Pharmaceutical

Global capabilities

Right Solutions • Right Partner

alsglobal.com

Company overview

ALS is the global benchmark for service and integrity.

65+ COUNTRIES

15k+ STAFF

350+ LOCATIONS

40+ YEARS IN OPERATION

ALS is an Australian Stock Exchange listed company (ASX:ALQ) that commenced operations in Queensland, Australia as Campbell Brothers in 1863. ALS has over 15,000 staff operating from over 350 locations in more than 65 countries. As one of the largest global analytical laboratory groups, we have facilities strategically located all over the world with key locations in Australia, Asia, North America, South America, Europe, the Middle East and Africa.

ALS has demonstrated over 40 years of strong business performance with global revenues exceeding $1.6 billion and reputation built on quality, client service, innovation, and technical excellence. The Company continues to remain at the forefront of the testing services industry as a provider of choice on a global scale. Servicing government, multi-national companies, manufacturers, retailers, consultants, and mining companies across the world, ALS processes more than 40 million samples per year and is one of the largest global testing, inspection and certification (TIC) companies.

The Company's extensive coverage benefits clients through technical leadership, access to emerging technology and regulatory trends, as well as a large pool of technical experts. This is balanced with a local focus to provide ease of use and market-specific knowledge and services.

Core values

As a company we can trace our history back to 1863, our core values drive the decisions we make today in building on this legacy.

Health, safety & environment

ALS is committed to a safe work culture. Our global foundation standard assists in managing health, safety and environment risks. ALS employs a team of Health and Safety professionals at both regional and corporate level to support continual improvement and best practice.

ALS believes the meeting of its safety and environmental obligations is essential to our long-term success. The company imparts its safety and environmental values from the first day the employee commences work with the company and throughout their term as a valued employee.

We do this by:

- Comprehensive safety training as part of the employee onboarding process.
- Ongoing Training such as tool box talks, formal training on core topics, regular whole staff site safety address, and personalised training where identified via risk assessment.
- Integration with our day to day operations via our 'safety first' program and BSI AS4801, OHSAS18001 and ISO14001 certified HSE management systems.
- Auditing, reporting and review at all levels of the organization.

ALS has a core value of '**Safety is a Priority**'. Being an employee of ALS is about putting safety first. This approach is identical for staff working in ALS Lima, Vancouver, Johannesburg, Hong Kong, or Sydney.

As part of this global approach, the foundation standard is driven by an ethic to deliver a consistently friendly and safe approach to work, regardless of differences in local laws.

The ALS HSE Foundation Standards requires each business to manage key risks by adopting the following:

- Ensuring health, safety and environmental resources are available;
- Ensuring managers are aware of their responsibilities;
- Implementing a plan for managing injuries and site emergencies;
- Ensuring contractors work safely;
- Ensuring that key safety information is available for all staff to view;
- Providing training on key safety risks;
- Ensuring that staff have an opportunity to provide feedback;
- Ensuring that work areas are designed and maintained in a safe manner;
- Ensuring that all incidents are reported so we can learn from our experiences;
- Completing a review of health and safety issues on a regular basis; and
- Ensuring that a monthly site audit of Safety issues is conducted.

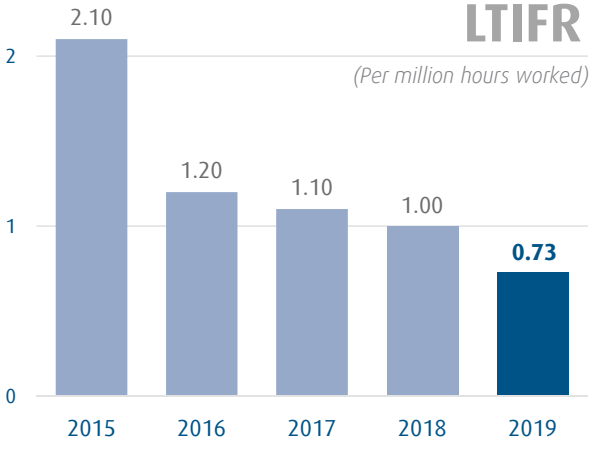
Fixed schedules are in place for auditing, reporting and review of the HSE management system by staff, supervisors, and management.

Environment

ALS is committed to minimizing its environmental footprint. To support this goal, each laboratory adheres to relevant legislation in their jurisdiction for waste storage and disposal. Samples and wastes are recycled or disposed in an environmentally responsible manner. Containers and packaging are recycled wherever possible.

