
 OFFICE LUXEMBOURGEOIS D'ACCREDITATION ET DE SURVEILLANCE	A004 - Models of Accreditation scope			
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A004

Models of Accreditation scope

Modifications: p.4, 7-11

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1 Introduction

The purpose of this appendix is to present the models of accreditation scopes used by OLAS included in application forms F001A, F001B, and F001C. These models are used to draft the accreditation scopes validated by the audit team.

The models presented here are used to identify the domains covered by the accreditation. The project of accreditation scope must be validated by a person authorized to commit the organization. This document is used as basic information to prepare the assessment of the body. The project can be amended if necessary to reflect the findings identified by the assessment team.

The models presented here are used to identify the domains covered by the accreditation. The project of accreditation scope must be validated by a person authorized to commit the organization. This document is used as basic information to prepare the assessment of the body. The project can be amended if necessary to reflect the findings open by the audit team. An accreditation scope is a dynamic document that evolves with extensions or withdrawals of areas as required by the accredited body.

The accreditation is only covering the domains included in the accreditation scope. This scope is linked to the certificate to give full comprehension of the accreditation. The scope is available in the National Register of accreditation on the OLAS website.

2 Definition

Scope of accreditation: See the definition given in the appendix A012 – Management of fixed and flexible scopes.

Annex to the accreditation certificate: N° According to standard For a

Version of the technical appendix of
Valid until

Accredited organisation:

Accredited sites:

Contact person:

PERSON

Phone: **NNNNNNNNNN**

Email **MMMMMMMMMM**

Document approved by:

Dominique Ferrand
Head of OLAS department

Accreditation scope for a testing laboratory

Objects submitted for testing	Characteristics or properties measured	Measurement principle and equipment	Test methods
(e.g. products, materials, samples, matrices, equipment)		(e.g. manual or automatic measurement)	(e.g. published, adapted, checked internally)
General domain:			
Technical domain:			
-	-	-	-

Accreditation scope for a medical laboratory

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
(e.g. products, materials, samples, matrices, equipment)		(e.g. manual or automatic measurement)	(e.g. published, adapted, checked internally)
General domain:			
Technical domain:			
-	-	-	-

Sample accreditation scopes for medical microbiology are provided in the [annex](#) of this document.

Accreditation scope for a calibration laboratory

Objects submitted to calibration	Characteristics or properties measured	Calibration methods	Measuring range	Calibration and Measurement Capability (CMC)
		(e.g. published, adapted, internally validated)		Enlarged uncertainty (k=2)
General domain:				
Technical domain:				
-	-	-	-	-

Accreditation scope for an inspection body

Object submitted to inspection	Phase and type of inspection	Reference frames
Installations, buildings, devices, components, equipment...	Inspection before final, periodic, prior commissioning, before delivery, conformance, of new products, etc.	<ul style="list-style-type: none"> - standards, - regulations - European directives (+modules, annex, articles, if applicable) - reference documents - internal procedures - technical specifications
General domain:		
Technical domain:		
-	-	-

Accreditation scope for a management system certification body

General domain:
Technical domain:
Technical cluster and codes :

Accreditation scope for a product, process or service certification body

Products or groups of materials	Reference frames
	<ul style="list-style-type: none"> - standards-based, - regulations - European directives (+modules, annex, articles, if applicable)
General domain:	
Technical domain:	
-	-

Accreditation scope for a service providers for digitization and electronic archiving certification body

General domain:
Technical domain:
Technical cluster and codes :

