Pilot Gene Technology(Hangzhou) Co., Ltd.

Tel.: +86 571 8763 5306
E-mail: market@pilotgene.com
Add.: 5-7F, Building 8, 168 Fengtu Street, Hongshan Sub-district, Xiaoshan District, 311227, Hangzhou, Zhejiang, P.R.C.

HOTLINE
+86 400 660 7889

www.pilotgene.com



Pilot Gene

Digital PCR Platform and Applications

Focus on
digital PCR solutions

Pilot
Gene Technology



Pilot Gene—Focus on dPCR Solutions

Company Profile

Pilot Gene is an innovative high-tech enterprise, providing products and services in the fields of R&D, molecular biology and genetics. With its head office in Hangzhou, it aims to be a top-ranking supplier of molecular diagnostics and life science products. Since the day it was founded, Pilot Gene has been appealing to the entire clinical and biotechnolgy market with its young, dynamic, and expert staff.

Pilot Gene focuses on the R&D of droplet digital PCR (ddPCR) technology. We have launched a series of high-throughput, high-performance, fully automatic digital PCR systems, which are widely used in clinical diagnosis, life science, public health and many other fields, providing users with one-stop solutions.

We will continue to innovate, and endeavor to provide strong support to its wide-range customer profile and business partners. With over 10 years of experience, we always aim further ,continue to strengthen independent research and innovation capacity, expand the production layout and strive to become the world's leading provider of molecular diagnostics products and services.

ISO13485

First dPCR System in China

Integrated System

Innovative
High-tech Enterprise

100+
Patents

CE
Certification

60%+
China's top 100 hospitals

Technical Principle

Digital PCR (dPCR) is the third generation of PCR that enables precise, highly sensitive quantification of nucleic acids. It works by dividing a reaction mixture into numerous individual reactions partitions and then measuring the end point fluorescence of each partition to determine the presence or absence of the target. Statistical methods (Poisson distribution) are then used to calculate the absolute concentration of the target based on the number of negtive and total partitions.



Sample preparation | Droplet generation | Nucleic acid amplification | Data analysis

The Third-generation: Digital PCR

Automated Digital PCR System
AD3207



Technical benefits of dPCR

Absolute Quantification

Independent of standard curves

High Sensitivity

Able to dectect single molecule

High Stability

Tolerant to Inhibitors and applicable to complex samples

AP10

Automated Nucleic Acid Detection Reaction Construction System

Multifunctional Device |

Integrates the functions of nucleic acid extraction, PCR reaction mixture setup, and chip loading

High Performance |

Optimised extraction protocols for high-purity and high-yield nucleic acid

Anti-contamination |

UV disinfection to reduce potential contamination of samples between batches

Compatibility |

Compatible with a variety of magnetic bead-based extraction solutions for different sample types

WORKFLOW

Automated Nucleic Acid Detection Reaction Construction System(AP10) + Automated Digital PCR System



Clinical sample | AP10 | AD3207 | Report output

Sample throughput	**10 samples**
TAT	**40 min**
Dimension	**710x540x460 mm (LWH)**
Net weight	**60 kg**



AD3207

Automated Digital PCR System

The Automated Digital PCR System AD3207 integrates droplet generation, PCR amplification, and multi-channel fluorescence detection & analysis.

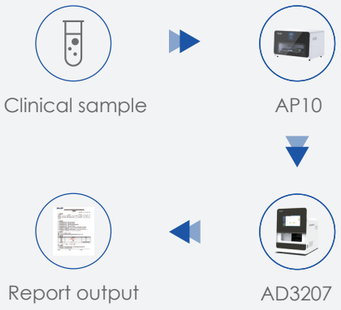
All-in-one Desktop Platform

7 Fluorescence Channels

Fully Automatic Instrument

TAT：3 hours

WORKFLOW





Sample throughput	**32 tests**
TAT	**3 hours**
Dimension	**550x570x590 mm (LWH)**
Net weight	**79 kg**

Pilot1200

Integrated Digital PCR Instrument

It integrates the functions of nucleic acid extraction and purification, PCR reaction mixture setup, chip loading, droplet generation, PCR amplification and chip reading.