Lost Time Injuries (LTIFR)

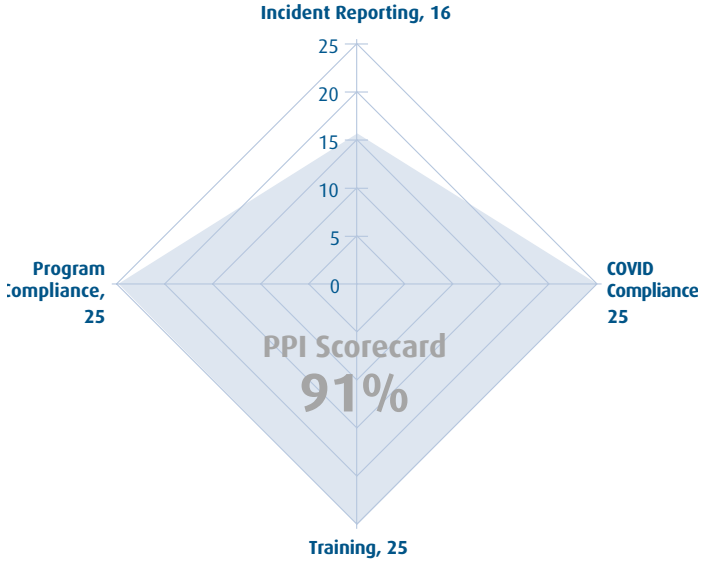
ALS continually tracks and strives to improve safety performance. Data is tracked by site, business, group and division regionally and globally with key information reported to staff and discussed at meetings and toolbox talks.



Positive Performance Indicator including leadership

The Positive Performance Indicators (PPI) System is designed as a proactive mechanism to continually improve safety culture. Current data for ALS Limited follows:

Profile: **ALS Limited**
Financial Year: **April 2020 – March 2021**
Total Score: **91%**
Staff Hours (12 mth Rolling Average): **26,705,614**



Pharmaceutical services

At ALS we have established an unrivalled testing service, incorporating the analysis of raw materials, intermediates and finished products.

We specialise in the validation of HPLC, LC-MS, GC, GC-MS, ICP and ICP-MS methods in particular, and have state of the art equipment to meet industry standards and your expectations.

With a comprehensive range of tests, experienced and skilled staff, our clients can have confidence in the integrity and quality of test results. All laboratories are GMP or GLP compliant, regularly inspected by local authorities.

Chemistry testing

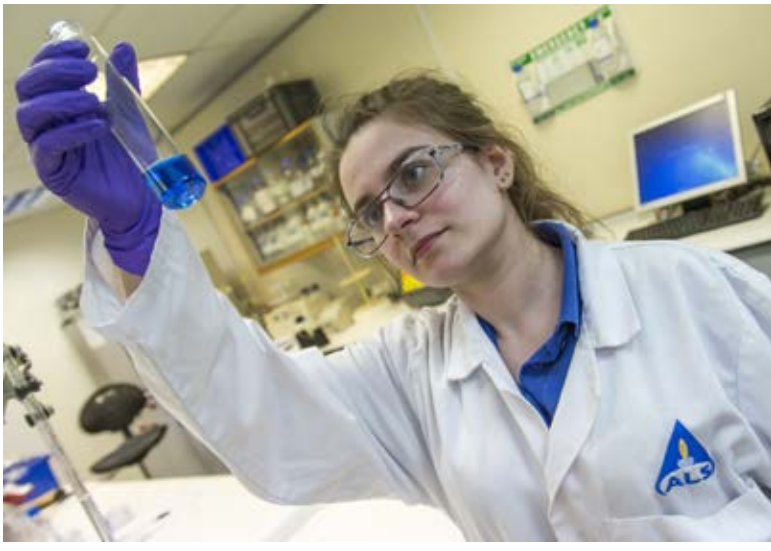
- **Finished product and raw material testing**
  - for QC batch release
- **Ph Eur (EP), BP, USP, JP Testing (others available)**
  - to meet your requirements
- **Water testing**
  - Pharmacopoeial analysis of potable and purified water and WFI
  - Water from steam sterilisers and washer disinfectors (CFPP01-01 Parts C & D, CFPP01-06, EN-285, HTM 2030 & 2031)

Technical projects

- **We offer a comprehensive range of services to support regulatory requirements including:**
  - Drug product ICH stability storage and testing
  - Test method validation (to ICH)
  - Test method development
  - Dissolution profile studies

Microbiology testing

- **Bioburden & pathogen testing**
  - Testing for Total Microbial Aerobic Count (TAMC) and Yeast and Mold Count (TYMC), fungi and specified pathogens in pharmaceuticals, cosmetics and medical devices
- **Endotoxin Testing**
  - Analysis performed on water, raw materials and finished products
- **Water Testing**
  - TVC and pathogens by membrane filtration employing various methods: pharmacopoeia, CFPP, HTM and client specific
- **Antimicrobial Preservative Efficacy Testing (PET)**
  - Pharmacopoeial testing for pharmaceuticals and cosmetics
- **Disinfectant Efficacy**
  - BS EN methods
  - Testing can be performed for manufacturers and end users
- **Sterility testing**
  - Membrane filtration and direct inoculation per USP & AAMI



Batch release testing

Within the European Union (EU), Good Manufacturing Practice (GMP) for Medicinal Products requires batch release against the approved product specification, for medicinal products holding a marketing authorisation. Our QC batch release testing laboratories utilise a wide ange of analytical technologies to provide responsive release testing using pharmacopoeial or client specific methods, confirming that products meet their specification. Routinely handling a diverse range of sample matrices leaves ALS well positioned to meet the needs of our clients' ever expanding product portfolios and diverse product ranges.

