

GE Healthcare
Life Sciences

Your needs, our capabilities

Supporting you from product concept
through commercialisation



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Custom and contract manufacturing

A collaboration with GE Healthcare Life Sciences offers real benefits

Many of GE Healthcare’s renowned portfolio of Amersham™ and Whatman™ products are used as tools and/or components in a range of applications in life sciences, diagnostics, pharmaceuticals, and environmental sciences. In addition, GE Healthcare can provide the extensive capabilities offered by our ISO-certified manufacturing centres and process rigour, including Design For Six Sigma (DFSS) and Lean manufacturing. Taken together, the portfolio and capabilities of GE Healthcare offer a leading custom and contract manufacturing operation that provides all aspects of the manufacturing process to an assured quality.

FIELDS OF EXPERTISE

- Filtration
- Separation
- Molecular biology
- Protein biochemistry
- Engineering
- Custom design
- Diagnostic components

CUSTOM MANUFACTURING

- Customisation of our standard catalogue portfolio
- Bulk supply
- Room temperature assay stabilisation
 - Individual reagents
 - Complete multiplex assays

CONTRACT MANUFACTURING

- Assay validation
- Formulation
- Kitting capability
 - Assembly and packaging
- Analytical services
- Final product testing
- Lean Six Sigma manufacturing

