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CLINICAL DIAGNOSTICS

IVD Raw Materials

Dear Reader

For ease of navigation, internal links are included in this document:

- Items in the list of Contents are linked to their corresponding pages
- Click on any page number or IVD Raw Materials Logo to return to the Contents page
- URLs in the document are linked to their websites (internet access required)
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Introduction

Technopath Clinical Diagnostics (Technopath) is a privately owned Irish company that manufacture and supply high quality IVD materials to a wide-ranging customer base. Our proprietary processing techniques satisfies the raw material requirements of the IVD industry and provides IVD raw materials made to our own "off-the-shelf" specification. In addition, we offer the added-value of developing and manufacturing raw materials that are fully customised to ensure customers receive the best solution possible for their specific applications and needs.

Technopath's IVD raw materials are manufactured by our experienced team at our FDA registered facility under an established quality system. The company holds an ISO: 13485 accreditation and customers can be confident in a high quality product.

Our objective is to provide IVD raw materials of the highest quality, tailored to customer requirements, when they need them, delivered anywhere in the world. We take pride in establishing long-lasting partnerships with customers and continuing to develop those relationships over the long term.

Our extensive experience of true third party quality control, reagent and calibrator manufacture is the foundation on which our industry leading range of human based IVD raw material products has been developed.

The unique expertise of Technopath's team has facilitated in the design and development of high quality and uniquely stabilised IVD raw materials, that add value to customers' research, manufacturing and production processes. This ensures partners are provided with materials that closely replicate the behaviour of patient samples on point-of-care, manual and automated test systems.

Our IVD raw material products are used by customers worldwide in the following areas:

- Research and Development
- Manufacture of IVD reagents, calibrators and controls
- Protein purification, human lipoprotein extraction
- Manufacture of proficiency testing samples and EQA specimens

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Why choose Technopath Clinical Diagnostics?

Save valuable time and resources in your manufacturing facility.

As Technopath manufacture the material to customer specific requirements, reduced levels of processing are required in the customer's facility.

Reduce your lead-time.

We have the ability to perform a significant portion of upstream processing ensuring that customers can focus on the core value-added elements of their manufacturing process.

Proven track-record for delivering on time to a global customer base.

For over 10 years, Technopath has supplied our IVD raw material products to customers in Europe, North and South America as well as across Asia.

Receive the material you need when you need it.

Technopath can provide customers with a call-off delivery model to facilitate level-loading of their production activity. In this case, scheduled deliveries of IVD raw materials to customers' facilities can be arranged to support just-in-time manufacturing practices.

Proprietary processing techniques

Proprietary processing techniques have been developed by Technopath to overcome the challenges of manufacturing human based IVD products. Technopath serum products do not contain bovine thrombin resulting in lower levels of protease activity in its serum products. As a result, analytes that are affected by increased levels of protease activity are not compromised in a finished product.

Reduced variation together with small to large-scale manufacturing capability.

Technopath have the capacity to manufacture material from small-scale to large-scale, with single batch volumes ranging from 100mL for research purposes to over 1,500 litres for large-scale production requirements. Product can be reserved for customers so the same lot number of IVD raw material can be used over an extended period of time, saving customers time and resources by reducing incoming raw material testing.

Technopath's Commercial Process

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Features and Benefits

Human Based Raw Materials

All Technopath's human sourced raw materials are collected from licensed and regulated facilities in both Europe and the USA.

Accreditation

Technopath's Quality Management System is accredited to ISO:13485 standard and our world-class facility is US FDA registered. The company's third party Multichem™ QC products are CE-marked, US FDA 510K and Chinese FDA approved.

Reliability

All plasma donations are tested at donor level for each of the mandatory viral markers as recommended by the US FDA, using either FDA or CE approved assays, each time that a donor presents for donation. The result is that to date Technopath have a very low instance of look-back notification events over a ten-year period.

Traceability

Technopath's IVD Raw Materials are fully traceable back to donor level.

Frozen Material

Technopath sources plasma that is frozen within 72 hours of donation meaning that our material is of the highest quality.

Stable Price Points

Technopath has long-term supply agreements in place with key plasma and blood suppliers, ensuring our customers are provided with a consistent source of material at a stable price-point.

Volume

Technopath have guaranteed access to over 250,000L of plasma annually. This ensures we can meet large volume requirements.

Understanding Customer Requirements

At Technopath, we understand the complexity of single analyte and multi-analyte quality control manufacture and these challenges are always at the forefront of our minds when developing and manufacturing IVD raw material products.