Fully Integrated |
System integration from sample preparation to result

Convenient and Fast |
"samples in, results out" in 70 minutes

Safe and Contamination-free |
No need to open the lid during the whole reaction to ensure biosafety

Application Scenario |

Meet the clinical demand of rapid detection for sepsis

SAMPLE IN, RESULT OUT





Sample throughput	**12 tests**
TAT	**70 min**
Dimension	**575x485x575 mm (LWH)**
Net weight	**65 kg**

Coming Soon

Sepsis
Rapid Detection Solution

Specimen Type: **Plasma or Whole blood**

Time to Result: **3 hours**

Specimen Volume: **2 mL (Plasma), 5 mL (Whole blood)**

Shelf Life: **12 months**

Panel	One	Two	Three	Four
Targets	*Pseudomonas aeruginosa, Escherichia coli, Klebsiella spp., Acinetobacter calcoaceticus-baumannii complex*	*Staphylococcus aureus, Candida spp.*, Enterococcus spp.*, Streptococcus spp.**	*Stenotrophomonas maltophilia, Enterobacter cloacae complex, Proteus mirabilis, Coagulase-negative staphylococci*, Serratia marcescens*	*KPC, mec A, OXA-48, NDM / IMP, vanA / vanB*

* *This target covers multiple species within its detection scope. For more information, please refer to our Instructions for Use (IFU).*

Dynamic Monitoring |

Dynamic monitoring for pathogens and antibiotic resistance genes in patients could be used to guide timely and precise adjustment of antimicrobial prescription

Rapid and Efficient |

It only takes 3 hours from sample to result, which dramatically meets the demand of clinical rapid detection for sepsis

High Positive Rate |

Compared with blood culture, the consistency >90% and the positive rate increased by more than 200%(30% vs 10%)

Little Sample Required |

Only 2-5 mL peripheral blood is required

Product Name	Tests/Kit
Twenty Bloodstream Pathogenic Microorganisms and Drug Resistance Genes Detection Kit CE	48



IFD
Rapid Detection Solution

Specimen Type: **Sputum, Bronchoalveolar lavage fluid (BALF) and Blood**

Time to Result: **3 hours**

Specimen Volume: **0.5-3 mL (Sputum), 5 mL (BALF), 5 mL (Blood)**

Shelf Life: **6 months**

Targets				
*Aspergillus**	*Cryptococcus**	*Mucorales**	*Talaromyces marneffei*	*Pneumocystis jirovecii*

★ ***Aspergillus:****Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger, Aspergillus terreus and Aspergillus fumigatus complex*
★ ***Cryptococcus:****Cryptococcus neoformans, Cryptococcus gattii*
★ ***Mucorales:****Mucor: Mucor circinelloides, Mucor irregularis, Rhizopus: Rhizopus arrhizus, Rhizopus stolonifer, Rhizopus oligosporus， Rhizopus sexualis*

Single-tube, multiplexed digital PCR detection for invasive fungus, saving time and cost

Highly sensitive method for identifying pathogens responsible for IFD

A promising tool for early diagnosis and dynamic monitoring for IFD



Product Name	Tests/Kit
Invasive Fungal Nucleic Acid Detection Kit CE	48

Human Herpesvirus Rapid Detection Solution

Specimen Type: **Plasma or Whole blood**

Specimen Volume: **2 mL (Plasma), 5 mL (Whole blood)**

Time to Result: **3 hours**

Shelf Life: **6 months**

Targets				
HSV1&2	VZV	EBV	CMV	HHV-6

Rapid detection for patients with viral sepsis

Prognosis monitoring for patients with viral sepsis

Patient immune status assessment



Product Name	Tests/Kit	Product Content
Human Herpesvirus (Type 1-6) Digital PCR Detection Kit	48	1）With chips and detection reagents; 2）HSV1&2 / VZV / EBV / CMV / HHV-6

