

INDUSTRY OVERVIEW

The information and statistics set out in this section and other sections of this document were extracted from the Frost & Sullivan Report, which was commissioned by us, and from various official government publications and other publicly available publications. We engaged Frost & Sullivan to prepare the Frost & Sullivan Report, and independent industry report, in connection with [REDACTED]. The information from official government sources has not been independently verified by us, the Joint Sponsors, [REDACTED], any of their respective directors and advisors, or any other persons or parties involved in the [REDACTED], and no representation is given as to its accuracy.

ANALYSIS OF THE ONCOLOGY TESTING MARKET

Current Status and Major Challenges of Oncology Testing in China

Global and China Cancer Epidemiology

Cancer is a major public-health challenge in the 21st century and is among the top three causes of death in most countries worldwide. According to IARC’s GLOBOCAN 2022 estimates (released in 2024), there were approximately 20.0 million new cancer cases and approximately 9.7 million cancer deaths across 185 countries in 2022. On a lifetime basis, about 1 in 5 people will develop cancer; approximately 1 in 9 men and 1 in 12 women will die from cancer.

China bears one of the world’s heaviest cancer burdens, accounting for roughly one quarter of global new cancer cases and deaths.

Top 5 Cancers by incidence in China and their mortality rate

The top five cancers by incidence in China are lung cancer, colorectal cancer, thyroid cancer, liver cancer, and stomach cancer and the main reasons are related to unhealthy diet, obesity, alcohol consumption, and other lifestyle problems.

The top five cancers by age-standardized mortality rate in China are lung cancer, liver cancer, stomach cancer, colorectal cancer, and esophageal and the main reasons are related to a lack of early detection methods, fast progression, and poor prognosis.

Limitation of Traditional Cancer Detection Methods

Traditional detection methods, such as imaging, immunoassays and FIT/FOBT, often have limited sensitivity for early-stage cancer and precancerous lesions, while higher-accuracy methods such as endoscopy are invasive, resource-intensive and difficult to scale for broad-based screening.

Across major cancer types, diagnosis still relies on established clinical pathways combining imaging and endoscopic evaluation, where applicable, with histopathology as the diagnostic gold standard. Molecular testing is an emerging approach in oncology detection, offering a fast, convenient and potentially more accurate means of identifying cancer-related genetic or molecular changes, and is increasingly used as a screening or surveillance adjunct rather than a replacement for confirmatory diagnosis.

DNA Methylation as a Modality in Cancer Molecular Testing

DNA methylation is an epigenetic modification in which methyl groups are added to cytosine, mainly at CpG sites, without altering the underlying DNA sequence. By affecting chromatin structure and transcription-factor binding, DNA methylation regulates gene

INDUSTRY OVERVIEW

expression. In cancer, methylation patterns are often disrupted, characterized by genome-wide hypomethylation and locus-specific hypermethylation, which may contribute to tumor initiation and progression.

DNA methylation has several key advantages for cancer detection. It is highly stable compared with RNA and proteins and can be detected in cfDNA from blood and, in certain settings, urine, saliva or sputum. It also provides information-rich and tumor-specific signals, as methylation changes often occur across multiple CpG sites and differ by tumor type, supporting tissue-of-origin analysis. In addition, abnormal methylation can arise in precancerous and early-stage disease, making it suitable for early detection.

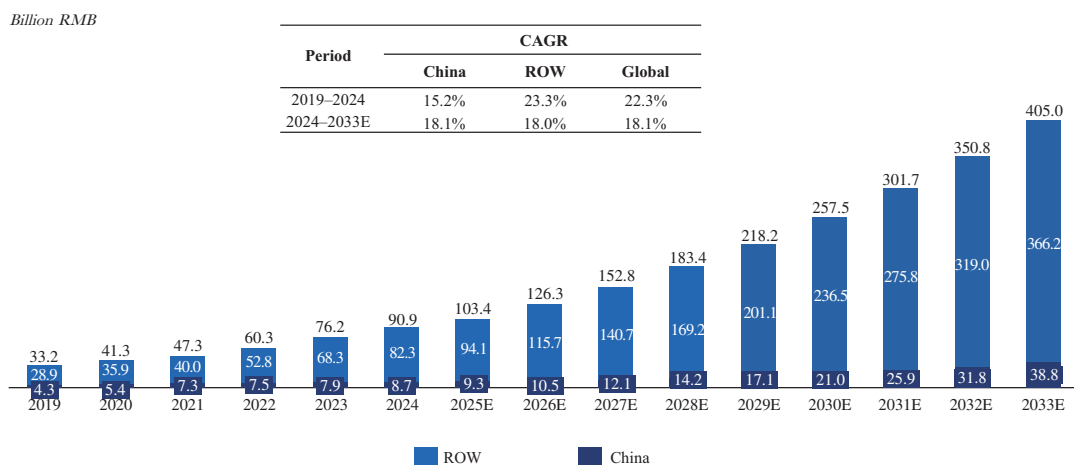
Owing to these advantages, DNA methylation-based assays have become a leading molecular approach in cancer testing globally. Across major markets, PCR-based methylation assays have generally achieved regulatory approval earlier and more consistently than NGS-based blood tests, reflecting the regulatory-readiness advantages of PCR methylation, including fixed targets, more mature analytics and lower assay complexity. As a result, PCR methylation is generally viewed as a more cost-effective and scalable first-line detection approach.