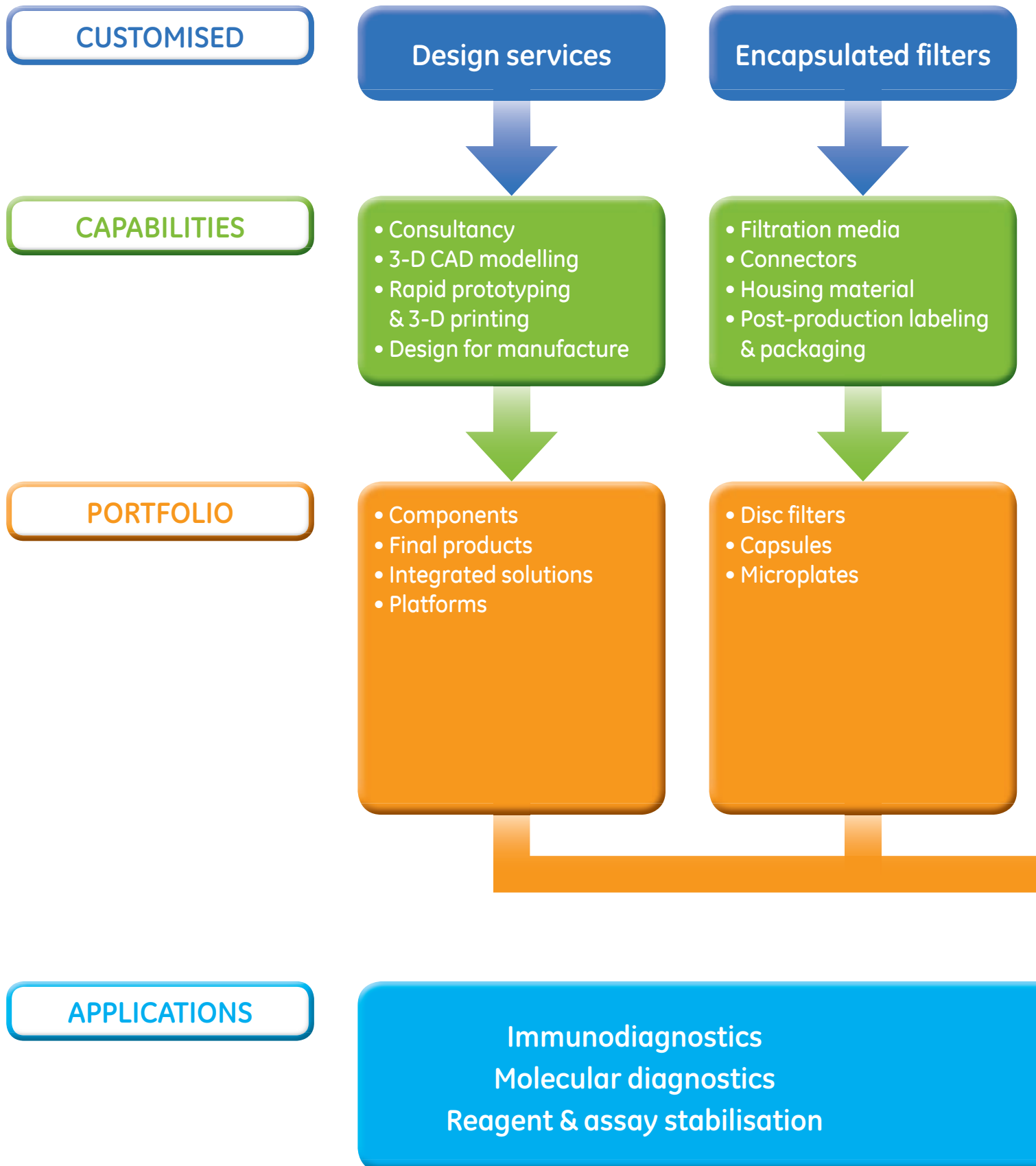
CERTIFICATIONS

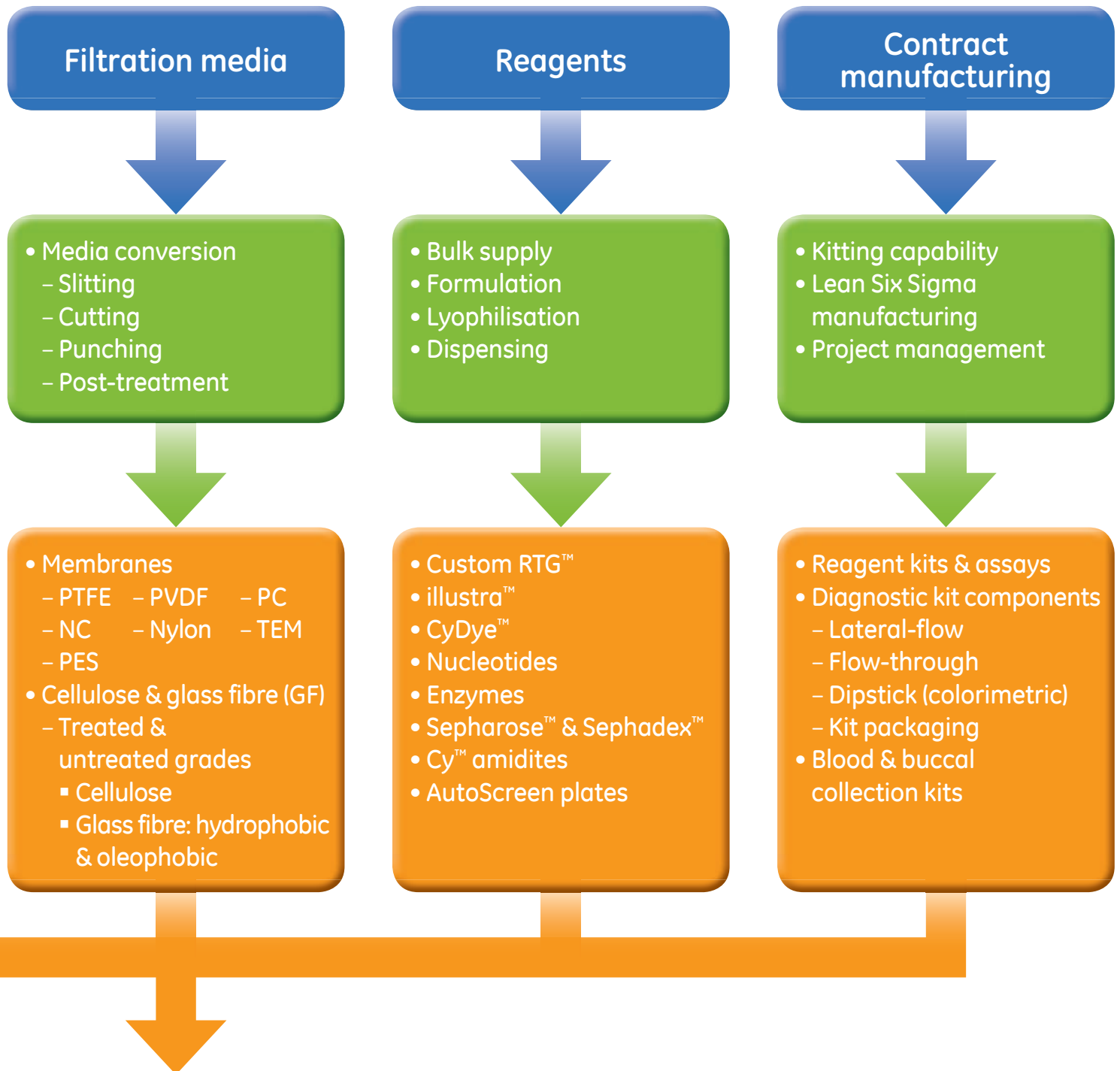
For our quality management systems

- ISO 9001: 2008
- ISO 13485: 2003

Choosing GE Healthcare for your manufacturing needs enables you to tailor the experience, portfolio, processes, and proven quality of GE Healthcare to your immediate and future needs.

Extensive capabilities... supporting a breadth of applications





Pharmaceutical analysis
Tools for medical media
Food & beverage

Genomics & protein analysis
Biothreat/biodefense
Environmental monitoring

Custom encapsulated filters

All filters

GE Healthcare encapsulated filters, which are designed to filter liquids or gases, contain filtration medium encased in plastic using a proprietary process. Multiple formats are available, including disc (syringe), capsule, and multiwell plates (microplates).

