RainSure
SCIENTIFIC

RainSure Digital PCR System

[CE IVD / FDA EUA / NMPA]

About **RainSure** Scientific

Founded in 2017, RainSure Scientific is a biotechnology company dedicated to advancing molecular diagnostics and life science research through innovation in microfluidics, engineering, and molecular biology.

Our team brings together scientific expertise from leading research universities across the United States, Europe, and China, combined with hands-on experience in optics, instrumentation, and software integration. This unique blend of academic depth and practical engineering enables RainSure to deliver reliable, high-performance tools that meet the real-world needs of laboratories worldwide.

RainSure's proprietary droplet fluorescent barcoding technology, integrated into its RS32 and DropDx digital PCR systems, provides unmatched multiplexing power — detecting up to 100 targets in a single reaction. These next-generation platforms set a new standard in digital PCR performance, precision, and scalability.

With headquarters in San Jose, California, and Suzhou, China, and a growing network of partners across Europe, Southeast Asia, and North America, RainSure continues to expand globally. Our product portfolio includes the RS32 and DropDx digital PCR systems, FastPlex™ ultra-multiplex sepsis assay, BCR-ABL quantification assay, and Fast-16 real-time PCR system.

Certificate

CONTENTS

Innovation

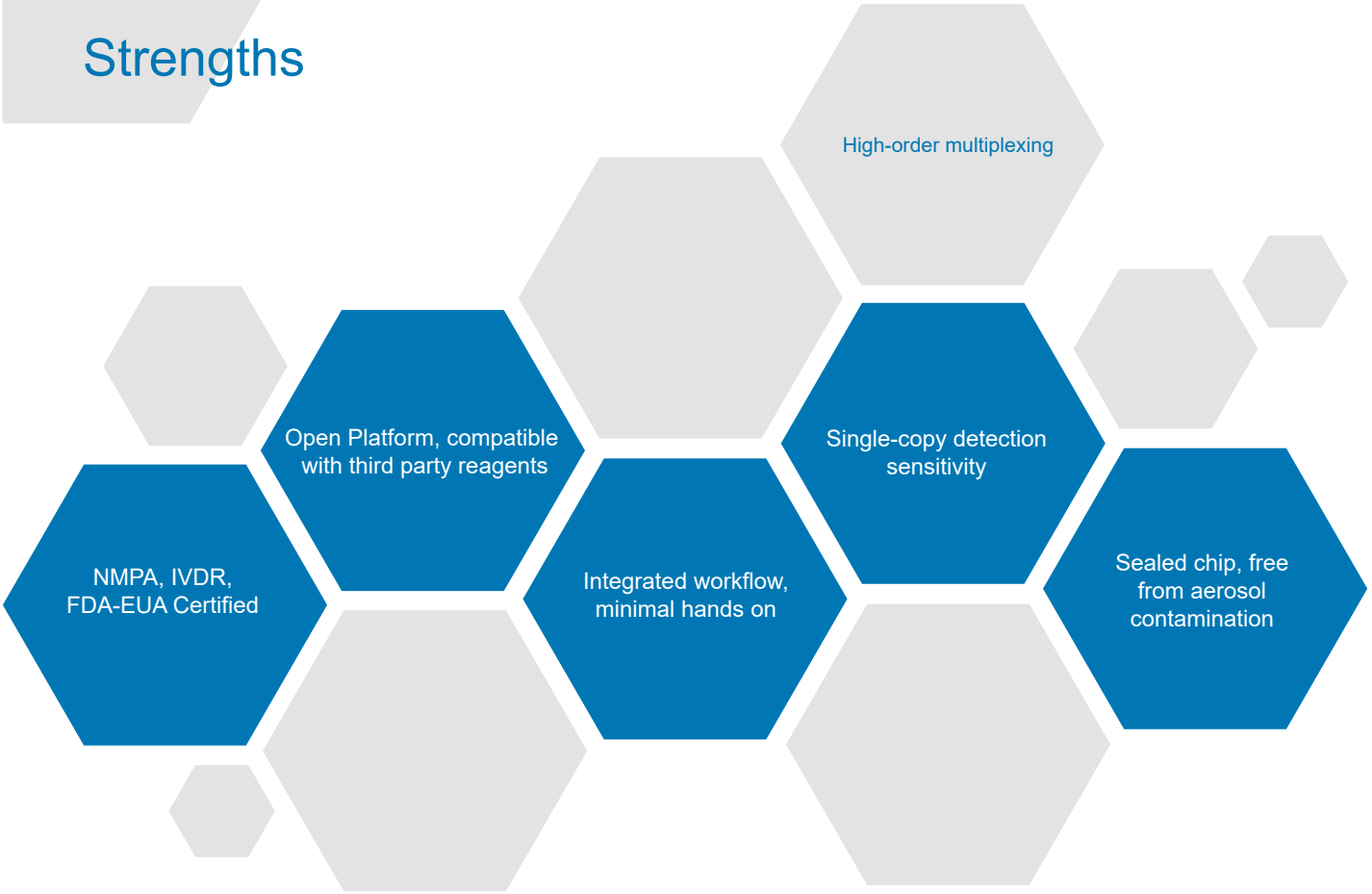
Intellectual Creations

Excellence in Life

RainSure
DropDx Series

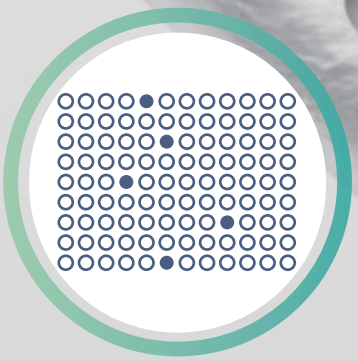
The DropDx series digital PCR system, designed specifically for diverse clinical testing scenarios, comprises a sample preparation workstation and a card scanner connected via a robotic arm (Optional). Users may choose to operate in integrated system mode or adopt a semi-automated workflow. The fully enclosed system prevents aerosol contamination while maintaining compatibility with third-party reagents to better meet clinical demands.