Molecular diagnostics prospects

Global and China Oncology Molecular Testing Market Size

The global oncology molecular testing market grew from RMB33.2 billion in 2019 to RMB90.9 billion in 2024, at a CAGR of 22.3%, and is projected to reach RMB405.0 billion by 2033 with a CAGR of 18.1%, driven by advances in PCR-based methylation assays and blood-based liquid-biopsy technologies. China’s market grew from RMB4.3 billion in 2019 to RMB8.7 billion in 2024 at a CAGR of 15.2% and is expected to reach RMB38.8 billion by 2033, with a CAGR of 18.1% from 2024 to 2033.

Global and China Oncology Molecular Testing Market Size, 2019–2033E



Source: Frost & Sullivan analysis

INDUSTRY OVERVIEW

Market Drivers

Growing Cancer Burden

The rising burden of cancer incidence and mortality in China is attributable to several factors, including the country’s aging population, the rapid pace of industrialization and urbanization, and the confluence of adverse factors.

Marketing Activity by Enterprises

Oncology early detection companies are expanding clinical access and market penetration by leveraging channel resources and collaborating with physicians to implement guideline-recommended detection in routine practice and, through real-world data and continuing medical education, to support updates to clinical consensus/guidelines over time.

Medical Insurance Coverage

China’s near-universal basic medical insurance system provides a broad reimbursement foundation for clinically indicated diagnostic testing. Payment reforms such as DRG/DIP further support adoption of diagnostics with clear clinical utility and cost-effectiveness.

Commercial Insurance Coverage

Huimin insurance and other inclusive commercial health insurance products can help reduce out-of-pocket costs for eligible tests, supporting earlier market adoption during initial commercialization. In some cities, such products also include preventive health benefits that may improve access to early detection services.

More Livelihood Programs

Government-led livelihood/public health programs can generate organized demand for early detection and screening and are generally viewed as relatively reliable execution channels because they are typically supported by public funding, designated providers and program-level management.

Future Trends

Application of DNA Methylation detection technology

Technological advancements have made this method more cost-effective and efficient, facilitating early detection of multiple cancers. Compared to single-cancer testing, multi-cancer early detection (MCED) is a more cost- and time-effective solution for patients.

AI Analysis

Multi-omics applications require data analysis, with noise reduction to improve signal-to-noise ratio being a key challenge. As industrial transformation advances, integrating artificial intelligence with biotechnology is increasingly important. Multimodal AI models that combine spatiotemporal omics data, dynamic imaging, and clinical records are essential to build intelligent analysis systems covering the entire tumor lifecycle. Additionally, accumulating real-world oncology data is critical for developing robust data platforms.

INDUSTRY OVERVIEW

LIVER CANCER EARLY DETECTION AND RECURRENCE MONITORING MARKET

Overview of Liver Cancer

Liver cancer mainly includes primary and metastatic liver cancer, with primary liver cancer, predominantly hepatocellular carcinoma (HCC), being more common in East Asia. In China, liver cancer was the fourth most common cancer and the second leading cause of cancer-related death in 2023.

Liver cancer detection methods mainly include imaging, serum biomarkers and liquid biopsy. Imaging methods include ultrasound and MRI; serum biomarker methods mainly include AFP and DCP testing; and relatively mature liquid biopsy approaches include cfDNA whole-genome sequencing and cfDNA methylation testing.

There is currently no single universally accepted standalone screening test for liver cancer. Surveillance in high-risk populations commonly relies on ultrasound, with or without AFP testing. Ultrasound combined with AFP remains the mainstream detection approach.

Incidence of Liver Cancer in China

Liver cancer is a common malignant tumor and a major health concern in China. Considering of the huge patient group with HBV and HCV as well as the unavoidable access to Aflatoxin (AFT), the number of liver cancer incidence would rise year by year.

Incidence of liver cancer increased from 343.4 thousand in 2019 to 382.8 thousand in 2024 at a CAGR of 2.2% and is projected to reach 443.8 thousand by 2033 at a CAGR of 1.7%.

Recommended Population for Early Detection of Liver Cancer in China

Consistent with the China Guideline for Liver Cancer Detection (《中國人群肝癌篩查指南》), we define the eligible detection cohort as men aged >35–64 and women aged >45–64, especially who are at high risk of HCC – particularly HBsAg-positive individuals and those with chronic HBV/HCV infection, liver cirrhosis, family history of HCC, MASLD/NAFLD or aflatoxin exposure – for whom abdominal ultrasound plus serum AFP every six months is recommended.

