09 Sep 2020

ICON Laboratory Services: Central Laboratory Statement

This document briefly outlines the general processes in place to ensure the quality of services provided by ICON Laboratory Services' Central Laboratory service line. Each section listed has a set of global Standard Operating Procedures, which are periodically reviewed and revised to ensure compliance to current regulations and guidelines. ILS is dedicated solely to clinical trial testing, so all systems and procedures are designed to comply with regulations and guidelines for Clinical Trials and Good Clinical Practices.

Specifications related to individual studies are described in the relevant study documentation.

Location of Facilities

ICON Laboratory Services (ILS) operates Central Laboratory facilities at the following locations:

- 123 Smith St. Farmingdale, New York 11735, United States of America
- South County Business Park, Leopardstown, Dublin 18, D18 X5R3, Ireland
- Block 30 Loyang Way, #2-15 Loyang Industrial Estate, Singapore 508769, Republic of Singapore
- 1st Floor, Building 3, No 8 Hongda North Road, Beijing Economic Technological Development Area, Beijing China. 100176

Licencing and Accreditation

All ILS Central Laboratory facilities are accredited by the College of American Pathologists (CAP), an internationally recognised gold standard for clinical laboratory accreditation. CAP accreditation provides clinical trial sponsors and regulatory bodies with a high degree of assurance that ILS maintains systems and procedures to ensure the best standard of laboratory results.

ILS also holds licences and certificates from applicable local regulatory requirements as well as industry specific certification, including but not limited to:

- US New York State Department of Health
- US Clinical Laboratory Improvement Amendments (CLIA)
- NGSP Haemoglobin A1c Level 1
- Singapore Ministry of Health
- China National Centre for Clinical Laboratory (NCCL)

Copies of current licences and certificates are available upon request.

Facility Security

All facilities have secure access control systems which restrict access to personnel and approved visitors only. Additional access restrictions apply to internal areas for specific testing, sample storage, data archive and server rooms.

Sample Traceability

Samples are labelled with visit specific barcodes by investigator sites to allow traceability of individual samples at all times from initial transport of samples, through the accessioning, analysis, and any applicable storage and shipment stages.

Samples may be stored temporarily following analysis to enable repeat testing or verification of sample identity if requested by sites/sponsors. This period is typically 2 weeks; however alternative timelines may be applicable according to local regulatory and protocol requirements for certain sample types. The samples are then discarded and destroyed by a waste management company contracted by ILS.

ILS may store pre-defined samples for longer terms as defined by the sponsor in study documentation. These samples are stored under controlled conditions, and are typically transported back to the sponsor or to a third party facility at the sponsor's request.

Subject Data Protection

ILS only records information necessary for processing results, including limited subject information as approved in advance by sponsors. This information is typically limited to date of birth, initials and gender, however further local restrictions may also apply. ILS does not collect or store subject names, social security / public service numbers, or other personal information unrelated to the clinical trial.

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Temperature Monitoring of Samples
Samples are stored in secure facilities with electronic systems in place to track samples to a specific location within storage units. Units are fitted with electronic systems for continuous environment monitoring, data recording and alarm notification. Samples are stored at pre-defined conditions as determined by sponsors and/or internal procedures. Sample storage conditions typically consist of Ambient, Refrigerated, -20°C, -80°C, or Liquid Nitrogen.

Training and Qualification of Personnel
Personnel are verified upon hire as having the appropriate qualifications and experience to perform their specific function. A comprehensive training program is in place to provide initial and on-going training for personnel.

Electronic Systems
Applicable electronic systems are appropriately validated and contain adequate access controls, audit trails, data security and backup measures. Electronic data is retained in our systems for defined periods as specified by relevant regulatory requirements and Good Clinical Practices.

Laboratory Analysis, Equipment and Instrumentation
ILS only performs analytical testing that is requested by our sponsors and defined in study documentation. Samples are not shared between protocols.

Infrastructure is in place to ensure standardisation of results between laboratories. Each location operates from a global set of Standard Operating Procedures and participates in External Quality Assurance schemes for each technical discipline.

Suitably qualified, state of the art instrumentation and equipment are used and maintained to ensure optimal performance. ILS uses the same instrument platform families and where possible, identical lots of reagent and quality control materials across facilities to ensure global consistency of laboratory results.

New analytical methods are investigated and validated internally to verify that the manufacturer's claims can be replicated in-house. Once a method is implemented a variety of procedures are in place to ensure standardisation:

- Quality Control process includes daily, weekly, monthly and quarterly reviews performed for each assay
- Regular Technical Committee meetings are held to review EQA and QC data
- Periodic management reviews performed to monitor performance and quality indicators
- Inter-laboratory comparison studies performed to ensure all locations have the ability to quantify in an indistinguishable manner

Quality Control
Appropriate checks and verification procedures are in place at critical process points to ensure data integrity is maintained during pre-analytical, analytical, and post-analytical stages of clinical trial operations within the central laboratory.

Quality Assurance & Internal Audit Program
Frequent process, system and technical audits are performed across all operational areas by an independent Quality Assurance unit to ensure compliance to applicable regulations and guidelines.

Kristina Nemeth
Kristina Nemeth
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Kristina Nemeth
QA Manager
Quality Assurance
ICON Laboratory Services

Date