- Select mutation markers based on WES of tumor tissue, design personalized panel for subsequent blood-based ctDNA testing
- **Advantage**: maximize performance, avoid false positive and false negative as much as possible
- **Disadvantage**: high cost, long design process and require tumor tissue sample

Advantage of Mutation Capsule in Solid-tumor MRD



Tumor-informed MRD

- Almost 100% success rate for personalized panel design from WES on the first try
- Support multiple tests from one single sample, therefore significantly reduces panel validation time

Tumor-naïve MRD

- Support different types of biomarkers for tumor-naïve MRD panel design, including mutation, methylation, fragmentation etc.
- Support head-to-head comparison of tumor-naïve MRD panels with personalized MRD panel

Tumor-informed MRD: Analytical Validation in Gastric Cancer

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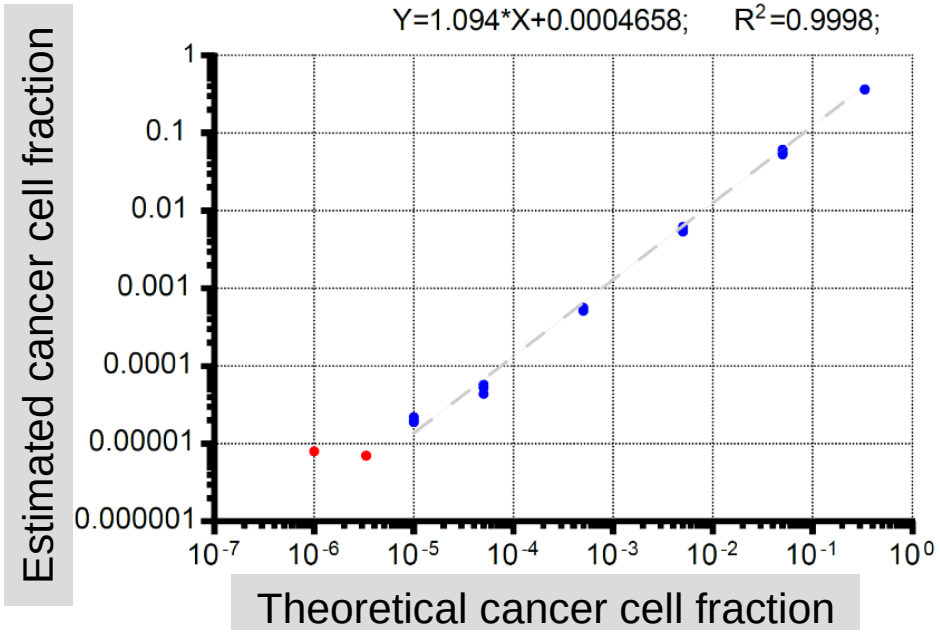
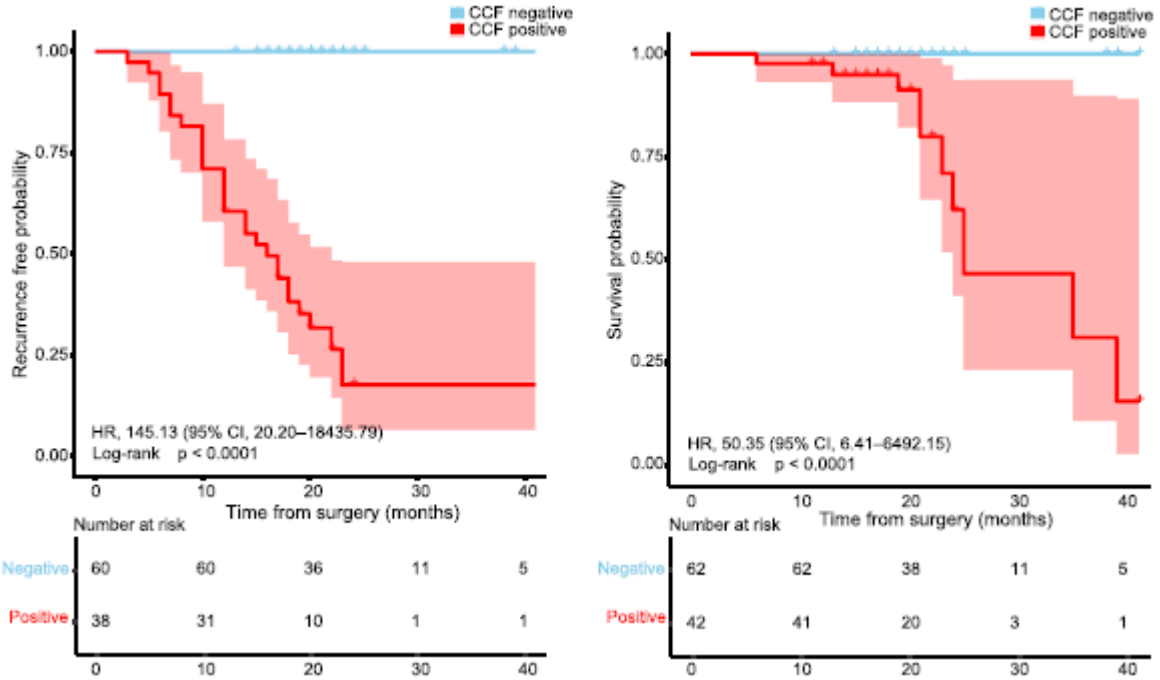
Validated ctDNA fraction model

- A mutation-based personalized MRD assay was developed to detect residual cancer cells from peritoneal lavage fluid
- Exhibited high sensitives with strong linear correlation between theoretical and estimated cancer cell dilution ratios up to 0.001%



Analytical validation in gastric cancer

- In a prospective cohort of 104 Gastric cancer (GC) patients, the MRD assay detected all the cases that developed peritoneal dissemination (PD) with 100% sensitivity and 85% specificity
- MRD-positive patients were associated with decreased recurrence free survival (RFS) and overall survival



Zhao, D., Yue, P., Wang, T. et al. *J Hematol Oncol* 14, 164 (2021).