Analytical Method Transfer (AMT) is performed as standard prior to conducting routine release testing.

Some examples of the sample matrices that we routinely handle:

- Tablets
- Capsules
- Powders and granules
- Syrups
- Creams, Ointments & Gels
- Oral and topical liquids
- Medical devices
- Injections
- High Potency / Cytotoxic

ALS offer both chemical and microbiology testing services, including:

- Disintegration
- Dissolution
- Hardness
- Friability
- Dimensions
- HPLC – UV, RI, DAD and fluorescence detectors
- Ion Chromatography
- Sterility
- Particulate matter testing for injectables
- Add Residual Solvents USP <467>
- Gas Chromatography – Direct Injection and Headspace with FID, TCD and MS detectors
- Compendial analysis (BP, EP, JP and USP etc.)
- Elemental Impurities by USP <232> <233> using ICP-MS
- Microbial Identification by DNA sequencing
- Complete microbiological testing including total viable counts (TVC) and pathogens, microbial identification, preservative efficacy testing (PET), microbial examination on non-sterile products per USP <61> <62>, bacterial endotoxin (LAL) testing

Physical & chemical analysis

At ALS, our pharmaceutical business provides a wide range of services to the pharmaceutical and healthcare industries. Committed to exceeding client expectations we are able to provide high quality solutions across a range of products, including human and veterinary products, intermediates and raw materials.

Testing is conducted according to international standards such as the British Pharmacopoeia, US Pharmacopoeia, European Pharmacopoeia and Japanese Pharmacopoeia or alternatively to documented client specifications.

Scope of services

- **Pharmacopoeial standards and methodologies**
  - BP - British Pharmacopoeia
  - USP - United States Pharmacopoeia
  - Ph. Eur. - European Pharmacopoeia
  - JP – Japanese Pharmacopoeia
  - CL - Czech Pharmacopoeia
  - ICH Guidelines

Physical testing

- Hardness
- Disintegration
- Dimensions
- Appearance / Colour / Odour
- Viscosity
- Melting Point
- Friability
- Uniformity of Weight
- Specific Gravity
- Sub-visible particles

Chemical techniques & equipment

- ICP-MS, ICP-OES & ICP-SFMS
- HPLC detection by UV-Vis (Dual λ and PDA), RI, Flourecence
- GC – Liquid and Headspace detection by FID and TCD
- GC-MS – Ion Chromatography
- Atomic Absorption Spectrophotometer
- Dissolution Testing
- FTIR
- Karl Fischer Titrator
- Auto-titrator
- Total Organic Carbon Analyser
- UV/VIS spectrophotometer
- Refractive Index
- Conductivity

Method development, validation & transfer

At ALS we have a proven track record of delivering method development and validation projects across a range of analytical methodologies.

Test method development and validation

Highly experienced in test method development and validation across various analytical techniques and product types in compliance with regulatory requirements.

ALS can assist throughout the entire process including project planning, protocol preparation, analytical testing to final project report.

Methods can be developed and validated in accordance with ICH guidelines which include the following parameters:

- Specificity
- Linearity
- Accuracy
- Precision (Repeatability And Intermediate)
- Detection Limit (LOD)
- Quantitation Limit (LOQ)
- Robustnes
- Forced Degradation

Key test method areas in which we have expertise include:

- Dissolution profile studies
- Compendial methodologies bespoke to your product formulation
- Stability indicating test methods to comply with ICH

Analytical Method Transfer (AMT)

Analytical Method Transfer (AMT) is performed as standard prior to conducting routine release testing in accordance with regulatory requirements.

Analytical method transfer is critical to ensure continuity of data and with our experience in performing this comparative testing we can assist you throughout the entire process; from protocol preparation including guidance on testing requirements and acceptance criteria, analytical testing to final transfer report.

Elemental impurities

The ICH Q3D guideline presenting a policy for limiting metals in drug products and pharmaceutical ingredients has now reached step 5 - the implementation stage. ICH Q3D applies to new finished drug products entering the market and new products containing existing drug products.

ICH Q3D has been adopted by CHMP and came into effect for new marketing authorization applications from June 2016. For existing medicinal products, the corresponding date is December 2017. USP has also aligned the effective date for their corresponding chapters, <232> and <233>, setting the date to 1 January 2018.