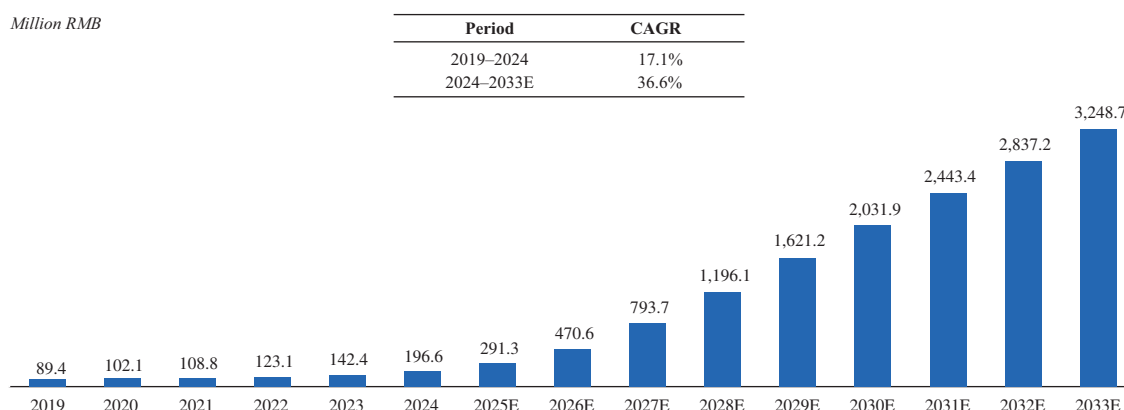
In China, the number of people recommended for regular liver cancer detection rose from 672.3 million in 2019 to 727.4 million in 2024 at a CAGR of 1.6% and is expected to reach 810.2 million by 2033 at a CAGR of 1.2%.

China Liver Cancer Early Detection Market Size

China liver cancer early detection market size is expected to grow from RMB89.4 million in 2019 to RMB196.6 million in 2024, with a CAGR of 17.1% for the period 2019-2024. The forecasted growth rate change to a CAGR of 36.6% from 2024 to 2033, with the market size projected to reach RMB3,248.7 million by 2033.

INDUSTRY OVERVIEW

China Liver Cancer Early Detection Market Size, 2019–2033E



Note: For years prior to 2023, the market size includes IVD products and laboratory testing services used for liver cancer detection in China and excludes imaging and interventional procedures.

Source: Frost & Sullivan analysis

Market Drivers of Liver Cancer Early Detection Market

Latency of liver cancer

Liver cancer is often asymptomatic at an early stage, and many patients are diagnosed only after the disease has progressed. This underscores the importance of regular early detection, particularly given the significantly better survival outcomes associated with early-stage diagnosis.

Large base of high-risk population

High-risk groups for liver cancer include individuals with chronic hepatitis B or C, liver cirrhosis, long-term alcohol use or a family history of liver cancer. China’s large high-risk population, particularly chronic hepatitis B carriers, provides a substantial demand base for regular liver cancer detection.

Competitive Landscape

NMPA has approved methylation-based digital PCR and qPCR assays for liver cancer early detection, with sensitivity up to 95% and specificity up to 96%, marking key progress in liquid biopsy commercialization. In general, qPCR is the workhorse platform for high-volume routine testing: it is fast, widely automated, and typically lower cost per test, with a broad dynamic range and mature multiplexing – making it well suited to predefined targets and scalable screening or follow-up programs. Digital PCR (dPCR/ddPCR) trades throughput and cost for measurement strength: by partitioning reactions it enables absolute quantification and typically delivers higher precision at very low target levels and better robustness to matrix effects, which can be valuable for low-abundance detection and longitudinal monitoring (e.g., rare variants or MRD-style applications). In practice, the choice is usually a scalability/cost-efficiency decision (qPCR) versus low-level quantification and precision (dPCR).

INDUSTRY OVERVIEW

Approval Year	Company	Brand name	Generic name	Target	Platform	Sensitivity	Specificity
2023	LAMH / Youze Bio (萊盟健康/優澤生物)	甘倍康	BMPRI1A/PLAC8 Gene Methylation Assay Kit (Digital PCR Method)	BMPRI1A/PLAC8 methylation	Digital PCR	95.42%	96.02%
2025	Ammunition Life Technology (艾米森)	IHepcomf (艾馨甘)	GNB4 and Riplet Gene Methylation Combined Detection Kit (qPCR)	GNB4/Riplet methylation	PCR	92.33%	93.35%
2025	Oriomics (翱銳基因)	利為平	TSPYL5/RASSF1A/DAB2IP/OTX1/PTPN18/HIST1H3G Gene Methylation Assay Kit (qPCR)	TSPYL5/RASSF1A/DAB2IP/OTX1/PTPN18/HIST1H3G methylation	qPCR	93.08%	93.70%
2026	Biochain (博爾誠)	思博甘	RNF135/PAX5/CHFR Gene Methylation Assay Kit (qPCR)	RNF135/PAX5/CHFR methylation	qPCR	94.40%	94.30%

