RainSure
SCIENTIFIC

RainSure Sepsis Pathogenic Microorganism Detection Kit (dPCR)

Digital PCR offers rapid and precise detection of microbial nucleic acids directly from whole blood, enabling earlier targeted treatment for sepsis. Compared with traditional blood culture methods, dPCR dramatically shortens turnaround time, improves pathogen detection rates, and brings a long-awaited breakthrough to sepsis diagnosis.

Sepsis: A critical global health challenge

A life-threatening organ dysfunction caused by a dysregulated host response to infection.

—— "Third International Consensus for Sepsis and Septic Shock (2016)"

01 High Incidence:

· Global: ~49 million cases/year (WHO, 2020)
· China: ~6.11 million cases/year
· US: More children die from sepsis than from cancer

02 High mortality:

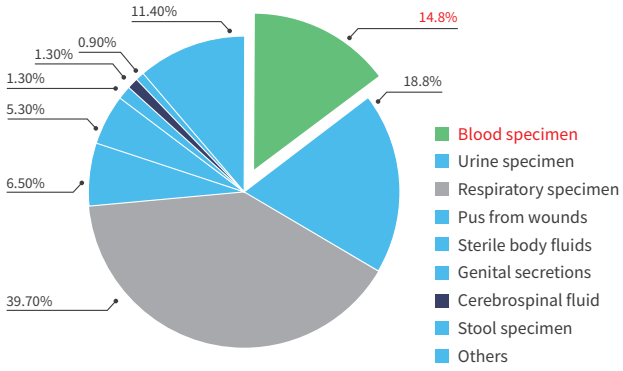
· Leading cause of death in U.S. hospitals
· Global deaths: ~11 million/year (WHO, 2020)
· ~30% case fatality rate; 16.7% develop cognitive dysfunction

03 Rapid onset:

· Mortality risk increases 58% every 6 hours of treatment delay
· A 2-day delay increases death risk 3.8×

04 Huge Clinical & Economic Burden

· ~14,000 amputations caused annually
· 60%+ survivors suffer long-term physical or cognitive decline
· AMR continues to rise, worsening prognosis
· > $36,000 USD median cost per patient (Sepsis Alliance, 2023)



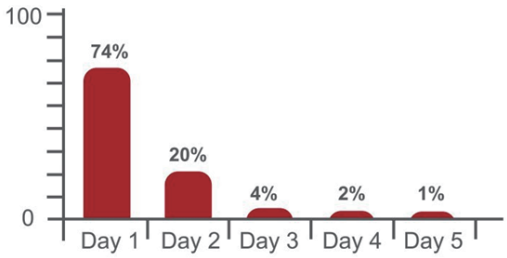
Blood specimens represent 14.8% of infectious sample testing

Challenges: Blood Culture (Gold Standard) — Detection rate <10%:

- Low bacterial load in early infection
- Low bacterial load in early infection
- Prior antibiotic use reduces culture positivity
- Long turnaround: 12 hours–5 days

Other Molecular Methods (qPCR/mNGS) — Limitations:

- Long processing time ~17–72 hours
- Less effective for polymicrobial infections
- Higher cost and access barriers



Clinical reality: <10% of patients receive precise antimicrobial guidance in early stages

Policy-driven, precision treatment is the future

Faster pathogen identification = Faster targeted therapy

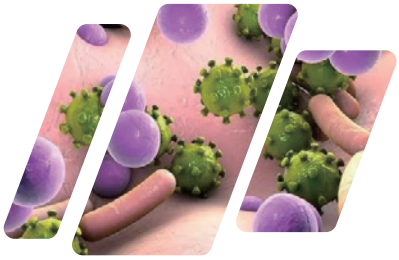
WHO Sepsis Guidelines (2024) — Early & Accurate Intervention

Recommend early antimicrobial therapy, ideally within 1 hour of recognition

- Empiric Therapy:
  Initiate broad-spectrum antibiotics immediately for suspected sepsis/septic shock.
- Targeted Therapy:
  Narrow selection once pathogens/resistance are identified.
- Continuous Re-evaluation:
  Adjust therapy based on culture/dPCR results and clinical evolution.
- De-escalation:
  Shorten antibiotic course after improvement or when no pathogen is detected.

