Specific Accreditation Guidance

Human Pathology

Clinical non-human specimen testing

June 2018

Medical Testing Field Application Document Annex: Clinical non-human specimen testing

This document provides guidance for facilities conducting clinical non-human specimen testing.

Applicant and accredited facilities must comply with ISO 15189, relevant NPAAC standards and the *General Accreditation Criteria: ISO 15189 Standard Application Document (Medical Testing Field Application Document)*.

Scope

A number of samples currently received for testing by medical microbiology laboratories may be considered to be 'non-human' in nature as they are sourced from in-dwelling medical devices (catheter tips, tubing) and prostheses, as well as the environment in response to an infection control investigation or outbreak.

Testing on such samples is largely limited to the clinical setting so that Medical Microbiologists are able to provide appropriate interpretation of results within their field of expertise. For this reason, the testing is of clinical significance as it relates to patient management, rather than environmental surveillance.

The following may be considered for accreditation of clinical non-human sample testing:

(1) Any samples from tubing, implanted prostheses, etc removed from a patient when only human pathogens are sought.

(2) Environmental swabbing in line with an infection control investigation for a known pathogen (not routine) or response to an outbreak of a human pathogen known in advance (e.g. MRSA, VRE, Acinetobacter, other resistant organisms).

(3) Gastrointestinal endoscope testing.

Note: There is uncertainty as to the value of this testing which will be subject to further review by the Medical Testing Accreditation Advisory Committee.

(4) Environmental air sampling in response to a clinical investigation or outbreak but not for routine surveillance.

(5) Spore strips/capsules from routine autoclave internal quality control.

(6) Dialysis waters – further details are provided below.

(7) Used blood product bags when looking for evidence of microbial contamination as part of the investigation of a transfusion reaction.

Samples not intended to be included in this category are those that fall under a purely environmental screening category (i.e. for environmental organisms), testing for sterility purposes, or where special skills are required such as resuscitation of organisms or neutralisation of inhibitors. This would therefore exclude routine surveillance by environmental air sampling, settle plates and general swabbing, hydrotherapy pool samples and drinking water samples. The accreditation of this testing remains under NATA's ISO/IEC 17025 program.

It should also be noted that accreditation for clinical non-human sample testing is not intended to replace any existing regulatory requirements (e.g. TGA requirements).

Dialysis waters

Those laboratories associated with or providing a service to Dialysis Units may be asked to conduct testing on water and solutions derived from dialysis. Such bacteriological surveillance in dialysis centres is designed to monitor and detect bacterial contamination of dialysis fluids which can lead to pyrogenic reactions in patients. Special techniques, media and interpretation of results are involved in this testing which have been standardised into guidance documents produced by the Association for the Advancement of Medical Instrumentation (AAMI) from the USA. These documents are widely accepted in Australian Dialysis Units as recommended practice for the microbiological monitoring of dialysis waters.

It is recommended that the guidelines for testing included in the AAMI documents (ANSI/AAMI RD52:2004 and RD62:2001) regarding water treatment and dialysate be used as suitable protocols for the microbiological testing of these samples.

References

Dialysate for hemodialysis ANSI/AAMI RD 52:2004

Water treatment equipment for hemodialysis applications ANSI/AAMI RD62:2006

Amendment Table

The table below provides a summary of changes made to the document with this issue.

Section or Clause	Amendment
New document	This document represents a direct adoption of the former Medical Testing Field Application Document Annex A. The document has been reviewed and updated to reflect the new accreditation criteria documentation structure.