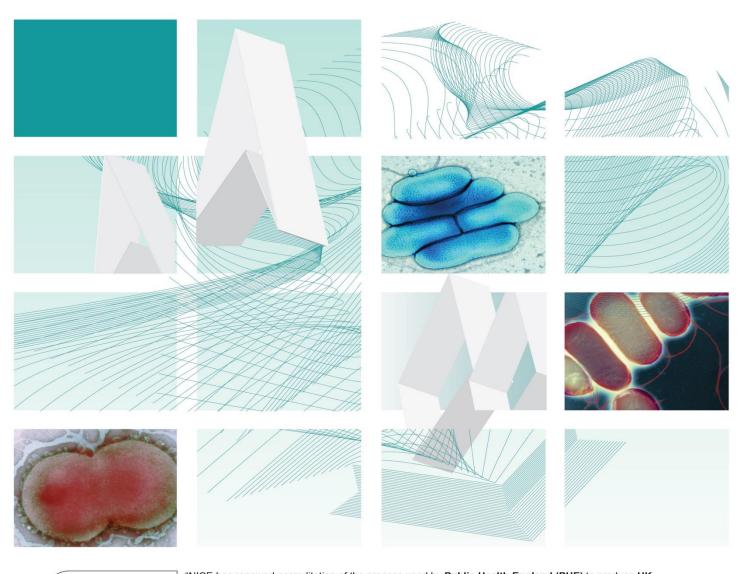


UK Standards for Microbiology Investigations

Abdominal organ transport fluid testing





"NICE has renewed accreditation of the process used by Public Health England (PHE) to produce UK Standards for Microbiology Investigations. The renewed accreditation is valid until 30 June 2021 and applies to guidance produced using the processes described in UK standards for microbiology investigations (UKSMIs) Development process, S9365', 2016. The original accreditation term began in July 2011."

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Amendment table

Each UK SMI method has an individual record of amendments. The current amendments are listed on this page. The amendment history is available from standards@phe.gov.uk.

New or revised documents should be controlled within the laboratory in accordance with the local quality management system.

Amendment number/date	-/29.01.20
Issue number discarded	-
Insert issue number	1
Anticipated next review date*	29.01.23
Section(s) involved	Amendment

^{*}Reviews can be extended up to five years subject to resources available.

1. General information

View general information related to UK SMIs.

2. Scientific information

View scientific information related to UK SMIs.

3. Scope of document

This UK SMI describes the examination of abdominal organ transport fluid (OTF) relating to abdominal organs destined for transplantation. It details the methodology for isolation and characterisation of potentially significant bacterial and fungal pathogens.

Isolation of microorganisms should not automatically trigger treatment. Treatment and management of positive results is a matter of clinical decision process and is outside the scope of this document.

This UK SMI should be used in conjunction with other relevant UK SMIs.

4. Background

Infectious complications are amongst the major causes of morbidity and mortality in patients undergoing solid organ transplantation, with proven donor-derived transmission of infection being an infrequent event. Contamination of the graft with subsequent recovery of micro-organisms from the OTF may represent a source of early post-surgical infection in transplant recipients. The OTF used to preserve the graft offers favourable conditions in which micro-organisms can survive; contamination may occur at different stages between retrieval and transplantation, including during multi-organ retrieval, back table manipulation of the organ in theatre, packaging and removal of the organ from the transport container.

The true clinical impact of microbiological contamination in abdominal organ transplantation remains unresolved, with isolation rates varying widely, from very low to up to $40\%^{1,2}$. Whilst positive culture results seem to be infrequently linked to infectious complications with the same organism in recipients, well documented cases have been reported where significant recipient morbidity has ensued, particularly in the case of *Candida* spp²⁻⁶.

The Organ Donation and Transplantation (ODT) directorate of NHS Blood and Transplant (NHSBT) is responsible for the procurement, characterisation and offering of organs from deceased donors in the UK. In 2017 it conducted a survey of microbiological practices in relation to microbiological culture of OTF amongst UK transplant centres, with a 52% response rate. The majority of responders (78.6%) indicated that microbiological culture of OTF has the potential to provide relevant information for patient management and that this information should be shared amongst centres receiving an organ from the same donor.

The audit also revealed that in the absence of guidance, there is wide variation in the methodology used and participants were keen to learn from the experiences of other

centres. Responders agreed that harmonisation of microbiological practices, including appropriate reporting of results, was highly desirable.

