

Examen Labs — Secure International Clinical Cold-Chain Logistics

Official Standard Operating Procedure (SOP) governing the secure transport of cryopreserved specimens from licensed international healthcare facilities worldwide to Examen Labs Central Facility, Belfast, United Kingdom.



-196°C Cryogenic Storage



Worldwide → Belfast Route



100% Chain of Custody



[View Full Protocol](#)

Regulatory Compliance & Control Profile

This SOP operates under a fully compliant Peer-to-Peer Scientific Exchange Exemption framework, satisfying all applicable local healthcare and international marketing laws. The originating node is a licensed international healthcare facility registered under the relevant national regulatory authority. The destination laboratory is Examen Labs Central Facility, Belfast, United Kingdom.



Document ID

EX-INTL-BELFAST-SOP-2026



Originating Node

Licensed International Healthcare Facility — Relevant National Regulatory Authority



Destination Laboratory

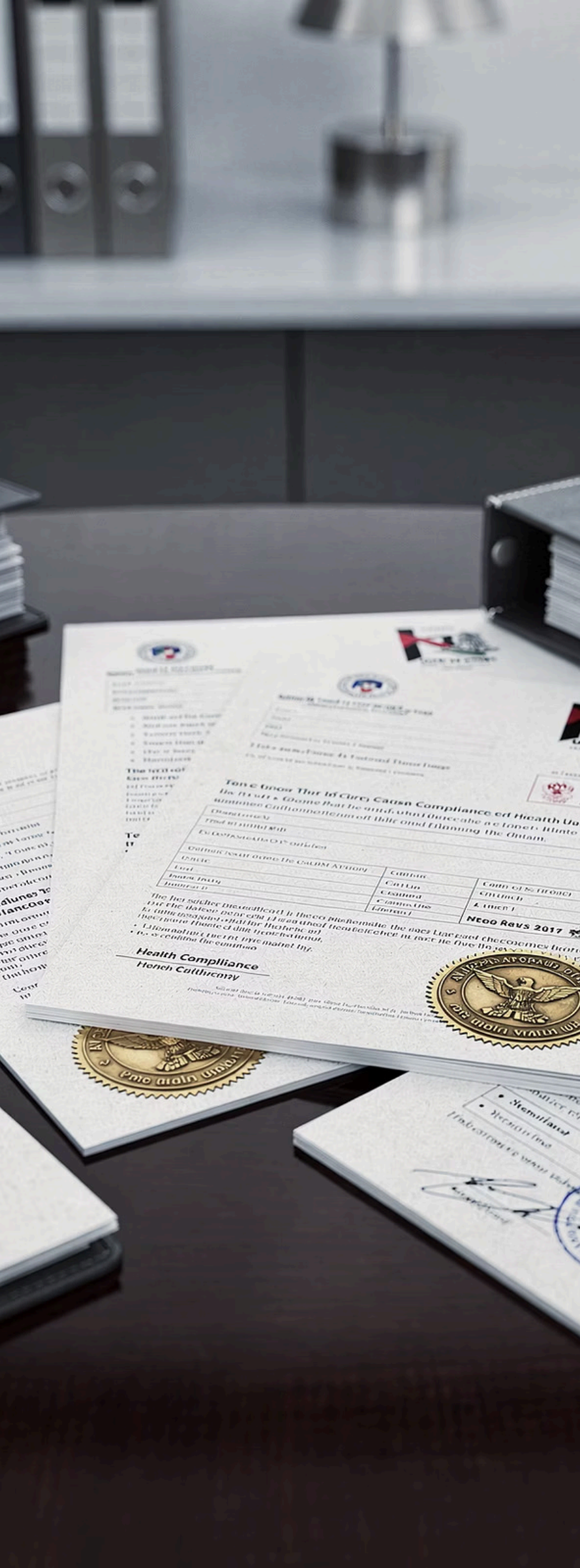
Examen Labs Central Facility, Belfast, United Kingdom



Compliance Framework

Peer-to-Peer Scientific Exchange Exemption — fully compliant with applicable local Healthcare and International Marketing Laws

All parties involved in the transit pipeline are required to adhere strictly to this document. Any deviation from the procedures outlined herein must be escalated immediately to the designated clinical logistics coordinator at Examen Labs Belfast. Regulatory compliance is non-negotiable at every stage of the cold-chain process, from specimen preparation through to final laboratory accessioning.



Pre-Transit Specimen Preparation & Cryopreservation

Rigorous specimen preparation is the foundation of a successful cold-chain transfer. Every step must be executed precisely to ensure sample viability upon arrival in Belfast. The following protocol governs all pre-transit handling of semen specimens at the originating UAE facility.



Liquefaction & Assessment

Semen specimens must undergo complete liquefaction at **37°C for 30 minutes** before any processing commences. This ensures accurate assessment of baseline parameters prior to cryopreservation.