Source: NMPA, Frost & Sullivan analysis

China Liver Cancer Recurrence Rate by Stage

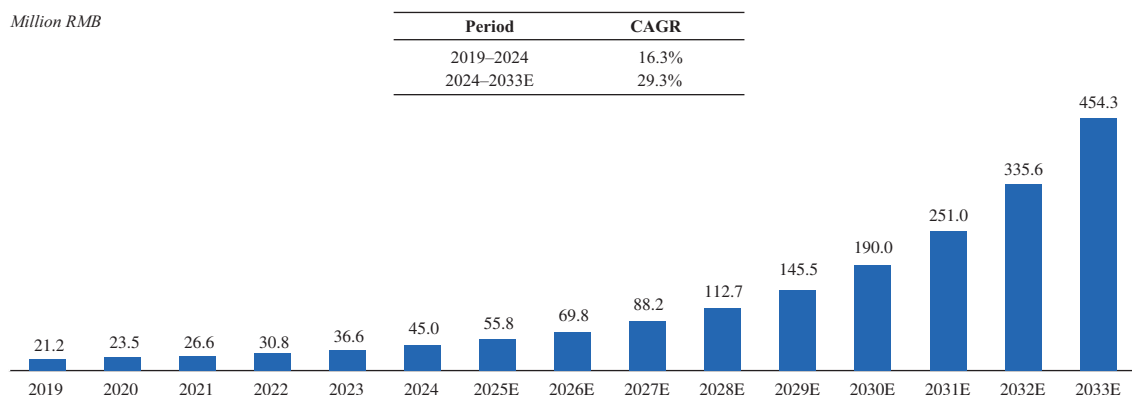
In China, liver cancer recurrence rates increase markedly with disease stage. Stage Ia patients show a recurrence rate of 39.8%, which rises to over 70.3% in Stage II and exceeds 85.2% in Stage IIb. Median survival time declines sharply from 35.5 months in Stage Ia to just 11.5 months in Stage IIb. Overall, the recurrence rate across all stages is 55.1%, with a median survival of 23.4 months, underscoring the need for earlier detection and more effective post-treatment monitoring.

China Liver Cancer Recurrence Prediction and Monitoring Market Size

China’s liver cancer recurrence prediction and monitoring market expanded from RMB21.2 million in 2019 to RMB45.0 million in 2024 at a CAGR of 16.3%. The market is projected to reach RMB454.3 million by 2033, implying a 2024–2033E CAGR of 29.3%. Growth is driven by (i) increasing recognition of the value of earlier recurrence detection to inform timely clinical decisions; and (ii) greater adoption of molecular-based monitoring (including MRD-related approaches) as laboratory capacity, workflow standardization and clinical evidence continue to improve. As a portion of monitoring in practice is delivered as service-based (including LDT) offerings, market growth also reflects expanding service availability and utilisation, rather than being limited to approved IVD products alone.

INDUSTRY OVERVIEW

China Liver Cancer Recurrence Prediction and Monitoring Market Size, 2019–2033E



Source: NMPA, company website, Frost & Sullivan analysis

Competitive Landscape of Liver Cancer Recurrence Prediction and Monitoring Products in China

Currently, NGS and PCR are the two main platforms for mutation- or methylation-based liver cancer recurrence monitoring, although no such products have been approved for commercialization. Compared with PCR-based MRD (~1–3 days, hundreds to low thousands of RMB), NGS-based MRD usually has longer turnaround (~7–14 days) and higher per-test charges (several thousand RMB or above) due to broader panels, deeper sequencing and bioinformatics analysis.

This also explains why most liver cancer recurrence prediction and monitoring candidates in China (other than IHepcomf) adopt NGS: it is better suited to multi-marker tracking and is more easily integrated into established sequencing-based LDT/service workflows, whereas PCR is more targeted and is typically used for high-frequency follow-up after marker validation.

Sample Type	Company	Candidate	Platform
Blood	Ammunition Life Technology (艾米森)	IHepcomf (艾馨甘)	PCR
	SmartQuerier Gene (慧算基因)	SMARTOnco MRD Mutation Assay	NGS
	Geneseeq (世和基因)	SHIELDING™ ULTRA (術寧ULTRA)	NGS
	HaploX (海普洛斯)	海微淨	NGS
Tissue & Blood	ChosenMed (求臻醫學)	ChosenPaceMRD2.0	NGS

Source: Company websites, Frost & Sullivan analysis

INDUSTRY OVERVIEW

UROTHELIAL CARCINOMA (UC) EARLY DETECTION AND RECURRENCE MONITORING MARKET

Overview of UC

Urothelial carcinoma originates in the urothelial cells that line not only the bladder but also the urethra, ureters, and renal pelvis. These cells are specialized to expand and contract in response to urine storage and release.