Strengths

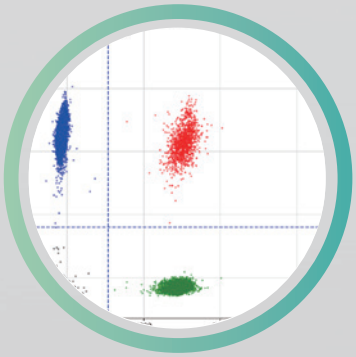


Testing Principle

01 Droplet generation, each reaction is partitioned into 20,000 individual droplet. Each droplet acts as an micro reaction unit



02 PCR amplification takes place independently in each micro reaction units



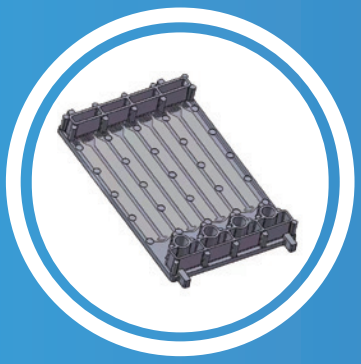
03 Fluorescence detection, results computation

Experiment Workflow

- Automated, only requires one manual step
- Sample-to-results takes 2.5 hours

01 Preparation of dPCR reaction mix

- Assemble all required components (sample, primer/probes and RainSure Digital PCR Mastermix)
- Compatible with third party reagents and allows qPCR assay transfer



02 Loading of dPCR reaction mix

- Transfer the dPCR reaction mix into the wells of a Digital PCR cartridge
- Seal the cartridge with Digital PCR cartridge sealing cover

03 Droplet generation and PCR

- Run the PCR protocol (hydrolysis probes)
- 4 x 20,000 droplets are generated from each cartridge in the RainSure Sample Prep Station

04 Read-out and analysis

- After PCR, scan the cartridge in the RainSure Cartridge Scanner
- Analyze with GeneCount Analysis Software

Technical Specifications

Product Name	Sample Prep Station
Model	SG8-3000 / SG-2000 / SG32-3000
Sample Throughput	8 / 16 / 32 samples/run
Patented Technology	Mono Flex™ Droplet Generation Technology, Universal Macro™ Reagent System, Flat Fast™ Microfluidic Flat Heating Technology
Expanded Function	Multiple Sample Prep Station can be integrated with a single cartridge Scanner to enhance testing efficiency
Specimen Type	All types of nucleic acids
Cartridge Size	4 samples/cartridge; manual loading of droplet generation oil
Droplet Count	20,000
PCR Amplification	Fully automated droplet generation and amplification system; support gradient PCR
Reagent Compatibility	Compatible with dye and probe based chemistry
Droplet Generation Time	2 min

Product Name	Cartridge Scanner
Model	DScanner3-1000 / DScanner4-1000 DScanner5-1000
Fluorescence Channels	3 / 4 / 5 colors
Supported Dyes	FAM / HEX / ROX / CY5 / CY5.5
Expanded Function	Multiple Sample Prep Station can be integrated with a single unit of Cartridge Scanner to increase testing efficiency
Sample Throughput	16 samples/run
Detection Method	Imaging (CMOS)
Sensitivity	0.01% down to single copy
Dynamic Range	5 logs
Precision	< 5% at moderate to high copy numbers
Sample Retrieval	Apply fixture to retrieve droplets and products
Cartridge Re-scanning	Catridges can be scanned repeatedly

Clinical Applications

Bloodstream Infection Detection Series

The world's first digital PCR kit quantitatively detecting sepsis-causing pathogens

What is Sepsis?

Sepsis is defined as life-threatening organ dysfunction caused by a dysregulated host response to infection. This condition is characterized by significant morbidity and mortality. According to the latest global statistics from 195 countries, one in five deaths is attributable to sepsis (Rudd 2020).

Quantitative detection of pathogenic microorganisms in whole blood/plasma samples from sepsis patients using digital PCR technology achieves a detection limit as low as single-copy levels, far surpassing traditional blood cultures and drug susceptibility testing. This technology not only significantly improves pathogen detection rates and shortens turnaround times but also guides precise clinical drug administration, pioneering a new paradigm for sepsis diagnosis and treatment.

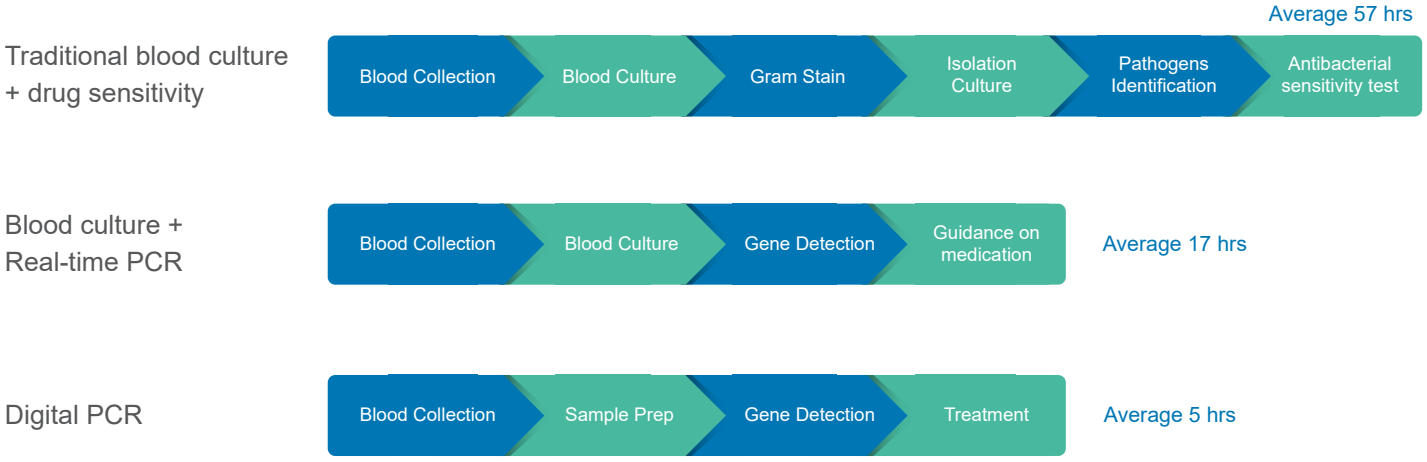
RainSure Pathogenic Microorganisms Detection Kit CE

		Position 1	Position 2	Position 3	Position 4	Position 5
Panel 1	FAM&HEX	*Staphylococcus capitis*	*Acinetobacter baumannii*	*Candida tropicalis*	*Candida krusei*	*Staphylococcus epidermis*
	ROX&Cy5	*Enterococcus faecium*	*Cryptococcus neoformans*	*Stenotrophomonas maltophilia*	*Klebsiella pneumoniae*	*Streptococcus pneumoniae*
	Cy5.5	*Serratia marescens*				
Panel 2	FAM&HEX	*Bacteroides fragilis*	*Escherichia coli*	*Candida parapsilosis*	*Candida glabrata*	*Enterobacter cloacae complex*
	ROX&Cy5	*Enterococcus faecalis*	*Haemophilus influenzae*	*Pseudomonas aeruginosa*	*Staphylococcus aureus*	*Candida albicans*
	Cy5.5	*Internal Control*				

This kit detects 21 of the most common sepsis pathogens, including 8 Gram-positive bacteria, 7 Gram-negative bacteria, and 6 fungi. The panel contains an internal reference gene for quality control of extraction and PCR.