Use the decision tree on page 5 to select the optimal filter format for your needs. We can also provide custom media, please see page 12.

Custom filter options include:

- Filtration medium
- Connectors: inlet and outlet dimensions
- Housing material and colour
- Labeling and packaging



Capsule filters for fast filtration of large sample volumes.

Disc and capsule filters

CAPABILITIES

- Clean room environment
- Welding
 - Ultrasonic
 - Spin
 - UV
- Thermal bonding
- Product integrity testing
 - Tensile stress
 - Compression
 - Hydrostatic burst
- Custom labeling
 - Hot stamping
 - Pad printing
- Custom options[†]
 - Media, including but not limited to
 - High flow PES
 - PTFE
 - Hydrophilic nylon
 - Hydrophobic glass microfibre
 - Granulated media
 - Inlet and outlet dimensions
 - SB; ½ SB; HB; MNPT; FNPT
 - ML; MLL; FLL; MSF

SB = stepped barb for 6 to 10 mm (¼–¾") tubing;
½ SB = stepped barb for 10 to 12 mm (¾–½") tubing;
MNPT = male national pipe thread (6 mm = ¼");
FNPT = female national pipe thread (10 mm = ¾");
HB = hose barb (12 mm = ½");
ML = male luer; MLL = male luer lock; FLL = female luer lock;
MSF = male slip fitting

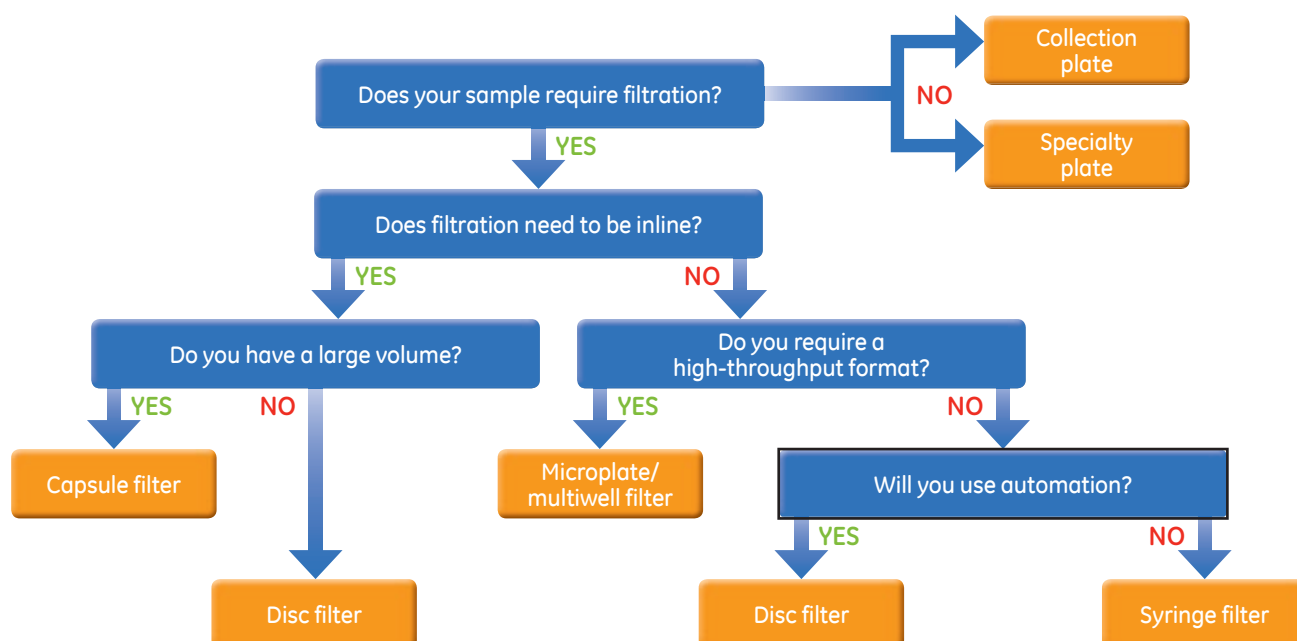
[†] Dependent on disc or capsule configuration

Features	Disc filters	Capsule filters
Housing	<ul style="list-style-type: none">• Polypropylene	<ul style="list-style-type: none">• Polypropylene
Sterilisation options	<ul style="list-style-type: none">• Autoclave• Ethylene oxide• Gamma irradiation	<ul style="list-style-type: none">• Autoclave• Ethylene oxide• Gamma irradiation[†]
Filter diameter	<ul style="list-style-type: none">• 4–60 mm	<ul style="list-style-type: none">• 36, 75, and 150 mm
Effective filtration area	<ul style="list-style-type: none">• 0.1–25 cm²*	<ul style="list-style-type: none">• 500–2000 cm²*
Operating pressure	<ul style="list-style-type: none">• 30–65 psi/2.1–4.5 bar	<ul style="list-style-type: none">• 60 psi/4.1 bar
Custom options		
	<ul style="list-style-type: none">• Disc filters from 4–60 mm can be customised with a range of media and connectors	<ul style="list-style-type: none">• Three capsule sizes can be customised with a range of media and connectors

* May vary; dependent on filtration medium
[†] Dependent on medium



Disc filters for filtration of small and medium sample volumes.



