INF1130/2 – Microbiological Screening Table

Blood and Transplant

Copy No:

Effective date: 18/07/2022

EOS terminology	Examples of Terminology used in Laboratory Reports	
Positive	**Reactive**	Reactivity detected as per manufacture's criteria; some laboratories may use the term for initially reactive results, pending confirmation. Check with laboratory if further tests are going to be carried out.
	Detected/Positive	Usually used interchangeably; meets pre-defined manufacturer's criteria for positivity. May need to check if this is a final result as for some markers, laboratories may do further tests to provide a final confirmatory result.
Indeterminate	**Equivocal**	Results falls within the negative and positive range, i.e., in a "grey zone" or are discrepant. Comments below also apply.
	Indeterminate/ Inconclusive	When test values do not completely fit in within pre-determined criteria for positive or negative results Terms indicate that results cannot be interpreted confidently as being negative or positive Further testing may be necessary
Negative	**Negative/Not Detected**	Usually used interchangeably; meets pre-defined manufacturer's criteria for negativity Indicates that the analyte tested for was not detected in the specimen

Table 1a: Mandatory Microbiological Screening of potential organ donors (Blood-borne viruses)

Simplified representation of results; must always be considered in conjunction with all other relevant information available at the time

Infection marker	Negative/Not Detected	Reactive	Detected/Positive	Equivocal	Indeterminate/Inconclusive
HBsAg **anti-HBcore** **HIV 1 and 2 (Antigen+Antibody)** **HTLV I and II Antibody** **HCV Antibody (+/- Antigen)** **HHV8 Antibody**	Follow normal procedure No special action required unless there are special circumstances (e.g., recent high-risk exposure). In which case, relevant information must be provided to the lab when sending samples for testing.	- Results must be verified carefully with laboratory staff; establish if further work is required and when to expect the final results. - Verify interpretation in the laboratory report; if unclear, contact Clinical Microbiologist in the testing laboratory to clarify. - Recipient centre to be put in contact with Medical Microbiologist in the testing laboratory if clarification of results required pre organ acceptance. - The SNOD should escalate their enquiry to the medical microbiologist at the local testing centre if: a. There is uncertainty about any result (i.e. the biomedical scientist raises concern about a result) b. Any situation where clinical presentation or laboratory results suggests any acute/active infection including IgM results (if reported) c. Any result which is not "negative/not detected", unless they relate to CMV IgG, EBV IgG or Toxoplasma IgG results. - If case falls outside MPD1131, Lead Microbiologist at MSL Colindale can be contacted in hours, if advice on management plan for recipient and family member(s) is required. - FRM5037 (Reporting of positive micro) must be filled in. Not all cases require discussion as protocols are in place to deal with positive Microbiology results, please refer to MPD1131 Appendix 2; for example, when the report indicates past HBV infection, which is the commonest set of positive blood-borne virus results encountered. RATIONALE: Solid organ recipient at potential risk of donor-derived infection, mitigation possible Members of family might have been exposed to infection (MPD1131)			

Table 1b: Mandatory Microbiological Screening of potential organ donors (Bacterial)
Simplified representation of results; must always be considered in conjunction with all other relevant information available at the time

Infection marker	Negative/ Not Detected	Reactive	Detected/Positive	Equivocal	Indeterminate/Inconclusive
Syphilis	Follow normal procedure No special action required	IMPORTANT NOTE: **positive result does not disqualify organ acceptability** **asT reponema infection can be treated; report must contain interpretation of result.** – Final result will inform need for further action re: management of recipient and need to inform sexual partner – Discuss with lab and refer to Medical Microbiologist if there are doubts about organ acceptability RATIONALE: Trepenoma pallidum is highly sensitive to antibiotic treatment (penicillin) hence mitigation is easily achievable			

IMPORTANT: Comments do not apply if diagnosis of this infection is currently being considered. Discuss with medical microbiologist.

Tables 2a to 2c: Non-mandatory Microbiological screening of potential organ donors
Simplified representation of results; must always be considered in conjunction with all other relevant information, particularly if there is any suspicion of acute/active infection caused by the pathogens being tested for.

Table 2a: Cytomegalovirus (CMV)

Infection marker	Negative/Not Detected	Reactive	Detected/Positive	Equivocal	Indeterminate/Inconclusive
CMV	**IMPORTANT NOTE:** Management of recipient will be based on donor and their own serostatus , pay attention to correct result, approximately 50% of the adult population in the UK is CMV IgG positive, so positive and negative results are equally frequent. Transfusions or IVIg in the previous 3 weeks can alter results, provide information to the Virology laboratory	High seroprevalence amongst adults: seropositive result in adults is common (IgG positive) (it is actually 50/50, see comment entered; so need to enter result correctly) – CMV causes lifelong infection, once IgG positive, remains positive – Anything that indicates the donor not to be negative (e.g., indeterminate/equivocal/inconclusive) should be regarded as positive until proven otherwise, as this is the safest option – Always provide information in the request form, indicating transfusions of blood components or receipt of blood products – Ask clarification regarding unusual CMV results, discuss with medical microbiologist if required. – The SNOD should escalate their enquiry to the medical microbiologist at the local testing centre if: a. There is uncertainty about any result (i.e., the biomedical scientist raises concern about a result) b. Any situation where clinical presentation or laboratory results suggests any acute/active infection including IgM results (if reported) c. Any result which is not "negative/not detected", unless they relate to CMV IgG, EBV IgG or Toxoplasma IgG results. (This is not in the right place?) – Post donation NoK management: No action required; positive IgG result does not need to be discussed with the family			