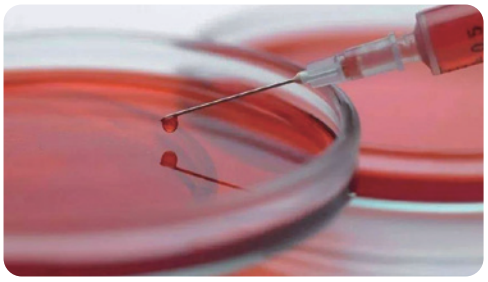
Rapid, Precise, and Cost-Effective

Sepsis kills when therapy is delayed. Conventional cultures take 48–72 hours; Rainsure dPCR detects pathogens within 5 hours, enabling targeted therapy that shortens ICU stay and improves outcomes. Studies show rapid molecular testing saves thousands dollars per patient when hospital stay drops by 4 days. Speed, precision, lower cost



Existing multiple methodologies cannot meet clinical needs

Although blood culture is considered the gold standard, it has several limitations.



Methodology	Detection time	Sensitivity	Specificity	Cost	Overall assceement
Blood culture	3-5 d	Low	High	Low	Technology is lagging behind and unable to meet clinical needs
mNGS	24 - 72 h	Low	Low	High	Severely affected by the host, poor sensitivity and specificity; poor timeliness; unable to detect drug-resistant genes
qPCR	17.2 h	Low	High	Low	Tests are conducted after blood culture, but results cannot be absolutely quantified
Digital PCR	3 - 5 h	High	High	Low	Absolutely Quantification High sensitivity + fast detection

Bloodstream infections: the core advantages of digital PCR – fast and accurate – meet the core clinical needs

Rainsure's Sepsis Pathogen Detection Kit (digital PCR)

Traditional blood culture + drug sensitivity

40 ml blood → Blood Collection → Blood Culture → Gram Stain → Isolation Culture → Pathogen Identification → Antimicrobial Sensitivity Test → Treatment

Average 57.4 hrs

Blood culture + FilmArray

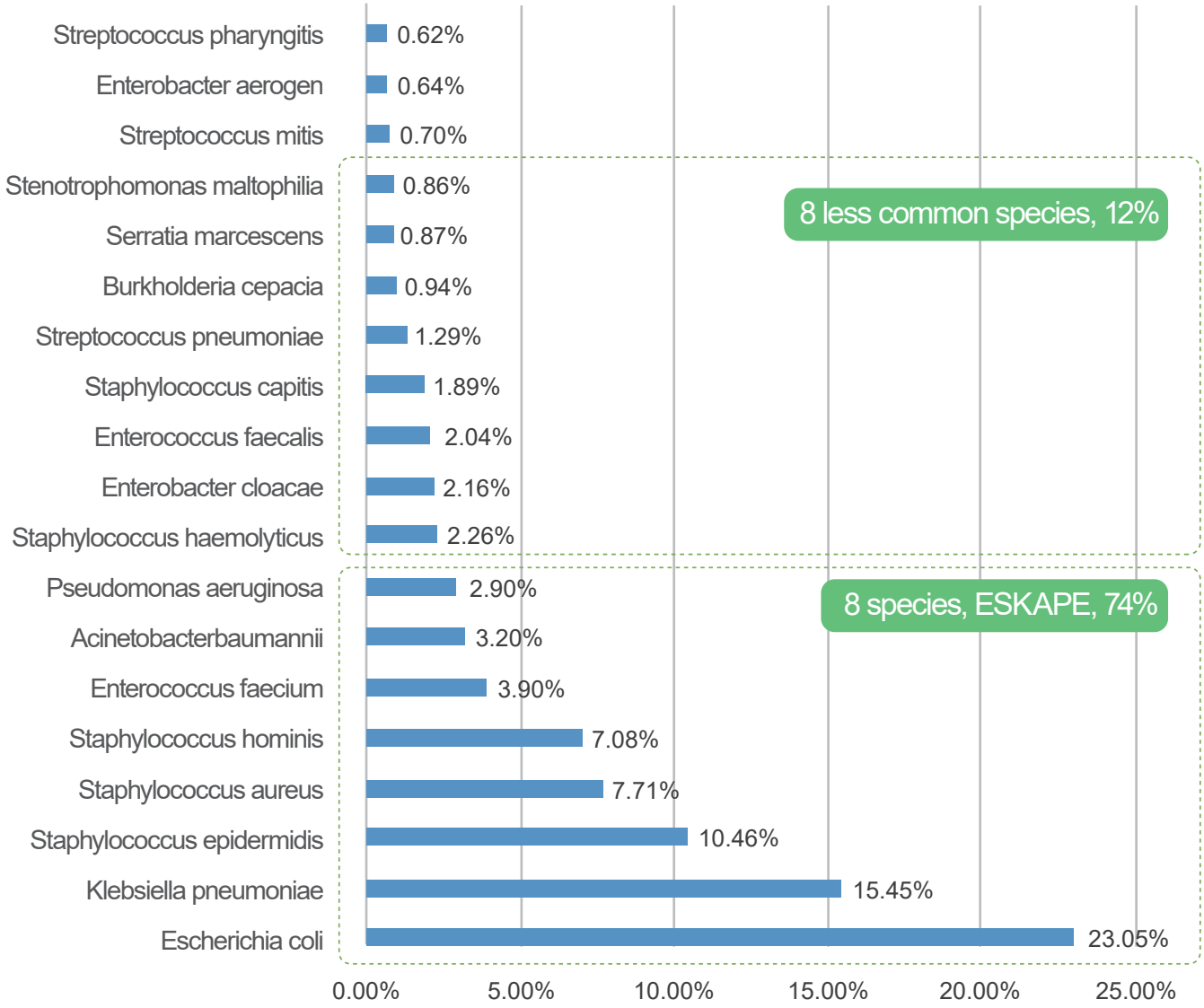
40 ml blood → Blood Collection → Blood Culture → Gene Detection → Treatment