21 major sepsis pathogens in 5 hours from 3 ml whole blood sample

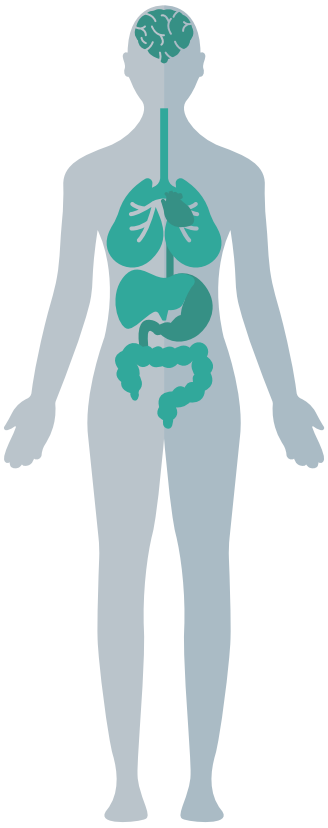
15 hours faster than culture+Real-time PCR techology



Oncology

Liquid Biopsy

- Minimal invasive
- Shorter time
- Highly sensitive
- Lower cost of sample isolations
- Monitors continuous tumor evolutions
- Real time monitoring of drug response
- Reveals spatial and temporal tumor heterogeneity



Tissue Biopsy

- Invasive
- Longer time
- Low sensitivity
- High cost of sample isolations
- Clinically validated
- Provide histological evaluation
- Organ penetration required
- Not capable of accessing tumor evolution
- No real time monitoring of drug response
- Repeated surgeries not feasible
- Dose not reveal tumor heterogeneity

Comparison between liquid biopsy and tissue biopsy (Lone *et al.*, 2022).

Liquid biopsy has revolutionized the field of clinical oncology, offering advantages such as: simplifying tumor sampling procedures, enabling continuous monitoring through repeated sampling, facilitating personalized treatment planning, and screening for treatment resistance.

Tumor tissue biopsy currently serves as the gold standard for clinical cancer diagnosis. However, issues such as invasiveness, sample contamination, and tissue heterogeneity during sample acquisition hinder the application of tumor tissue biopsy in cancer diagnosis.

Liquid biopsy is a minimally invasive technique capable of detecting minute cancer biomarkers while addressing tumor heterogeneity. Early cancer risk assessment through liquid biopsy relies on relevant disease biomarkers, including disease protein markers and DNA epigenetic markers. DNA molecules from tumor cells are released into the bloodstream during apoptosis or necrosis. Detecting cancer markers in blood directly reflects the occurrence and evolution of tumor cells within the body.
Research confirms that cancer biomarker levels in patients' blood differ from those in healthy individuals. Consequently, detecting circulating tumor DNA (ctDNA) and RNA in blood serves as a primary screening method for cancer detection (Lone et al., 2022).

The oncology assays developed by RainSure cover common tumor gene mutation targets. The assays provide a basis for mutation detection, disease classification, and guided treatment- a step towards personalized medicine

Human *KRAS* Gene Mutation Detection Kit Series

The *K-RAS* gene, also known as p21, encodes a 21-kD *RAS* protein. Among the *RAS* genes, *K-RAS* has the greatest impact on human cancers. It regulates cell proliferation, and when mutated, it causes cells to continue growing and prevents the cells from self-destruction. It is involved in intracellular signaling, when the *K-RAS* gene is mutated, the gene is permanently activated and is unable to produce normal *RAS* protein, leading to dysregulated intracellular signaling, uncontrolled cell proliferation, and finally cancers.

Human *KRAS* Gene Mutation Detection	Specification
Human *KRAS* Gene G12A Mutation Assay	24rxn | 96rxn
Human *KRAS* Gene G12C Mutation Assay	
Human *KRAS* Gene G12D Mutation Assay	
Human *KRAS* Gene G12S Mutation Assay	
Human *KRAS* Gene G12V Mutation Assay	
Human *KRAS* Gene G13D Mutation Assay	
Human *KRAS* Gene Mutation Detection Kit (6 loci)	24rxn

For research use only, not for clinical diagnosis

Human *IDH1* Gene Mutation Detection Kit Series

The *IDH1* gene encodes the isocitrate dehydrogenase 1 protein. The mutation at the R132 locus of the *IDH1* gene causes a gain of function in the encoded mutant protein, which converts a-ketodioic acid into 2-HG, while 2-HG accumulation leads to tumorigenesis. Tumors caused by this mechanism include gliomas, intrahepatic cholangiocarcinomas and acute myeloid leukemia. Among the gliomas, patients with *IDH1* R132 mutations usually present with low-grade qliomas and secondary glioblastomas.

Product	Specification
Human *IDH1* Gene R132C Mutation Assay	24rxn | 96rxn
Human *IDH1* Gene R132G Mutation Assay	
Human *IDH1* Gene R132H Mutation Assay	
Human *IDH1* Gene Mutation Detection Kit (3 loci)	24rxn

For research use only, not for clinical diagnosis

Human *EGFR* Gene Mutation Detection Kit Series

These kits are used to detect human epidermal growth factor receptor EGFR mutations in tissue DNA and plasma cfDNA.

In Asian patients with non-small cell lung cancer, the frequency of driver *EGFR* gene mutation is about 30%, of which EGFR-19del mutation frequency accounts for about 47%, which is a drug sensitivity-related mutation.