Microplates

GE Healthcare can manufacture customised microplates for your high-throughput applications. Utilising our proprietary process, your chosen filtration medium can be encapsulated in microplates to ensure no crosstalk or contamination between wells.

Features (by category)	Custom options (UNIFILTER™)
All microplates (filter or not) <ul style="list-style-type: none"> High-throughput applications <ul style="list-style-type: none"> Automated (robotics) Manual (centrifuge) 	Plate material <ul style="list-style-type: none"> Polystyrene, natural, and glass-filled polypropylene, Barex™, and MultiChem™
UNIFILTER microplates <ul style="list-style-type: none"> Encapsulated filter media <ul style="list-style-type: none"> Proprietary process No crosstalk between wells Accessories <ul style="list-style-type: none"> Collection and analysis <ul style="list-style-type: none"> UNIPLATE microplates: 24-, 48-, 96-, 384-well Other <ul style="list-style-type: none"> Cap mats, lids, and seals 	Colour <ul style="list-style-type: none"> Polystyrene: white, black, and clear Polypropylene: semi-clear
Specialty microplates (no filters) <ul style="list-style-type: none"> Fluorescence and microscopic analysis <ul style="list-style-type: none"> Glass bottom microplates <ul style="list-style-type: none"> Suitable for FRET and GFP 96-well, 300 µl volume Clear View microplates <ul style="list-style-type: none"> Optically clear Grow, observe, count, and assay cells in a single microplate 	Well bottom shape <ul style="list-style-type: none"> Round, square to round, flat, "V", and filter
	Media <ul style="list-style-type: none"> Gel filtration and ion exchange chromatography media (resin) Cellulose acetate Nylon PVDF Nitrocellulose Glass fibre
	Surface coating <ul style="list-style-type: none"> Tissue culture treatment for cell adhesion
	Plate well configurations <ul style="list-style-type: none"> ANSI/SBS1 standards <ul style="list-style-type: none"> 384-well: 100 µl volume 96-well: 150, 350, 800, and 2000 µl 24-well: 10 ml

Microplate applications

- Drug discovery
- Nucleic acid sample preparation
- Immunology (ELISA)
- Sample collection and storage
- HPLC sample preparation
- Cell harvest/capture

CAPABILITIES

- Coating facilities
 - Dedicated
 - Environmentally controlled
- Plate filling
 - Automated
- Shipping
 - Controlled temperature
- Run capacity
 - 100–1200 plates per run
- OD variation across plate
 - CoV < 5%
- Nonspecific binding
 - < 0.1 OD units

FRET = fluorescence resonance energy transfer; GFP = green fluorescent protein; PVDF = polyvinylidene fluoride; ELISA = enzyme-linked immunosorbent assay; HPLC = high-performance liquid chromatography; CoV = coefficient of variation; OD = optical density

Custom design services

Design for manufacture

CAPABILITIES

- Design for manufacture
- Design history support
 - Traceability
- Re-engineering
- 3-D CAD
- Rapid prototyping
 - 3-D printing
 - Produces prototypes in hours
 - Accuracy: 0.025 to 0.05 mm
 - CNC machining
- ISO 8 class clean room assembly
 - 2000 m² of available space
- Ultrasonic and UV welding
- Thermal bonding
- Custom labeling
 - Hot stamping
 - Pad printing

CNC = computer numerical control

Custom design services

- Components for diagnostics
- Environmental monitoring
- Custom labware and plasticware
- Automation

Examples

- Components for lateral-flow and flow-through immunodiagnostic assays
- Microplate/multiwell format for molecular diagnostic assays

Design concept, optimisation, development, and manufacturing... translating your concept into a manufactured product

