Specific Accreditation Guidance

Human Pathology

Clinical non-human specimen testing

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Clinical non-human specimen testing

Purpose

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*.

Background information

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

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 infection control) or response to an outbreak of a human pathogen known in advance (e.g. MRSA, VRE, Acinetobacter, other resistant organisms).

(3) Gastrointestinal endoscope testing.

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

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

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

Samples not included in this activity are those that fall under a routine 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, water cooling plants, 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 when a contamination event is suspected.

Further information can be found in the following:

ISO 23500 series Preparation and quality management of fluids for haemodialysis and related therapies.

Autoclave internal quality control

Spore strips/capsules from routine autoclave internal quality control may also be considered for accreditation under this service, noting this testing is not related to an outbreak investigation. The spore strips are used in each load and incubated to check sterilisation conditions occurred during the processing of an autoclave load.

The Human Pathology Scope Descriptor for this activity is :

Microbiology - Environmental investigations and/or infection control (Clinical non-human specimen testing)

Amendment Table

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

Section or Clause	Amendment
Dialysis waters	Reference updated