There are numerous potential sources of elemental impurities in the manufacturing process of drug products. While the most significant risk comes from intentionally added metal catalysts, other sources such as manufacturing equipment, solvents, water and reagents should also be considered. Particularly challenging is assessing the potential contribution of elemental impurities from excipients. Environmental factors will have a significant impact, meaning it is important to consider the source of the excipient.

ALS offers tailor-made screening analyses for client-specific needs, from a single element to packages of all elements included in ICH Q3D, USP <232>, or even up to 70 elements in a single certificate of analysis. In the risk assessment process, non-validated analytical methods may be used. The results can thereafter be used to determine which elements to test for on a regular basis using a validated method.

ALS has successfully completed well over 100 method validations compliant with ICH Q2 (R1), USP <233> and Ph.Eur. 2.4.20 for clients in the pharmaceutical industry.

Our laboratory holds 11 ICP-SFMS (high resolution ICP-MS) instruments. Combined with decades of experience with ICP-techniques and method validations, this makes ALS a reliable partner with solid backup capacity.

Microbiological analysis

ALS provide a microbiological testing service to ensure raw materials, finished products, medical devices and production environments are safe from microbiological contamination.

Through our dedicated GMP compliant laboratory, highly experienced staff and extensive range of microbiological tests, ALS Pharmaceutical provides customers with cost-effective quality assurance.

Microbiological quality testing includes:

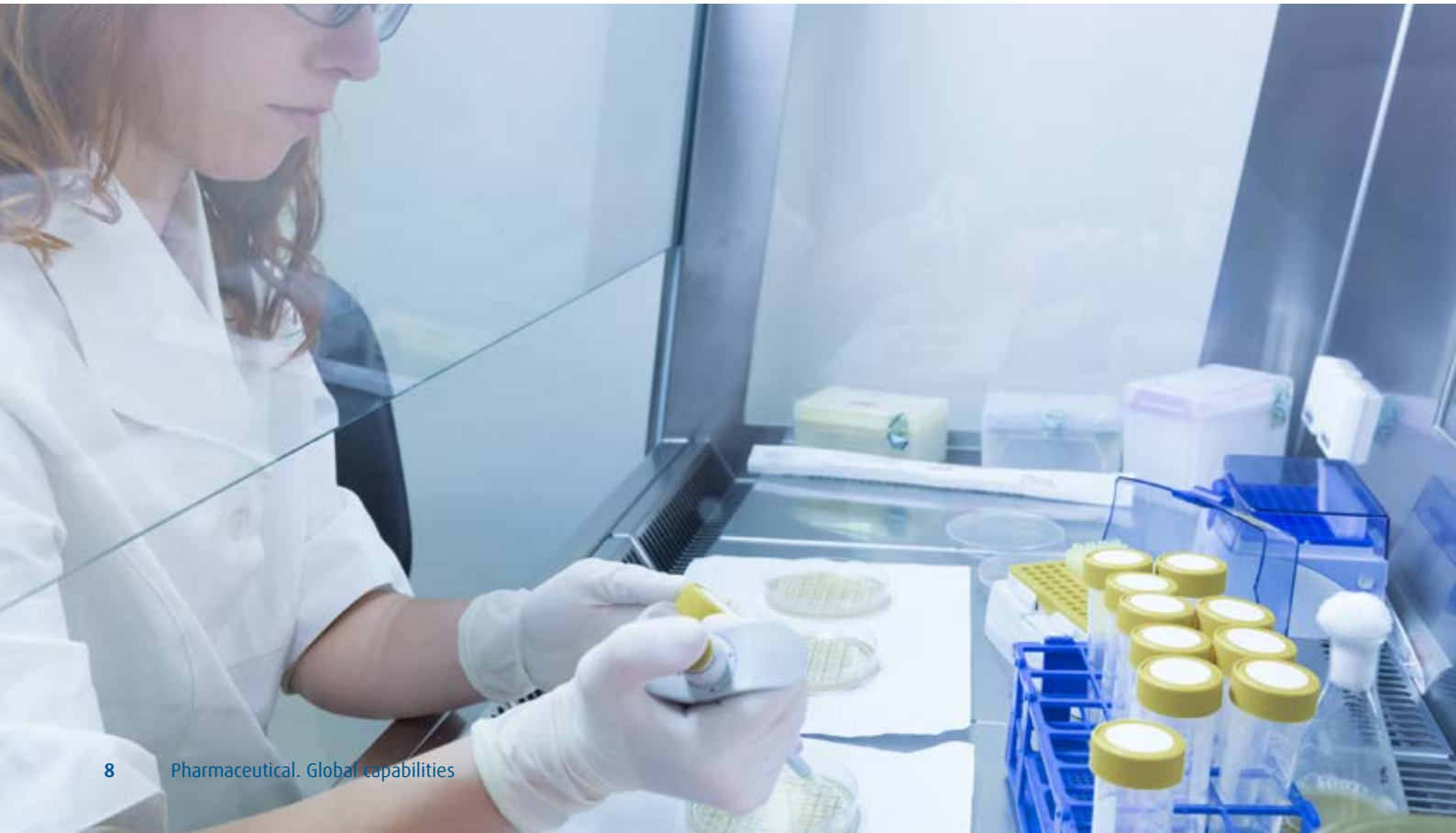
- Microbial Examination of non-sterile products
- Total Viable Count (TVC)
- Total Yeast, Mould & Fungi Count
- Microbial Identification
- **Absence of Specific Pathogens**
  - Staphylococcus aureus
  - Pseudomonas aeruginosa per USP<62>, EP/BP, JP. and harmonized methodology
  - Escherichia coli
  - Salmonella
  - Candida albicans
  - Bile Tolerant Gram Negative Bacteria
  - Clostridia

