



Schweizerische Eidgenossenschaft

Confédération suisse

Confederazione Svizzera

Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs,  
Education and Research EAER

**State Secretariat for Economic Affairs SECO**

Swiss Accreditation Service SAS

## STS Directory

**Accreditation number: STS 0268**

International standard: ISO/IEC 17025:2017

Swiss standard: SN EN ISO/IEC 17025:2018

Bioexam AG  
Maihofstrasse 95a  
P. O. Box 6858  
6000 Lucerne 6

Head: Michael Meier  
Responsible for MS: Andreas Kistler  
Telephone: +41 41 429 31 33  
E-mail: [michael.meier@bioexam.ch](mailto:michael.meier@bioexam.ch)  
Internet: [www.bioexam.ch](http://www.bioexam.ch)  
Initial accreditation: 08.08.2000  
Current accreditation: 27.07.2019 until 26.07.2024  
Scope of accreditation see: [www.sas.admin.ch](http://www.sas.admin.ch)  
(accredited bodies)

### Scope of accreditation as of 28.11.2022

**Testing laboratory for examinations in the fields of pharmaceuticals, medical devices, cosmetics, food, environment and hygiene (production, personnel and hospital hygiene)**

Group of products or materials, field of activity	Principle of measurement <sup>2)</sup> (characteristics, measuring ranges, type of test)	Test methods, remarks (national, international standards, in-house test methods)
<b>Pharmaceuticals and medicinal products</b> (including raw materials and intermediates)	<b>MICROBIOLOGICAL METHODS</b> Sterility test  Aerobic mesophilic count (TAMC)  Burkholderia cepacia complex  Yeast and moulds (TYMC)  Candida albicans  Clostridia  Escherichia coli	Ph. Eur. 2.6.1.; USP <71>  Ph. Eur. 2.6.12.; USP <61>  USP <60>  Ph. Eur. 2.6.12.; USP <61>  Ph. Eur. 2.6.13.; USP <62>  Ph. Eur. 2.6.13.; USP <62>  Ph. Eur. 2.6.13.; 2.6.31.; USP <62>



## STS Directory

**Accreditation number: STS 0268**

<b>Group of products or materials, field of activity</b>	<b>Principle of measurement<sup>2)</sup> (characteristics, measuring ranges, type of test)</b>	<b>Test methods, remarks (national, international standards, in-house test methods)</b>
<b>Cosmetics</b>	Bile-tolerant gram-negative bacteria	Ph. Eur. 2.6.13.; 2.6.31.; USP <62>
	Pseudomonas aeruginosa	Ph. Eur. 2.6.13.; USP <62>
	Salmonellae	Ph. Eur. 2.6.13.; 2.6.31.; USP <62>
	Staphylococcus aureus	Ph. Eur. 2.6.13.; USP <62>
	Determination of the population of microorganisms on products (bioburden)	ISO 11737-1
	Efficacy of antimicrobial preservation	Ph. Eur. 5.1.3.; USP <51>
	Test for bacterial endotoxins (gel clot method)	Ph. Eur. 2.6.14.; USP <85>
	Evaluation of media fills (aseptic process validation)	PIC/S, document no. 007-6
	Zone of growth inhibition determination	ASM chap. 71 (AV 23.3307)
	Determination of the minimal inhibitory and the minimal bactericidal concentrations	ASM chap. 71/74-75 (mod.) (AV 23.3308)
<b>Food</b>	Aerobic mesophilic germs	ISO 21149
	Yeast and moulds	ISO 16212
	Specified and non-specified microorganisms (qualitative)	ISO 18415
	Efficacy of antimicrobial preservation	ISO 11930
	<b>Quantitative test methods</b>	
	Aerobic mesophilic germs	ISO 4833-1/-2; GME
	Aerobic mesophilic micro-organisms not belonging to the fermentation flora	In-house method based on SFC 1988 chap. 56 / 7.03 (AV 23.3202)
	Aerobic mesophilic spores	ISO 4833-1/-2 (mod.) (AV 23.3203)
	Aerobic thermophilic germs	ISO 4833-1/-2 (mod.) (AV 23.3201)
	Aerobic thermophilic spores	ISO 4833-1/-2 (mod.) (AV 23.3203)



