	S/W/M/B	Patient Trial Number					Last four digits of Patient ID					Date of Sample							Time of Sample				
Sample ID Number																							

Case Record Form (Final Version 1.1 - 29/07/2010)

The clinical diagnostic validity of rapid detection of healthcare-associated blood stream infection in intensive care using multi-pathogen real-time polymerase chain reaction (RT-PCR) technology

HTA project No: 08/13/16

Investigators:

Dr G Warhurst[1]
Consultant NHS Scientist
Tel: [redacted]

Dr PM Dark[2]
Senior Lecturer / Honorary Consultant Intensivist
Tel: [redacted]
Pager: [redacted]

Dr A Bentley[3]
Consultant in Respiratory & Critical Care Medicine
Tel: [redacted]

Dr J Eddleston[4]
Consultant in Intensive Care Medicine
Tel: [redacted]

Dr P Dean[5]
Consultant Anaesthesia and Intensive Care Medicine
Tel: [redacted]

[1] Clinical Sciences Building, Salford Royal NHS Foundation Trust, M6 8HD
[2] Intensive Care Unit, Salford Royal NHS Foundation Trust, M6 8HD
[3] Acute Intensive Care Unit, University Hospital of South Manchester M23 9LT
[4] Intensive Care Department, Central Manchester University Hospitals, M13 9WL
[5] Intensive Care Department, Royal Blackburn Hospital, BB2 3HH

NHS National Institute for Health Research

HTA

Salford Royal NHS NHS Foundation Trust

University Teaching Hospital

	S/W/M/B	Patient Trial Number					Last four digits of Patient ID					Date of Sample							Time of Sample			
Sample ID Number																						

Recruitment

Inclusion criteria

Patient must meet all the following criteria to be eligible for recruitment into the study

- Patient currently receiving critical care ☐
- Patient 16yrs or over ☐
- Suspected HCAI infection ☐
- Patient meets the SIRS Criteria ☐

Exclusion criteria:

Any patient must be excluded if they are any of the following

- Patient admitted to hospital < 48 hours ☐
- Patient under 16yrs ☐
- Patients is on care of the dying pathway ☐

SIRS Criteria

HR: > 90 bpm ☐

RR: ≥ 20 breaths/min ☐
or $PaCO_2$ < 4.3 kPa
or Mechanically ventilated

Temp: <36 or >38 ☐

WBC: ≥ 12,000 or ≤ 4,000 c/mm ☐
or > 10% bands

	S/W/M/B	Patient Trial Number					Last four digits of Patient ID					Date of Sample							Time of Sample			
Sample ID Number																						

Significant admission details & specific details regarding last 7 days

	S/W/M/B	Patient Trial Number		Last four digits of Patient ID		Date of Sample		Time of Sample
Sample ID Number								

Trial Sample Data

Reason for BC / significant events

	Date	**Site**	**Time**	**Designation**
Primary BC	/ /			
Primary PCR samples 4ml	/ /			
Secondary PCR Sample	/ /			
Whole Blood 1	/ /			
Whole Blood 2	/ /			
Secondary BC	/ /			

Sample Labelling

Primary PCR Sample ☐ Secondary PCR Sample ☐ Whole Blood ☐ Plasma ☐

Number of Plasma aliquots ☐ Date spun ☐☐☐☐☐☐ Time spun ☐☐☐☐

Sample transport

Transport arranged with trials office Date: ☐☐ / ☐☐ / ☐☐☐☐ **for:**
(Tel: [redacted])
Samples given to courier Date: ☐☐ / ☐☐ / ☐☐☐☐

Nurse: Recipient:

Signature: Signature:

	S/W/M/B	Patient Trial Number					Last four digits of Patient ID					Date of Sample							Time of Sample				
Sample ID Number																							

Assent/Consent

Assent Checklist

	Yes	No
Can patient consent at approach	☐	☐
Relative / Patients information sheet reviewed	☐	☐
Written and informed assent obtained	☐	☐
Copy of assent form given to relative/ patient	☐	☐*

* (If 'no' arrange for deferred assent from Independent mental capacity advocate)

Patient Consent obtained from survivors	☐	☐

Assent appointments & Notes

	S/W/M/B	Patient Trial Number					Last four digits of Patient ID					Date of Sample							Time of Sample			
Sample ID Number																						