While bladder cancer is not caused by a single factor, exposure to carcinogen-containing chemicals – such as those found in tobacco smoke or industrial substances – is a major risk factor.

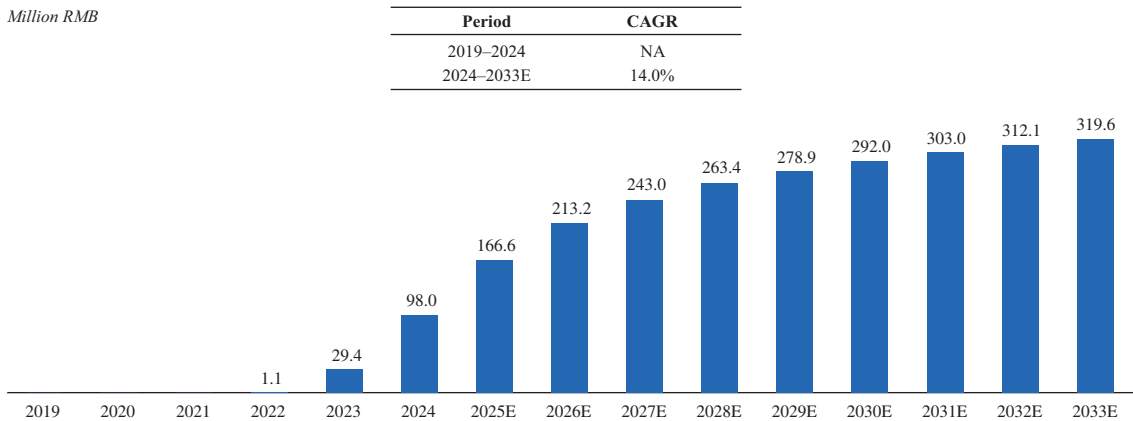
Incidence of Bladder Cancer in China

Bladder cancer is one of the most common urological malignancies in China, with incidence steadily increasing. New cases rose from 84.8 thousand in 2019 to 98.8 thousand in 2024, representing a CAGR of 3.1%. The number is projected to reach 123.4 thousand by 2033, with a CAGR of 2.5% from 2024 to 2033.

China Bladder Cancer Early Detection Market Size

China’s bladder cancer early detection market has expanded rapidly since 2022, reaching RMB98.0 million in 2024. The market is projected to grow at a CAGR of 14.0% from 2024 to 2033, reaching RMB319.6 million by 2033.

China Bladder Cancer Early Detection Market Size, 2019–2033E



Note: Only include IVD products and services; With the first product approved in 2022, 2019–2021 market size is negligible.

Source: Frost & Sullivan analysis

Since 2022, multiple qPCR assays for bladder cancer early detection have been approved by NMPA, demonstrating 85.9–92.5% sensitivity and 90–95.8% specificity, validating the clinical utility of non-invasive molecular testing.

INDUSTRY OVERVIEW

Approval Year	Company	Brand name	Generic name	Target	Platform	Sensitivity	Specificity
2022	Targene Biotech (達健生物)	泌安健	Twist1 Gene Methylation Test Kit (Fluorescent PCR Method)	Twist gene methylation	qPCR	~ 90%	~ 90%
2024	AnchorDx Medical (基準醫療)	泌益檢	ONECUT2/VIM Gene Methylation Test Kit (Fluorescent PCR Method)	ONECUT2/ VIM gene methylation	qPCR	89.74%	92.46%
2024	AcornMed (橡鑫生物)	金橡·優愛	FGFR3/TERT Gene Mutation and ONECUT2/VIM Gene Methylation Combined PCR Kit (PCR Fluorescent Probe Method)	FGFR3/TERT gene mutations + ONECUT2/VIM gene methylation	qPCR	92.50%	95.80%
2025	MicroDiag Biomedicine (為真生物)	泌優檢	Twist1/Vimentin Gene Methylation Test Kit (Fluorescent PCR Method)	Twist1/Vimentin gene methylation	qPCR	85.93%	92.11%
2025	Life Technology	艾光樂	Twist1/Vimentin Gene Methylation Test Kit (Fluorescent PCR Method)	Twist1/Vimentin gene methylation	qPCR	92.94%	92.83%

Source: Frost & Sullivan analysis

Market Drivers of Bladder Cancer Early Detection Market

Limitations of Current Detection Methods Create Demand for Innovation

Due to the lack of standard detection, most cases are identified only after symptoms like painless hematuria, often mistaken for minor issues. Cystoscopy is invasive and poorly tolerated, while urine cytology has low sensitivity for early or low-grade tumors. This highlights the need for accurate, non-invasive molecular tests—such as urine-based methylation or ctDNA assays – to enable earlier and more accessible diagnosis.

High-Risk Population with Occupational and Lifestyle Exposure

Bladder cancer risk is high in China due to widespread smoking and occupational exposure to carcinogens like aromatic amines. The disease is aggressive, with rapid progression and high recurrence. Once metastasized, average survival drops to 18 months. Regular monitoring every 3–6 months is essential for high-risk and post-surgical patients. This large at-risk population presents strong potential for early detection solutions.