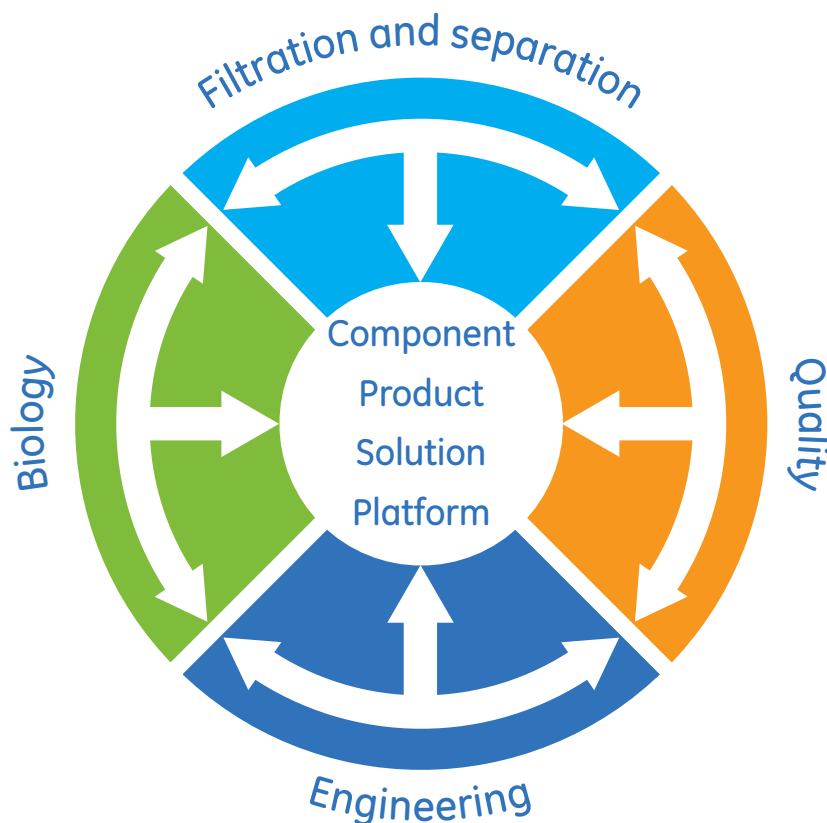
GE Healthcare has extensive, innovative capabilities for design concept, optimisation, and development of custom components, products, solutions, and platforms. By working with our custom design team from early in your conceptual stages, we can support your design for optimal manufacturing.

Our custom design services function comprises an inter-disciplinary team of engineers, biochemists, biologists, and filtration and separation experts.

Our design process

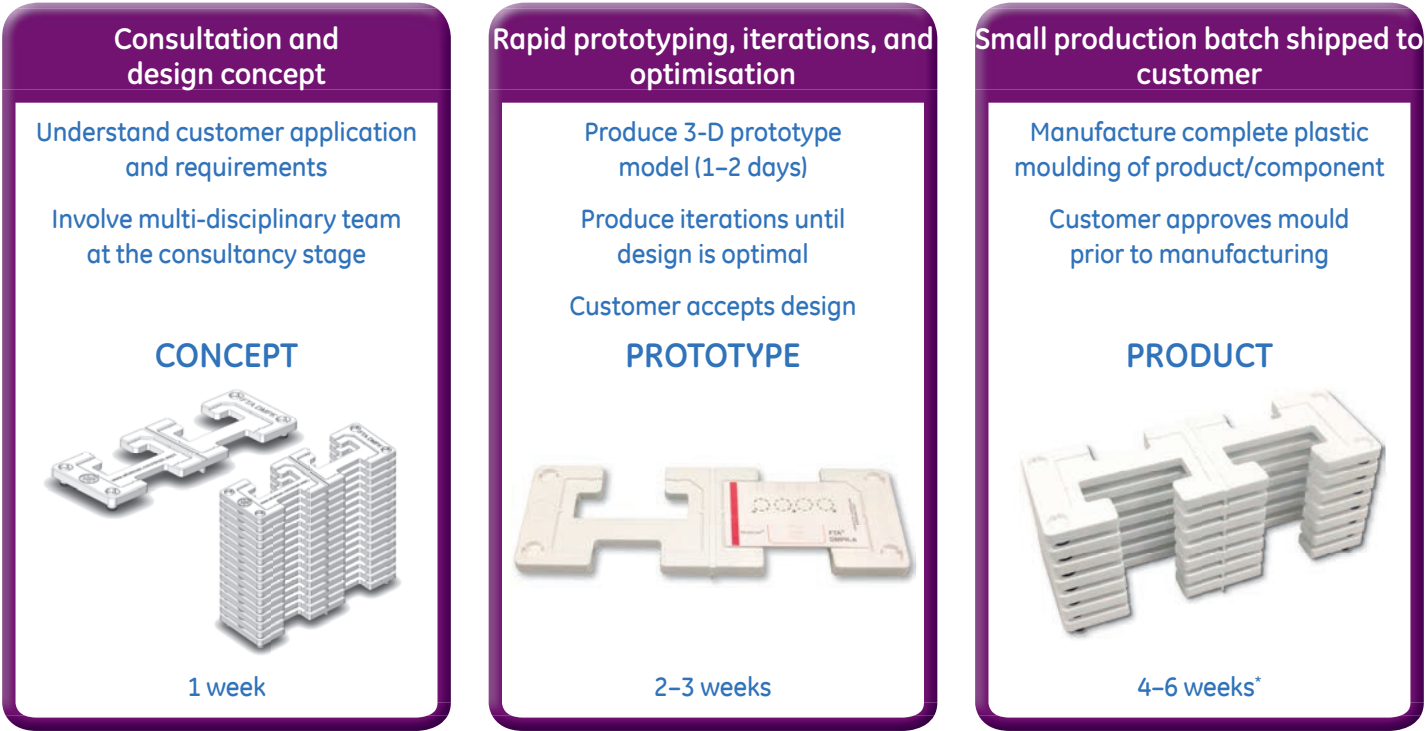
The benefits of our custom design process include

- Design complexities are resolved early in the process
- Prototypes are generated for functional proof-of-principle testing
- Costs of product development cycles are reduced, and time-to-market of new products is shortened
- Design development is optimised for manufacturing



Case study

Our design process in practice for the development of sample handling spotting racks.