Tumor-informed MRD: Clinical Validation

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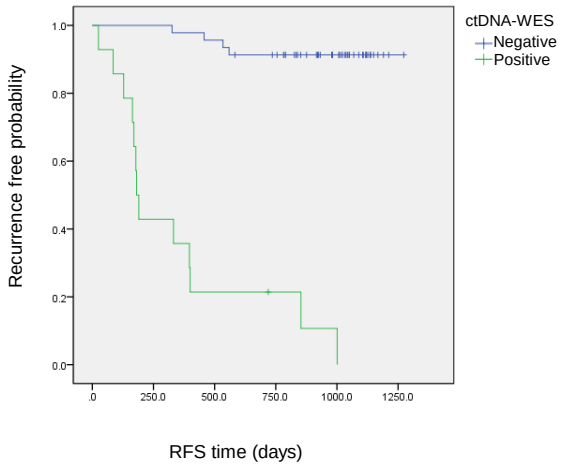
Head-to-head comparison between personalized and non-personalized assays in rectal cancer patients

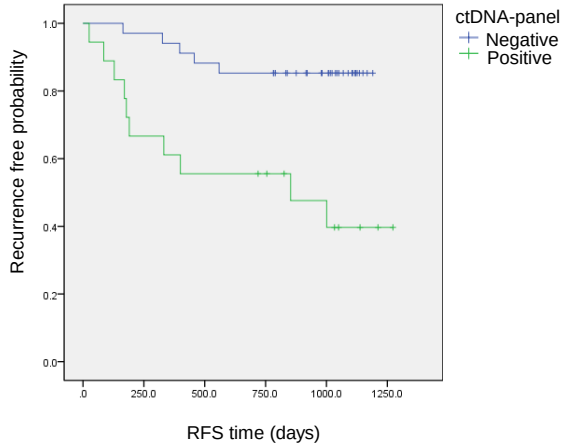
Personalized panel

HR= 27; P < 0.0001



Fixed panel

HR = 5; P = 0.001

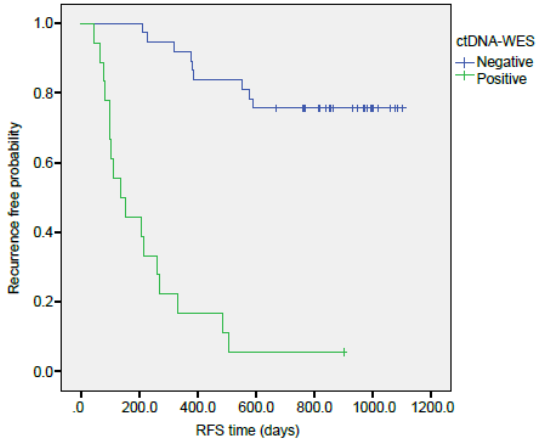


Published on EBioMedicine 2022

Head-to-head comparison between personalized and non-personalized assays in HCC patients

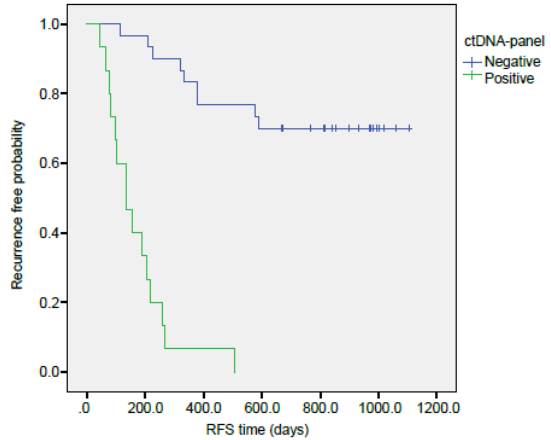
Personalized panel

HR=12; P<0.0001



Fixed panel

HR=13, P<0.0001



Pending publication data

Seq-MRD® for Hematologic Cancer

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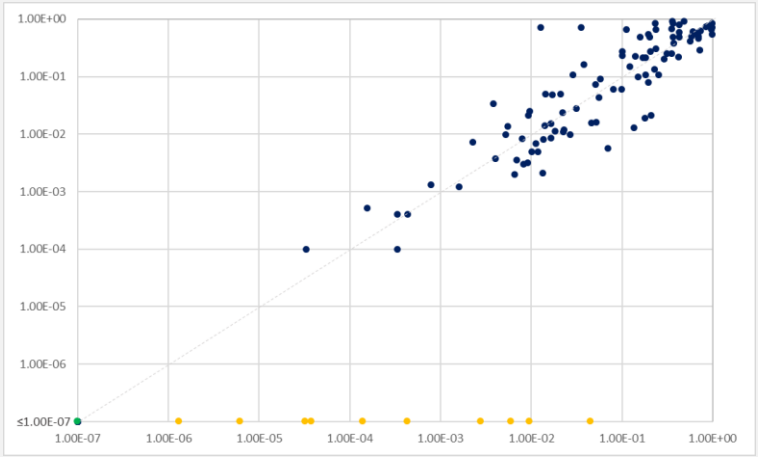
Enabled by One-step Seq + fully automated bioinformatics solutions

Higher sensitivity compared with FCM

- In the performance verification test for ALL, CLL and MM, when loading 20μg sample
  - For ALL and MM sample，the LOD (Limit of Detection) is 6.5×10^{-7}
  - For CLL sample，the LOD (Limit of Detection) is 9.75×10^{-7}
- Based on validation data from 128 clinically confirmed patients' samples (including 47 B-ALL, 39 CLL, and 42 MM). The positive detection results of traditional flow cytometry (FCM) and Seq-MRD were highly consistent
- Among them, 10 cases were detected MRD positive by Seq-MRD but negative by FCM, which reflected the **higher sensitivity** of Seq-MRD



	FCM MRD+	FCM MRD-	PPA (95%CI)	NPA 95%CI)
Seq-MRD+	98	10	100% (96.23%-100%)	66.67% (48.78%-80.77%)
Seq-MRD-	0	20		

Initiated commercialization in China

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- Exclusively collaborating with Fosun Pharma in hematologic-focused hospitals and clinics in China
- Fosun has 1,500 sales reps to sell innovative drugs that target hematologic and lymphoid malignancies, and solid tumors

ALL: acute lymphoblastic leukemia MM: multiple myeloma CLL: chronic lymphoid leukemia

#1 in Drug Development Services for Biopharma

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AstraZeneca · Roche · BAYER · janssen · 药明巨诺 JW Therapeutics · 正大天晴 CHIATAI TIANQING · 康宁杰瑞 ALPHAMAB ONCOLOGY · innovent 信达生物制药 · FOSUN 复星 · HUTCHMED · INNOCARE Science Drives Innovation · 基石药业 CSTONE PHARMACEUTICALS · EDIGENE 博雅辑因 · 亚盛醫藥 Ascentage Pharma

- Strategic partnerships with **60** leading global and Chinese biopharma companies
- Continue to see a strong pipeline as to form partnerships through our key products including **Seq-MRD, Onco Panscan, Fusion Scan**, etc.

Global clinical drug trials and CDx development

- CLIA lab in Maryland, US - a solid platform to offer services for cross-border trials and CDx developments
- Strategic partnership with NeoGenomics NEO GENOMICS

CDx: Companion diagnostics

Note: Partner number as of December 31, 2021

8-Gene Kit + S5 Instrument - Efficient Solution for Hospitals

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Lung Cancer 8-Gene Kit ✚ **Genetron S5**

Accurate Testing	High sequencing consistency, repetition rate and accuracy
Speedy Process	2-day turn around time
Small Sample Demand	As little as 20ng of sample DNA

Comprehensive 8-gene coverage

Gene	Chinese population mutation rate[1]
EGFR	50.1%
KRAS	12.3%
BRAF	4.4%
PIK3CA	12%
HER2	6.3%
ALK	7.8%
ROS1	1.3%
MET	3.4%

1.Oncologist. 2019 Nov;24(11):e1070-e1081.