Human *EGFR* Gene Mutation Detection	Specification
Human *EGFR* Gene 797S (COSM5945664) Mutation Assay	24rxn | 96rxn
Human *EGFR* Gene C797S (COSM6493937) Mutation Assay	
Human *EGFR* gene D770_N771insG Mutation Assay	
Human *EGFR* Gene E746_A750delELREA (COSM6223) Mutation Assay	
Human *EGFR* Gene E746_A750delELREA (COSM6225) Mutation Assay	
Human *EGFR* Gene E747_A750delinsP (COSM2238) Mutation Assay	
Human *EGFR* gene E747_A750delinsP (COSM2239) Mutation Assay	
Human *EGFR* Gene G465R Mutation Assay	
Human *EGFR* Gene G719A Mutation Assay	

Human *EGFR* Gene Mutation Detection	Specification
Human *EGFR* Gene G719S Mutation Assay	24rxn | 96rxn
Human *EGFR* gene L747_P753>S Mutation Assay	
Human *EGFR* Gene 1858R Mutation Assay	
Human *EGFR* Gene L861Q Mutation Assay	
Human *EGFR* Gene S768I Mutation Assay	
Human *EGFR* Gene T790M Mutation Assay	
Human *EGFR* Gene V769_D770insASV Mutation Assay	
Human *EGFR* Gene Exon 12,18-21 Mutation Detection Kit (15 loci)	24rxn

For research use only, not for clinical diagnosis

Other Tumor Gene Mutation Detection Kit Series

Human *ALK* Gene Mutation Detection	Specification
Human *ALK* Gene G1269A Mutation Assay	24rxn | 96rxn

Human *BRAF* Gene Mutation Detection	Specification
Human *BRAF* Gene V600E Mutation Assay	24rxn | 96rxn
Human *BRAF* Gene Mutation Detection Kit (3 loci)	24rxn

Human *ESR1* Gene Mutation Detection	Specification
Human *ESR1* Gene D538G Mutation Assay	24rxn | 96rxn
Human *ESR1* Gene Y537S Mutation Assay	

Human *JAk2* Gene Mutation Detection	Specification
CE Human *JAK2* Gene V617F Mutation Detection Kit	24rxn | 96rxn

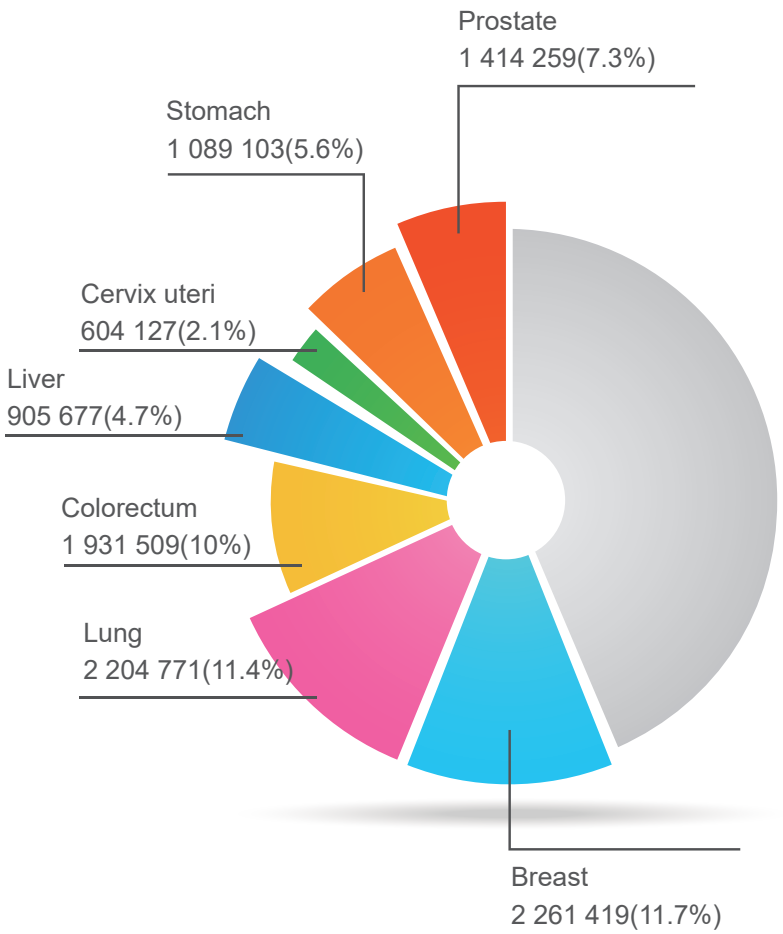
Human *NRAS* Gene Mutation Detection	Specification
Human *NRAS* Gene G12V Mutation Assay	24rxn | 96rxn
Human *NRAS* Gene Q6lR Mutation Assay	
Human *NRAS* Gene Mutation Detection Kit (2 loci)	24rxn

Human *TP53* Gene Mutation Detection	Specification
Human *TP53* Gene R175H Mutation Assay	24rxn | 96rxn
Human *TP53* Gene R248L Mutation Assay	
Human *TP53* Gene R273C Mutation Assay	
Human *TP53* Gene R273H Mutation Assay	
Human *TP53* Gene Mutation Combination detection kit (4 loci)	24rxn