MTB/NTM Rapid Detection Solution

Specimen Type: **Sputum, Bronchoalveolar lavage fluid (BALF)**

Specimen Volume: **0.5-3 mL (Sputum), 5 mL (BALF)**

Time to Result: **3 hours**

Shelf Life: **6 months**

Targets	
Mycobacterium tuberculosis complex	Non-tuberculous Mycobacteri

High senstitivity to improve the decetion rate of pathogens

Improves therapeutic effect evaluation of smear negative PTB

Entiryly enclosed operation to prevent pollution

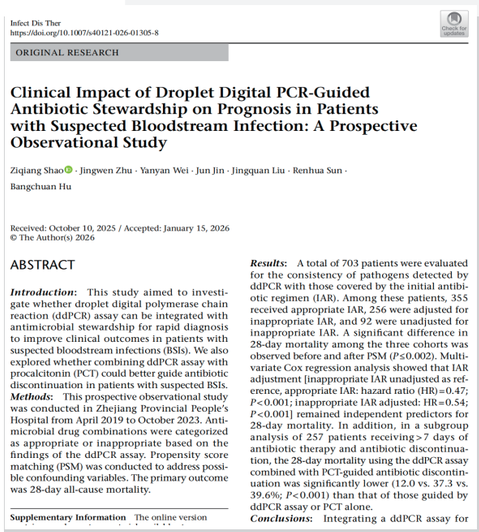


Coming Soon

Product Name	Tests/Kit	Product Content
MTB/NTM Digital PCR Detection Kit **Coming soon**	48	1）With chips and detection reagents; 2）*Mycobacterium tuberculosis* complex, non-tuberculous Mycobacterium

Application Cases

Sepsis clinical research based on the ddPCR solution



Infect Dis Ther
https://doi.org/10.1007/s40121-026-01305-8

ORIGINAL RESEARCH

Clinical Impact of Droplet Digital PCR-Guided Antibiotic Stewardship on Prognosis in Patients with Suspected Bloodstream Infection: A Prospective Observational Study

Ziqiang Shao · Jingwen Zhu · Yanyan Wei · Jun Jin · Jingquan Liu · Renhua Sun · Bangchuan Hu

Received: October 10, 2025 / Accepted: January 15, 2026
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ABSTRACT

***Introduction*:** This study aimed to investigate whether droplet digital polymerase chain reaction (ddPCR) assay can be integrated with antimicrobial stewardship for rapid diagnosis to improve clinical outcomes in patients with suspected bloodstream infections (BSIs). We also explored whether combining ddPCR assay with procalcitonin (PCT) could better guide antibiotic discontinuation in patients with suspected BSIs.
***Methods*:** This prospective observational study was conducted in Zhejiang Provincial People's Hospital from April 2019 to October 2023. Antimicrobial drug combinations were categorized as appropriate or inappropriate based on the findings of the ddPCR assay. Propensity score matching (PSM) was conducted to address possible confounding variables. The primary outcome was 28-day all-cause mortality.
***Results*:** A total of 703 patients were evaluated for the consistency of pathogens detected by ddPCR with those covered by the initial antibiotic regimen (IAR). Among these patients, 355 received appropriate IAR, 256 were adjusted for inappropriate IAR, and 92 were unadjusted for inappropriate IAR. A significant difference in 28-day mortality among the three cohorts was observed before and after PSM ($P \leq 0.002$). Multivariate Cox regression analysis showed that IAR adjustment [inappropriate IAR unadjusted as reference, appropriate IAR: hazard ratio (HR) = 0.47; $P < 0.001$; inappropriate IAR adjusted: HR = 0.54; $P < 0.001$] remained independent predictors for 28-day mortality. In addition, in a subgroup analysis of 257 patients receiving > 7 days of antibiotic therapy and antibiotic discontinuation, the 28-day mortality using the ddPCR assay combined with PCT-guided antibiotic discontinuation was significantly lower (12.0 vs. 37.3 vs. 39.6%; $P < 0.001$) than that of those guided by ddPCR assay or PCT alone.
***Conclusions*:** Integrating a ddPCR assay for

Supplementary Information The online version

Prognostic value of poly-microorganisms detected by droplet digital PCR and pathogen load kinetics in sepsis patients: a multi-center prospective cohort study, Microbiology Spectrum，2024