Production Capability

Technopath has the ability to manufacture batches of material from 100mL up to 1500L in volume - satisfying customer requirements from R&D activities right through to full-scale production.

IVD Raw Material Products

- ✔ Fresh frozen human plasma (Available as individual units or pooled)
- ✔ Liquid recovered human plasma (Available as individual units or pooled)
- ✔ Normal human serum
- ✔ Human RF Positive serum and plasma
- ✔ Delipidated/delipidized human serum (low cholesterol human serum)
- ✔ Off-clot human serum (Available as individual units or pooled)
- ✔ Human Disease state and allergy plasma and serum
- ✔ Human Low density lipoprotein extract (HLDL)
- ✔ Human High density lipoprotein extract (HHDL)
- ✔ Human lipoprotein extract (HLPX- combination of LDL and HDL in physiological ratios)
- ✔ Triglyceride concentrate (avian source)
- ✔ Normal human urine (stabilised uric acid and creatinine)
- ✔ Human lysed and stabilised Red Blood cells
- ✔ Human whole blood A1c concentrate
- ✔ Bovine Serum Albumin (lyophilised powder or liquid frozen format)
- ✔ Human Serum Albumin (lyophilised powder or liquid frozen format)
- ✔ Albumin enriched human serum
- ✔ IgE serum and plasma
- ✔ Depleted sera (Low TSH, low Vitamin D, and many more options available)

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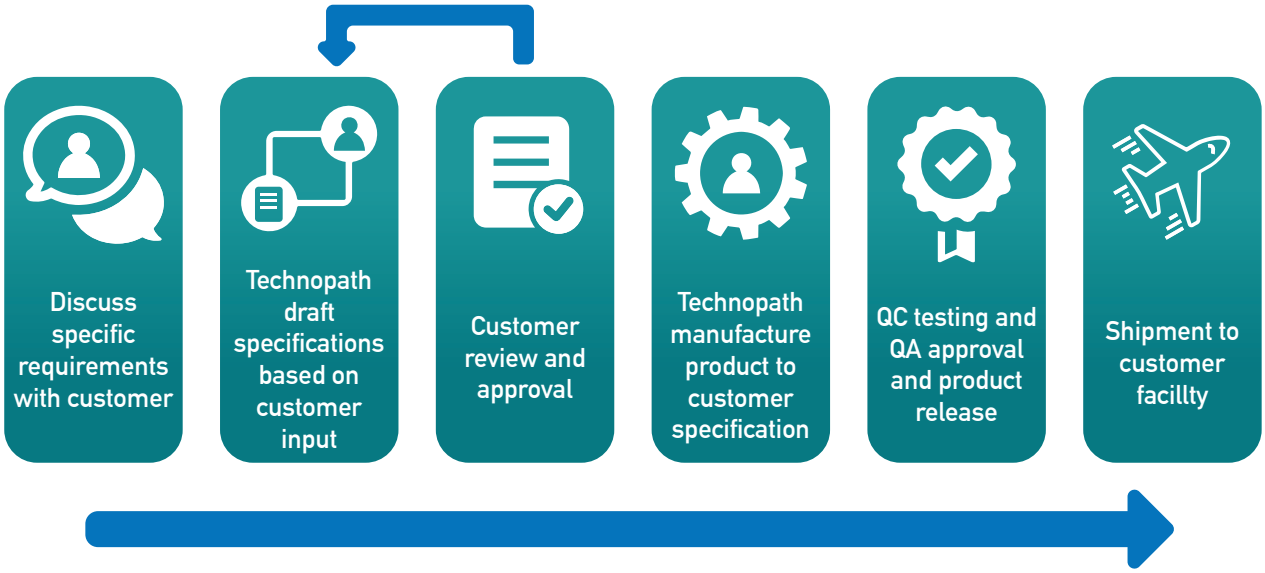
IVD Raw Material Customisation

Technopath's IVD raw material products can be customised to satisfy specific customer requirements.

By working with customers, our expert team at Technopath can tailor each product to a customer's desired preferences. To provide some examples, our customisation process ranges from base matrix selection, preservative cocktail composition, analyte selection and targeting as well as aliquot size.

We adhere to the following workflow to ensure our customers' needs are satisfied:



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Contact Us

Technopath's customised IVD raw materials can be shipped world wide from our FDA registered facility in Tipperary, Ireland.

For further details on IVD raw materials from Technopath Clinical Diagnostics, please contact us:

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