Environmental

- Settle Plates – Total Bacteria, Yeast and Mould
- Air Plates – Total Bacteria, Yeast and Mould
- Contact plate analysis
- Swab and sponge analysis
- Gowning – contact plates
- Finger dabs
- Non viable particulate matter sampling

Other microbiological services

- **Preservative Efficacy Testing (PET)**
  - Pharmaceutical formulations – oral, topical, injectable
  - Cosmetic formulations
- **Disinfectant Efficacy Testing**
  - Suspension testing, BSEN 1276, 1650, 13704 (Phase 2,step 1) for bacterial, fungicidal and sporicidal assessments
  - Surface testing BSEN 13697 (Phase 2, step 2) for bacterial and fungicidal assessments. USP 1072, disinfectant and antiseptic testing
  - Tailored to client specific requirements - to conclusively demonstrate that their disinfectants are effective under the conditions in which they are used
  - Testing can be performed for manufacturers as well as end users
- **Bacterial Endotoxin Test (LAL)**
  - Gel Clot, Turbidimetric and Kinetic methods per USP, and per EP/BP, and per Harmonized Pharmaceutical Method (USP, EP/BP, JP)
- **Sterility testing**
  - Membrane filtration and direct inoculation
- **Microbial identification by DNA sequencing**
- **Particulate Matter USP & EP**
  - Light Obscuration (HIAC) method
  - Microscopic method



Stability testing & storage

Being an essential component of pharmaceutical development, stability studies allow the evaluation of product stability under the influence of various environmental conditions. These include temperature, humidity and light, simulating different climatic zones from around the world. The data from such studies can be used to establish recommended storage conditions, retest periods and shelf life.

ALS offer ICH stability storage and testing programs for a wide range of API's, pharmaceuticals, biopharmaceuticals, medical devices, chemicals and cosmetics, whether required for initial product registration and/or Product Quality Review (PQR).

Our purpose-built reach-in stability chambers and walk-in stability rooms are fully validated to meet GMP regulations and can be utilised for both long-term and short-term shelf life studies. All rooms are monitored in real time and our monitoring systems are fully validated and compliant with 21 CFR Part 11 requirements.

We operate emergency back-up facilities on site, allowing business continuity and complete peace of mind for our clients.

We can provide a solution tailored to your requirements - storage only or full storage plus testing. Samples can be stored and scheduled for testing or shipped to your chosen location at each time point or as required.

Security

- All chambers are kept locked, with restricted access
- Audible and visual alarms for temperature and humidity (above and below set conditions)
- Data loggers have email and auto dial alert functionality
- UPS on data logger ensuring continuous monitoring and alarm call outs
- Back-up power

Photostability

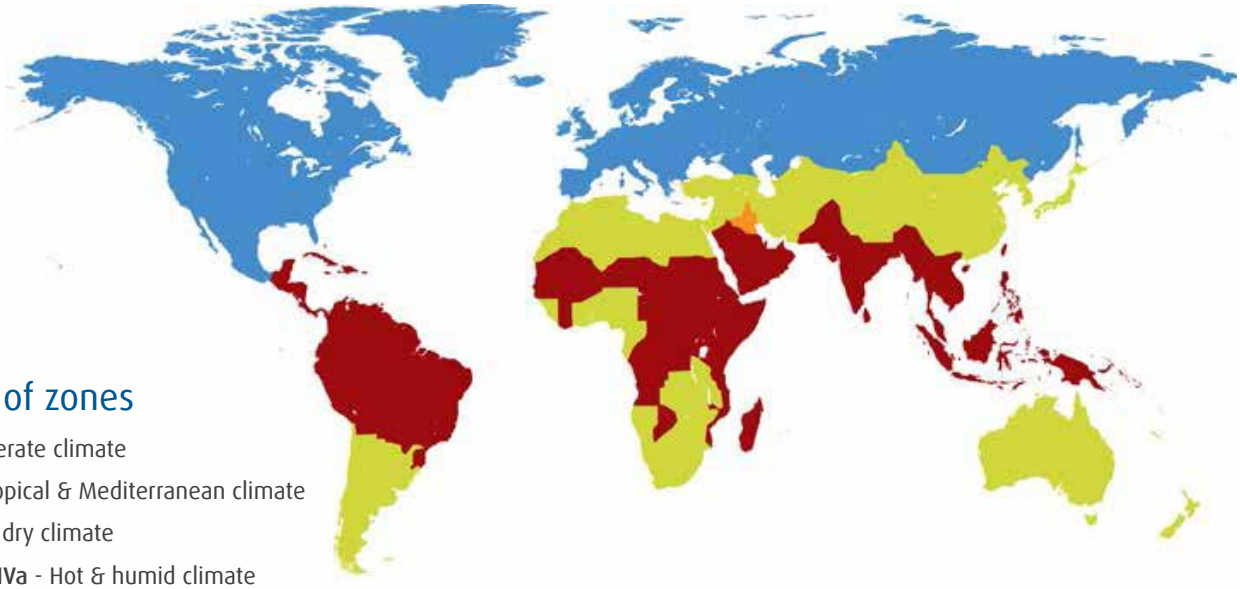
ALS also offer photostability testing in accordance with ICH Q1B (option 2).