Patient Observations Day Zero

Date: ☐☐ / ☐☐ / ☐☐☐☐

a) Patient's observations at initial sampling

		Supporting Treatments
WCC		
BP		
HR		
Temp		
FiO_2		
PaO_2		
CRP		

Critical Care minimum dataset derived score

Score	**0**	**1**	**2**	
	No support	**Basic Support**	**Advanced Support**	
Respiratory support				
Cardiovascular support				
Renal Support				
Neurological Support				
GI Support				
Dermatological Support				
Liver Support				**CCMDS Score**
SubTotal				=

	Yes	No		Yes	No
Indwelling urinary catheter in-situ	☐	☐	Urinary catheter within last 7 days	☐	☐
Other bladder instrumentation in-situ	☐	☐	Other bladder instrumentation with last 7days	☐	☐
Peripheral intravascular catheter in-situ	☐	☐	Peripheral intravascular catheter within last 7 days	☐	☐
Peripheral venous in-situ	☐	☐	Peripheral venous in-situ within last 7 days	☐	☐
Peripheral Arterial in-situ	☐	☐	Peripheral Arterial in-situ within last 7 days	☐	☐
Central intravascular catheter in-situ	☐	☐	Central intravascular catheter within last 7 days	☐	☐
Mechanical ventilation	☐	☐	Mechanical ventilation within last 7 days	☐	☐
Parenteral nutrition	☐	☐	Parenteral nutrition within last 7 days	☐	☐
Currently receiving systemic antibiotics	☐	☐	IV antibiotics within last 7 days	☐	☐
Picc Line	☐	☐	Picc Line within last 7 days	☐	☐
Surgery within **last 30 days**	☐	☐	Other invasive procedure within last 7 days	☐	☐

	S/W/M/B	Patient Trial Number					Last four digits of Patient ID					Date of Sample							Time of Sample			
Sample ID Number																						

Patient Observations Day Zero

Date: ☐☐ / ☐☐ / ☐☐☐☐

Clinical Pulmonary infection score calculation	
Temperature (°C)	Circle corresponding score
Between 36.5 and 38.4	0
Between 38.5 and 38.9	1
Less than 36 or greater than 39	2
Blood leukocytes, mm^3	
Between 4,000 and 11,000	0
Less than 4,000 or greater than 11,000	1
+ band forms > equal to 50%	1
Tracheal secretions	
Absence of tracheal secretions	0
Presence of non-purulent tracheal secretions	1
Presence of purulent tracheal secretions	2
Oxygenation: $Pa_{O2}/Fi_{O2,}$ KPa (**may need to ask Consultant or Registrar**)	
Greater than 32 or ARDS (ARDS defined as $Pa_{O2}/Fi_{O2,}$ or equal to 26.7, pulmonary arterial wedge pressure less than 18 mmHg and acute bilateral inflitrates)	0
Less than or equal to 32 and no ARDS	2
Pulmonary radiography (ask Consultant or Registrar on Unit)	
No infiltrate	0
Diffuse (or patchy infiltrate)	1
Localized infiltrate	2
Progression of pulmonary infiltrate	
No radiographic progression	0
Radiographic progression (after CHF and ARDS excluded)	2
Culture of Tracheal aspirate (can be scored at Clinical Adjudication)	
Pathogenic bacteria cultured in rare or light quantity or no growth	0
Pathogenic bacteria cultured in moderate or heavy quantity	1
Same pathogenic bacteria seen on Gram stain	1
Total	

Any relevant imaging for infection source identification?
Any relevant procedures for infection source identification?

	S/W/M/B	Patient Trial Number					Last four digits of Patient ID					Date of Sample							Time of Sample			
Sample ID Number																						

Patient Observations - Antibiotics (include previous 7 days)

Start date	Antibiotic	Reason for start	Dose	Route	Frequency	Stop date	Reason for stoppage

	S/W/M/B	Patient Trial Number					Last four digits of Patient ID					Date of Sample							Time of Sample			
Sample ID Number																						

Patient Observations- Microbiology results

Date sample collected	Sample	Site	Reason	Date of Results	Result

	S/W/M/B	Patient Trial Number					Last four digits of Patient ID					Date of Sample							Time of Sample			
Sample ID Number																						

Patient Surveillance

Study Day | 1

Date: ☐☐ / ☐☐ / ☐☐☐☐

Significant Clinical events

Observations		**Supporting Treatments**
WCC		
Temp		
HR		
BP		
FiO_2		
PaO_2		
CRP		