## STS Directory

**Accreditation number: STS 0268**

<b>Group of products or materials, field of activity</b>	<b>Principle of measurement<sup>2)</sup> (characteristics, measuring ranges, type of test)</b>	<b>Test methods, remarks (national, international standards, in-house test methods)</b>
	Sulphite-reducing anaerobic germs/spores	ISO 15213, corresponding to GME (mod.)
	Anaerobic mesophilic germs	In-house method based on SFC 1988 chap. 56 / 7.04 (AV 23.3204)
	Anaerobic mesophilic spores	In-house method based on SFC 1988 chap. 56 / 7.05 (mod.) (AV 23.3205)
	Anaerobic thermophilic germs	In-house method based on SFC 1988 chap. 56 / 7.04 (mod.) (AV 23.3204)
	Anaerobic thermophilic spores	In-house method based on SFC 1988 chap. 56 / 7.05 (mod.) (AV 23.3205)
	Bacillus cereus (presumptive)	BACARA 2® (bioMérieux, corresponding to ISO 7932)
	Clostridium perfringens	ISO 7937
	Coliforms	chromID™ Coli (bioMérieux, corresponding to ISO 4832)
	Enterobacteriaceae	ISO 21528-2
	Enterococci	ISO 7899-2 (mod.) (AV 23.3211)
	Escherichia coli	ISO 16649-2
	Listeria monocytogenes / Listeria spp.	ALOA® Count (bioMérieux, corresponding to ISO 11290-2)
	Lactic acid bacteria (mesophilic)	ISO 15214
	Pseudomonads (meat and meat products)	ISO 13720 (mod.) (AV 23.3237)
	Staphylococci, coagulase-pos. (S. aureus)	Brilliance Staph 24 (Oxoid, corresponding to ISO 6888-1)
	<b>Qualitative test methods</b>	
	Bacillus cereus (presumptive)	ISO 21871
	Coliforms	ISO 21528-1 (mod.) (AV 23.3229)
	Enterobacteriaceae	ISO 21528-1
	Escherichia coli	ISO 16649-3; GME
	Listeria monocytogenes / Listeria spp.	ALOA® One Day (bioMérieux, corresponding to ISO 11290-1)



## STS Directory

**Accreditation number: STS 0268**

<b>Group of products or materials, field of activity</b>	<b>Principle of measurement<sup>2)</sup> (characteristics, measuring ranges, type of test)</b>	<b>Test methods, remarks (national, international standards, in-house test methods)</b>
<b>Water</b>	Salmonellae	SALMA® One Day (bioMérieux, corresponding to ISO 6579 / GME)
Production water (pharmaceutical field)	Aerobic mesophilic count (TAMC)	Ph. Eur.: 2.6.12. and monographs no. 0008, 0169, and 2249; USP: <61> and <1231>
	Coliforms	ISO 9308-1
	Enterococci	ISO 7899-2
	Escherichia coli	ISO 9308-1
	Pseudomonas aeruginosa	ISO 16266
Drinking, mineral and process water	Aerobic mesophilic germs	ISO 6222 (mod.) (AV 23.3243)
	Clostridium perfringens	ISO 14189
	Coliforms	ISO 9308-1
	Enterococci	ISO 7899-2
	Escherichia coli	ISO 9308-1
	Legionellae	ISO 11731
	Pseudomonas aeruginosa	ISO 16266
Bathing water	Aerobic mesophilic germs	ISO 6222 (mod.) (AV 23.3243)
	Escherichia coli	ISO 9308-1
	Legionellae	ISO 11731
	Pseudomonas aeruginosa	ISO 16266
	Enterococci	ISO 7899-2
Water for dialysis	Aerobic mesophilic germs	ISO 23500-3
Final rinsing water for washers-disinfectors	Aerobic mesophilic germs	ISO 15883-1
	Mycobacteria	ISO 15883-4
<b>Hygiene</b>		
Microbial count of surfaces	Contact plate method (excl. sampling)	ISO 18593 (AV 23.3401)
	Swab method (excl. sampling)	ISO 18593 (AV 23.3402)
	Rinsing method	ISO 11737-1