Conditions

Stability storage conditions available*:

- -84° to -66°C
  Ultra Low Freezer
- -20° to -10°C or -25° to -15°C
  Freezer conditions
- 5 °C
  Long term conditions for cold stored products or retained/ control samples
- 25˚C/60%RH or AH
  Long term conditions for climatic zones I and II
- 30˚C/65%RH
  Intermediate and long term conditions for climatic zones I, II, III and IVa
- 30˚C/75%RH
  Long term conditions for climatic zone IVb
- 40˚C/75%RH or AH
  Accelerated conditions for climatic zones I, II, III and IV
- 40C/Not more than 25%RH Accelerated condition for semi-permeable containers
- 45° or 50° with ambient humidity
  Accelerated conditions
- Photostability chamber
- Other conditions available on request

** Conditions may vary from location to location please enquire with your nearest facility for more details.*



Definition of zones

Zone I Temperate climate

Zone II Subtropical & Mediterranean climate

Zone III Hot & dry climate

Zone IV **Zone IVa** - Hot & humid climate
Zone IVb - Hot & very humid climate

Purified water testing

Purified water is a vital ingredient used in the manufacturing of most pharmaceutical products. Therefore, it is essential that water purification systems are validated and routinely checked to ensure that the water produced is consistent and meets the specified quality requirements.

ALS provides a complete service for water testing in the pharmaceutical industry. We provide pharmacopoeial analysis of highly purified water, purified water, water for injection (WFI), in addition to water from steam sterilisers and washer disinfectors.

Testing can be undertaken to various standards and guidelines including CFPP01-06, CFPP01-01 Parts C and D, HTM 2030 & 2031, EN285.

Physical & chemical

- Conductivity
- Total Organic Carbon (TOC)
- Heavy Metals
- Nitrates
- pH
- Acidity or Alkalinity
- Oxidisable substances
- Chloride, Sulfates & Ammonium
- Calcium & Magnesium
- Residue on evaporation
- Aluminium
- Iron, Silicates, Phosphates
- Ultra-trace elemental analysis

Microbiological:

- **Analysis by membrane filtration for:**
  - Heterotrophic Plate Count
  - Coliforms
  - Escherichia.coli
  - Pseudomonas aeruginosa

Performing efficiently & ethically at all times

ALS is committed to performing duties in efficient and ethical ways at all times.

Compliance

ALS believes that meeting compliance obligations is a responsibility essential to its long-term success. The company is committed to adhering to all legislation relating to ALS operations. All ALS employees are responsible for complying with policies and procedures established to ensure that ALS fulfils requisite legislative requirements. Every employee, contractor, or agent of the company is held accountable to conform to the law and act ethically at all times.

Confidentiality

ALS employees understand the importance of confidentiality and have implemented policies that ensure the protection of client information. Employees are required to sign and follow ethics, conflict of interest, and confidentiality policies. These agreements are required to ensure that all employees are aware of the following items:

- Laboratory policy regarding ethics and the standards of integrity that are expected of them
- The notion that they are free from any undue pressures that might affect the quality of their work

Client confidentiality ensures that procedures for sending test results by mail, facsimile, email, or electronically meet client requirements. Requests for records made by a third party must be accompanied by written consent from the client. All employees assure clients that confidentiality is observed at all times when presenting records.

System integrity

- cGMP and US-FDA CFR 21 part 11 compliant systems
- Back-up of all data
- Redundancy of major equipment and services
- Professionally managed and maintained
- Custom developed LIMS

Service approach & value adds

Our growth has been built on long-term relationships. Our clients are accustomed to receiving high quality data, technical support and open communication. This approach includes project and client managers, skilled and qualified client services teams, access to technical experts and a management team committed to service delivery.