Annex: Sample accreditation scopes for medical microbiology

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
(e.g. products, materials, samples, matrices, equipment)		(e.g. manual or automatic measurement)	(e.g. published, adapted, checked internally)
General domain: MED1 – Clinical biochemistry			
Technical domain: General and specialized biochemistry			
Urine / Urine sediment	Bacteriuria	- <i>Indicate if manual or automated method?</i> - <i>Specify equipment (supplier and model)</i>	Nitrite reductase activity Rapid tests / urine dipstick
	Leukocyturia	- <i>Indicate if manual or automated method?</i> - <i>Specify equipment (supplier and model)</i>	Leukocyte esterase activity Rapid tests / urine dipstick
Stool / Diarrhea	pH	- <i>Indicate if manual or automated method?</i> - <i>Specify equipment (supplier and model)</i>	Potentiometry
General domain: MED4 – Medical microbiology			
Technical domains: MED4.2 – Medical bacteriology / MED4.3 – Medical parasitology / MED4.4 – Medical mycology / Medical virology			
Macro- and microscopic examinations			
URINARY TRACT INFECTION / CYTOBACTERIOLOGICAL EXAMINATION OF URINE			
Urine / Urine sediment	Red blood cells, leukocytes, epithelial cells and crystals	- <i>Indicate if manual or automated method?</i> - <i>Specify equipment (supplier and model)</i>	Light microscopy KOVA Red blood cell and leukocyte count
			Flow cytometry Enumeration of red and white blood cells, epithelial cells and crystals
	Microorganisms	Light microscopy - <i>Indicate if manual or automated method?</i> - <i>Specify equipment (supplier and model)</i>	Fresh state: Search for microorganisms on the slide Direct examination: Search for bacteria and yeast on a GRAM stained slide

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
	Bacteria and yeast	<ul style="list-style-type: none"> - <i>Indicate if manual or automated method?</i> - <i>Specify equipment (supplier and model)</i> 	Manual or automated plating Culture and recognition of colonies by manual or automated methods
DIGESTIVE INFECTION / STOOL CULTURE			
Stool / Diarrhea	Mucus, pus and blood		Macroscopic examination
	Bacteria and yeasts - Parasites	Light microscopy <ul style="list-style-type: none"> - <i>Indicate if manual or automated method?</i> - <i>Specify equipment (supplier and model)</i> 	Fresh state: Search for microorganisms on the slide Direct examination: Search for bacteria and yeast on a GRAM stained slide
	Acid-fast bacilli		Kinyoun staining
	Bacteria and yeast	<ul style="list-style-type: none"> - <i>Indicate if manual or automated method?</i> - <i>Specify equipment (supplier and model)</i> 	Manual or automated plating Culture and recognition of colonies by manual or automated methods
UROGENITAL AND SEXUALLY TRANSMITTED INFECTIONS			
Vaginal swab	Pus - drainage		Macroscopic examination
	Bacteria and yeast	Light microscopy /smear Manual methods	Fresh state: Search for microorganisms on the slide
	Bacteria and yeast	Light microscopy <ul style="list-style-type: none"> - <i>Indicate if manual or automated method?</i> - <i>Specify equipment (supplier and model)</i> 	Direct examination: Search for bacteria and yeast on a GRAM / MGG stained slide
	Bacteria and yeast	<ul style="list-style-type: none"> - <i>Indicate if manual or automated method?</i> - <i>Specify equipment (supplier and model)</i> 	Manual or automated plating Culture and recognition of colonies by manual or automated methods
	Viruses (<i>specify which ones</i>)	<ul style="list-style-type: none"> - <i>Indicate if manual or automated method?</i> - <i>Specify equipment (supplier and model)</i> 	Viral antigen testing by ELISA or single test