For research use only, not for clinical diagnosis

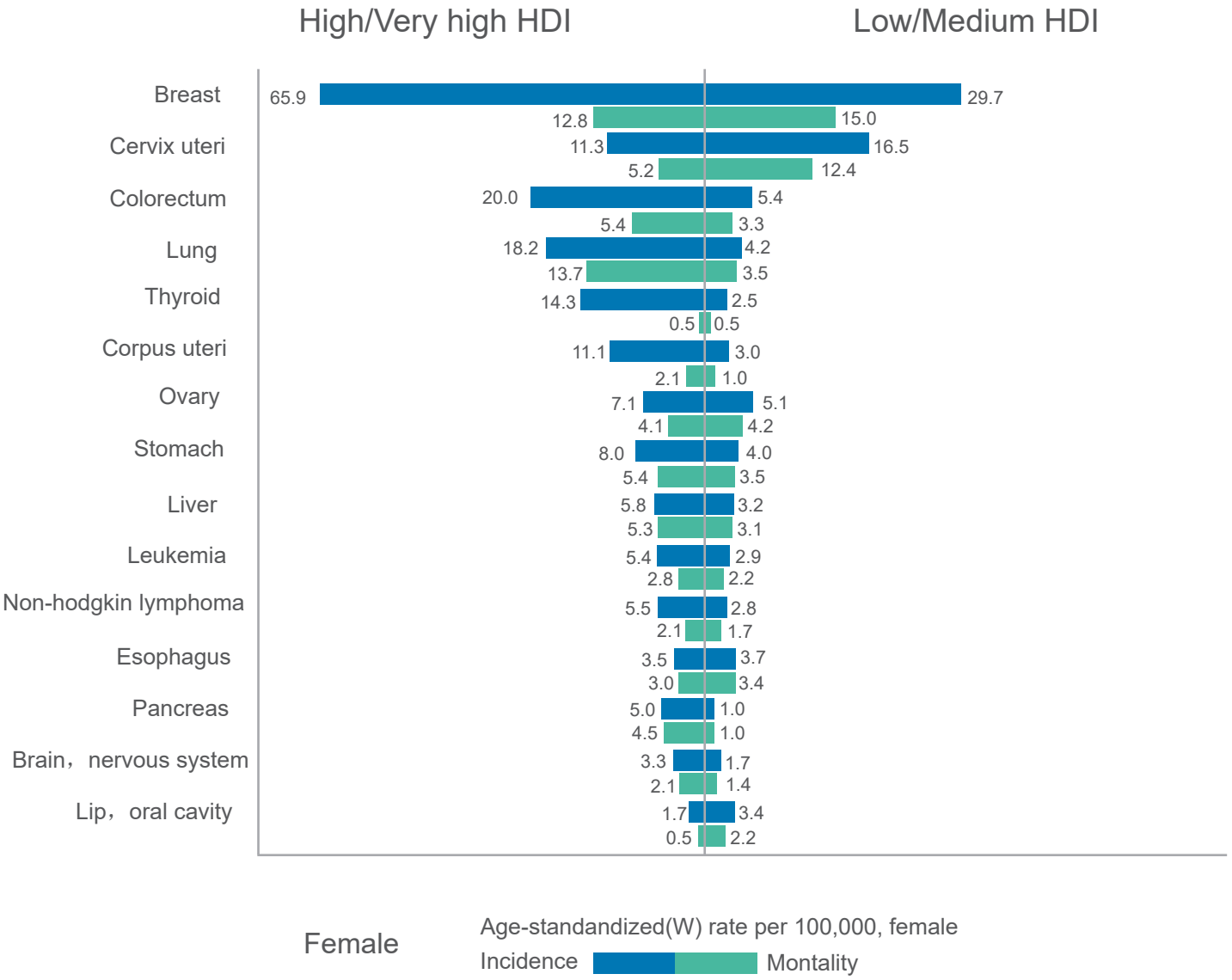
Breast Cancer Detection Assays

Breast cancer remains one of the most significant health challenges for women worldwide. Based on global cancer data from the WHO's International Agency for Research on Cancer (IARC), over 2.3 million women were diagnosed with breast cancer in 2020, with 685,000 lives lost. The need for earlier, more accurate detection has never been more critical — and innovation is driving change (WHO, 2021).



Global incidence of the ten most common cancers in 2020.

In 2020, breast cancer surpassed lung cancer to become the most commonly diagnosed cancer on the planet, representing 11.7% of all new cancer cases. The positive news? With timely diagnosis and effective treatment, breast cancer patients now have an excellent chance of recovery. Today, nearly 8 million women diagnosed in the past five years are living healthier lives, highlighting the impact of early detection and advanced screening approaches (GLOBOCAN, 2020).



In 2020, female breast cancer mortality varied significantly across regions — with lower- and medium-HDI countries experiencing disproportionately higher fatality rates compared to high/very high HDI regions. Globally, breast cancer ranked as the fifth leading cause of cancer-related death, resulting in 685,000 deaths (Bray et al., 2018).

Facing this growing clinical demand, RainSure has introduced a dedicated portfolio of breast cancer detection reagents. Powered by RainSure DropDx or RS32 instrument platform, our solution delivers:

- Significantly shorter turnaround time (TAT)
- Simple, user-friendly operation
- Ultra-high sensitivity for early detection

Together, RainSure offers a smarter, more reliable alternative for routine diagnostics, helping labs make faster decisions and improving the potential for successful treatment.

Human PIK3CA Gene Mutation Multiplex Detection Kit (11 Loci, dPCR)

Fast Accurate High-Sensitivity Detection for Breast Cancer and Other Solid Tumors

To meet the growing needs of precision oncology, RainSure has developed a multiplex digital PCR detection kit for PIK3CA gene mutations (11 loci). This solution enables rapid, sensitive, and accurate identification of key mutation sites, providing clinicians and researchers with valuable genetic insights for personalized treatment strategies and targeted therapy decision-making.

Wide Loci Coverage

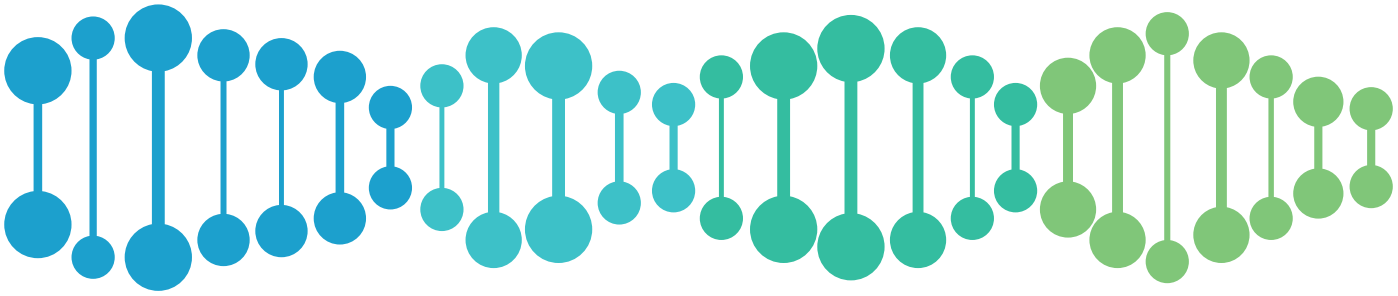
Designed for breast cancer and related tumors, covering 11 clinically relevant mutation sites in one assay

Ultra-High Sensitivity

Up to ~100× more sensitive than qPCR, allowing detection of low-frequency mutations with confidence

Easy, Efficient Workflow

Compatible with RainSure digital PCR platform for streamlined operation and simultaneous detection of 11 loci in a single run



Human *PIK3CA* Gene Mutation Detection	
Human *PIK3CA* Gene E542K Mutation Assay	Detection of PIK3CA mutations in NSCLC, colorectal cancer, breast cancer, and other solid tumors for targeted therapy guidance
Human *PIK3CA* Gene E545K Mutation Assay	
Human *PIK3CA* Gene H1047R Mutation Assay	
CE Human *PIK3CA* Gene Mutations Multiplex Detection Kit (11 loci)	

Human *HER2* Gene Copy Number Variation Detection	
Human *HER2* Gene Copy Number Variation Assay	Supports research on drug efficacy and prognosis evaluation in breast and gastric cancer

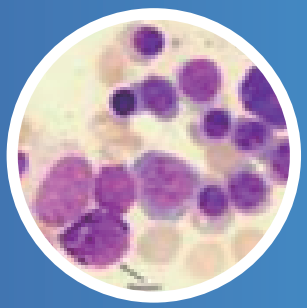
For research use only, not for clinical diagnosis