Average 17.2 hrs

RainSure dPCR test

3 ml blood → Blood Collection → Sample Prep → Gene Detection → Treatment

Average 3-5 hrs



Clinical Bacterial Distribution (Top 19; China Drug-Resistant Surveillance, 2018)

From >57 hours to 3–5 hours — a step-change in clinical workflow efficiency.

Clinical Blood Sample Testing Results

Rapid and accurate pathogen identification is critical for early sepsis diagnosis and effective treatment — directly influencing survival outcomes.

Digital PCR (dPCR) provides **high sensitivity, culture-independent detection** and enables absolute quantification of sepsis-causing microorganisms.

A retrospective study using RainSure's bloodstream infection detection kit examined **69 ICU patients with suspected sepsis**. Results showed that **multiplex dPCR far outperformed blood culture** in identifying the 15 most common sepsis-related pathogens.

- 92 bacterial strains detected by dPCR
- Quantification range: 34 copies/mL → 105,800 copies/mL
- Overall detection rate: 73.91% (51/69) with dPCR
- Compared to blood culture: 27.53% (19/69)

dPCR identified nearly 3× more positive cases than blood culture in the same patient cohort.

These results demonstrate dPCR's strength in **early pathogen detection, higher sensitivity, and broader pathogen coverage**. RainSure's kit delivers **quantitative, multi-pathogen results within hours**, supporting timely clinical decisions and targeted antimicrobial therapy.

As a rapid and powerful diagnostic tool, digital PCR offers a major advancement for **sepsis diagnosis, antibiotic stewardship**, and **precision-guided treatment**.

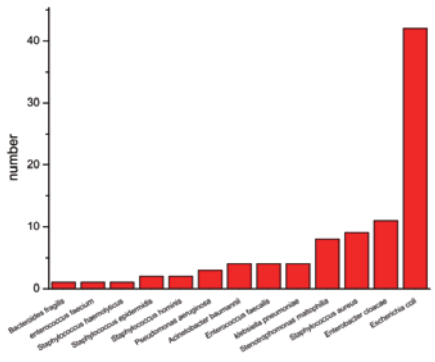


Fig. 1. Distribution of 13 bacteria species detected by dPCR.

Method	Positive	Negative	Total
dPCR	51	18	69
Blood Culture	19	50	69

RainSure dPCR detected 32 additional positive patients missed by blood culture.

Reference

Zhao Z, Wang Y, Kang Y, et al. *A retrospective study of the detection of sepsis pathogens comparing blood culture and culture-independent digital PCR*. **Heliyon. 2024;10(6):e27523. doi:10.1016/j.heliyon.2024.e27523**

RainSure Sepsis Pathogenic Microorganism Detection Kit (dPCR)

The first rapid, high-sensitivity whole-blood sepsis test.