Target at China hospital market

Teamed up with Siemens Healthineers to advance the use of Genetron S5 platform and lung cancer 8-gene IVD assay in hospitals market

SIEMENS Healthineers

New commercialization opportunity

Received CE Mark for 8-gene Lung Cancer Assay, the second regulatory milestone for this assay

CDx development collaboration

Partnered with HUTCHMED for Orpathys (savolitinib) in China

HUTCHMED

IVD: Approved Products and Registration Pipeline

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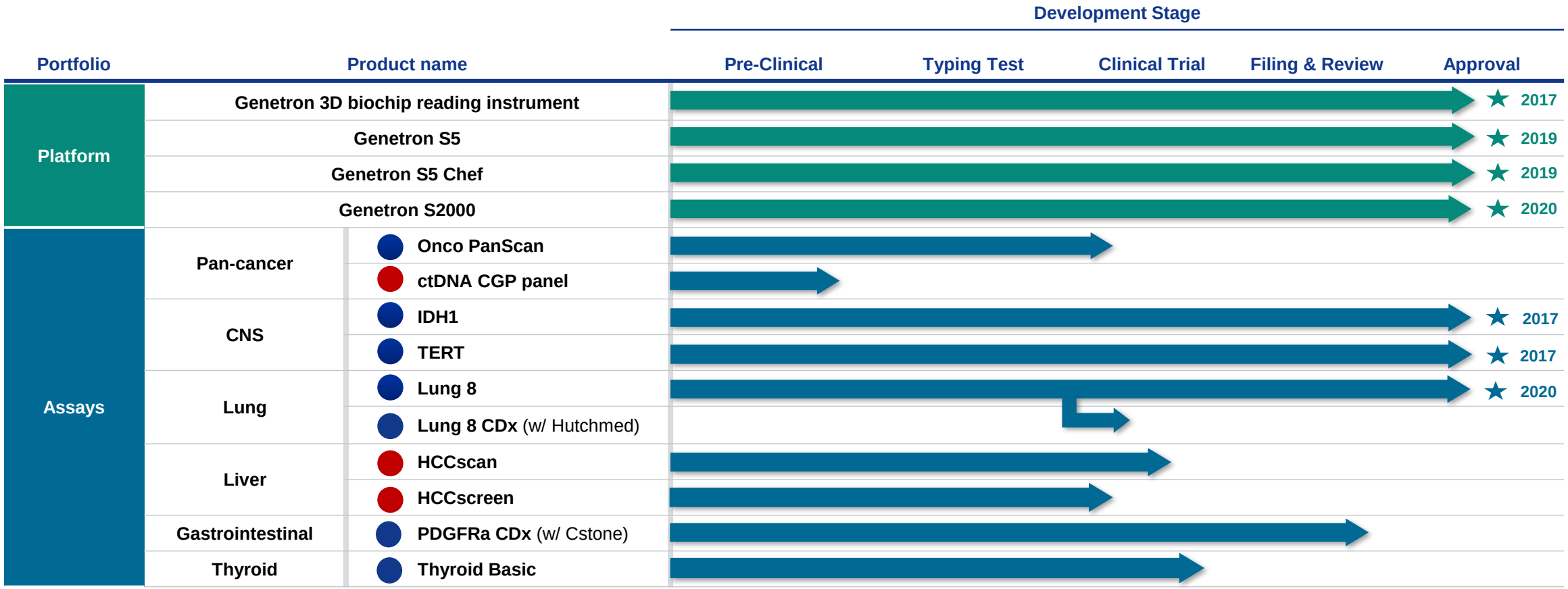