Critical Care minimum dataset derived score

Score	**0**	**1**	**2**	
	No support	**Basic Support**	**Advanced Support**	
Respiratory support				
Cardiovascular support				
Renal Support				
Neurological Support				
GI Support				
Dermatological Support				
Liver Support				**CCMDS Score**
SubTotal				=

	S/W/M/B	Patient Trial Number					Last four digits of Patient ID					Date of Sample							Time of Sample			
Sample ID Number																						

Patient Surveillance

Study Day 2

Date: ☐☐ / ☐☐ / ☐☐☐☐

Significant Clinical events

Observations		**Supporting Treatments**
WCC		
Temp		
HR		
BP		
FiO_2		
PaO_2		
CRP		

Critical Care minimum dataset derived score

Score	**0**	**1**	**2**		
	No support	**Basic Support**	**Advanced Support**		
Respiratory support					
Cardiovascular support					
Renal Support					
Neurological Support					
GI Support					
Dermatological Support					
Liver Support					**CCMDS Score**
SubTotal				=	

	S/W/M/B	Patient Trial Number					Last four digits of Patient ID					Date of Sample							Time of Sample			
Sample ID Number																						

Patient Surveillance

Study Day | 3

Date: ☐☐ / ☐☐ / ☐☐☐☐

Significant Clinical events

Observations		**Supporting Treatments**
WCC		
Temp		
HR		
BP		
FiO_2		
PaO_2		
CRP		

Critical Care minimum dataset derived score

Score	**0**	**1**	**2**	
	No support	**Basic Support**	**Advanced Support**	
Respiratory support				
Cardiovascular support				
Renal Support				
Neurological Support				
GI Support				
Dermatological Support				
Liver Support				**CCMDS Score**
SubTotal				=

	S/W/M/B	Patient Trial Number					Last four digits of Patient ID					Date of Sample							Time of Sample			
Sample ID Number																						

Patient Surveillance

Study Day | 4

Date: ☐☐ / ☐☐ / ☐☐☐☐

Significant Clinical events

Observations		**Supporting Treatments**
WCC		
Temp		
HR		
BP		
FiO_2		
PaO_2		
CRP		

Critical Care minimum dataset derived score

Score	**0**	**1**	**2**	
	No support	**Basic Support**	**Advanced Support**	
Respiratory support				
Cardiovascular support				
Renal Support				
Neurological Support				
GI Support				
Dermatological Support				
Liver Support				**CCMDS Score**
SubTotal				=

	S/W/M/B	Patient Trial Number					Last four digits of Patient ID					Date of Sample							Time of Sample			
Sample ID Number																						

Patient Surveillance

Study Day | 5

Date: ☐☐ / ☐☐ / ☐☐☐☐

Significant Clinical events

Observations		Supporting Treatments
WCC		
Temp		
HR		
BP		
FiO_2		
PaO_2		
CRP		

Critical Care minimum dataset derived score

Score	0	1	2	
	No support	**Basic Support**	**Advanced Support**	
Respiratory support				
Cardiovascular support				
Renal Support				
Neurological Support				
GI Support				
Dermatological Support				
Liver Support				**CCMDS Score**
SubTotal				=

	S/W/M/B	Patient Trial Number					Last four digits of Patient ID					Date of Sample							Time of Sample			
Sample ID Number																						

Patient Surveillance

Study Day | 6

Date: ☐☐ / ☐☐ / ☐☐☐☐

Significant Clinical events

Observations		**Supporting Treatments**
WCC		
Temp		
HR		
BP		
FiO_2		
PaO_2		
CRP		

Critical Care minimum dataset derived score

Score	**0**	**1**	**2**	
	No support	**Basic Support**	**Advanced Support**	
Respiratory support				
Cardiovascular support				
Renal Support				
Neurological Support				
GI Support				
Dermatological Support				
Liver Support				**CCMDS Score**
SubTotal				=

	S/W/M/B	Patient Trial Number					Last four digits of Patient ID					Date of Sample							Time of Sample			
Sample ID Number																						

Patient Surveillance Summary

Patient Outcome

- Critical care length of stay (total) on this admission
- 28 day survival Y/
- Survival to hospital discharge Y/

Any Study related adverse or critical incidences	No		…if No this form is now ready for clinical sign off
	Yes		…if yes Detail below

Signature of Completion

All relevant sections of CRF is complete
Any loose sheets stapled to rear of CRF
Emailed trials office to signify completion

Name: _____

Signature: _____

	S/W/M/B	Patient Trial Number					Last four digits of Patient ID					Date of Sample							Time of Sample			
Sample ID Number																						