Blood Disorder Detection Assays
Precision detection solutions for leukemia and lymphoma research

AML

BCR-ABL *NPM1*

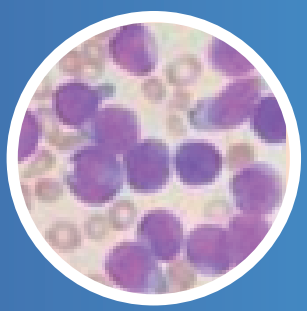
- Risk Stratification
- MRD Assessment



CML

BCR-ABL

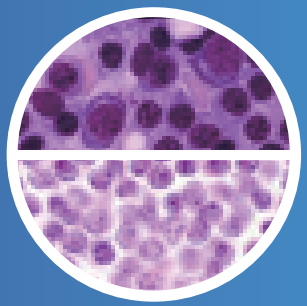
- Disease Evaluation
- Treatment Recommendation
- Treatment Response Monitoring
- Disease Relapse Tracking



ALL

BCR-ABL *JAK2*

- Diagnosis Support
- Cytogenetic Risk Assessment
- Treatment Recommendation
- MRD Monitoring



Lymphoma

BCR-ABL *MYD88*

- Diagnostic Research
- Disease Management Monitoring

Early and accurate detection of leukemia biomarkers plays a key role in guiding treatment strategies and predicting patient outcomes. Conventional RT-qPCR often struggles with low sensitivity and reference-gene interference, making it difficult for clinicians to precisely assess disease progression or minimal residual disease (MRD).

RainSure digital PCR (dPCR) provides a powerful alternative — delivering absolute quantification, ultra-high sensitivity, and reliable detection of low-level MRD, helping researchers monitor tumor burden more precisely and supporting individualized treatment decisions.

According to NCCN (2022), testing for BCR-ABL1, JAK2, MYD88, and NPM1 mutations is recommended for the research and management of major hematologic malignancies, including acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL), chronic myeloid leukemia (CML), and lymphoma.

Human BCR-ABL (P210) Fusion Gene Quantitative Detection Kit (dPCR)

High-precision quantification for CML molecular response evaluation

Chronic myeloid leukemia (CML) is a hematologic malignancy characterized by the clonal proliferation of hematopoietic stem cells. Globally, CML affects approximately 1–2 individuals per 100,000 people annually, accounting for 15%–20% of adult leukemia cases. Accurate quantification of BCR-ABL is crucial for treatment monitoring and response evaluation.

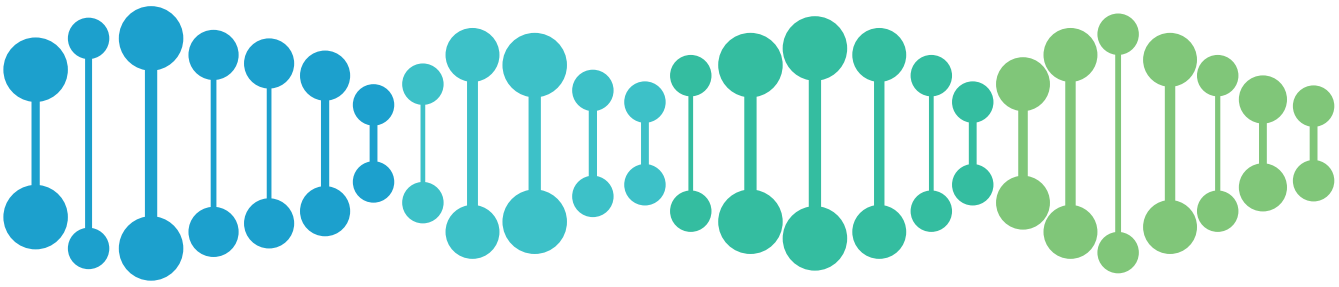
Molecular Response

Major Molecular Response (MMR)	*BCR-ABL* ≤ 0.1% (IS)
MR4.0	BCR-ABL ≤ 0.01% (IS), or BCR-ABL undetectable when ABL transcript > 10,000
MR4.5	BCR-ABL ≤ 0.0032% (IS), or BCR-ABL undetectable when ABL transcript > 32,000
MR5.0	BCR-ABL ≤ 0.001% (IS), or BCR-ABL undetectable when ABL transcript > 100,000

Molecular response reflects the level of BCR-ABL transcripts detected by PCR.

- **MR3.0 (MMR)** indicates a 3-log reduction in leukemia cells with 0.1% residual level.
- **MR4.5** represents a ~4.5-log reduction with 0.0032% residual.
- **MR5.0** indicates a 5-log reduction with 0.001% residual, supporting ultra-deep monitoring for minimal residual disease (MRD) (Leukemia & Lymphoma Society, 2020).

The BCR-ABL fusion gene results from the translocation of BCR and ABL, forming the hallmark oncogenic driver of CML. It is found in nearly all CML patients, also present in some acute lymphoblastic leukemia (ALL) cases, and rarely observed in acute myeloid leukemia (AML).



Key Advantages:

- Ultra-sensitive detection down to MR5.0
- Reliable monitoring of minimal residual disease
- Ideal for treatment evaluation & research labs
- Digital PCR for absolute quantification accuracy

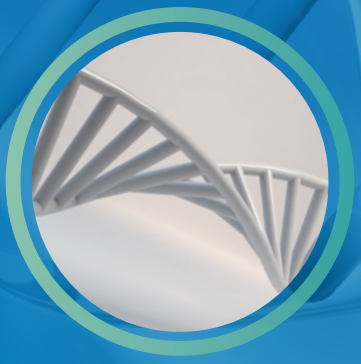
Experiment Workflow (Specimen Type: Blood)

Nucleic acid extraction → Reverse transcription → Droplet generation & amplification → Data acquisition & analysis (TAT: 2.5–3 h)

01

Sample Collection

Blood / CSF / Tissue



02

Extraction & Prep

Nucleic acid extraction + reaction mix

03

Sample Loading

Transfer to dPCR cartridges

04

Generate → Amplify → Analyze

dPCR reaction & data readout

Human *BCR-ABL* Gene Mutation & Fusion Gene Detection Assays	
Human BCR-ABL P210 Fusion Gene Assay	Includes primers & probes. Mainly used for CML typing, minimal residual disease (MRD) detection, and prognosis evaluation.
Human BCR-ABL T315I Mutation Assay	Includes primers & probes. Mainly for the detection of TKI resistance in CML patients.
Human BCR-ABL (P210) Fusion Gene Quantitative Detection Kit	Contains reverse transcriptase, RT reaction mix, master mix, 10% IS positive control, 0.1% IS positive control, negative control, etc. Mainly used for CML typing, MRD detection, and prognosis evaluation.