Background:
This study aimed to investi□gate whether ddPCR assay can be integrated with
antimicrobial stewardship for rapid diagnosis to improve clinical outcomes in patients with BSIs. We also explored whether combining ddPCR assay with
PCT could better guide antibiotic discontinuation in patients with suspected BSIs

Conclusion:

A total of 703 patients were evaluated for the consistency of pathogens detected by ddPCR with those covered by the initial antibi otic regimen (IAR).Among these patients, 355 received appropriate IAR, 256 were adjusted for inappropriate IAR, and 92 were unadjusted for inappropriate IAR. A significant difference in
28-day mortality among the three cohorts was observed before and after PSM. Multi variate Cox regression analysis showed that IAR
adjustment remained independent predictors for 28-day mortality. In addition, in a subgroup analysis of 257 patients receiving > 7 days of antibiotic therapy and antibiotic discontinuation, the 28-day mortality using the ddPCR assay combined with PCT-guided antibiotic discontin uation was significantly lower (12.0 vs. 37.3 vs. 39.6%; P < 0.001) than that of those guided by ddPCR assay or PCT alone.

IFD clinical research based on the ddPCR solution

Table 1. Target pathogens detection for ddPCR.

Fluorescence channel	Genus	Target pathogens
FAM	*Pneumocystis*	*Pneumocystis jiroveci*
ROX	*Aspergillus*	*Aspergillus fumigatus / Aspergillus flavus / Aspergillus niger / Aspergillus terreus / Aspergillus nidulans*
CY5	*Cryptococcus*	*Cryptococcus neoformans / Cryptococcus gattii*

Table 4. The inconsistent results between ddPCR and qPCR were verified by mNGS.

Specimen No.	ASP DNA for ddPCR (copies/test)	PJ DNA for ddPCR (copies/test)	ASP DNA for qPCR (Ct value)	PJ DNA for qPCR (Ct value)	mNGS
Patient 1	51	0	Undetermined	Undetermined	Aspergillus-positive
Patient 2	42	0	Undetermined	Undetermined	Aspergillus-positive
Patient 3	46.5	0	Undetermined	Undetermined	Aspergillus-positive
Patient 4	43.5	0	Undetermined	Undetermined	Aspergillus-positive
Patient 5	3.5	31.5	Undetermined	Undetermined	Pneumocystis-positive
Patient 6	2.75	27	Undetermined	Undetermined	Pneumocystis-positive

Result:

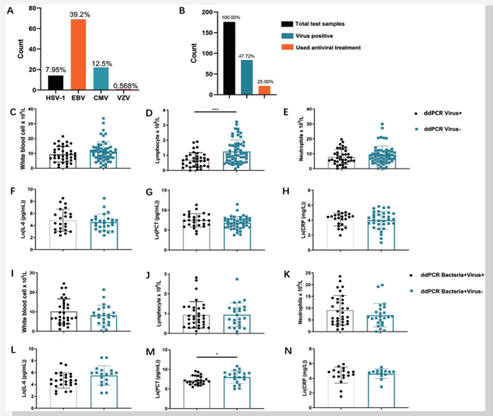
While the qPCR identified 16 (9.41%) cases of Aspergillus and 6 (3.53%) cases of Pneumocystis, ddPCR detected 20 (11.76%) Aspergillus cases and 8 (4.71%) Pneumocystis cases.

Conclusion:

These findings demonstrated that the ddPCR assay is a highly sensitive method for identifying pathogens responsible for invasive fungal pulmonary infections, and is a promising tool for early diagnosis.

Analytical and clinical validation of multiplex droplet digital PCR assay for detecting pathogenic fungal infection in lungs [J].Mycology. 2023

Human herpesvirus clinical research based on the ddPCR



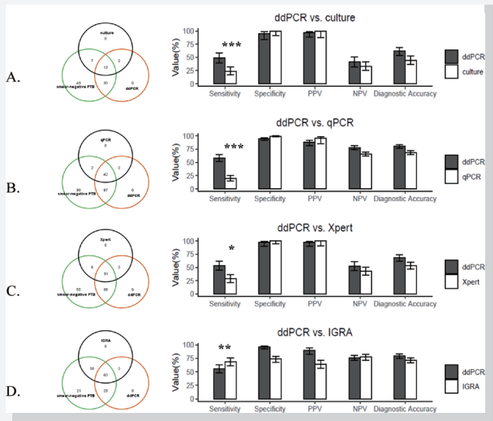
Background:
The present study undertook a comprehensive assessment of the diagnostic potential of ddPCR in detecting viremia. The investigation centered on 176 patients clinically diagnosed with BSI, delving into the presence of EBV, CMV, HSV and VZV within this cohort.