Tissue biopsy Liquid biopsy / Approved by NMPA

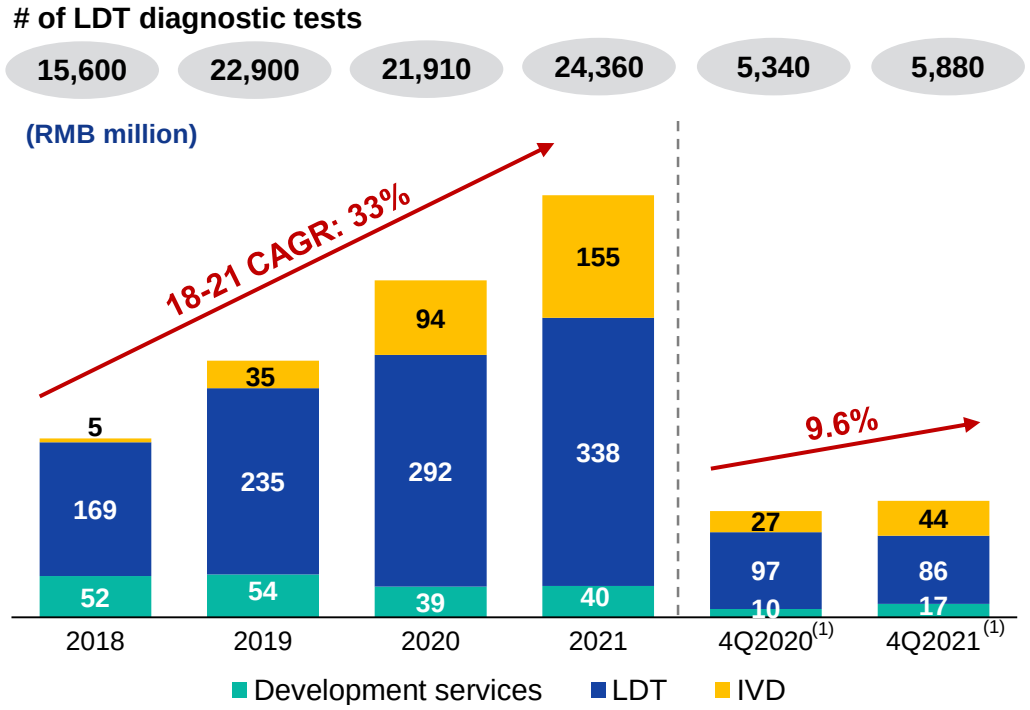
** Including software*

Table of Contents

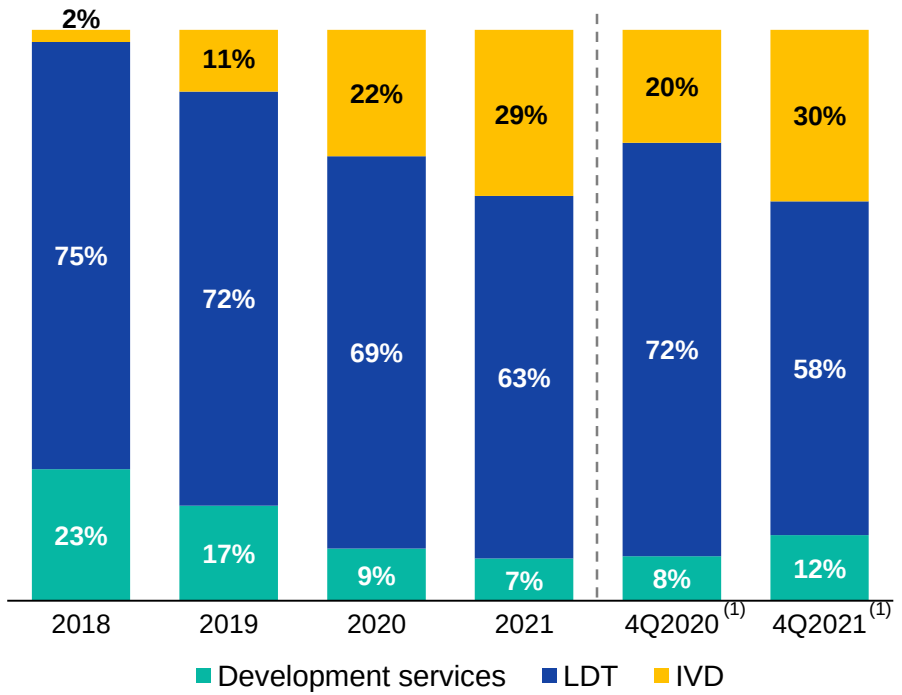
4Q 2021 Revenue

- Increased IVD revenue was driven by increasing sales of Genetron S5 instrument and 8-gene Lung Cancer Assay (Tissue)
- Development services: driven by the growth in revenue generated from biopharmaceutical services
- LDT revenue impacted based on general COVID-related disruptions, as well as early screening sales slowdown in the city of Wuxi. In addition, 4Q2021 presented a higher base for comparison

Revenue growth in 4Q2021



IVD revenue as a percentage of total revenue increased in 4Q2021



Note:
(1) Unaudited financial numbers

Winning the China Hospital Market

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"LDT + IVD" Business Model

Laboratory developed test (LDT)

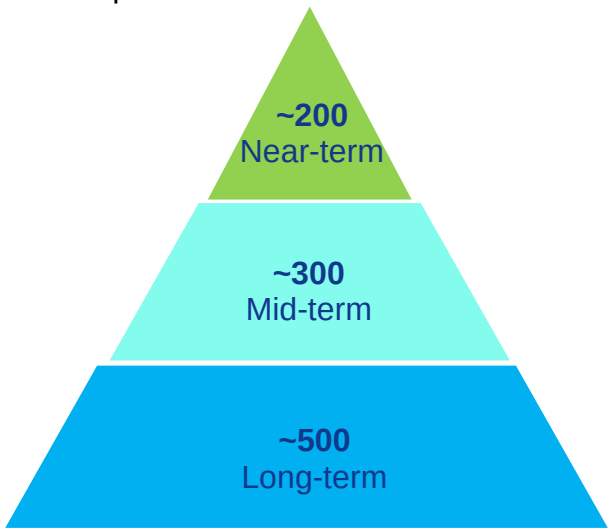
- Initially hospitals unable to run complex NGS testing in house
- Third party labs provide service to hospitals
- Fast adoption of latest technology

+

In vitro diagnostics (IVD)

- Generate incremental revenue for hospitals
- Currently the only pathway to public medical insurance
- Lengthy large size clinical trials required by NMPA

Targeting ~1000 Class 3 Grade A hospitals for cancer treatment in China



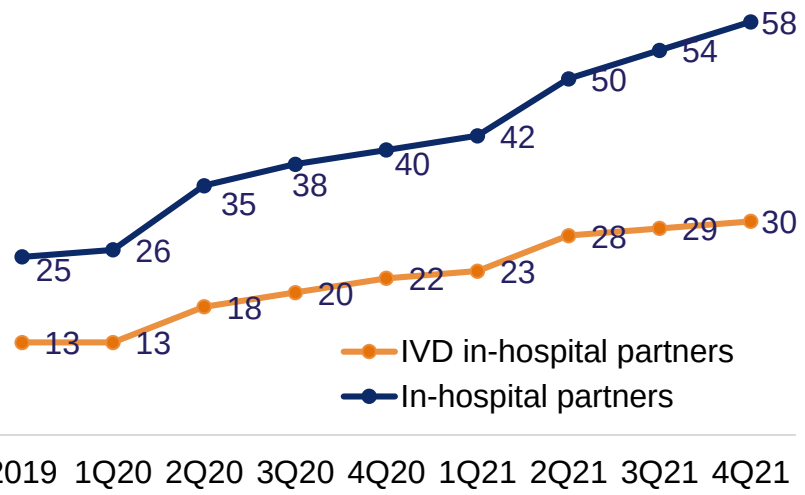
350+ internal direct sales and marketing rep

Teamed up with Siemens Healthineers to advance the use of Genetron S5 platform and lung cancer 8-gene IVD assay in hospitals

500+ hospitals ordered tests from us

58 in-hospital partners(1) including 30 IVD In-hospital partners(2)

Number of In-hospital Partners



(1) The number of total in-hospital partners include both sales of LDT services and IVD products.
(2) By December 31, 2021

4Q 2021 Gross Margin

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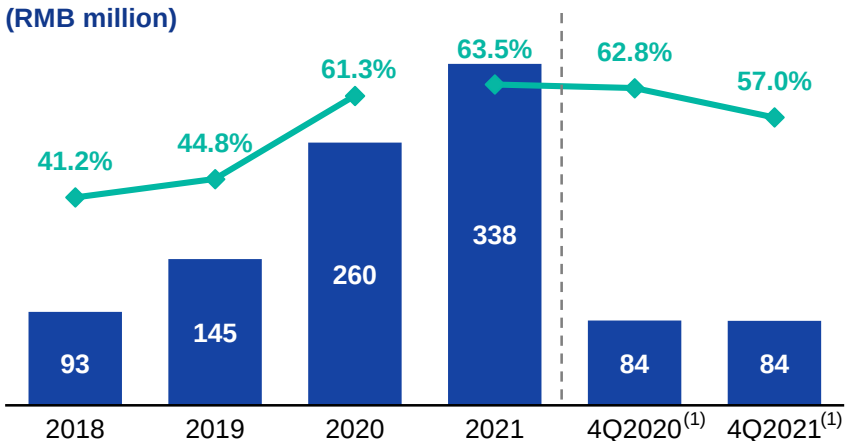
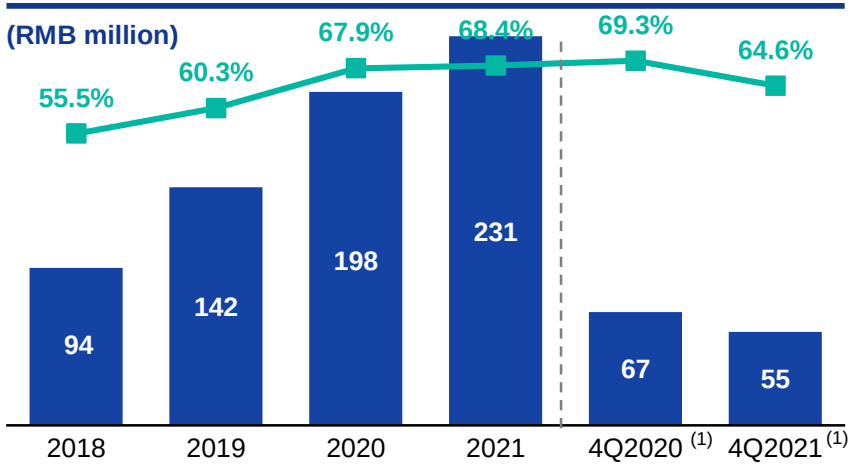
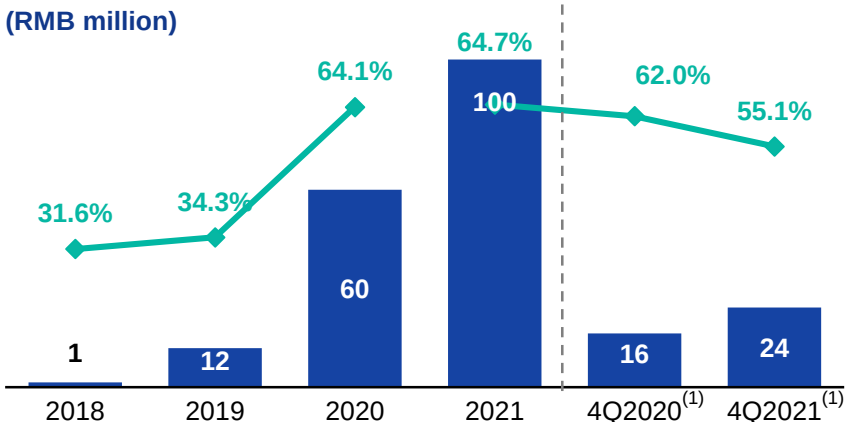
Gross profit and margin



