

Schweizerische Eidgenossenschaft Confédération suisse Confederazione Svizzera Confederaziun svizra

Swiss Confederation

## STS Directory

Federal Department of Economic Affairs, Education and Research EAER

State Secretariat for Economic Affairs SECO Swiss Accreditation Service SAS

## Accreditation number: STS 0408

| International standard:<br>Swiss standard:       | ISO/IEC 17025:2017<br>SN EN ISO/IEC 17025:2018                                                                                                        |                                                                                                                                                                                               |
|--------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Biolytix Ltd.<br>Neumattweg 16<br>4243 Dittingen | Head:<br>Responsible for MS:<br>Telephone:<br>E-Mail:<br>Internet:<br>Initial accreditation:<br>Current accreditation:<br>Scope of accreditation see: | Dr. Anna Henger<br>Dr. Diana Hormisch<br>+41 61 725 20 70<br>info@biolytix.ch<br>http://www.biolytix.ch<br>24.05.2004<br>24.05.2024 bis 23.05.2029<br>www.sas.admin.ch<br>(Accredited bodies) |

Scope of accreditation as of 24.05.2024

Testing laboratory for analytical laboratory services in food, animal feed, water and environment, agronomy, luxury foods, cosmetics, pharma as well as for the development and performance of gene expression studies

| Group of products or materials, field of activity                                                  | Principle of measurement <sup>2), 3)</sup><br>(characteristics, measuring<br>ranges, type of test) | Test methods, remarks (national,<br>international standards, in-<br>house test methods) |
|----------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
|                                                                                                    | Molecular biological methods for the detection of GMO <sup>3)</sup>                                |                                                                                         |
| Tobacco, food and animal feed,<br>seeds, plant material, pharmaceu-<br>tical and cosmetic products | DNA extraction<br>Qualitative PCR<br>Quantitative real-time PCR                                    | Standard procedures and in-house test methods                                           |
|                                                                                                    | Genotyping by molecular<br>biological methods <sup>3)</sup>                                        |                                                                                         |
| Animal, plant and human tissues<br>and cell cultures                                               | DNA extraction<br>Qualitative PCR<br>Quantitative real-time PCR                                    | In-house test methods                                                                   |

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1) Scope of accreditation type A (fix)



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|----------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|
|                                                                                                    | Molecular biological methods<br>for the development and<br>measurement of gene<br>expression <sup>3)</sup>                                                                                   |                                                                                                               |
| Animal, plant and human tissues<br>and cell cultures                                               | RNA extraction<br>Reverse Transcription<br>Quantitative real-time PCR                                                                                                                        | Commercial and in-house test methods                                                                          |
|                                                                                                    | Molecular biological methods for the detection of animal and plant species <sup>3)</sup>                                                                                                     |                                                                                                               |
| Tobacco, food and animal feed,<br>seeds, plant material, pharmaceu-<br>tical and cosmetic products | DNA extraction<br>Qualitative PCR<br>Quantitative real-time PCR                                                                                                                              | Standard procedures and in-house test methods                                                                 |
|                                                                                                    | Molecular biological methods<br>for the detection of<br>microorganisms and viruses <sup>3)</sup>                                                                                             |                                                                                                               |
| Food and feed, plant material, wa-<br>ter and environmental samples                                | Qualitative real-time PCR for the detection of:                                                                                                                                              | Standard procedures, commercial and in-house test methods                                                     |
|                                                                                                    | Salmonella spp.<br>Campylobacter jejuni/coli<br>Listeria monocytogenes<br>Shigatoxin forming E. coli (STEC)<br>Cronobacter sakazakii<br>Norovirus<br>Hepatitis A                             |                                                                                                               |
|                                                                                                    | Microbiological methods                                                                                                                                                                      |                                                                                                               |
|                                                                                                    | Quantitative determination by classical cultivation methods <sup>2)</sup>                                                                                                                    |                                                                                                               |
| Water (aqua purificata) for phar-<br>maceutical and cosmetic products                              | Aerobic, mesophilic germs                                                                                                                                                                    | Ph. Eur. 0008                                                                                                 |
| Drinking water, bath water, shower<br>water, other water and environ-<br>mental samples            | Aerobic, mesophilic germs<br>Escherichia coli<br>Enterococci<br>Pseudomonas aeruginosa<br>Legionella pneumophila                                                                             | ISO 6222 modified acc. TBDV<br>ISO 9308-1<br>ISO 7899-2<br>ISO 16266<br>ISO 11731 modified (SOP054)           |
| Food and animal feed, seeds,<br>plant material, water, environmen-<br>tal samples                  | Aerobic, mesophilic germs<br>Enterobacteriaceae<br>Escherichia coli<br>Coagulase positive Staphylococci<br>Bacillus cereus<br>Yeast and moulds<br>Pseudomonas spp.<br>Listeria monocytogenes | ISO 4833<br>ISO 21528-2<br>ISO 16649-1<br>ISO 6888-2<br>ISO 7932<br>ISO 21527-1/2<br>ISO 13720<br>ISO 11290-2 |