Result:

The detected frequencies encompassed 69 occurrences of EBV (39.20%), 22 occurrences of CMV (12.5%), 14 occurrences of HSV (7.95%), and 1 occurrence of VZV (0.568%).
A noteworthy 47.72% (84/176) of ddPCR analyses revealed viral positivity, with 20.45% (36/176) of these instanced indicating concurrent bacterial or fungal infections.

Reliability of Droplet Digital PCR Alone and in Combination with Interleukin-6 and Procalcitonin for Prognosis of Bloodstream Infection. Infection and Drug Resistance. 2024

MTB clinical research based on the ddPCR solution



Background:

ddPCR was compared with other conventional tuberculosis detection methods to explore the diagnostic performance of ddPCR in a quantitative study of *Mycobacterium tuberculosis*.

Result:

The sensitivity, specificity, PPV, NPV and accuracy of ddPCR were 53.08%, 97.10%, 97.18%, 52.34% and 68.34% respectively. The sensitivity of ddPCR was better than that of Xpert, culture and qPCR.

Conclusion:

ddPCR can improve the diagnosis of smear-negative pulmonary tuberculosis and assist in the evaluation of therapeutic effect.

A new droplet digital PCR assay: improving detection of paucibacillary smear-negative pulmonary tuberculosis[J]. International Journal of Infectious Diseases. 2022



Pilot Gene — Ordering Information

Instrument

Product Name	Model
Automated Nucleic Acid Detection Reaction Construction System CE	AP10
Automated Digital PCR System(7 channels) CE	AD3207
Integrated Digital PCR Instrument(7 channels) Coming soon	Pilot1200

Consumable and Pre-treatment reagents

Product Name	Unit Size
Microfluidic Chip CE	16 tests/plate × 3 boards
Digital PCR Universal Kit CE	48 tests/pack
Instrument Calibration and Verification Kit	40 Tests/Box
Droplet Digital PCR Reaction Premix （5X）	1 Tube/Unit
Droplet Digital PCR Reaction Premix （2X）	1 Tube/Unit
Nucleic Acid Extraction（plasma） CE	48 Tests/Box
Nucleic Acid Extraction（sputum, BALF） CE	48 Tests/Box

Detection Kits

Product Name	Tests/Kit	Test Item
MTB/NTM Digital PCR Detection Kit (Digital PCR Method) Coming soon	48	1) With chips and detection reagents; 2) *Mycobacterium tuberculosis* complex,non-tuberculous Mycobacterium
Invasive Fungal Nucleic Acid Detection Kit (Digital PCR Method) CE	48	1) With chips and detection reagents; 2) *Aspergillus (Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger, Aspergillus terreus and Aspergillus fumigatus complex);* *Cryptococcus (Cryptococcus neoformans, Cryptococcus gattii);* *Mucorales (Mucor: Mucor circinelloides, Mucor irregularis, Rhizopus: Rhizopus arrhizus, Rhizopus stolonifer, Rhizopus oligosporus， Rhizopus sexualis);* *Talaromyces marneffei;* *Pneumocystis jirovecii*
Human Herpesvirus (Type 1-6) Digital PCR Detection Kit	48	1) With chips and detection reagents; 2) HSV1&2 / VZV / EBV / CMV / HHV-6
Twenty Bloodstream Pathogenic Microorganisms and Drug Resistance Genes Detection Kit (Digital PCR Method) CE	48	1) With chips and detection reagents; 2) *Pseudomonas aeruginosa, Escherichia coli, Klebsiella pneumoniae, Acinetobacter baumannii;* *Staphylococcus aureus, Enterococcus(Enterococcus faecalis, Enterococcus faecium), Candida(Candida albicans, Candida glabrata, Candida parapsilosis, Candida tropicalis, Candida krusei), Streptococcus (Streptococcus pneumoniae, Streptococcus anginosus, Streptococcus pyogenes, Streptococcus mitis and Streptococcus agalactiae);* *Stenotrophomonas maltophilia, Enterobacter cloacae, Proteus mirabilis, Coagulase-negative staphylococci(Staphylococcus epidermidis, Staphylococcus hominis, Staphylococcus cephalae, Staphylococcus haemolyticus, Staphylococcus lugdunensis, Staphylococcus warneri), Serratia marcescens;* *KPC, mec A, OXA - 48, NDM/IMP, vanA/vanB*