Spermatic Aliquoting

Divide the raw ejaculate into dedicated cryovials with clear barcode labels linked to the client ID. Accurate labelling is critical for chain-of-custody integrity throughout transit.



Flash-Freezing Matrix

Cool specimens progressively before flash-freezing to **-80°C**, or immerse directly in Liquid Nitrogen (LN2). Progressive cooling minimises ice crystal formation and protects cellular integrity.

❌ **CRITICAL:** Samples must not thaw at any point during transit. Exposure to temperatures above **-40°C** will trigger irreversible genomic degradation, rendering specimens non-viable for SpermComet® analysis.





Dry Vapour Shipper Charging Protocol

The dry vapour shipper is the cornerstone of safe cryogenic transport. Approved hardware includes **MVE Chart** and **Taylor-Wharton** Liquid Nitrogen Dry Vapor Shippers, both equipped with hydrophobic absorbent layers that eliminate liquid spill hazards — a mandatory requirement for international air freight compliance.



LN2 Saturation Phase

Fill the shipper with liquid nitrogen and allow it to sit for a minimum of **2 hours** until the internal matrix is completely saturated. This saturation phase is essential to achieving and maintaining the required holding temperature throughout the entire transit duration.



Vapour Holding Matrix

The chamber temperature must register at **-150°C or colder** before specimens are loaded. This dry vapour environment maintains cryogenic temperatures without the presence of free liquid nitrogen, eliminating spill risk during air transport and ensuring full compliance with IATA Dangerous Goods Regulations for biological specimens.

Global Transit Pipeline — Overview

The international-to-Belfast cold-chain pipeline is a precisely coordinated, multi-stage logistics operation. Each step is designed to minimise handling risk, reduce border dwell times, and maintain unbroken cryogenic integrity from the originating international facility to the Examen Labs accessioning queue in Belfast.



The pipeline is managed end-to-end by dedicated medical logistics partners operating under strict SLA agreements with Examen Labs. Real-time temperature monitoring via continuous data loggers accompanies every shipment, providing an auditable record of thermal compliance at every stage of the journey from the originating country to the United Kingdom.

Transit Pipeline — Step-by-Step Detail



Laboratory Lock

Specimens are secured inside the dry shipper's internal canister with **single-use tamper-evident security tags**. The shipper is sealed and logged with a unique shipment reference number linked to the client ID and data logger serial.



Customs Manifest

The shipment travels under a **pre-cleared, priority biological diagnostic manifest** to minimise border dwell times. All documentation is prepared in advance to satisfy the originating country's export and UK import regulatory requirements.



Belfast Accessioning

Upon arrival at the Belfast facility, technicians verify the data logger profile and accession samples directly into the **SpermComet®** testing queue, initiating the diagnostic workflow without delay.



Courier Handoff

Dedicated medical logistics teams — including **DHL Medical Express** and **World Courier** — collect the shipper directly from the originating facility. Chain-of-custody documentation is signed and timestamped at handoff.



Express Air Routing

Priority air freight routes the shipper directly from the nearest international departure hub to UK connection hubs, ensuring the fastest available transit time and minimising thermal exposure risk.



Air Routing & Courier Partners

Express air routing is the critical link in the international-to-Belfast cold-chain. Shipments depart from the nearest available international airport, utilising priority biological freight channels to reach UK connection hubs with minimal transit time. The selection of departure airport is determined by the originating facility's location and the earliest available priority freight slot.

Approved medical logistics partners — including **DHL Medical Express** and **World Courier** — are contracted to handle cryogenic biological specimens in full compliance with **IATA Dangerous Goods Regulations**. These partners maintain dedicated cold-chain handling capabilities at international departure airports and UK arrival hubs worldwide, ensuring the dry vapour shipper is never subjected to inappropriate storage conditions or unnecessary delays during ground handling.



Departure Airports

Nearest available international departure airport — priority biological freight channels utilised for fastest available routing to the UK.



Approved Couriers

DHL Medical Express and World Courier — both operating under IATA Dangerous Goods Regulations for cryogenic biological specimens.