## STS Directory

**Accreditation number: STS 0268**

<b>Group of products or materials, field of activity</b>	<b>Principle of measurement<sup>2)</sup> (characteristics, measuring ranges, type of test)</b>	<b>Test methods, remarks (national, international standards, in-house test methods)</b>
Microbial count of air	Impaction method	MBV MAS-100 Air Sampler (AV 23.3403)
Bioindicators for disinfection and sterilisation processes	Evaluation by cultivation (qualitative and quantitative)	Ph. Eur. 5.1.2.; USP <55>; VHD
Endoscopes (rinsing solutions and swabs)	Microbial examination of cleaning/disinfection processes	Swiss guideline for the reprocessing of flexible endoscopes (SSG/SGP/SGSH/SVEP) (AV 23.3412)
<b>Microbiological media</b>	Quality control	Ph. Eur. 2.6.12., 2.6.13. and monographs no. 0008 and 0169
<b>Identification of microorganisms</b>	Mass spectrometric identification of bacteria and yeasts (MALDI-TOF) Biochemical identification of bacteria Macroscopic and microscopic identification (incl. staining methods) of bacteria and fungi	MALDI Biotype (Bruker Daltonics GmbH) (AV 23.3527) AV 23.3524 AV 23.3524
<b>Chemical disinfectants and antiseptics</b>	Quantitative suspension test, bactericidal activity (phase 2 / step 1) Quantitative suspension test, fungicidal/yeasticidal activity (phase 2 / step 1) Quantitative surface test, bactericidal and fungicidal activity (phase 2 / step 2) Hygienic hand disinfection (phase 2 / step 2) Disinfecting hand washing (phase 2 / step 2)	EN 1276 EN 1650 EN 13697 EN 1500 EN 1499
<b>Antimicrobial polymers</b>	Determination of the antimicrobial activity	ASTM E 2180 (mod.) (AV 23.3449)
<b>SPECTROMETRIC METHODS</b>		
<b>Eluates</b>	Protein determination	ISO 15883-5

In case of contradictions in the language versions of the directories, the German version shall apply.



Schweizerische Eidgenossenschaft

Confédération suisse

Confederazione Svizzera

Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs,  
Education and Research EAER

**State Secretariat for Economic Affairs SECO**

Swiss Accreditation Service SAS

## STS Directory

**Accreditation number: STS 0268**

Abbreviation	Signification
ASM	J. H. Jorgensen and M. A. Pfaller (editors in chief), Manual of Clinical Microbiology, 11 <sup>th</sup> edition, ASM Press, Washington, D. C., 2015)
ASTM	American Society for Testing and Materials
EN	European Standard
GME	Monograph „Standardised Methods for the Testing of Edible Gelatin“ of the GME (Gelatin Manufacturers of Europe)
ISO	International Standardisation Organisation
MALDI	Matrix-assisted Laser Desorption/Ionization
Ph. Eur.	Pharmacopoeia Europaea
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
SFC	(former) Swiss Food Compendium
SGG	Schweizerische Gesellschaft für Gastroenterologie
SGP	Schweizerische Gesellschaft für Pneumologie
SGSH	Schweizerische Gesellschaft für Spitalhygiene
SVEP	Schweizerische Vereinigung für Endoskopiepersonal
TAMC	Total Aerobic Microbial Count
TYMC	Total Combined Yeasts and Moulds Count
USP	United States Pharmacopeia
VHD	Vereinigung der Hygiene-Fachkräfte der Bundesrepublik Deutschland e.V. („Checkliste hygienerelevanter Umgebungsuntersuchungen“)

\* / \* / \* / \* / \*