Published Papers

Based on Pilot Gene Droplet Digital PCR Platform

Article: Clinical application evaluation of droplet digital PCR based on multi-point monitoring in the real world for patients with suspected bloodstream infection in the ICU
Journal: Int J Infect Dis
Publication Time: 2026 - 03

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Article: Clinical Utility of a Droplet Digital PCR-Based Assay for Quantitative Detection of Pneumocystis jirovecii in Suspected Fungal Pneumonia
Journal: Infect Drug Resist
Publication Time: 2026 - 02

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Article: Diagnostic Performance of Droplet Digital PCR for Detecting Pathogens and Resistance Genes in Patients with Suspected Bloodstream Infections
Journal: Infect Drug Resist
Publication Time: 2026 - 01

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Article: Diagnostic advantage of droplet digital PCR over blood culture in sepsis: a retrospective study of 115 patients
Journal: Eur J Med Res
Publication Time: 2026-01

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Article: Multiplex droplet digital polymerase chain reaction for rapid diagnosing suspected bloodstream infections in patients with hematologic malignancies
Journal: Transl Cancer Res
Publication Time: 2026-01

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Article: Clinical Impact of Droplet Digital PCR-Guided Antibiotic Stewardship on Prognosis in Patients with Suspected Bloodstream Infection: A Prospective Observational Study
Journal: Infectious Diseases and Therapy
Publication Time: 2026 - 01

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Article: Droplet Digital PCR Outperforms Conventional Methods for Early Relapse Prediction in AML/MDS Patients Posttransplantation
Journal: Transplantation and Cellular Therapy
Publication Time: 2025 - 12

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Article: The value of pathogen DNA load in evaluating the efficacy of bloodstream infection:a prospective observational study
Journal: BMC Infectious Diseases
Publication Time: 2025 - 12

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Article: Joint application of multiplex drop-offdigital PCR, droplet digital PCR, and metagenomic next-generation sequencing for the diagnosis of suspected infectious diseases: A retrospective cohort study
Journal: Journal of Intensive Medicine
Publication Time: 2025 - 10

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Article: Comparative analysis between digital PCR and blood culture for blood pathogen detection
Journal: Frontiers in Medicine
Publication Time: 2025-09