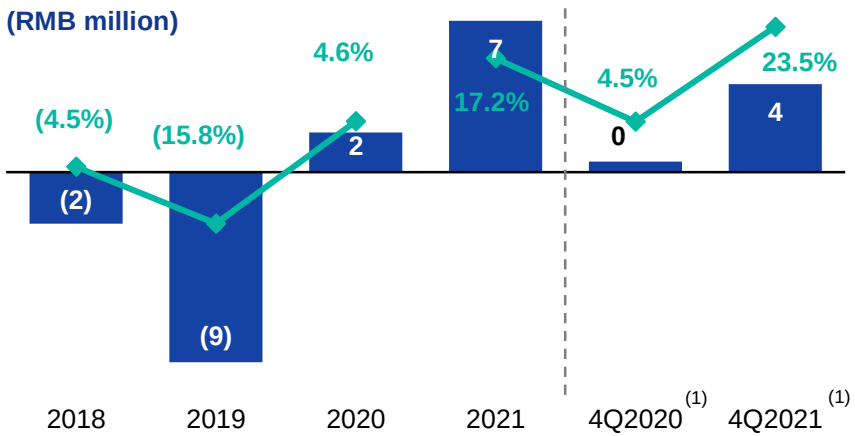
Gross profit and margin (LDT)



Gross profit and margin (IVD)



Gross profit and margin (Development services)



Note:
(1) Unaudited financial numbers

4Q 2021 Operating expenses

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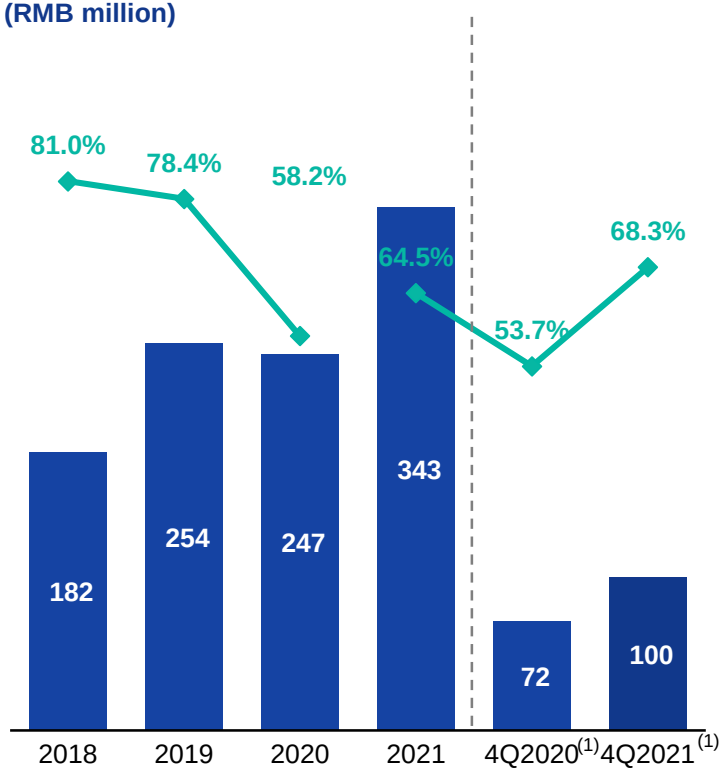
Selling expenses

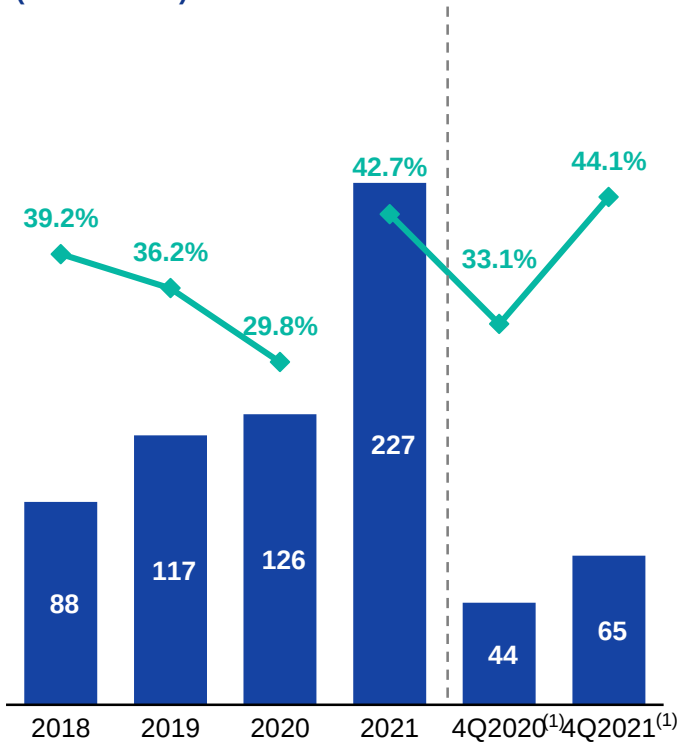
(RMB million)