Standard offering

Our clients have access to a number of value-add services including:

- Results reported electronically in a secure PDF format
- Leading tailored electronic data delivery formats (EDD)
- Full Chain of Custody Protocols including receipt acknowledgement (SRN)
- Expert technical advice and support on scientific issues
- Laboratory inspections and tours
- Technical newsletters
- Webtrieve™

Webtrieve™ service approach and value adds online data access and mobile apps

Real-time results to save you time and money

WebTrieve™ is a secure, internet-based application that provides real-time access to your laboratory data with the following convenient features:

- Internet access to view validated results
- Exclusive, complimentary service to our clients
- Export results to MS-Excel
- Security protection against unauthorized users
- Reports emailed directly to your address
- Multiple levels of access available
- Compare results to guidelines
- Data access 24 hrs/day, 7 days/wk, 365 days/yr
- Online request for quotes and bottle orders
- Online communication with ALS

Technical bulletins

These publications are designed to communicate technical developments and act as an educational resource.

Regulatory, analysis, new technologies and key industry information are routinely featured.

Why choose ALS?

The choice of contract laboratory usually depends on either the quality of service & the integrity of results or costs. At ALS, we are confident in our ability to meet both and add some other factors on top of it:

Quality first

Having provided pharmaceutical testing for over 35 years in accordance with internationality recognised standards, ALS continues to keep quality and transparency at the very core of everything we do. This is evidenced both through the quality systems and equipment we have on site as well as the quality and experience of our staff.

Trust and reliability

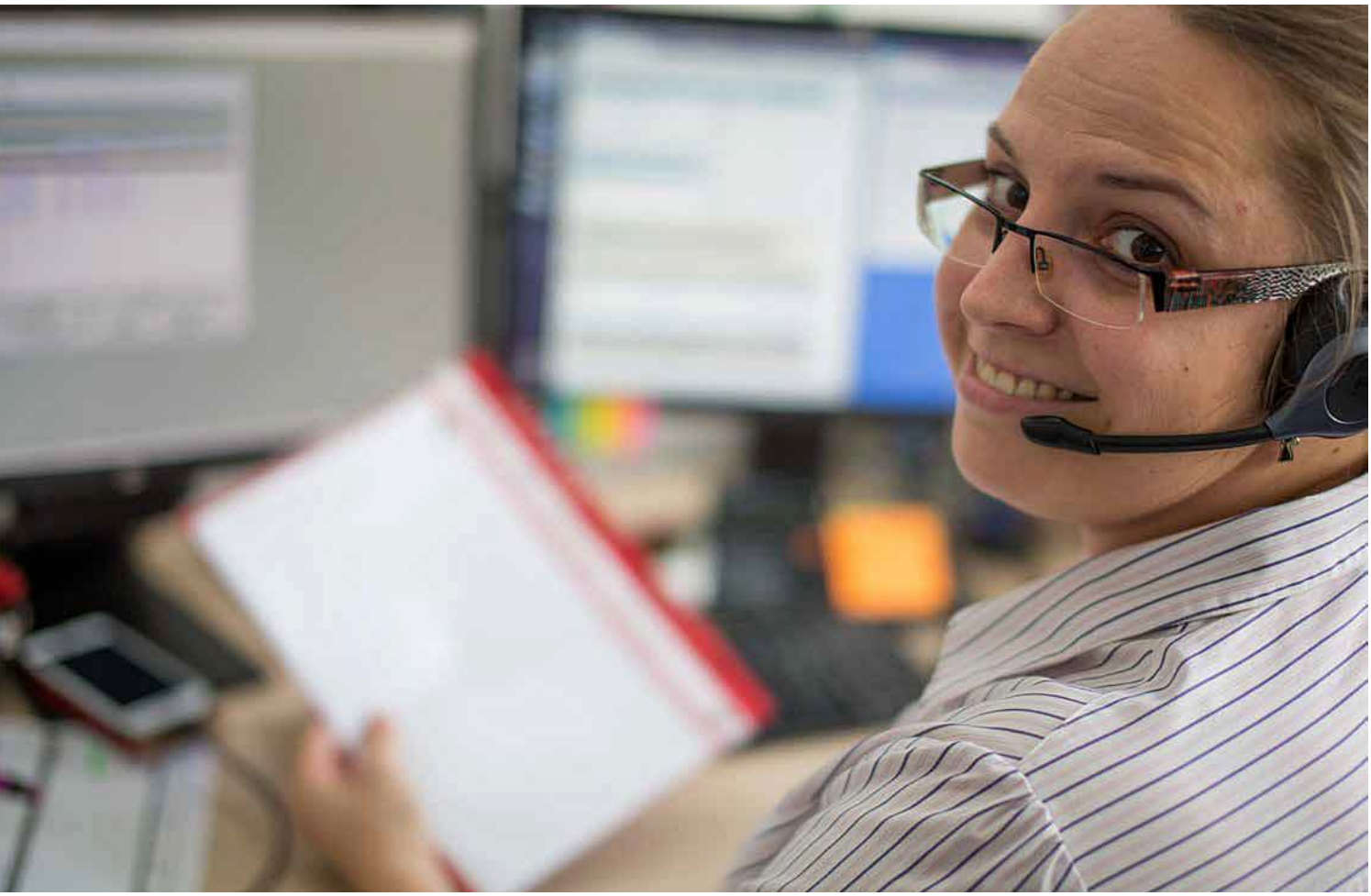
At ALS, we understand that it is not just the quality of testing which is of paramount importance but the opportunity to develop strong and longstanding relationships with our clients. We always strive to go the extra mile for our clients and in times of need, you can be assured that ALS will be right behind you.