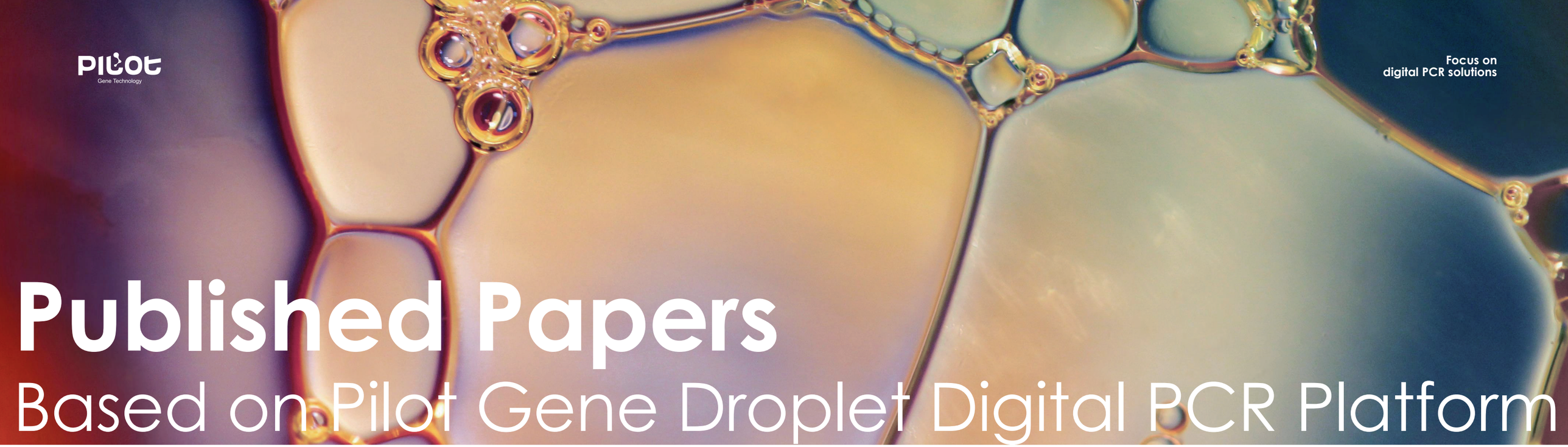
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Article: Clinical Evaluation of Digital PCR for Rapid Pathogen Detection in Suspected Bloodstream Infections
Journal: British Journal of Hospital Medicine
Publication Time: 2025-08

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Article: Comparison of microbial culture, metagenomic next-generation sequencing and droplet digital polymerase chain reaction methods for pathogen detection in patients with neurosurgical central nervous system infection
Journal: Frontiers in Cellular and Infection Microbiology
Publication Time: 2025-07

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Published Papers

Based on Pilot Gene Droplet Digital PCR Platform

Article: Plasma ddPCR for etiological diagnosis of focal bacterial infections
Journal: Frontiers in Medicine
Publication Time: 2025-07

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Article: Clinical evaluation of droplet digital PCR in suspected invasive pulmonary aspergillosis
Journal: Clinica Chimica Acta
Publication Time: 2025-05

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Article: Rapid molecular assays versus blood culture for bloodstream infections: a systematic review and meta-analysis
Journal: eClinicalMedicine
Publication Time: 2025-01

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Article: Droplet digital polymerase chain reaction (ddPCR) for bloodstream infections A meta-analysis
Journal: Journal of Infection
Publication Time: 2024-12

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Article: Plasma microbial cell-free DNA characterization in different populations based on the droplet digital PCR method a multi-cohort study
Journal: Frontiers in Microbiology
Publication Time: 2025-04

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Article: Plasma cell-free DNA Droplet Digital PCR provides rapid and efficient infectious microbiology diagnosis for febrile haematological patients
Journal: Frontiers in Cellular and Infection Microbiology
Publication Time: 2025-02

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Article: Modified lentiviral globin gene therapy for pediatric β⁰/β⁰ transfusion-dependent β-thalassemia: A single-center, single-arm pilot trial
Journal: Cell Stem Cell
Publication Time: 2024-07

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Article: Clinical evaluation of droplet digital PCR in the early identification of suspected sepsis patients in the emergency department: a prospective observational study
Journal: Frontiers in Cellular and Infection Microbiology
Publication Time: 2024-06

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Article: Clinical evaluation of a multiplex droplet digital PCR for diagnosing suspected bloodstream infections a prospective study
Journal: Frontiers in Cellular and Infection Microbiology
Publication Time: 2025-02

Scan the QR code to read the text

Article: Performance of ddPCR-GNB for microbial diagnosis of suspected bloodstream infection due to the four most common gram-negative bacteria a prospective, multicenter study
Journal: Microbiology Spectrum
Publication Time: 2025-02

Scan the QR code to read the text

Article: Prognostic value of poly-microorganisms detected by droplet digital PCR and pathogen load kinetics in sepsis patients: a multi-center prospective cohort study
Journal: Microbiology spectrum
Publication Time: 2024-05

Scan the QR code to read the text

Article: Sensitive and rapid identification of pathogens by droplet digital PCR in a cohort of septic patients: a prospective diagnostic study
Journal: Infectious Diseases
Publication Time: 2024-05

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