Selling expenses Percentage of total revenue

Administrative expenses

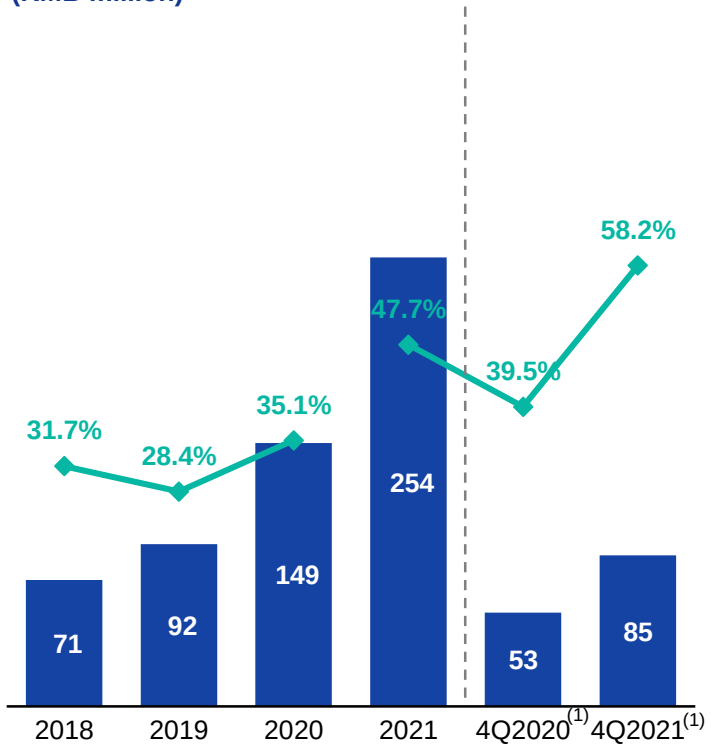
(RMB million)



Administrative expenses Percentage of total revenue

R&D expenses

(RMB million)



R&D expense Percentage of total revenue

Note:
(1) Unaudited financial numbers

4Q 2021 Financial Highlights

	Fourth Quarter		
(in RMB million)	**Q4 2021**	**Q4 2020**	**Y/Y Change**
Revenue	146.9	133.9	9.6%
Diagnosis & monitoring - LDT	85.9	96.9	(11.4%)
Diagnosis & monitoring - IVD	44.1	26.5	66.4%
Development services	16.9	10.5	60.9%
Gross margin	57.0%	62.8%	(580bps)
Selling expenses (% of rev)	68.3%	53.7%	1460bps
R&D expenses (% of rev)	58.2%	39.5%	1870bps
Admin expenses (% of rev)	44.1%	33.1%	1100bps
Operating loss	(183.8)	(88.9)	-
Net loss	(165.3)	(73.2)	-
Non-IFRS loss[1]	(153.1)	(62.5)	-

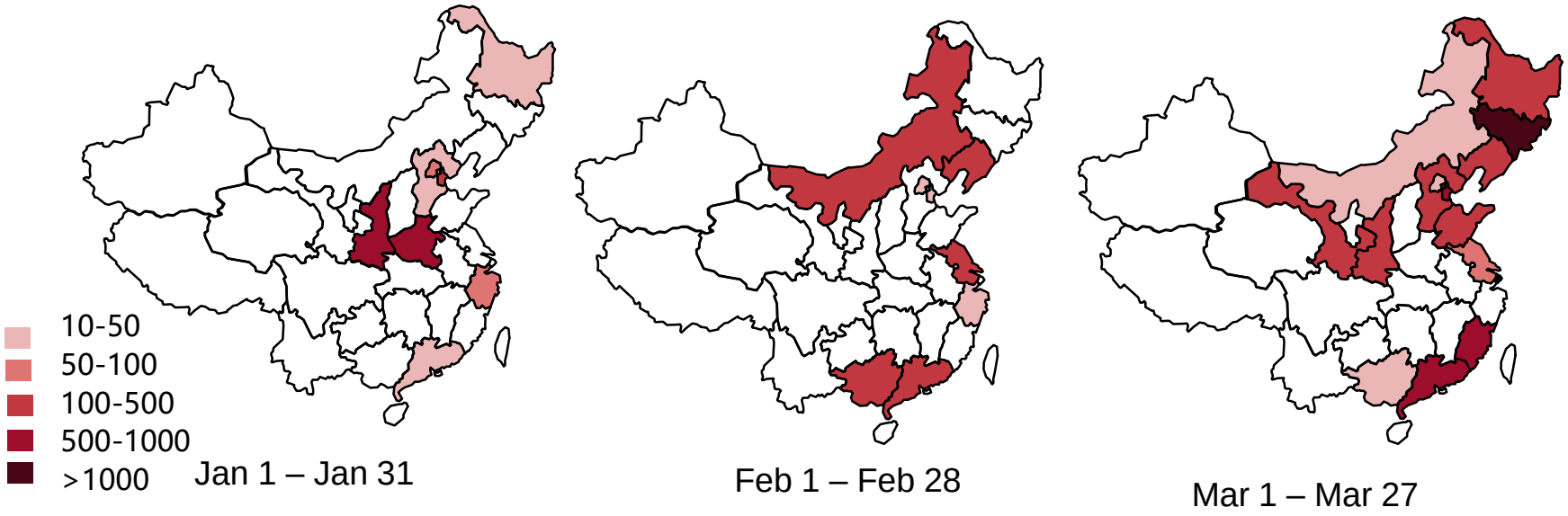
As of December 31, 2021, cash and cash equivalents, restricted cash and current financial assets at fair value through profit or loss were RMB790.5 million

1. Non-IFRS loss represents net results excluding share-based expenses, fair value change and other loss of financial instruments with preferred rights. Please refer to appendix for the reconciliation of non-IFRS loss for the year/period to net loss for the year/period

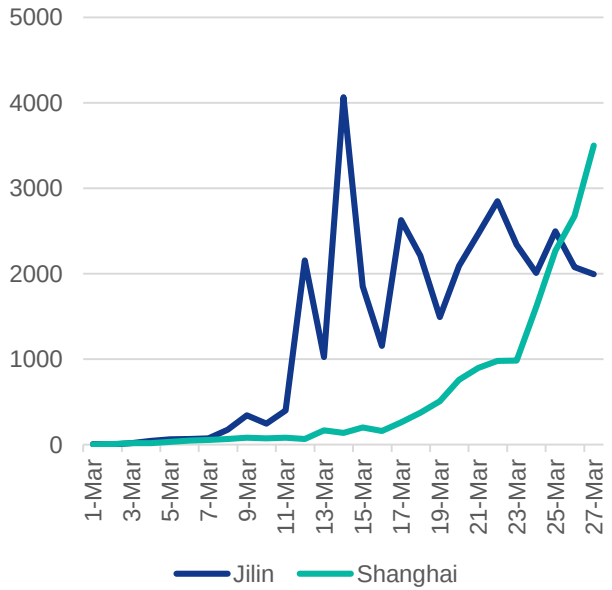
Covid-19 Situation in China

- In first quarter of 2022, Covid-19 situation in China worsened and caused multiple regions' lockdowns including Beijing, Shenzhen, parts of Shandong and Jilin provinces.
- In March, Shanghai started its most extensive, large-scale lockdown in 2 years
- First quarter of 2022 sales is estimated to be RMB106M, or 15.1% yoy
- We expect full year 2022 revenue to be around RMB 585-638 million, representing 10-20% growth over 2021

