

# Clinical value of LightCycler® SeptiFast Test compared to conventional blood cultures for antimicrobial detection in post-surgical septic patients

<b>Submission date</b> 17/07/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 18/09/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/02/2016	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
EA1/043/09

## Study information

**Scientific Title**

Clinical value of LightCycler® SeptiFast Test compared to conventional blood cultures for antimicrobial detection in post-operative septic patients: a prospective, randomised single-centre trial

**Acronym**

SeptiFast

**Study objectives**

Antimicrobial detection in septic patients with the LightCycler® SeptiFast Test leads to accelerated administration of appropriate antibiotic therapy.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics Committee of Charité - University Medicine Berlin, 12/03/2009, ref: EA1/043/09

**Study design**

Prospective randomised controlled single-centre trial

**Primary study design**

Interventional

**Study type(s)**

Diagnostic

**Health condition(s) or problem(s) studied**

Sepsis due to abdominal infection or hospital acquired pneumonia

**Interventions**

Patients will be randomised in two groups. Samples for the LightCycler® SeptiFast Test will be taken in both groups parallel to conventional blood cultures. In group 1, the results of the LightCycler® SeptiFast Test will be made available for the treating physician, in group 2, results of the LightCycler® SeptiFast Test will be analysed retrospectively. Both groups will be assessed for changes in the initial empirical therapy (end of intervention), both groups will be followed up until resolution of all clinical signs of sepsis or discharge from the Intensive Care Unit (ICU) or for a maximum period of 30 days.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Frequency of changes of the initial antibiotic treatment related to diagnostic procedures and time until appropriate antibiotic treatment, assessed at the end of data collection.

**Key secondary outcome(s)**

1. Rate of patients with organisms detected by the LightCycler® SeptiFast Test compared to all patients with clinically confirmed sepsis
2. Rate of empirical treatment that was retrospectively confirmed to be appropriate
3. Number of days with antibiotic treatment
4. Decreasing severity of illness (Simplified Acute Physiology Score [SAPS], Sequential Organ Failure Assessment [SOFA], 28-item Therapeutic Intervention Score [TISS-28]) during treatment
5. Length of mechanical ventilation
6. Length of intensive care unit (ICU) stay
7. Length of hospital stay
8. Therapy costs

All assessed at the end of data collection.

### **Completion date**

30/04/2012

## **Eligibility**

### **Key inclusion criteria**

1. Post-surgical patients with suspected intra-abdominal infection or hospital acquired pneumonia
2. Suspected or known infection that clinically indicates investigation by blood cultures
3. Inclusion within 72 hours of diagnosis
4. Presence of at least two criteria for systemic inflammatory response syndrome (SIRS):
  - 4.1. Temperature greater than 38°C or less than 36°C
  - 4.2. Heart rate greater than 90 beats/minute
  - 4.3. Respiratory rate greater than 20 breaths/minute or partial pressure of carbon dioxide in arterial blood (PaCO<sub>2</sub>) less than 32 mmHg/4.3 kPa
  - 4.4. White blood cell count (WBC) greater than 12.000/mm<sup>3</sup> or less than 4.000/mm<sup>3</sup> or 10% immature
5. Age greater than 17 years, either sex

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

1. Moribund patients with expected survival less than 24 hours
2. Less than 18 years of age
3. Pregnancy
4. Known and confirmed organism responsible for infection
5. Participation in an other prospective clinical study during the passed 30 days
6. Consent of the patient or legal guardian cannot be obtained

**Date of first enrolment**

11/08/2010

**Date of final enrolment**

29/03/2012

## Locations

**Countries of recruitment**

Germany

**Study participating centre**

Department of Anaesthesiology and Intensive Care Medicine

Berlin

Germany

13353

## Sponsor information

**Organisation**

Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

**ROR**

<https://ror.org/001w7jn25>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Charité Universitätsmedizin Berlin

**Alternative Name(s)**

Medical School - Charité - University Medicine Berlin

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**  
Germany

## Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/06/2015		Yes	No