Bladder Cancer Recurrence Prediction and Monitoring Market Overview

China and Europe both represent sizable markets for bladder cancer recurrence prediction and monitoring, supported by large prevalent patient pools and intensive long-term surveillance needs.

INDUSTRY OVERVIEW

In China, bladder cancer is one of the most common urological malignancies, with 98.8 thousand new cases in 2024, while a GBD-based study estimated 570,636 prevalent bladder cancer cases in 2021, indicating a substantial surveillance pool. This is particularly relevant because non-muscle-invasive bladder cancer (NMIBC) accounts for approximately 75%–80% of newly diagnosed bladder cancer cases and is characterized by frequent recurrence, with reported one-year recurrence rates of 15%–61% and five-year recurrence rates of 31%–78%. Chinese clinical practice recommendations also require intensive and repeated follow-up, including regular cystoscopy and urine cytology at short intervals in the first two years and continued long-term surveillance thereafter.

Similarly, in Europe, the EUROCARE-6 study reported approximately 1.03 million male prevalent cases of urinary bladder cancer in 2020, while EU-funded UROMOL materials note that bladder cancer patients often live with the disease for many years (median approximately 7 years) and that around 460,000 cystoscopies are performed annually in the EU. This is consistent with the EAU 2025 guideline, under which low-risk patients are followed at 3 months, 12 months and then annually, while high-/very-high-risk patients are followed every 3 months for 2 years, every 6 months until 5 years, and annually thereafter lifelong. Taken together, these factors support a meaningful and recurring need for urine-based adjunctive tests in both China and Europe.

COLORECTAL CANCER (CRC) EARLY DETECTION MARKET

Overview of Colorectal Cancer

Colorectal cancer (CRC) refers to any cancer that affects the colon and the rectum. The colon is part of the large intestine, while the rectum is the passageway connecting the colon to the anus. Most CRCs initially develop as polyps – abnormal growths within the colon or rectum – which may become cancerous if not removed. In China, the incidence and mortality rates of CRC ranked third and fifth, respectively, among all malignant tumors in 2019.

Global and China Incidence of Colorectal Cancer

Colorectal cancer (CRC) is among the most common cancers globally. New cases grew from 1.85 million in 2019 to 2.01 million in 2024 (CAGR 1.6%) and are expected to reach 2.47 million by 2033.

In China, CRC incidence rose from 477 thousand in 2019 to 542 thousand in 2024 (CAGR 2.6%) and is projected to reach 642 thousand by 2033 (CAGR 1.9%).

Recommended Population for Early Detection of CRC in China

Given the dietary patterns and lower average onset age of colorectal cancer in China, the China Anti-Cancer Association recommends regular detection for individuals aged 40–74.

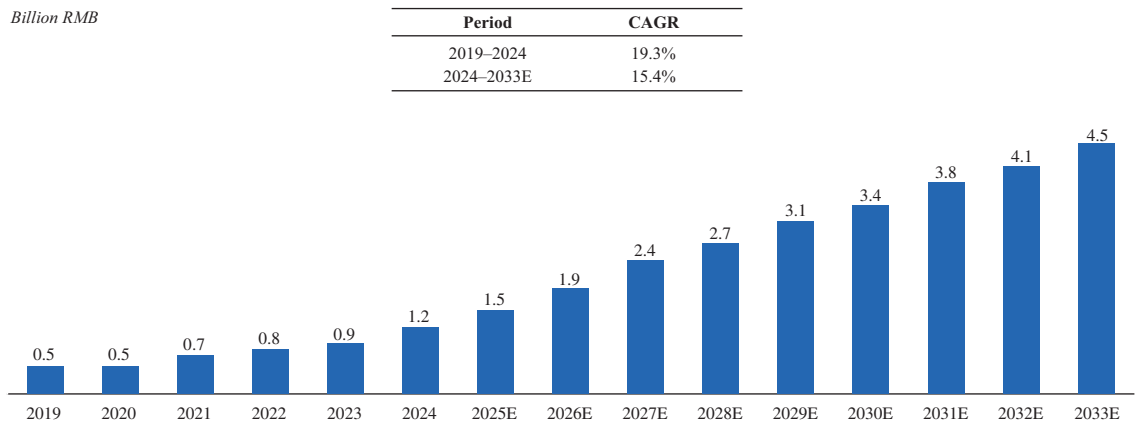
The target population for early detection grew from 608.1 million in 2019 to 644.7 million in 2024 (CAGR 1.2%), and is expected to reach 698.5 million by 2033 (CAGR 0.9%).

China CRC Early Detection Market Size

China’s market grew from RMB0.5 billion to RMB1.2 billion from 2019 to 2024 (CAGR 19.3%) and is expected to reach RMB4.5 billion by 2033 (CAGR 15.4%).