Human *NPM1* RNA Detection Assays	
Human NPM1 Type A RNA Assay	Includes primers & probes. Mainly for detection of NPM1 mutation (Type A) in AML.
Human NPM1 Type B RNA Assay	Includes primers & probes. Mainly for detection of NPM1 mutation (Type B) in AML.
Human NPM1 Type D RNA Assay	Includes primers & probes. Mainly for detection of NPM1 mutation (Type D) in AML.

Human *MYD88* Gene Mutation Detection Assays	
Human MYD88 Gene L265P Mutation Assay	Includes primers & probes. MYD88 L265P mutation is present in ~90% lymphoplasmacytic lymphoma/Waldenström macroglobulinemia cases, and 60%–80% of IgM MGUS. Useful for mutation screening and treatment guidance.

For research use only.

Product List

(All reagents compatible with real-time PCR & digital PCR platforms.)

Infectious Pathogens

Product	Specification	Remark
Human Influenza A Virus H1N1-2009 Nucleic Acids Assay	24rxn | 96rxn	RUO
Human Influenza A H3N2 Nucleic Acids Assay	24rxn | 96rxn	RUO
Human Influenza A Virus H7N9 Nucleic Acids Assay	24rxn | 96rxn	RUO
Human Influenza B Virus BY Nucleic Acids Assay	24rxn | 96rxn	RUO
Human Influenza B Virus BV Nucleic Acids Assay	24rxn | 96rxn	RUO
Human Epstein-Barr Virus (BamHI-W) Nucleic Acids Assay	24rxn | 96rxn	RUO
Human Epstein-Barr Virus (EBNA1) Nucleic Acids Assay	24rxn | 96rxn	RUO
Human CMV Virus Nucleic Acids Assay	24rxn | 96rxn	RUO
Human VZV Virus Nucleic Acids Assay	24rxn | 96rxn	RUO
Human HSV-1 Virus Nucleic Acids Assay	24rxn | 96rxn	RUO
Human HSV-2 Virus Nucleic Acids Assay	24rxn | 96rxn	RUO
Hepatitis B Virus Nucleic Acids Assay	24rxn | 96rxn	RUO
Human HPV-16 Virus Nucleic Acids Assay	24rxn | 96rxn	RUO
Human HPV-18 Virus Nucleic Acids Assay	24rxn | 96rxn	RUO
Novel Coronavirus (COVID-19) Nucleic Acids Assay	24rxn | 96rxn	CE
Monkeypox Nucleic Acids Detection Kit	24rxn | 96rxn	CE
Malaria Nucleic Acids Detection Kit	24rxn | 96rxn	CE
Sepsis Pathogenic Bacteria Detection Kit	24rxn	CE
Cryptococcus neoforans Nucleic Acids Assay	24rxn | 96rxn	RUO
Candida albicans Nucleic Acids Assay	24rxn | 96rxn	RUO
Candida parapsilosis Nucleic Acids Assay	24rxn | 96rxn	RUO
Candida tropicalis Nucleic Acids Assay	24rxn | 96rxn	RUO
Candida glabrata Nucleic Acids Assay	24rxn | 96rxn	RUO
Pneumocystis jirovecii Nucleic Acids Assay	24rxn | 96rxn	RUO
Aspergillus fumigatus Nucleic Acids Assay	24rxn | 96rxn	RUO

For research use only

Solid Tumor & Blood Cancer Mutation Detection Assays

Product	Specification	Remark
Human *ALK* Gene G1269A Mutation Assay	96rxn	RUO
Human *BRAF* Gene V600E Mutation Assay	96rxn	RUO
Human *BRAF* Gene Mutation Detection Kit (3 loci)	24rxn	RUO
Human *EGFR* Gene G465R Mutation Assay	96rxn	RUO
Human *EGFR* Gene G719S Mutation Assay	96rxn	RUO
Human *EGFR* Gene G719A Mutation Assay	96rxn	RUO
Human *EGFR* Gene E746_A750delELREA (COSM6223) Mutation Assay	96rxn	RUO
Human *EGFR* Gene E746-A750delELREA(COSM6225) Mutation Assay	96rxn	RUO
Human *EGFR* Gene E747 A750delinsP (COSM2238) Mutation Assay	96rxn	RUO
Human *EGFR* Gene E747 A750delinsP(COSM2239) Mutation Assay	96rxn	RUO
Human *EGFR* Gene L747_P753>S Mutation Assay	96rxn	RUO
Human *EGFR* Gene S768I Mutation Assay	96rxn	RUO
Human *EGFR* Gene V769 D770insASV Mutation Assay	96rxn	RUO
Human *EGFR* Gene D770_N771insG Mutation Assay	96rxn	RUO
Human *EGFR* Gene T790M Mutation Assay	96rxn	RUO
Human *EGFR* Gene C797S (COSM6493937) Mutation Assay	96rxn	RUO
Human *EGFR* Gene C797S (COSM5945664) Mutation Assay	96rxn	RUO
Human *EGFR* Gene L858R Mutation Assay	96rxn	RUO
Human *EGFR* Gene L861Q Mutation Assay	96rxn	RUO
Human *EGFR* Gene Exon 12,18-21 Mutation Detection Kit (15 loci)	24rxn	RUO
Human *ESR1* Gene Y537S Mutation Assay	96rxn	RUO
Human *ESR1* Gene D538G Mutation Assay	96rxn	RUO
Human *KRAS* Gene G12D Mutation Assay	96rxn	RUO
Human *KRAS* Gene 612V Mutation Assay	96rxn	RUO
Human *KRAS* Gene G12C Mutation Assay	96rxn	RUO
Human *KRAS* Gene G12A Mutation Assay	96rxn	RUO
Human *KRAS* Gene G12S Mutation Assay	96rxn	RUO
Human *KRAS* Gene Mutation Detection Kit (6 loci)	24rxn	RUO
Human *KRAS* Gene G13D Mutation Assay	96rxn	RUO
Human *NRAS* Gene G12V Mutation Assay	96rxn	RUO
Human *NRAS* Gene Q61R Mutation Assay	96rxn	RUO