Table 2b: Epstein Barr Virus (EBV)

Infection marker	Negative/Not Detected	Reactive	Detected/Positive	Equivocal	Indeterminate/Inconclusive

EBV	**IMPORTANT NOTE:** Management of recipient will be informed by donor serostatus, particularly important for paediatric recipients Seronegative adult donors (IgG negative) not very common, pay attention to correct result	IMPORTANT NOTE: Result not required for organ acceptance; donor/recipient matching for EBV serostatus not done in practice High seroprevalence amongst adults: seropositive result in adults is common (great majority of adults are IgG positive) – EBV causes lifelong infection, once IgG positive, remains positive – Post donation NoHK management: No action required; positive IgG result does not need to be discussed with family

Table 2c: Toxoplasma Gondii

Infection marker	Negative/Not Detected	Reactive	Detected/ Positive	Equivocal	Indeterminate/ Inconclusive
Toxoplasma Gondii	Management of recipient will be informed by donor serostatus, particularly important for heart recipients Follow normal procedure No special action required	IMPORTANT NOTE: Result not required for organ acceptance, **positive result does not disqualify organ acceptability** IgG positivity is common. – The SNOD should escalate their enquiry to the medical microbiologist at the local testing centre if: a. There is uncertainty about any result (i.e., the biomedical scientist raises concern about a result) b. Any situation where clinical presentation or laboratory results suggests any acute/active infection including IgM results (if reported) c. Any result which is not "negative/not detected", unless they relate to CMV IgG, EBV IgG or Toxoplasma IgG results. – No special action required, but **serology particularly important in cardiac or skeletal muscle transplantation** RATIONALE: Seropositive donors are common. Trimethoprim used for routine prophylaxis is effective against T. gondii.			

IMPORTANT: Comments do not apply if diagnosis of this infection is currently being considered. Discuss with medical microbiologist.

Table 2d: West Nile Virus

Infection marker	Negative/ Not Detected	Reactive	Detected/Positive	Equivocal	Indeterminate/Inconclusive
West Nile Virus	Follow normal procedure No special action required	Positive result for WNV RNA is clinically significant. Donation team should hear from Clinical Microbiology Lead to accompany result. Donation team should hear from Micro Lead to discuss actions. Transplant centre clinicians need to be informed.		Tx centre to be advised of the inconclusive result – interpretative comments will Post donation management of NOK: discuss case by case with Lead Microbiologist. Usually, no implication to NOK as this infection is spread through mosquito bite. There may be cases where NOK might have been in the endemic area with the donor, so details required for assessment	

Table 2e: Malaria

Infection marker	Negative/ Not Detected	Reactive	Detected/Positive	Equivocal	Indeterminate/Inconclusive

Malaria	Follow normal procedure No special action required	Two possibilities exist: (1) Malaria antibody detected but malaria DNA NOT detected. Laboratory report contains comment advising transplant centre to consider malaria in the diagnostic differential of any episode of fever in the first 4 months' post transplantation. Provide the lab report (2) Malaria antibody and DNA POSITIVE. Donation team should hear from the Lead Microbiologist to discuss action. In any case, laboratory report will be issued with interpretation and advice. Provide lab report to transplant centre for immediate action which includes patient assessment and contact with the consultant parasitologist at the Hospital for Tropical Diseases. In the case of inconclusive antibody result, a report will be issued with interpretation and advice. As a precautionary measure, we tell tx centres to consider including malaria in the diagnostic differential etc (as above)

Table 2f: T-Cruzi

Infection marker	Negative/ Not Detected	Reactive	Detected/Positive	Equivocal	Indeterminate/Inconclusive
T-Cruzi	Follow normal procedure No special action required	Antibody positive result is of clinical significance. Donation team should hear from the Lead Microbiologist consultant to discuss actions. Report will contain interpretation and advice. This will be a rare occurrence and a specific set of actions will have to be triggered to mitigate harm to recipients. We will involve the Consultant parasitologist at the Hospital for Tropical Diseases.			

Table 2g: Hepatitis E Virus (HEV)

Infection marker	Negative/ Not Detected	Reactive	Detected/Positive	Equivocal	Indeterminate/Inconclusive
HEV	Follow normal procedure No special action required	HEV RNA positive result has implications for the recipients. Laboratory report will have interpretation and advice tx centres. Recipients must be tested for HEV at certain time points to exclude infection.		On occasion, indeterminate/inconclusive RNA results are obtained. Laboratory report will have interpretation and advice. Tx centres are encouraged to check the HEV status of the recipient as a precautionary measure to exclude infection.	
		Post donation management of NoK: No action required as HEV is a food-borne infection			

For SARS-CoV2 refer to POL304