INDUSTRY OVERVIEW

China CRC Early Detection Market Size, 2019–2033E



Note: Only include IVD products and services

Source: Frost & Sullivan analysis

Approved CRC Early Detection Products in China

NMPA has approved multiple methylation-based PCR assays for CRC early detection using blood sample, with sensitivity up to 91% and specificity up to 96%.

Approval Year	Company	Brand name	Generic name	Target	Platform	Sensitivity	Specificity
2015	BioChain (博爾誠)	思博定	Septin9 Gene Methylation Detection Kit (qPCR)	Septin9 methylation	PCR	76.63% (CRC)	95.93%
2018	MicroDiag (為真生物)	常久安	Septin9 Gene Methylation Detection Kit (qPCR)	Septin9 methylation	PCR	76.45% (CRC)	90.32%
2019	Tellgen (透景生命)	Colon S9	Septin9 Gene Methylation Detection Kit (qPCR)	Septin9 methylation	PCR	~70% (CRC)	>94%
2022	AKL health (艾克倫)	艾長衛	Septin9/SDC2/BCAT1 Gene Methylation Detection Kit (qPCR)	Septin9/SDC2/BCAT1 methylation	PCR	84.75% (CRC)	94.22%
2023	USK bio (優聖康)	長優康	Septin9 Gene Methylation Detection Kit (qPCR)	Septin9 methylation	PCR	77.34% (CRC) 54.29% (HGIN)	95.95%
2024	Singlera (鵬遠生物)	ColonAiQ (常艾克)	Septin9/BCAT1/IKZF1/BCAN/VAV3 Gene Methylation Detection Kit (qPCR)	Septin9/Septin9-2/BCAT1/IKZF1/BCAN/VAV3 methylation	PCR	87.3% (CRC) 41.2% (Advanced adenoma)	91.1%

INDUSTRY OVERVIEW

Approval Year	Company	Brand name	Generic name	Target	Platform	Sensitivity	Specificity
2024	Ammunition Life Technology (艾米森)	IColohunter (艾長健)	NTMT1/MAP3K14-AS1 Gene Methylation Detection Kit (qPCR)	NTMT1/ MAP3K14-AS1 methylation	PCR	91.42% (CRC) 44.16% (Advanced adenoma) 73.53% (HGIN)	91.74%

Note: Source: NMPA, company website, Frost & Sullivan analysis

NMPA has approved multiple methylation-based PCR assays for CRC early detection using stool sample, with sensitivity up to 96% and specificity up to 98%.

Approval Year	Company	Brand name	Generic name	Target	Platform	Sensitivity	Specificity
2018	Creative Bio (康立明)	長安心	Human SDC2 Gene Methylation Detection Kit (qPCR)	SDC2 methylation	PCR	84.22% (CRC)	97.85%
2018	Gene Bio Health (晉百慧生物)	REColon (睿長太)	miR-92a Detection Kit (Reverse Transcription-PCR)	miR-92a	PCR	71.76% (CRC)	90.23%
2020	New Horizon Bio (諾輝健康)	ColoClear (腸衛清)	KRAS gene mutation and BMP3/NDRG4 gene methylation and fecal occult blood test kit (qPCR and colloidal gold method)	KRAS mutation and BMP3/NDRG4 methylation	PCR	95.54% (CRC)	87.11%
2021	AmoyDx (艾德生物)	暢青松	Human SDC2 Gene Methylation Detection Kit (qPCR)	SDC2 methylation	PCR	86.32% (CRC) 53.33% (Advanced adenoma)	92.99%
2022	Real Bio (銳翌生物)	ColoWell (常易舒)	Human SFRP2/SDC2 Gene Methylation Detection Kit (qPCR)	SFRP2/SDC2 methylation	PCR	92.20% (CRC)	91.90%
2022	Ammunition Life Technology (艾米森)	IColocomf (艾長康)	SDC2/TFPI2 Gene Methylation Detection Kit (qPCR)	SDC2/TFPI2 methylation	PCR	95.3% (CRC) 63.4% (Advanced adenoma)	90.30%
2023	Targene (達健生物)	暢達健	Human SDC2/NPY/FGF5/PDX1 Gene Methylation Detection Kit (qPCR)	SDC2/NPY/ FGF5/PDX1 methylation	PCR	91.17% (CRC) 67.44% (precancerous lesion) 75.81% (Advanced adenoma) 84.85% (HGIN)	91%
2023	BGI (華大基因)	華常康	Human SDC2/ADHFE1/PPP2R5C Gene Methylation Detection Kit (qPCR)	SDC2/ADHFE1/ PPP2R5C methylation	PCR	87.74% (CRC)	92.37%