Accumulated Local Covid-19 Case in 1Q2022



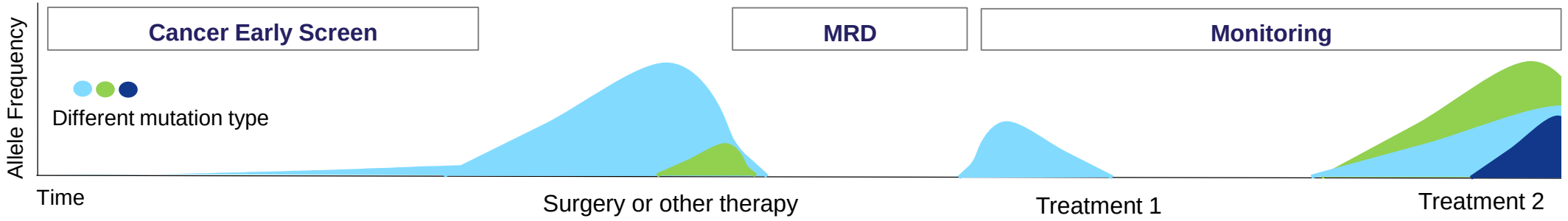
Number of confirmed and asymptomatic cases



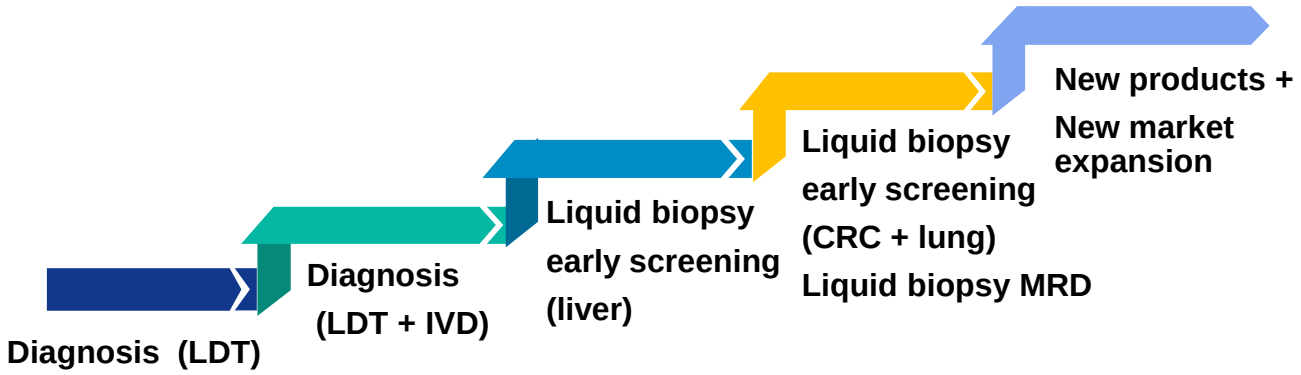
Source: National Health Commision

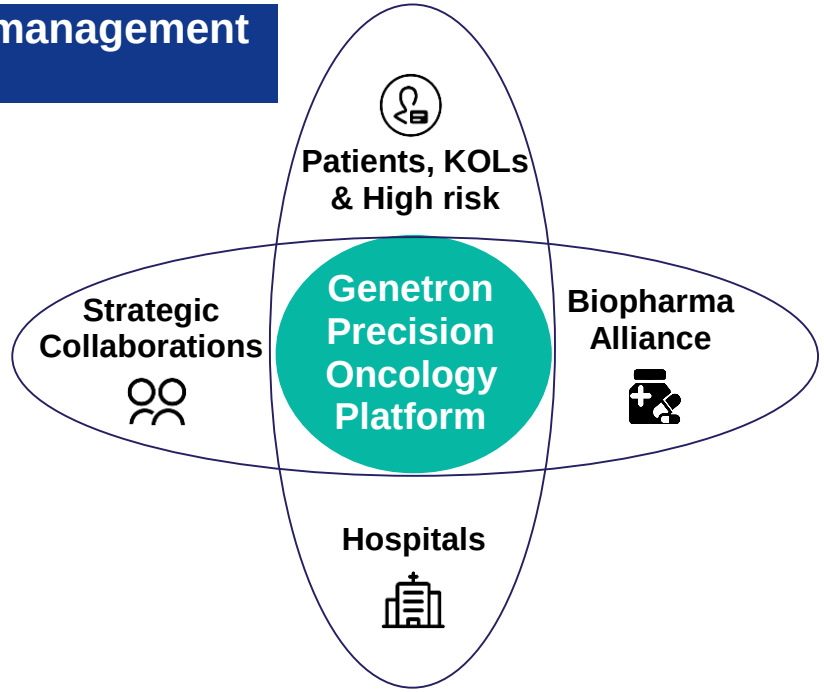
Table of Contents

Become A Prominent Player in Liquid Biopsy



Develop liquid biopsy-based solutions across the full-cycle cancer management
Continue to ramp up our commercialization efforts





Key Catalysts

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Focused on Transforming the Lifecycle Management of Cancer

Early Screening

2021:

- ✓ Data readout for large-scale HCC[2] prospective clinical trial
- ✓ HCCscan registrational trial initiated
- ✓ Data readout for CRC[3]

2022:

- ■ HCCscreen registrational trial initiation
- ■ CRC data publication

2023:

- ■ HCCscan and HCCscreen IVD approvals

MRD[1] Detection

2021:

- ✓ **Seq-MRD** pilot launch for hematological tumor MRD[2]

2022:

- ■ **Seq-MRD** full launch with Fosun
- ■ Complete product development for **solid tumor MRD assay with AZ** and commercial launch
- ■ Data publication for solid tumor MRD

Medication Guidance

2021:

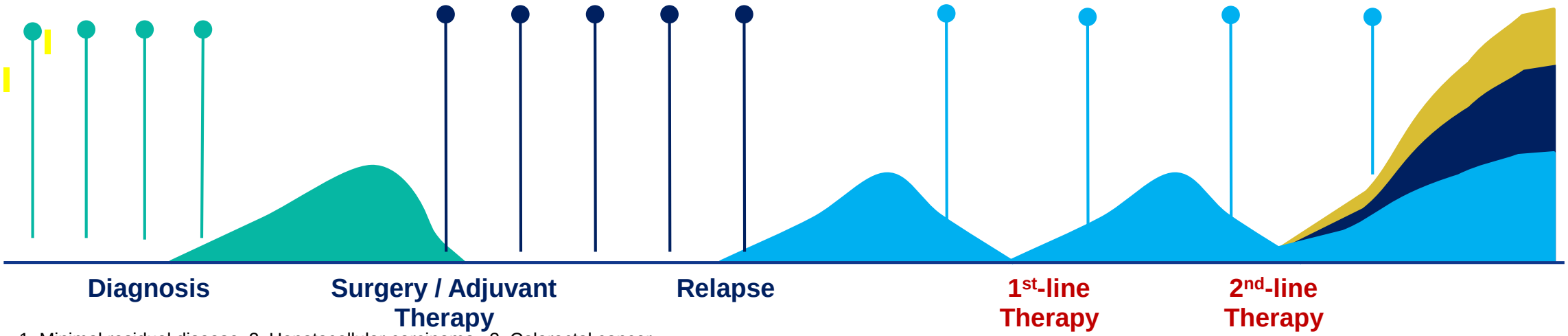
- ✓ OncoPan Scan received CE mark

2022:

- ■ Onco PanScan large-panel registrational trial initiation
- ■ Avapritinib CDx kit registration in priority review
- ■ Thyroid assay registrational trial completion
- ■ Next generation liquid biopsy panel launch

2023:

- ■ Thyroid assay IVD approval



1. Minimal residual disease 2. Hepatocellular carcinoma 3. Colorectal cancer

Table of Contents

Mutation Capsule – Our Innovative and Proprietary Technology

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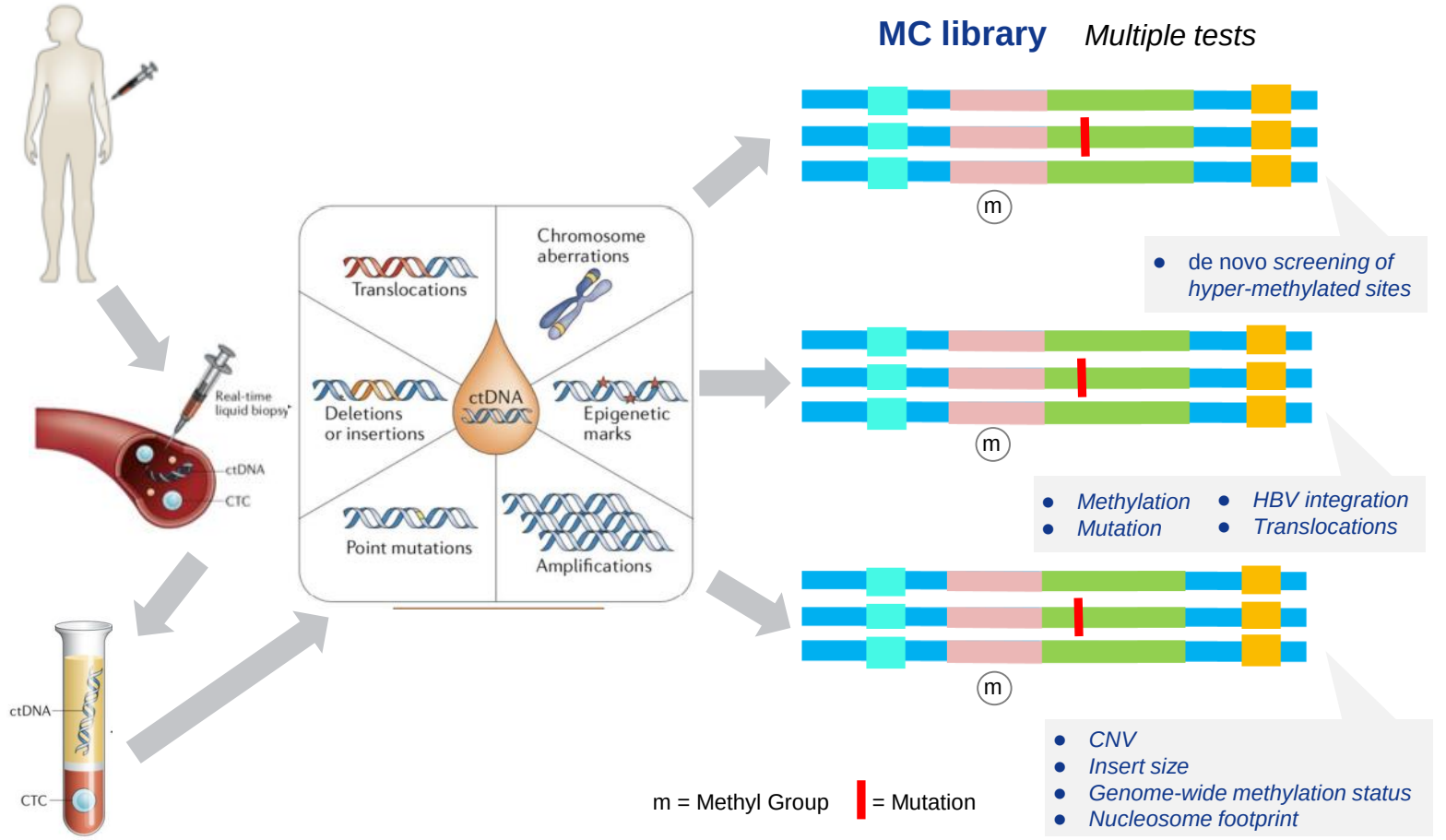

Features & Advantages

- In parallel profiling of **mutation and methylation markers**
- ***De novo* discovery of methylation sites**
- Support **multiple tests** from a single ctDNA sample
- **Strong performance** with significant time and cost savings

Source: Pantel et al., Nat Rev Clin Oncol, 2019

Proprietary One-Step Seq Method Presents Significant Advantage For Hospitals in China

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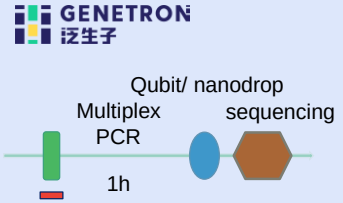
Genetron One-Step Seq vs Amplicon / Hybridization based methods

OneStep-seq



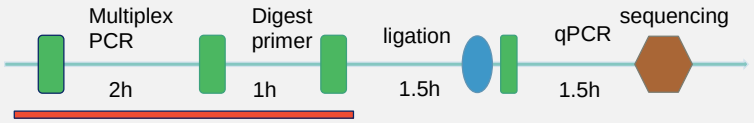
Reaction: 5-20 min
Purification: 20 min
With risk of contamination

Hands-on steps	Very simple (10 min)
Total time (from DNA to library)	1.5 hours
Contamination risk	Low
Laboratory section requirement	Low

VS

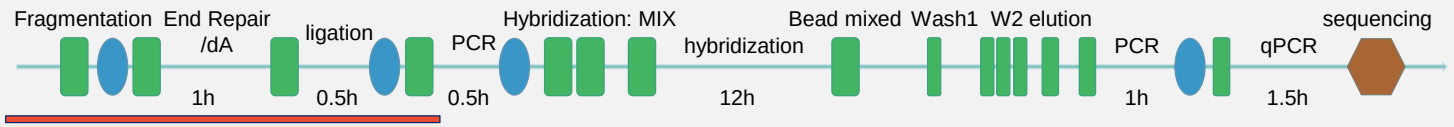
Commonly used sequencing methods by peers

Ampli-seq



Hands-on steps	Complicated (40 min)
Total time (from DNA to library)	8 hours
Contamination risk	High
Laboratory section requirement	Medium

Hybridization capture



Hands-on steps	Very complicated
Total time (from DNA to library)	24 hours
Contamination risk	High
Laboratory section requirement	High

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