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
HEMOCULTURES			
Blood	Bacteria and yeast	Automated methods - <i>Specify equipment (supplier and model)</i>	Liquid blood culture
	Bacteria and yeast	- <i>Indicate if manual or automated method?</i> - <i>Specify equipment (supplier and model)</i>	Direct examination: Search for bacteria and yeast on a GRAM stained slide
Blood Broth of positive bottles (intravascular device, dialysis fluid)	Bacteria and yeast	- <i>Indicate if manual or automated method?</i> - <i>Specify equipment (supplier and model)</i>	Manual or automated plating Culture and recognition of colonies by manual or automated methods
CENTRAL NERVOUS SYSTEM INFECTION			
Cerebrospinal fluid	Leukocytes / red blood cells		Macroscopic appearance
	Leukocytes / red blood cells	White blood cell count Manual methods	Light microscopy: Enumeration of red blood cells and leukocytes
	Bacteria	Light microscopy	GRAM staining
	Yeast	Light microscopy	India ink staining
	Yeast and mycobacteria	Light microscopy	Ziehl-Neelsen staining
	Mycobacteria	Light microscopy	Fluorescent auramin staining
	Bacteria and yeast	- <i>Indicate if manual or automated method?</i> - <i>Specify equipment (supplier and model)</i>	Manual or automated plating Culture and recognition of colonies by manual or automated methods
OTHER TYPES OF INFECTIONS			
Sperm Secretion and exudates of the otorhinolaryngeal sphere Expectoration Expectoration in the cystic fibrosis patient Bronchoalveolar lavage	<i>To specify</i>		Macroscopic examination
	<i>To specify</i>	Light microscopy - <i>Indicate if manual or automated method?</i> - <i>Specify equipment (supplier and model)</i>	Fresh state: Search for microorganisms on the slide
	<i>To specify</i>		Direct examination: Search for bacteria on the slide Specify type of staining

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Puncture fluid Urethral swab Intrauterine device (IUD) Ocular specimen Skin Wound Pus Puncture fluid	<i>To specify</i>	<ul style="list-style-type: none"> - <i>Indicate if manual or automated method?</i> - <i>Specify equipment (supplier and model)</i> 	Manual or automated plating Culture and recognition of colonies by manual or automated methods
Antibiograms and additional tests			
Culture * and/or **	Antibiotic susceptibility	Diameter measurement <ul style="list-style-type: none"> - <i>Indicate if manual or automated method?</i> - <i>Specify equipment (supplier and model)</i> 	ANTIMICROBIAL SUSCEPTIBILITY TESTING MIC and complementary tests in solid media: diffusion in agar media
Culture * nd/or **	Antibiotic susceptibility	Spectrophotometry / Colorimetry <ul style="list-style-type: none"> - <i>Indicate if manual or automated method?</i> - <i>Specify equipment (supplier and model)</i> 	ANTIMICROBIAL SUSCEPTIBILITY TESTING MIC and complementary tests: Measurement of growth inhibition in liquid medium in the presence of antibiotics
To specify ** nd/or ****	MRSA	Manual method	Qualitative method on specific chromogenic media
			Rapid test Immunochromatography
To specify ** nd/or ***	ESBL	Manual method	Qualitative method on specific chromogenic media

Objects submitted for analysis	Characteristics or properties measured	Measurement principle and equipment	Analysis methods
Identification			
Culture * and/or **	Identification of bacteria / yeast / dermatophytes / moulds Search for MRSA Search for ESBL Search for VRE	- <i>Indicate if manual or automated method?</i> - <i>Specify equipment (supplier and model)</i>	Identification: Morphological aspect of cultures / Automated methods
			Manual identification by biochemical profiles and spectrophotometric reading
			Automated identification by biochemical profiles and spectrophotometric reading
			Automated identification by mass spectrometry
	<i>To specify</i>	- <i>Indicate if manual or automated method?</i> - <i>Specify equipment (supplier and model)</i>	Slide agglutination serotyping
General domain: MED4 – Medical microbiology			
Technical domain: MED4.6 – Infectious molecular biology			
<i>To specify</i> ** and/or ***	<i>To specify</i>	Automated methods - <i>Specify equipment (supplier and model)</i>	Targeted real-time PCR Multiplex real-time PCR

* * Culture from matrices for which prior biochemical, macro- and microscopic analyses are included in the scope of accreditation.

** Culture / Sample received as a second intention laboratory

*** Samples for which any prior biochemical, macro- and microscopic analyses are included in the scope of accreditation.