Multiplex Detection Panels:

Panels 1 & 2 (CE-IVD Certified):

- Detect 21 key bloodstream pathogens
- 8 Gram-negative, 7 Gram-positive, 6 fungi)

Panel 3 (Research Use Only):

- Detects 10 additional sepsis-related pathogens

Panel 4 (Research Use Only):

- Detects 9 antimicrobial resistance genes (ARGs)

> Flexible panels for routine diagnosis and expanded research

		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*				
Panel 3	FAM&HEX	*Burkholderia cepacia*	*Citrobacter freundii*	*Streptococcus pyogenes*	*Morganella morganii*	*Staphylococcus haemolyticus*
	ROX&CY5	*Klebsiella aerogenes*	*Klebsiella oxytoca*	*Corynebacterium striatum*	*Proteus mirabilis*	*Moraxella catarrhalis*
Panel 4	FAM&HEX	OXA23	VanA	VanB		
	ROX&Cy5	OXA48	MecA	MecC	blaKPC	blaNDM
	Cy5.5	SmeDEF				

21 CE-IVD pathogens + resistance genes for research expansion

- From sample to answer in 5 hours
- Whole-blood test— no culture required*
- Absolute quantification for confident clinical decisions*

Fast Sensitive Pathogens Detection from Whole Blood

Clinically tested blood samples dPCR results are highly consistent with mNGS.

Sample name	mNGS sequencing	digital PCR	notes
1	K. pneumoniae	K. pneumoniae	consistent
2	K. pneumoniae	K. pneumoniae	consistent
3	K. pneumoniae	K. pneumoniae	consistent
4	K. pneumoniae	K. pneumoniae	consistent
5	K. pneumoniae	K. pneumoniae	consistent
6	K. pneumoniae	K. pneumoniae	consistent
7	B. fragilis	B. fragilis	consistent
8	K. pneumoniae	K. pneumoniae	consistent
9	K. pneumoniae	K. pneumoniae	consistent
10	Negative	Negative	consistent
11	E. faecium, B. fragilis	E. faecium, B. fragilis	consistent
12	K.pneumoniae, A. baumannii	K. pneumoniae, A. baumannii	consistent
13	B. fragilis，P. aeruginosa, K. pneumoniae	B. fragilis，P. aeruginosa, K. pneumoniae	consistent
14	S. maltophilia, S. aureus	S. maltophilia, S. aureus	consistent
15	K. pneumoniae	K. pneumoniae	consistent
16	P. aeruginosa	P. aeruginosa	consistent
17	P. aeruginosa，S. maltophilia	P. aeruginosa，S. maltophilia	consistent
18	P. aeruginosa，K. pneumoniae	P. aeruginosa，K. pneumoniae	consistent
19	K. pneumoniae	K. pneumoniae	consistent
20	K. pneumoniae	K. pneumoniae	consistent
21	A. baumannii，K. pneumoniae	A.baumannii，K. pneumoniae	consistent
22	K. pneumoniae	K. pneumoniae	consistent
23	K. pneumoniae	K. pneumoniae	consistent
24	Negative	Negative	consistent
25	S. pneumoniae	S. pneumoniae	consistent
26	Negative	Negative	consistent
27	A. baumannii	A. baumannii	consistent
28	A. baumannii，K. pneumoniae	A. baumannii,K. pneumoniae,S. aureus	partial consistent
29	P. aeruginosa，K. pneumoniae	K. pneumoniae	partial consistent
30	E. faecium, K. pneumoniae	K. pneumoniae	partial consistent
31	E. faecium, K. pneumoniae，B. fragilis	E. faecium, K. pneumoniae	partial consistent
32	E. coli	E. coli,S. maltophilia	partial consistent
33	E. faecium, ，B. fragilis	B. fragilis	partial consistent
34	Negative	Pseudomonas aeruginosa	ddPCR positive
35	Negative	S. aureus	ddPCR positive

Case Study 1: dPCR Results Align with Blood Culture, NGS, and Sputum M-ROSE Findings

Changes in the Course of Sepsis and dPCR Results in a Sepsis Patient

A 53-year-old male was transferred to the ICU on November 23, 2023 due to persistent vomiting after alcohol consumption for one week, accompanied by lethargy and limb tremors for 3 days. On admission, he was diagnosed with sepsis, pulmonary infection, and acute-on-chronic liver failure.