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| Group of products or materials, field of activity                                                                    | Principle of measurement <sup>2), 3)</sup><br>(characteristics, measuring<br>ranges, type of test)                                             | Test methods, remarks (national,<br>international standards, in-<br>house test methods)                                                                                           |
|----------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                      | Qualitative detection by enrichment <sup>2)</sup>                                                                                              |                                                                                                                                                                                   |
|                                                                                                                      | Salmonella spp.<br>Cronobacter sakazakii<br>Escherichia coli<br>Shigatoxin forming E. coli (STEC<br>Listeria monocytogenes                     | ISO 6579<br>ISO/TS 22964<br>ISO 16649-2<br>ISO 13136<br>ISO 11290-1                                                                                                               |
|                                                                                                                      | Microbiological determination by MPN method <sup>2)</sup>                                                                                      |                                                                                                                                                                                   |
| Food, feeding stuff                                                                                                  | Aerobic, mesophilic germs<br>Bacillus cereus<br>Enterobacteriaceae<br>Escherichia coli<br>Coagulase positive Staphylococci<br>Yeast and moulds | TEMPO® (Biomérieux)                                                                                                                                                               |
|                                                                                                                      | Quantitative determination by elution, filtration and classical cultivation methods <sup>2)</sup>                                              |                                                                                                                                                                                   |
| Medical devices, plastic materials                                                                                   | Aerobic, mesophilic germs<br>Yeast & moulds<br>Anaerobic, mesophilic germs                                                                     | ISO11737-1                                                                                                                                                                        |
| Cleaning solutions and swabs from endoscopes                                                                         | Microbiological testing of the processing of endoscopes                                                                                        | SOP 641_Microbiological control of<br>endoscope processing from clean-<br>ing solutions and swab samples<br>based on the Swiss guideline for<br>processing of flexible endoscopes |
|                                                                                                                      | Immunochemical methods                                                                                                                         |                                                                                                                                                                                   |
|                                                                                                                      | ELISA-methods <sup>3)</sup>                                                                                                                    |                                                                                                                                                                                   |
| Food and animal feed, pharma-<br>ceutical products                                                                   | for the detection of:<br>Allergens<br>Mycotoxins                                                                                               | Standard procedures, commercial test methods                                                                                                                                      |
|                                                                                                                      | Spectroscopic/ spectrometric methods                                                                                                           |                                                                                                                                                                                   |
|                                                                                                                      | Ultraviolet/visible/fluorescence<br>spectroscopy/spectrometry <sup>3)</sup>                                                                    |                                                                                                                                                                                   |
| Food and animal feed, water,<br>pharmaceutical products, plastic<br>materials, consumer goods and<br>medical devices | for the detection of:<br>Allergens<br>Sugars<br>Molecules                                                                                      | Standard procedures, commercial and in-house test methods                                                                                                                         |

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|----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
|                                                                                                                      | Biochemical methods <sup>3)</sup>                                                                  |                                                                                         |
| Food and animal feed, water,<br>pharmaceutical products, plastic<br>materials, consumer goods and<br>medical devices | Enzymatic activities                                                                               | Standard procedures, commercial and in-house test methods                               |

The testing laboratory maintains a list with detailed information on the activities within the scope of accreditation. This is available on request from the laboratory.

In the event of inconsistencies in the language versions of the lists, the German version shall apply.

| Abbreviation | Signification                                                                                                   |
|--------------|-----------------------------------------------------------------------------------------------------------------|
| DNA          | Desoxyribonucleic acid                                                                                          |
| ELISA        | Enzyme-linked Immunosorbent Assay                                                                               |
| GMO          | Genetically modified organism                                                                                   |
| ISO          | International Organization for Standardization                                                                  |
| ISO/TS       | ISO/Technical Spezification                                                                                     |
| MPN          | Most Probable Number                                                                                            |
| PCR          | Polymerase Chain Reaction                                                                                       |
| Ph. Eur.     | European Pharmacopoeia                                                                                          |
| RNA          | Ribonucleic acid                                                                                                |
| SOP          | Standard operation procedure                                                                                    |
| TBDV         | FDHA ordinance on Drinking Water and Water in Publicly Accessible Baths and Shower Facilities, Swiss Regulation |

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3) Scope of accreditation type C (flexible)