* For a simple design, as in this case



ProJet™ HD 3000 3-D printer.
Image reprinted with permission from the

Custom reagents

Proven tools for molecular biology

CAPABILITIES

- Reagent stabilisation
- Biomolecule labeling and detection
- Bulk supply of reagents
- Extensive organic synthesis
- Large-scale fermentation
- Automated bottling and packaging
- Quality Assurance
- Lean Six Sigma manufacturing
- Technical consultancy

Applications

- Custom reagents for:
 - Proteomics and protein analysis
 - Genomics and molecular biology
 - Bioassays and cellular assays
 - Components for diagnostics
- Kit assembly of these reagents/components (please see page 9)

We understand that your specific needs for certain products may fall outside of our standard configurations, formulations, and concentrations. With this in mind, we can customise a comprehensive range of protein and nucleic acid sample preparation, labeling, and detection products with a proven track record of performance and reliability. If desired, we can incorporate these products into the manufacturing of kits that you design.

Further, for high-throughput applications that consume large volumes of reagents, our custom bulk products, including reagents, nucleotides, Cy amidites, enzymes, and CyDyes, deliver performance with lot-to-lot consistency ensured.

Custom reagents

Nucleotides*

- Free from DNase and RNase
- Greater than 99% triphosphate purity
- Buffer-free and ready to use solutions in multiple formats
- Functionally tested for long PCR and sequencing

CyDye fluorescence reagents

- For protein and nucleic acid labeling
- Cy2, Cy3, Cy5, Cy5.5, and Cy7
- pH- and photo-stable
- High quantum yields
- For example, we can provide Cy amidites

Sequencing and Ready-To-Go (RTG) products

- Bulk dispensing, packaging, and shipping

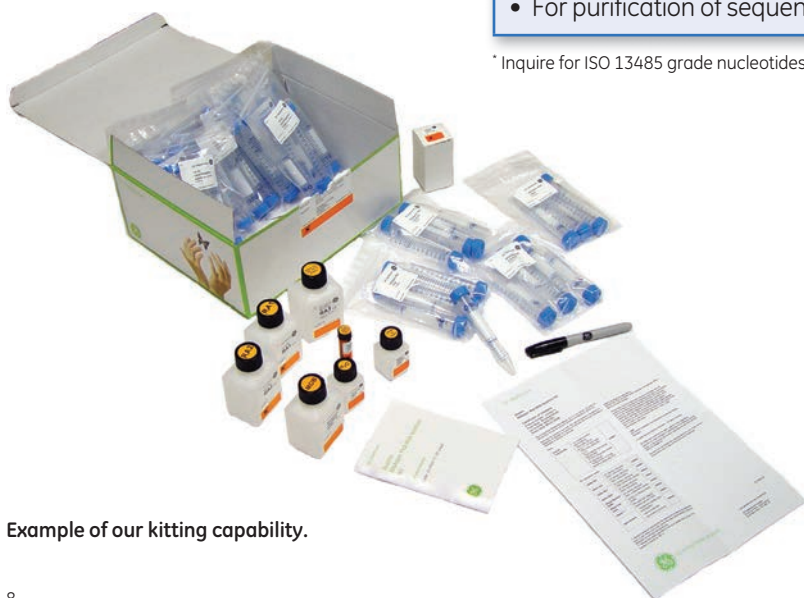
Enzymes

- For PCR and other applications
- Bulk dispensing, packaging, and shipping

AutoScreen 96-well plates

- Filter plates containing DNA Grade Sephadex G-50
- For purification of sequencing reactions and other size exclusion applications

* Inquire for ISO 13485 grade nucleotides



Example of our kitting capability.

Contract manufacturing

A collaboration with GE Healthcare offers real benefits

From simple buffers to multi-component kits, large or small batch sizes, we have over 50 years' experience manufacturing products for use in pharmaceuticals, diagnostic applications, and life science research, that will meet your specific requirements.

We will design and manufacture to your specifications. We can provide:

- Sourcing and validating raw material
- Custom design services
- Custom formulations, volumes, and concentrations
- Custom packaging and labeling
- Custom testing and documentation
- Secured supply and delivery according to your own forecast
- Scale-up capabilities to meet all of your needs
- Stability studies



Example of a Cy labeled product.