This UK Standard for Microbiology Investigations aims to address those gaps by developing an agreed methodology for culture of OTF, including the reporting of results, so as to contribute to improved and safer practices in abdominal organ transplantation. It does not prescribe treatment of isolates as a result of using this methodology.

It is hoped that with the harmonization of methodologies and practices, data can be collected to understand better and evaluate the role of microbiological culture of OTF.

5. Safety considerations

Containment Level 2.

6. Investigation

6.1 Culture of abdominal organ transport fluid

6.1.1 Specimen type

Abdominal organ transport fluid also known as perfusion fluid or transport perfusion fluid, is used to submerge abdominal organs during transportation between donor hospital and recipient transplant centres.

Abdominal organs (liver, pancreas and kidney) are packaged and cold stored by submersion in transport fluid. In the UK, two OTF types are used: University of Wisconsin (UW) solution and Soltran solution.

6.1.2 Pre-laboratory processes

Specimen collection, transport and storage⁷:

Type of specimen and sample registration

Samples should be clearly labelled as 'Organ Transport Fluid' and must be registered on the laboratory information management system under this specific specimen type.

Samples need to be logged and processed following local procedures in a manner that will allow the ODT Hub coordinator to link the results between donor(s) and recipient(s).

Optimal time and method of collection

For safety considerations refer to Section 5.

Collect specimen from fluid surrounding the organ immediately after the organ has been lifted from the transport bag for implantation.

Collect specimen into appropriate CE marked leak proof containers and place in sealed plastic bags.

Volume of material to submit for analysis⁸

The volume of transport fluid used differs depending on the size of organ being transplanted. A minimum of approximately 5% of the total volume in the organ transport bag should be used for analysis (ideally a minimum of 20mL).

Optimal transport and storage conditions

If not processed immediately following collection, specimens should be refrigerated and processed within 18 hours.

In accordance with ISO15189 standards, laboratories are responsible for monitoring the sample journey from collection through to commencement of processing to ensure specimen integrity and that samples are received within clinically-meaningful time-frames⁸.

6.1.3 Laboratory processes (analytical stage)

Culture

Specimen processing

Centrifuge a minimum of 20mL of specimen (see 6.1) and use for inoculation of media plates:

- centrifuge in a sterile, capped, conical-bottomed container at 1200xg for 5mins
- remove all but the last 0.5mL of the supernatant using a sterile pipette
- re-suspend the deposit in the remaining fluid
- microscopy is not recommended
- inoculate each agar plate with the centrifuged deposit (see Q 5 Inoculation of culture media for bacteriology) using a sterile pipette
- for the isolation of individual colonies, spread inoculum with a sterile loop

Table 1: Culture media, conditions and organisms

Standard media	Incubation			Cultures read	Target organism(s)	
media	Temp °C	Atmosphere	Time	reau		
Blood agar	35-37	5-10% CO ₂	40-48 hrs	16-24 hours	Any organism	
				and		
				40-48 hours		
Sabouraud agar	28-30	Air	5 days	Day 2	Moulds and Yeasts	
				and		
				Day 5		
CLED	35-37	Air	16-24 hours	≥16hr	Enterobacterales	

Identification:

Refer to individual UK SMIs for organism identification.

Minimum level of identification in the laboratory

All organisms should be identified to species level.

Mixed growth is not common.

Matrix-assisted laser desorption-ionization time-of-flight mass spectrometry (MALDITOF MS) has been shown to be a rapid and powerful identification tool for cultured isolates because of its reproducibility, speed and sensitivity of analysis and is available in most laboratories. Refer to UK SMI TP 40 - MALDI TOF MS test procedure.

6.1.4 Post-laboratory processes (reporting procedures)

Routine local laboratory reporting

Report:

- · Clinically significant organisms with antimicrobial susceptibility results
- No growth of clinically significant organisms*
- No growth

Communicating results to ODT

The communication process below is in addition to the routine reporting and communication of results between the laboratory and clinical teams, according to local protocols.

Local protocols should ensure that results are reported to and received from the ODT Hub with the timely involvement of clinical transplant and microbiology specialists.

It is acknowledged that local algorithms will determine whether communication of results to ODT Hub is done by the transplant team or the microbiology team.