Diagnostic Timeline & Findings

◆ **Nov 21 – NGS** detected Enterococcus faecalis, Aspergillus fumigatus, human herpesvirus, and hepatitis B virus

◆ **Nov 23 – Sputum smear** revealed cocci and bacilli

◆ **Nov 24 – Sputum dPCR** detected Candida krusei, Staphylococcus epidermidis, Enterococcus faecium, Enterococcus faecalis, Stenotrophomonas maltophilia (bacilli), Candida parapsilosis

◆ **Nov 23 – Blood culture** later reported E. faecium (confirmed Nov 26)

Treatment initiated: voriconazole + amphotericin B nebulization + vancomycin

◆ **Nov 27 – Sputum culture** identified S. maltophilia and A. baumannii

→ **dPCR confirmed the same pathogens**

Treatment adjusted: amphotericin B + voriconazole + tigecycline + imipenem + minocycline

◆ **Dec 1 – M-ROSE sputum analysis** reported A. baumannii

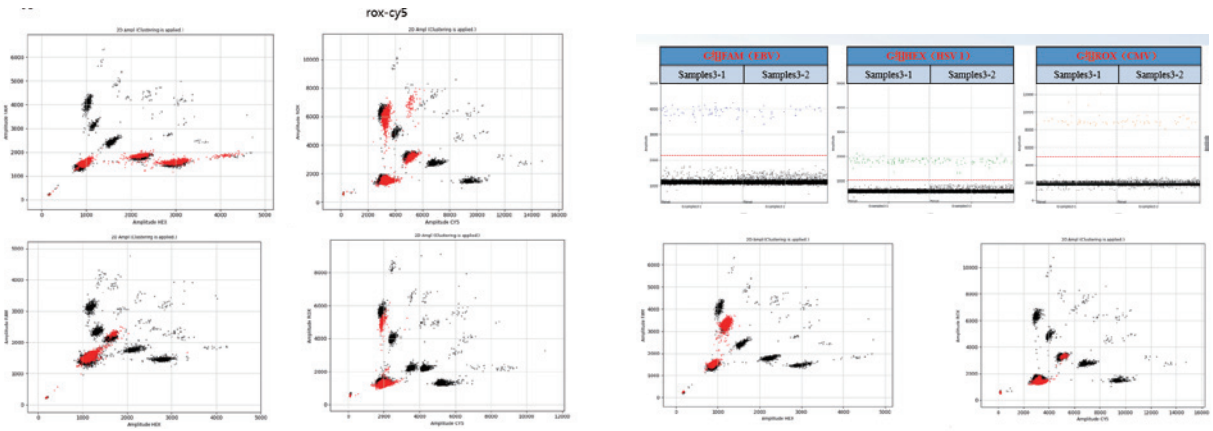
→ **Sputum dPCR also detected A. baumannii**

◆ **Dec 3 – Blood dPCR** detected **EBV, HSV-1, CMV, and hepatitis B virus**

Clinical Significance

The patient experienced **severe, recurrent mixed infections** that were difficult to control. **Repeated dPCR analyses consistently matched NGS, blood culture, and M-ROSE sputum results**, providing rapid pathogen identification throughout disease progression.

dPCR enabled dynamic monitoring of multiple pathogens with high sensitivity — supporting timely treatment adjustments during complex sepsis progression.



Case 2: Digital PCR Enables Dynamic Treatment Monitoring in Sepsis

dPCR tracks infection clearance in real-time — guiding confident treatment decisions.

A 67-year-old male was admitted on September 27, 2023 with sudden high fever for three days and one episode of unconsciousness. He was diagnosed with sepsis, CKD stage 5, and heart failure.

Diagnostic and Treatment Course

◆ **Sept 27**

- Sputum smear and **sputum dPCR both detected Pseudomonas aeruginosa and Candida albicans**
- **Treatment started:** tigecycline + cefoperazone/sulbactam + minocycline

◆ **Sept 28**

- Patient developed a low-grade fever (**37.5°C**)
- Sputum smear and **dPCR again confirmed P. aeruginosa**

◆ **Sept 29**

- Fever slightly increased to **37.6°C**
- dPCR continued to show **persistent P. aeruginosa infection**, indicating ongoing bacterial load

◆ **Oct 2**

- Patient became **afebrile**, with **declining WBCs and neutrophils**
- **Both sputum smear and dPCR results turned negative**, suggesting effective infection control

The patient's clinical condition stabilized and the family requested discharge.