CAPABILITIES

- Technical and regulatory consultancy
- Kit design
- Project management
- Product manufacturing
 - Formulation
 - Dispensing
 - Lyophilisation
- Analytical services for testing
 - TOF-MS, LC-MS, NMR, HPLC, UV, IR, and DSC
- Design and manufacture of final packaging

TOF-MS = Time-of-flight mass spectrometry;
LC-MS = liquid chromatography-mass spectrometry;
NMR = nuclear magnetic resonance;
HPLC = high-performance liquid chromatography;
UV = ultraviolet; IR = infrared;
DSC = differential scanning calorimetry

Formulation	Dispensing	Lyophilisation
Components <ul style="list-style-type: none">• Single• Multiple Volumes <ul style="list-style-type: none">• Liquid: µl to 1000 l• Suspensions/slurries: up to 50 l Heating of solutions <ul style="list-style-type: none">• Nontoxic: up to 20 l• Toxic: up to 5 l Autoclaving <ul style="list-style-type: none">• Up to 200 l	Dispensed into <ul style="list-style-type: none">• Vials• Bottles• Tubes• Microplates Volume <ul style="list-style-type: none">• From µl to hundreds of ml Dispensing tolerance <ul style="list-style-type: none">• To 0.01% Facilities <ul style="list-style-type: none">• Dedicated for temperature-, light-, or moisture-sensitive materials Slurries <ul style="list-style-type: none">• Dispensed into columns Liquids* <ul style="list-style-type: none">• Up to 10 000 vials/day• 96- or 384-well microplates; 6–30 min/plate• Bung, cap, and label up to 3000 vials/day†	Throughput <ul style="list-style-type: none">• 200 to 13 000 vials/day† Volume <ul style="list-style-type: none">• Max: up to 70 ml/bottle Lyophilised in/on <ul style="list-style-type: none">• Vials• Bottles• Microplates• Membranes

* Dependent on equipment and on sample viscosity

† Dependent on sample volume

Custom Ready-To-Go

Stabilise and simplify

GE Healthcare's Ready-To-Go (RTG) technology is proven and established for stabilisation of individual enzymes/reagents and complete multiplex assays, building on our 10 years' development and manufacturing experience in this field.

The patented technology stabilises individual proteins and reagents, as well as complete multiplex assays by providing a molecular environment that protects against conformational changes in protein structure. The result is a product that is stable at room temperature.



Pipette your aqueous mix into the tube and the RTG cake dissolves in seconds.

Benefits of RTG technology

Stabilisation	Sample integrity is maintained <ul style="list-style-type: none">• Provides up to 2 years room temperature stability (no activity loss)*• Is stable at a wide range of temperatures
Simplification	Pre-dispensed, single-dose reagents <ul style="list-style-type: none">• Requires fewer pipetting steps• Requires less sample handling• Improves data quality• Supports reduced training requirements• Is compatible with downstream applications and automation
Shipping	No need for a logistics specialist <ul style="list-style-type: none">• Does not require dry or wet ice shipment• Simplifies shipping across countries• Provides significant cost savings
Storage	No need for refrigerator or freezer storage <ul style="list-style-type: none">• Supports applications for field use• Enables storage in remote or low accessibility regions• Enables storage in locations with insufficient infrastructure• Provides significant cost savings

* Based on GE Healthcare's standard RTG portfolio

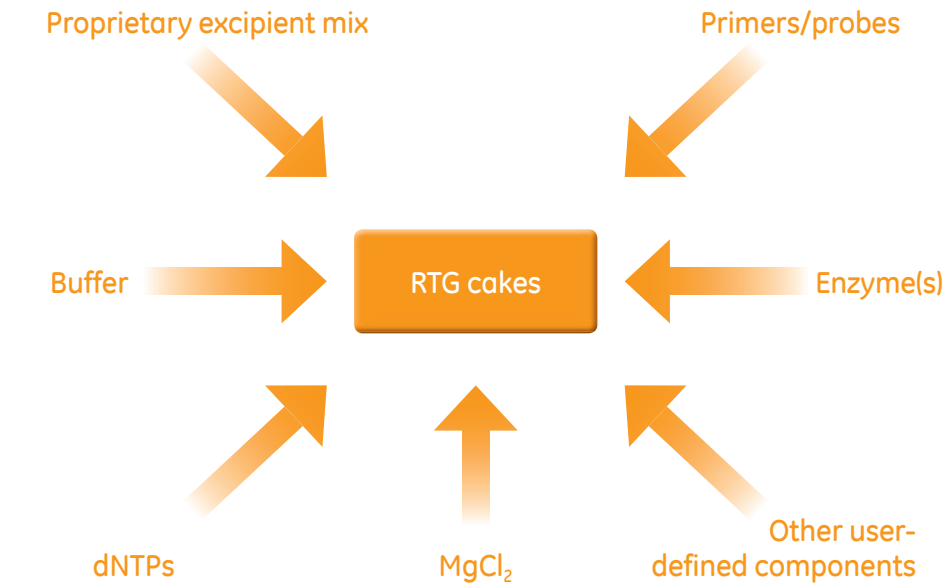
Custom RTG applications

- Component reagents for molecular diagnostics and immunodiagnostics
- Food testing
- Environmental testing
- Biothreat/biodefense