Product	Specification	Remark
Human *NRAS* Gene Mutation Detection Kit (2 loci)	24rxn	RUO
Human *PIK3CA* Gene E542K Mutation Assay	96rxn	RUO
Human *PIK3CA* Gene E545K Mutation Assay	96rxn	RUO
Human *PIK3CA* Gene H1047R Mutation Assay	96rxn	RUO
Human *PIK3CA* Gene Mutations Multiplex Detection kit	96rxn	CE
Human *NPM1* Type A RNA Assay	96rxn	RUO
Human *NPM1* Type B RNA Assay	96rxn	RUO
Human *NPM1* Type D RNA Assay	96rxn	RUO
Human *HER2* Gene Copy Number Variation Assay	96rxn	RUO
Human *BCR-ABL* (P210) Fusion Gene Quantitative Detection kit	24rxn | 96rxn	CE
Human *BCR-ABL* T3151 Mutation Assay	24rxn | 96rxn	RUO
Human *IDH1* Gene R132C Mutation Assay	24rxn | 96rxn	RUO
Human *IDH1* Gene R132G Mutation Assay	24rxn | 96rxn	RUO
Human *IDH1* Gene R132H Mutation Assay	24rxn | 96rxn	RUO
Human *IDH1* Gene Mutation Detection Kit (3 loci)	24rxn	RUO
Human *JAK2* Gene V617F Mutation Detection kit	24rxn | 96rxn	RUO
Human *MYD88* Gene L265P Mutation Assay	24rxn | 96rxn	RUO
Human *TP53* Gene R175H Mutation Assay	24rxn | 96rxn	RUO
Human *TP53* Gene R248L Mutation Assay	24rxn | 96rxn	RUO
Human *TP53* Gene R273C Mutation Assay	24rxn | 96rxn	RUO
Human *TP53* Gene R273H Mutation Assay	24rxn | 96rxn	RUO
Human *TP53* Gene Mutation Combination Assay Kit (3 loci)	24xn	RUO
Organ Transplant Graft-derived cfDNA Assay	96rxn	RUO

For research use only, not for clinical diagnosis unless EU CE marked

RainSure Scientific

Leading provider of innovative molecular diagnostics and digital PCR solutions for research and clinical applications worldwide.

- info@rainsurebio.com
- US (617) 803 3169
- www.rainsurebio.com

RainSure RS32 Series
Fully Automatic Integrated Digital PCR System

RainSure's cutting-edge RS32 series of digital PCR system represents a seamless fusion of droplet generation, PCR thermal cycling, and fluorescence signal analysis within a singular, advanced device. Contrasting RainSure's previous generation DropX individual digital PCR system, the RS32 series seamlessly unites the PCR Amplifying Apparatus and the Biochip Scanner into a harmonious whole, achieving true fully automatic integration following the introduction of nucleic acid samples. Once the RS32 series is loaded with digital PCR cartridges, the entire process proceeds without the need for additional manual interventions. This system is devoid of aerosol contamination, exhibits compatibility with third-party reagents, and serves as a formidable ally in advancing your research pursuits.

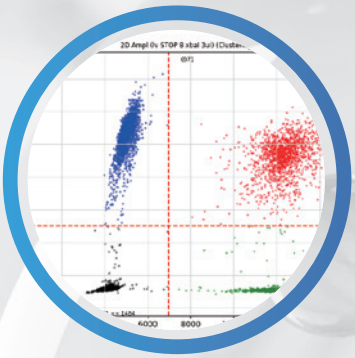
Product highlights

- Up to 7 fluorescence channels for multiplexing
- Open platform; compatible with third-party reagents
- High sensitivity; the detection limit is as low as single copy
- Integration of droplet generation, PCR amplification, and fluorescence signal reading, achieving full automation after sample addition
- Sealed chip design eliminates sample contamination

Detection Principle

01 Droplet generation, each reaction is partitioned into 20,000 - 25,000 individual droplets.
Each droplet acts as a micro reaction unit

02 PCR amplification takes place independently in each micro reaction unit



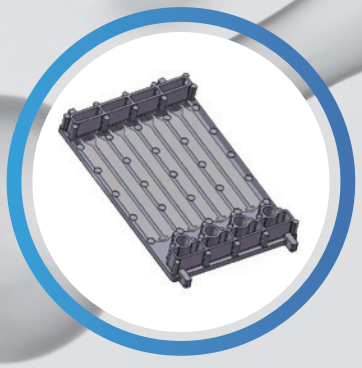
03 Fluorescence detection, results computation

Experiment Workflow

- Automated, only requires one manual step
- Sample-to-results takes 2.5 hours

01 Preparation of dPCR reaction mix

- Assemble all required components (sample, primer/probes and RainSure Digital PCR Mastermix)
- Compatible with third party reagents and allows qPCR assay transfer



02 Loading of dPCR reaction mix

- Transfer the dPCR reaction mix into the wells of a Digital PCR cartridge
- Seal the cartridge with Digital PCR cartridge sealing cover

03 Droplet generation, PCR, read-out, and analysis

- Post-sample addition, manual intervention is unnecessary.
- The on-machine detection operates with a single click.

Technical Specifications

Product Name	Fully Automatic Integrated Digital PCR System
Model	RS 3204 / RS3207 / RS3205 / RS3206
Patent Technology	Mono Flex™ Droplet Generation Technology, Universal Macro™ Microfluidic Flat Heating Technology
Sample Types	All types of nucleic acids
Sample Throughput	4-32 samples/run
Cartridge Specifications	4 samples/cartridge, 8 cartridges/run
Dimension	500 (W) *750 (D) *600 (H) (mm)
Weight	≤ 50 kg
Sample Preparation	Manually load samples and droplet generation oil; also compatible with RainSure's fully automatic sample preparation workstation (automated nucleic acid extraction and digital PCR cartridge loading), no manual operation required
Droplet Generation	2 minutes
Droplet Count	20,000
PCR Amplification	Fully automatic integrated droplet generation and amplification system, supports PCR temperature gradient function
Reagent Type	Compatible with various dye- and probe-based kits
Fluorescence Channels	4 colors/ 5 colors/ 6 colors / 7colors
Fluorescence	FAM/HEX/ ROX/Cy5 / FAM/HEX/ROX/ Cy5/Cy5.5 / Atto425/FAM/HEX/ ROX/ CY5/Cy5.5 or FAM/HEX/ROX/CY5/ Cy5.5/CY7 / Atto425/FAM/HEX/ROX/ CY5/Cy5.5/CY7
Detection Method	CMOS, able to identify negative droplets without the need for reference dye
Sensitivity	Detectable mutation frequency as low as 0.001%, enabling single-copy detection
Dynamic Range	5 log
Sample Recovery	Supports sample recovery by applying pressure to the cartridge
Cartridge Re-scanning	Supports long-term storage and re-scanning of cartridge