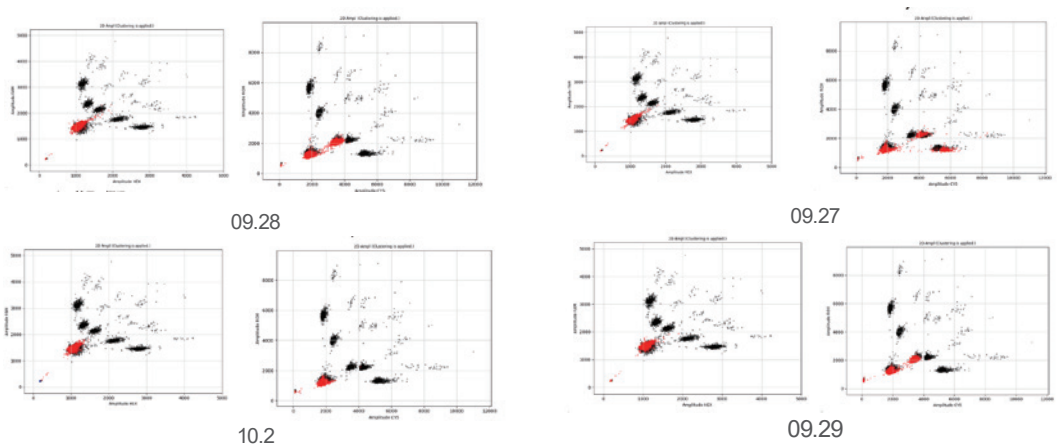
Clinical Significance

dPCR provided fast and reliable pathogen monitoring during treatment — detecting infection persistence and confirming recovery earlier and more consistently than conventional methods.

Real-time assessment of therapeutic response

Correlation with clinical symptoms and lab indicators

Rapid negative conversion demonstrated effective treatment



Case Study 3: dPCR Identifies Multi-Pathogen Sepsis Earlier Than Conventional Methods

A 72-year-old female was admitted on October 27, 2023, with 9 months of recurrent fever and 1 month of slurred speech. She was diagnosed with sepsis, pneumonia, respiratory failure, and systemic lupus erythematosus.

Diagnostic & Treatment Timeline

◆ **Oct 27 — Early Testing**

- Sputum dPCR detected: A. baumannii + S. maltophilia
- Sputum smear: only showed bacilli (missed co-infection)

→ dPCR revealed multi-pathogen infection earlier and more accurately

◆ **Oct 27 → Nov 1 — Treatment Initiated**

- Therapy: **cefoperazone/sulbactam**
- **Nov 1 sputum dPCR:** A. baumannii, S. maltophilia, + K. pneumoniae
- **Smear still only showed bacilli**

◆ **Nov 3 — Treatment Adjusted**

- **Meropenem introduced**
- **dPCR findings remained consistent**, showing persistent multi-infection

→ Provided clear evidence for continued targeted therapy

◆ **Nov 11 — Recovery Stage**

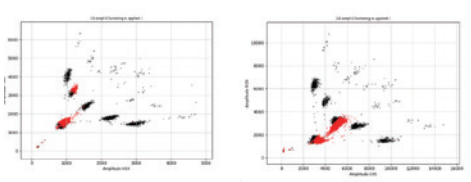
- Patient **afebrile**, ventilator removed
- **dPCR negative, smear negative**

→ Successful infection clearance confirmed

Clinical Significance

dPCR identified multiple pathogens earlier, tracked treatment response, and confirmed recovery — even when smear results lagged behind.

- Early multi-infection detection
- Higher pathogen sensitivity than smear
- Clear guidance for therapy adjustment
- Fast confirmation of infection clearance



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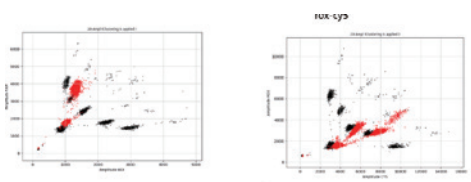

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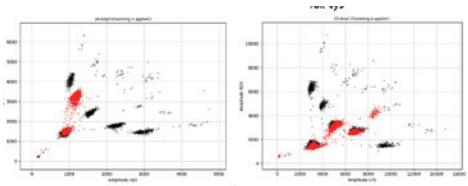

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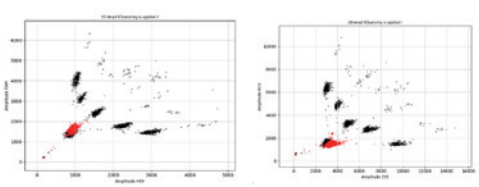

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info@rainsurebio.com
US: +1 617 803 3169
www.rainsurebio.com