Summary of definitions of levels of organs support in the critical care minimum data set

Organ System	Definition of level support
Basic Respiratory	• > 50% oxygen delivered by face mask • Close observation due to the potential for acute deterioration • Physiotherapy or suction to clear secretions at least two hourly • Patients recently extubated after a prolonged period of intubation and mechanical ventilation • Mask CPAP or non-invasive ventilation. • Patients who are intubated to protect the airway but needing no ventilatory support and who are otherwise stable
Advanced Respiratory	• Invasive mechanical ventilatory support • Extracorporeal respiratory support
Basic Cardiovascular	• Treatment of circulatory instability due to hypovolaemia • Use of a CVP line for basic monitoring or central access • Use of an arterial line for basic monitoring or sampling • Single intravenous vasoactive • Intravenous drugs to control cardiac arrhythmias • Non-invasive measurement of cardiac
Advanced cardiovascular	• Multiple intravenous vasoactive and/or rhythm controlling drugs • Patients resuscitated after cardiac arrest where intensive therapy is considered clinically appropriate. • Observation of cardiac output and derived • Intra aortic balloon pumping. • Temporary cardiac • Placement of a gastrointestinal tonometer
Renal	• Acute renal replacement therapy
Neurological	• Central nervous system depression sufficient to prejudice the airway and protective reflexes • Invasive neurological monitoring • Severely agitated or epileptic patients requiring constant nursing attention and/or heavy sedation
Gastrointestinal	• Feeding with parenteral or enteral nutrition
Dermatological	• Patients with major skin rashes, exfoliation or burns • Use of multiple, large trauma dressings • Use of complex dressings
Liver	• Extracorporeal liver replacement device

	S/W/M/B	Patient Trial Number		Last four digits of Patient ID		Date of Sample		Time of Sample
Sample ID Number								

-Use handbook definitions please-
Clinical Adjudication (Within previous 7 days from sample date)

Bloodstream infection (BSI) No ☐ Yes ☐

	Yes	No
Picc Line Related	☐	☐
Central line related	☐	☐
Peripheral line related	☐	☐
Cannula Related	☐	☐
Arterial line related	☐	☐

Pneumonia No ☐ Yes ☐

Type of pneumonia

Clinically defined pneumonia	☐	Secondary bloodstream infection	☐ ☐
Pneumonia with specific laboratory findings	☐		
Pneumonia in immunocompromised patients	☐	Ventilator related pneumonia	☐ ☐

Urinary tract infection No ☐ Yes ☐

Type of UTI

Symptomatic urinary tract infection	☐	Secondary bloodstream infection	☐ ☐
Asymptomatic bacteraemia	☐		
Other infection of the urinary tract	☐	Catheter related	☐ ☐

Surgical site infection No ☐ Yes ☐

Type of SSI

Superficial incisional	☐	Secondary bloodstream infection	☐ ☐
Deep incisional	☐		
Organ/Space	☐	Procedure category (Appendix)	☐☐

	S/W/M/B	Patient Trial Number					Last four digits of Patient ID					Date of Sample							Time of Sample			
Sample ID Number																						

-Use handbook definitions please-

Other healthcare associated infections (within previous 7 days from sample date)

				Device/procedure related		**Secondary BSI**	
	No	Yes		Yes	No	Yes	No
Bone and Joint	☐	☐	→	☐	☐	☐	☐
Central nervous system	☐	☐	→	☐	☐	☐	☐
Cardiovascular system	☐	☐	→	☐	☐	☐	☐
Eyes, ENT or Mouth	☐	☐	→	☐	☐	☐	☐
Gastrointestinal system	☐	☐	→	☐	☐	☐	☐
Reproductive tract	☐	☐	→	☐	☐	☐	☐
Skin & Soft tissue	☐	☐	→	☐	☐	☐	☐
Systemic infection	☐	☐	→	☐	☐	☐	☐
Lower respiratory tract –not pneumonia	☐	☐	→	☐	☐	☐	☐

	S/W/M/B	Patient Trial Number		Last four digits of Patient ID		Date of Sample		Time of Sample
Sample ID Number								

-Use handbook definitions please-
Clinical Adjudication (sample day only)

Bloodstream infection (BSI) — No ☐ Yes ☐

	Yes	No
Picc Line Related	☐	☐
Central line related	☐	☐
Peripheral line related	☐	☐
Cannula Related	☐	☐
Arterial line related	☐	☐