Table 2: Organisms to be communicated to ODT Hub

Organism	When to send the Rapid Alert
Candida spp. Filamentous fungi Staphylococcus aureus Group A Streptococci	Communicate these organisms as soon as they are identified; antibiotic sensitivities to follow, when available
Enterobacterales Enterococcus spp. Pseudomonas aeruginosa Pyogenic streptococci (other than Group A)	Communicate organism ID and sensitivities together when both are finalised
Other organisms considered locally to be of potential clinical significance	At local laboratory discretion
No growth of clinically significant organisms' or 'No Growth'	Not to be communicated to ODT Hub

^{*} Identification should not be reported for organisms of no clinical significance.

Mechanism of communication with ODT Hub

Refer to 'Appendix - ODT reporting form' for communication of results to ODT Hub, as detailed in Table 2 above.

All reports received by the ODT hub are forwarded promptly to all other transplant centres where organs from the common donors have been transplanted. These do not undergo clinical vetting and are cascaded immediately, for consideration by the recipient transplant centres.

7. Antimicrobial susceptibly testing

Refer to **EUCAST** guidelines.

Choice of agents to be tested for susceptibility should follow laboratory practice for isolates obtained from sterile sites.

Isolates requiring antimicrobial susceptibility testing

- Candida spp.
- Enterobacterales
- Enterococcus spp.
- Filamentous fungi
- Pseudomonas aeruginosa
- Group A streptococci
- Pyogenic streptococci (other than Group A)
- Staphylococcus aureus
- Other organisms considered locally to be potentially clinically significant

This UK SMI does not recommend susceptibility testing of isolates not deemed to be clinically significant.

8. Referral for incident investigations

As part of investigations, including possible transmission events and clinical incidents, laboratories are requested to assist the organ procurement organisation (ODT) by referring samples or isolates on request.

9. Referral to reference laboratories

For information on the tests offered, turnaround times, transport procedure and the other requirements of the reference laboratory <u>click here for user manuals and request</u> forms.

Organisms with unusual or unexpected resistance, or associated with a laboratory or clinical problem, or anomaly that requires elucidation should be sent to the appropriate reference laboratory.

Contact appropriate devolved national reference laboratory for information on the tests available, turnaround times, transport procedure and any other requirements for sample submission:

England and Wales

https://www.gov.uk/specialist-and-reference-microbiology-laboratory-tests-and-services

Scotland

http://www.hps.scot.nhs.uk/reflab/index.aspx

Northern Ireland

http://www.publichealth.hscni.net/directorate-public-health/health-protection

Notes: In case of sending away to laboratories for processing, ensure that specimen is placed in appropriate package and transported accordingly.

Appendix: ODT rapid alert form

				ALERT – ID & Se Organ Transport		lt
Donor Information	OI	OT Number			Case number	
	Fo	orename			Date of Birth	
	Sı	ırname		,	1	
uid Result	fron (for e	Which organ was transport fluid from: (for example left kidney, liver, pancreas) Screenshot or copy of report attached? (please delete as appropriate): Y/N (If 'N', please fill in details of isolate below)				
sport FI	Name of Organism(s)					
Organ Transport Fluid Result	Antibiotic sensitivities (Organism with asterisk on list below – sensitivities to follow)			No need to fill in if attaching repo	rt	
no	gy	Laboratory				
rmatic	Microbiology	Contact name/rol	е			
Contact Details for Further Information	Micr	Phone number				
	Transplant team	RCPOC name/rol	е			
		Phone number				
		Name and role of person completing form				
ŭ		Date of completion	on			

Criteria for Communication of Results to ODT Hub according to organisms isolated

Organism	When to send the Rapid Alert
Candida spp.	
Filamentous fungi	Communicate these organisms as soon as they are
Staphylococcus aureus	identified; antibiotic sensitivities to follow, when available
Streptococcus pyogenes	
Enterobacterales	
Enterococcus spp.	Communicate organism ID and sensitivities together
Pseudomonas aeruginosa	when both are finalised
Pyogenic streptococci (other than Group A)	
Other organisms considered locally to be of potential clinical	At local laboratory discretion
significance	
No growth of clinically significant organisms' or 'No Growth'	Not to be communicated to ODT Hub

Email a completed copy of this form **immediately** to: <u>odthub.operations@nhsbt.nhs.uk</u> and they will disseminate to all relevant centres.

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