Size, scale and diversity

ALS offers its clients access to a global network of accredited laboratories that provide a comprehensive range of tests and services. We cater for businesses of all shapes and sizes and through a process of continuous improvement and investment in our sites we work hard to tailor our solutions to meet the specific needs of each organisation.

Making change easier

At ALS, we appreciate that changing your testing provider is never an easy decision to make. With this in mind, we have a specific implementation process in place (developed over the past several years with other new clients) that ensures all aspects of our service are set up accurately from the outset and that we provide you with the very best of service levels from day one.



Quality management system

The integrity of our test results is of paramount importance, allowing our clients to make informed decisions. Clients work with us safe in the knowledge that their results are reliable, repeatable and meet regulatory requirements.

Regulatory compliance

ALS pharmaceutical laboratory achieves premium service levels through continued investment in quality systems and technology to guarantee on-going compliance.

ALS pharmaceutical laboratories host more than 100 audits annually including:

- US-FDA
- National Regulatory Agencies (GMP, GLP)
- National Accreditation Bodies (ISO 9001)
- International pharmaceutical companies

ALS welcomes clients to visit and/or audit our laboratories. In addition to external audits, we have our internal, independent quality department, which undertakes a programme of self-inspection.

	GLP	GMP	ISO 17025
Ely		✓	✓
Prague		✓	✓
Luleå	✓	✓	✓
Sollentuna		✓	✓
Landskrona		✓	✓
California	✓	✓	✓
Sao Paulo		✓	✓
Mexico		✓	✓
Sao Roque		✓	✓
Campinas		✓	✓
Melbourne		✓	✓
Sydney		✓	✓
Bangalore		✓	✓
Singapore, Malaysia, Thailand & Hong Kong		✓	✓

Proficiency schemes

To provide our clients with additional confidence in our tests results we regularly participate in proficiency schemes.

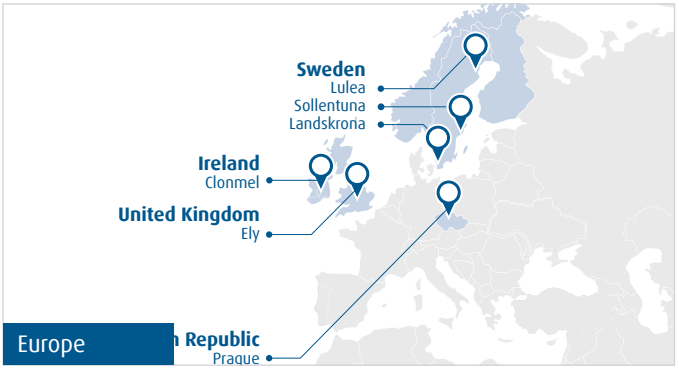
Schemes undertaken include:

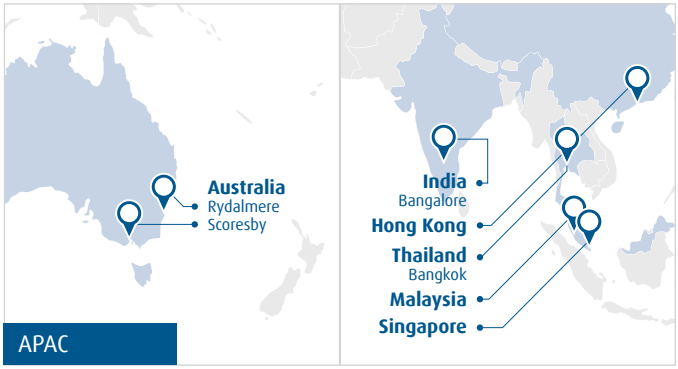
Scheme	Provider	Scope
EDQM	European Pharmacopoeia	Various analytical techniques and product types for pharmaceutical testing (as per Ph.Eur)
Pharmassure	LGC	Various chemical and microbiological techniques and products.
LEAP	FPAS	Chemical Water Analysis
ILPQ	ACC	Endotoxin Analysis
EV - Inter-Lab Ring Trial	Evans Vanodine	Disinfectant Analysis

Certifications & accreditations

ALS global laboratory network holds and maintains a number of certifications and accreditations.

Laboratory network





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