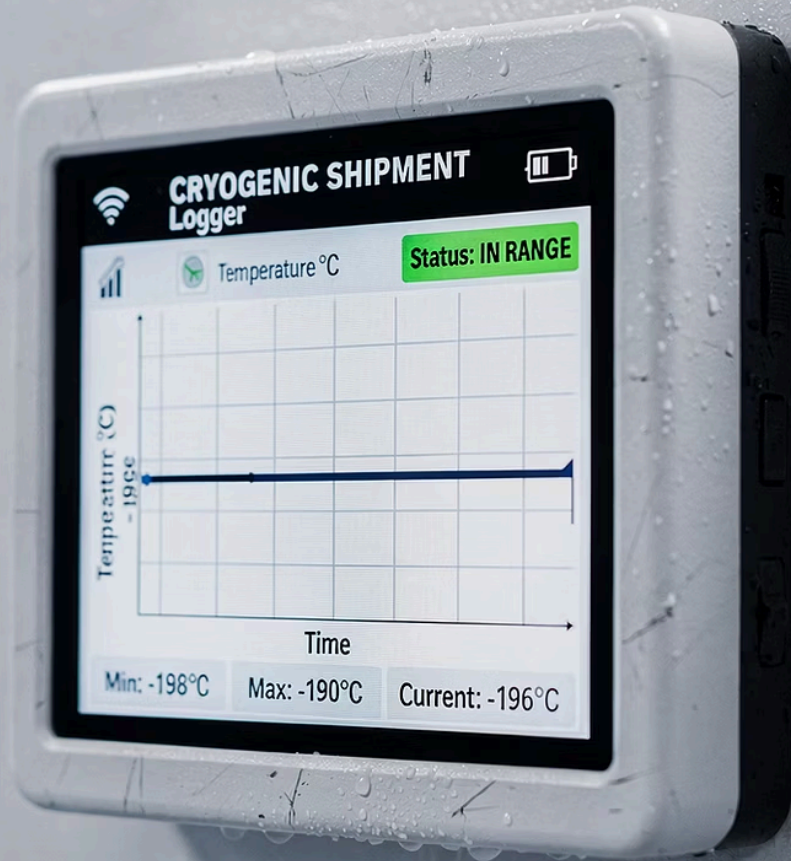
Pre-Cleared Manifests

All customs documentation is prepared in advance to minimise border dwell times and ensure uninterrupted cold-chain continuity.



Service Level Agreements & Temperature Compliance

Examen Labs operates under clearly defined Service Level Agreements (SLAs) that govern temperature compliance, turnaround times, and data security standards. These commitments apply to every shipment processed through the international-to-Belfast cold-chain pipeline, without exception.



Temperature Data Audit

The dry vapour shipper's continuous data logger profile is audited upon arrival at the Belfast facility. The audit verifies unbroken temperature compliance throughout the entire transit duration. Any excursion above the critical threshold is flagged immediately and escalated to the clinical team before accessioning proceeds.



Turnaround Commitment

Comprehensive **SpermComet® reporting indexes** are uploaded to the secure clinic portal within **7 working days** of sample arrival and accessioning. This turnaround commitment ensures referring clinicians and patients receive actionable diagnostic results without unnecessary delay.



Data Security Standards

All diagnostic data transmission utilises secure portals fully compliant with regional and international privacy standards. Patient data is handled in accordance with applicable UK and originating country data protection legislation throughout the diagnostic and reporting workflow.

SpermComet® Reporting & Portal Access

Upon successful accessioning at the Belfast facility, specimens enter the **SpermComet®** testing queue — Examen Labs' proprietary DNA fragmentation analysis platform. **SpermComet®** provides a comprehensive suite of reporting indexes that give referring clinicians a detailed picture of sperm DNA integrity, enabling more informed clinical decision-making for patients undergoing fertility investigation or treatment.

Results are compiled into a structured diagnostic report and uploaded to the secure clinic portal within **7 working days** of sample arrival. The portal provides referring clinicians with direct, secure access to all reporting indexes, supporting seamless integration into the patient's ongoing clinical pathway. All data transmission is encrypted and fully compliant with both **UK GDPR** and applicable local data protection regulations in the originating country, ensuring patient confidentiality is maintained at every stage of the reporting process.

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Working Days

Maximum turnaround from sample arrival to SpermComet® report upload on the secure clinic portal.

-150°C

Holding Temperature

Minimum chamber temperature required in the dry vapour shipper throughout the entire transit pipeline.

37°C

Liquefaction Temp

Required specimen liquefaction temperature maintained for 30 minutes prior to cryopreservation processing.



Summary: End-to-End Cold-Chain Assurance

The Examen Labs International Cold-Chain SOP (**EX-INTL-BELFAST-SOP-2026**) represents a fully integrated, regulatory-compliant logistics and laboratory protocol designed to ensure the safe, secure, and scientifically rigorous transfer of cryopreserved specimens from licensed international healthcare facilities worldwide to Examen Labs Central Facility in Belfast, United Kingdom.

From pre-transit specimen preparation and dry vapour shipper charging, through express air routing and customs clearance, to Belfast accessioning and **SpermComet®** reporting — every stage of this pipeline is governed by strict SLAs, continuous temperature monitoring, and internationally recognised data security standards. The result is a seamless, end-to-end service that clinicians and patients can rely upon with confidence.



Regulatory Compliance

Nationally registered healthcare facility required. Peer-to-Peer Scientific Exchange Exemption fully satisfied.



Cryogenic Integrity

Unbroken cold-chain at **-150°C** or colder from UAE laboratory to Belfast accessioning queue.



Rapid Reporting

SpermComet® results delivered to the secure clinic portal within **7 working days** of arrival.



Data Security

UK GDPR and applicable local data protection compliant. Fully encrypted secure portal transmission.