Culture Collections Customer Information Pack

Purpose

This pack has been put together to provide you with information relating to the approval of Culture Collections as a supplier to your organisation. Here you can find out about our company information, quality accreditation, quality management system, and other controls relevant to the products we supply.

About UKHSA

The UK Health Security Agency (UKHSA) operates four internationally recognised Culture Collections of preserved, authenticated cell lines, bacteria, viruses and fungi. Maintained by highly skilled specialists and operated to ISO 9001:2015 quality standards, these resources provide scientists with trusted reference materials of known provenance.

The UKHSA is an executive agency sponsored by the Department of Health and Social Care.

Contact Information

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Certification and Accreditation

- We have held accreditation to ISO/IEC 17025 since 2015, for testing of biological samples and media.
- We have held certification to ISO 9001 since 2012.
- We hold a licence under the Human Tissue Act 2004 for the storage of material (whole blood and peripheral blood lymphocytes) for specific research purposes.
- Our certificates can be downloaded here: Quality accreditations | Culture Collections

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Quality Management

We operate a Quality Management System that meets the requirements of ISO 9001 This includes processes covering training and competency, maintenance, document control, complaints and feedback, change management, supplier management, internal audit, nonconformance, improvement and corrective actions, and management review.

Laboratory Management

We hold accreditation to ISO 17025 for testing. The laboratory management system includes processes covering competency, maintenance of equipment, calibration, validation of methods, sample management, technical records, reporting of results, and control of non-conforming products.

FAQs

We have prepared information on some of the most commonly asked questions below to help you understand the processes and controls we have in place.

Policy	
Do you have corporate policies for social and economic responsibility?	These are available to view and download from the gov.uk website: https://www.gov.uk/government/news/our-commitment-to-corporate-social-responsibility-csr
Do you have a business continuity plan (BCP)?	We maintain a documented BCP and impact assessment to ensure we can swiftly respond in the event of potential disruption .
Quality documentation	
Do you have a Quality Manual?	We have a Quality Manual that is designed around the requirements of ISO 9001 and ISO 17025. It is reviewed and updated annually.
Do you have a Quality Policy?	This is available to view and download on our website: Quality accreditations | Culture Collections
Do you use SOPs for processes?	All quality, laboratory and administrative processes are described in SOPs.
How often are SOPs reviewed	SOPs have a maximum review period of three years.
Who approves your quality documentation?	All SOPs are reviewed and approved by a second person trained and competent to do so, typically a team leader or member of management or QA.
How long do you retain records for?	Records are retained according to a retention schedule in line with the NHS Records Management Code of Practice.
Quality Management Systems	
Do you have a change control process? Are your customers notified of changes?	We have a documented change control procedure. Customers are notified of significant changes or recalls of products. We can put change notification agreements in place with our customers on request.

Do you have an internal audit or self-inspection programme?	We have an internal audit programme to ensure compliance to required standards and regulations. This includes planned horizontal, vertical and witness audits of all accredited activities.
Do you have a process to manage non-conformance and corrective action?	Non-conformances are logged, including consideration of the need for corrective action. Preventive actions and quality improvements are also logged in our quality management system.
Do you have a complaints procedure?	All feedback from customers is managed according to our Customer Services Policy: Customer service policy | Culture Collections
Personnel	
Do you have a system in place to ensure employees are suitably trained?	We have systems to ensure employees are trained and competent to perform the activities they are responsible for. All accredited laboratory activities are subject to regular competency assessments for all staff.
How is training recorded?	Training and competency are documented in electronic training records, including supervisor sign-off where relevant.
How is competency assessed?	A combination of observation, supervision, internal and external quality assessment, and witness audit. Final sign-off is by a competent supervisor.
Facilities and Equipment	
Do you have a preventative maintenance programme?	All facilities, utilities and equipment are subject to planned preventive maintenance where this is assessed as needed.
Do you have a calibration programme?	All measuring equipment is subject to regular scheduled calibration, ensuring metrological traceability is documented.
Do you have procedures for lab cleaning and maintenance to prevent cross-contamination?	All labs are subject to regular, documented cleaning and maintenance. Environmental monitoring provides additional confidence of suitability of lab environment.
Do you have a pest control programme?	There is a pest control programme in our facilities.
Are controlled temperature units monitored and alarmed?	All controlled temperature units (fridges, freezers and incubators) in accredited labs are subject to continuous temperature monitoring and discrepancy alarms. Units are also temperature mapped (validated) to provide assurance of performance throughout the storage area.
Warehousing and Transport	
How are your warehouses maintained?	Materials in long terms storage or awaiting shipment in our warehouses are stored in appropriate, monitored and alarmed conditions. Warehouse areas are subject to regular cleaning, inspection and maintenance. Inventory control is strictly managed and audited regularly.

How are products shipped from your facility?	We use appropriate packaging and temperature control depending on the product. This includes ambient shipment, protective packaging, and/or dry ice as needed. Shipments are via approved courier and are tracked during transit.
Supplier Management	
Do you have a supplier qualification programme?	Suppliers are assessed and approved based on audit and/or provision of suitable evidence of accreditation or certification.
Are any activities outsourced relating to your schedule of accreditation?	No.
Are any other activities outsourced?	Calibration and maintenance of equipment is performed by an approved third party.
Production	
Do you record batch manufacturing information?	All manufactured batches are documented on Manufacturing Batch Records.
Do you supplier certificates of analysis (CofA) for your products?	All products may be supplied with a CofA. The vast majority are available to download from our website. Some of our older products can have a CofA made on request.
Do you use animal by-products in any of your production?	Some of our cell lines are grown using FBS, and some bacterial strains are grown using horse serum or on agar containing animal products (such as horse blood agar) We can provide the name of the suppliers of this material on request.
Quality Control	
Are your testing procedures validated?	Accredited laboratory procedures are validated.
What controls do you use as part of testing?	We use standard controls for all our accredited tests.
What other processes do you use to give confidence in your testing results?	We regularly perform IQA (internal quality assessment) and EQA (external quality assessment) testing. Use of controls in testing is subject to monitoring and KPI trending. Our tests are subject to regular competency assessment and internal audit.