INDUSTRY OVERVIEW

Approval Year	Company	Brand name	Generic name	Target	Platform	Sensitivity	Specificity
2024	Genetalks Medical (人和未來)	/	SDC2/NDRG4 Gene Methylation Detection Kit (qPCR)	SDC2/NDRG4 methylation	PCR	84% (CRC) 38% (Advanced adenoma)	>90%
2025	CW bio (康為世紀)	/	Human Septin9, SDC2, and NDRG4 Gene Methylation Detection Kit (qPCR)	Septin9/SDC2/NDRG4 methylation	PCR	95.34% (CRC) 61.65% (Advanced adenoma)	N/A
2025	YZY Med	/	Human SDC2 Gene Methylation Detection Kit (qPCR)	SDC2 methylation	PCR	N/A	N/A
2025	Biomedlab (伯豪診斷)	/	Human SDC2 and LIFR Gene Methylation Detection Kit (Fluorescence PCR)	SDC2/LIFR	PCR	89.00%	95.00%
2026	Aperbio (艾普拜生物)	/	Human SDC2/NDRG4/WIF1/TFPI2 Gene Methylation Detection Kit (Fluorescence PCR)	SDC2/NDRG4/WIF1/TFPI2	PCR	92.79%	94.21%
2026	HealzoneBio (慧眾同康)	常慧寧	Human SDC2 Gene Methylation Detection Kit (Fluorescence PCR)	SDC2	PCR	N/A	N/A

Source: NMPA, company website, Frost & Sullivan analysis

ESOPHAGEAL CANCER EARLY DETECTION MARKET

Overview of Esophageal Cancer

Esophageal cancer comprises two main histologies: esophageal squamous-cell carcinoma (ESCC) and esophageal adenocarcinoma (EAC). ESCC predominates in China and many developing countries, whereas EAC is more common in North America, Western Europe, and other developed regions.

In China, the incidence and mortality rates are 15.87/100,000 and 13.28/100,000, respectively, with a general downward trend. However, prognosis remains poor, and the 5-year survival rate, though improved in recent years, is still low.

Recommended Population for Early Detection of Esophageal Cancer in China

According to the National Health Commission (NHC), individuals aged 45–74 with no history of upper gastrointestinal cancer and no contraindications to endoscopy are recommended for early detection of esophageal cancer.

The recommended population for early detection in China grew from 513.6 million in 2019 to 545.1 million in 2024 (CAGR 1.2%), and is projected to reach 587.2 million by 2033 (CAGR 0.8%), driven by population aging and lifestyle factors.

INDUSTRY OVERVIEW

Currently, four DNA methylation-based products for esophageal cancer detection have been approved by the NMPA.

Approval Year	Company	Brand name	Generic name	Target	Platform	Sensitivity	Specificity
2024	Biochain (博爾誠)	思博士	MT-1A/Epo/Septin9 Gene Methylation Assay Kit (qPCR)	MT-1A/Epo/Septin9 Methylation	PCR	85.50%	93.60%
2025	Ammunition Life Technology (艾米森)	IEsohunter (艾思寧)	KCNA3/OTOP2 Gene Methylation Assay Kit (qPCR)	KCNA3/OTOP2 Methylation	PCR	87.40%	93.30%
2025	Targene (達健醫學)	食安健	ZNF154 Gene Methylation Assay Kit (qPCR)	ZNF154	qPCR	91.46%	90.82%
2026	Excellen Medical (艾克倫醫療)	艾真至	Septin9/TFPI2/FHIT Gene Methylation Assay Kit (qPCR)	Septin9/TFPI2/FHIT	qPCR	82.08%	91.84%

Source: NMPA, Frost & Sullivan analysis

REPORT COMMISSIONED BY THE COMPANY AND PREPARED BY FROST & SULLIVAN

In connection with the [REDACTED], we have engaged Frost & Sullivan to conduct a detailed analysis and to prepare an industry report on the global cancer and cancer detection market. Frost & Sullivan is an independent global market research and consulting company founded in 1961 and is based in the U.S. Services provided by Frost & Sullivan include market assessments, competitive benchmarking and strategic and market planning for a variety of industries. We have included certain information from the Frost & Sullivan Report in this document because we believe such information facilitates an understanding of the cancer detection market for potential [REDACTED]. Frost & Sullivan prepared its report based on its in-house database, independent third-party reports and publicly available data from reputable industry organizations. Where necessary, Frost & Sullivan contacts companies operating in the industry to gather and synthesize information in relation to the market, prices and other relevant information. Frost & Sullivan believes that the basic assumptions used in preparing the Frost & Sullivan Report, including those used to make future projections, are factual, correct and not misleading. Frost & Sullivan has independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected. Frost & Sullivan research may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources. We have agreed to pay Frost & Sullivan a fee of RMB450,000 for the preparation of the Frost & Sullivan Report. The payment of such amount was not contingent upon our successful [REDACTED] or on the content of the Frost & Sullivan Report. Except for the Frost & Sullivan Report, we did not commission any other industry report in connection with the [REDACTED]. We confirm that after taking reasonable care, there has been no adverse change in the market information since the date of the report prepared by Frost & Sullivan, which may qualify, contradict or have an impact on the information set forth in this section in any material respect.