Pneumonia — No ☐ Yes ☐

Type of pneumonia

Clinically defined pneumonia	☐
Pneumonia with specific laboratory findings	☐
Pneumonia in immunocompromised patients	☐

	Yes	No
Secondary bloodstream infection	☐	☐
Ventilator related pneumonia	☐	☐

Urinary tract infection — No ☐ Yes ☐

Type of UTI

Symptomatic urinary tract infection	☐
Asymptomatic bacteraemia	☐
Other infection of the urinary tract	☐

	Yes	No
Secondary bloodstream infection	☐	☐
Catheter related	☐	☐

Surgical site infection — No ☐ Yes ☐

Type of SSI

Superficial incisional	☐
Deep incisional	☐
Organ/Space	☐

	Yes	No
Secondary bloodstream infection	☐	☐
Procedure category (Appendix)	☐☐	

	S/W/M/B	Patient Trial Number					Last four digits of Patient ID					Date of Sample							Time of Sample			
Sample ID Number																						

-Use handbook definitions please-

Other healthcare associated infections (sample day only)

				Device/procedure related		**Secondary BSI**	
	No	Yes		Yes	No	Yes	No
Bone and Joint	☐	☐	→	☐	☐	☐	☐
Central nervous system	☐	☐	→	☐	☐	☐	☐
Cardiovascular system	☐	☐	→	☐	☐	☐	☐
Eyes, ENT or Mouth	☐	☐	→	☐	☐	☐	☐
Gastrointestinal system	☐	☐	→	☐	☐	☐	☐
Reproductive tract	☐	☐	→	☐	☐	☐	☐
Skin & Soft tissue	☐	☐	→	☐	☐	☐	☐
Systemic infection	☐	☐	→	☐	☐	☐	☐
Lower respiratory tract –not pneumonia	☐	☐	→	☐	☐	☐	☐

	S/W/M/B	Patient Trial Number		Last four digits of Patient ID		Date of Sample		Time of Sample
Sample ID Number								

-Use handbook definitions please-

Clinical Adjudication (within 7 days following sample day)

Bloodstream infection (BSI) No ☐ Yes ☐

Yes ☐ No ☐ Picc Line Related

Yes ☐ No ☐ Central line related

Yes ☐ No ☐ Peripheral line related

Yes ☐ No ☐ Cannula Related

Yes ☐ No ☐ Arterial line related

Pneumonia No ☐ Yes ☐

Type of pneumonia

Clinically defined pneumonia ☐

Pneumonia with specific laboratory findings ☐

Pneumonia in immunocompromised patients ☐

Yes ☐ No ☐ Secondary bloodstream infection

Yes ☐ No ☐ Ventilator related pneumonia

Urinary tract infection No ☐ Yes ☐

Type of UTI

Symptomatic urinary tract infection ☐

Asymptomatic bacteraemia ☐

Other infection of the urinary tract ☐

Yes ☐ No ☐ Secondary bloodstream infection

Yes ☐ No ☐ Catheter related

Surgical site infection No ☐ Yes ☐

Type of SSI

Superficial incisional ☐

Deep incisional ☐

Organ/Space ☐

Yes ☐ No ☐ Secondary bloodstream infection

Procedure category (Appendix) ☐☐

	S/W/M/B	Patient Trial Number					Last four digits of Patient ID					Date of Sample							Time of Sample			
Sample ID Number																						

-Use handbook definitions please-

Other healthcare associated infections (within 7 days following sample day)

				Device/procedure related		**Secondary BSI**	
	No	Yes		Yes	No	Yes	No
Bone and Joint	☐	☐	→	☐	☐	☐	☐
Central nervous system	☐	☐	→	☐	☐	☐	☐
Cardiovascular system	☐	☐	→	☐	☐	☐	☐
Eyes, ENT or Mouth	☐	☐	→	☐	☐	☐	☐
Gastrointestinal system	☐	☐	→	☐	☐	☐	☐
Reproductive tract	☐	☐	→	☐	☐	☐	☐
Skin & Soft tissue	☐	☐	→	☐	☐	☐	☐
Systemic infection	☐	☐	→	☐	☐	☐	☐
Lower respiratory tract –not pneumonia	☐	☐	→	☐	☐	☐	☐

	S/W/M/B	Patient Trial Number					Last four digits of Patient ID					Date of Sample							Time of Sample				
Sample ID Number																							

Adjudication/Clinical Summary

Summary notes on adjudication

Adjudicator 1:_____ Adjudicator 2: _____

Signature: _____ Signature:_____