CAPABILITIES

- Freeze drying/lyophilisation
- Proof-of-principle facility
 - HEPA filtered air
 - Humidity and temperature control
 - UV scrubbers
 - Dry nitrogen dispensing cabinet
- Validation and small-scale production of up to 30 plates
- Clean room environment
- Dedicated team
 - Consultation and development
- Custom formulation
 - Enzyme
 - Reagent mixture
 - Complete assay: to date, up to 30 components in a multiplex assay
- Pre-dispensed into
 - Microplates
 - 96- and 384-well (96-well perforated option)
 - Tubes (0.75–2 ml)
 - Custom formats
- Product sealing
 - Controlled environment
- Product testing
 - Visual inspection
 - Stability
 - Accelerated shelf life studies
 - Glass transition temperature
 - Karl Fisher Moisture analysis (tolerance:< 4%)

Add your sample and you are ready to go, from individual enzymes/reagents to complete multiplex assays!



Example of an amplification-based custom RTG formulation.

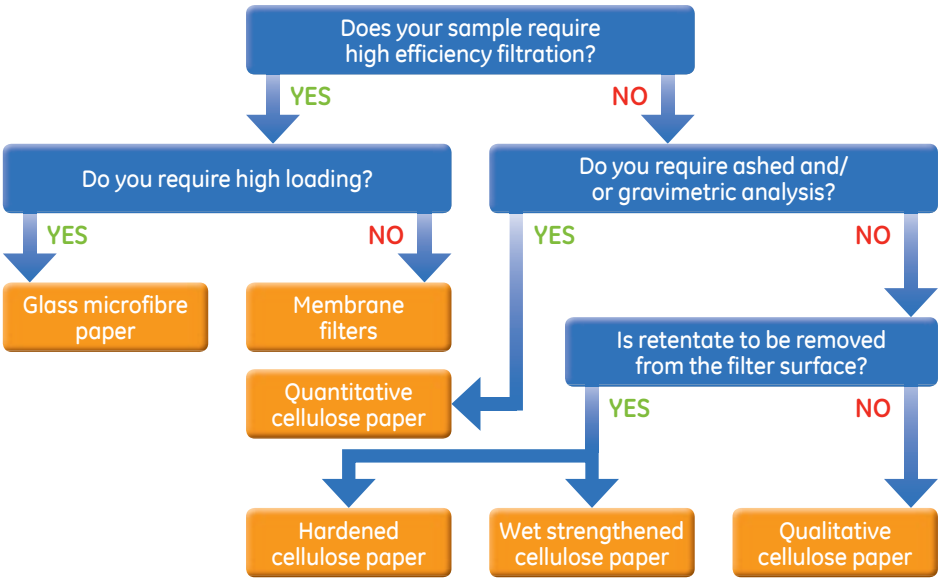


Packaging of RTG cakes in a 96-well plate.

Filtration media

GE Healthcare offers a wide range of membranes and filtration media, including cellulose and glass fibre, for customisation into a range of filtration formats.

Use the decision tree to select the optimal filtration medium for your needs. Papers (cellulose and glass fibre) are discussed below; membranes are discussed on page 14.



Papers: cellulose and glass fibre

Our high-quality Whatman cellulose and glass fibre (GF) products are used globally in the filtration of liquids and gases in the pharmaceutical, diagnostic, and food and beverage industries, as well as in environmental analysis and academia. Our papers may be used in the following applications: diagnostics, DNA archiving, laboratory filtration, sample preparation, and air safety. These applications and uses are summarised in the table below.

Application*	Use
Laboratory filtration	Filter circles Whatman GD/X™ syringe filters
Components for diagnostic assays	Blood separation, sample application, reaction pad, and absorbent sink
Neonatal screening	Blood collection, 903
DNA collection, storage, archiving	Specimen collection, including blood and buccal
Tools for medical media	Medical media
Environmental analysis	Pollution monitoring

*All applications use cellulose. All except neonatal screening also use glass microfibre.



Cellulose papers.

Options for custom paper production

Material	Grades and properties	Conversion [†]
Cellulose <ul style="list-style-type: none"> • Cotton* <ul style="list-style-type: none"> – Highest purity source of cellulose <ul style="list-style-type: none"> ▪ 99.9% alpha cellulose Glass fibre <ul style="list-style-type: none"> • Borosilicate • Low sodium • Quartz • Graded density media Manufacturing specifications <ul style="list-style-type: none"> • Airflow • Grammage • Thickness • Mechanical strength • Particle retention • Wicking rate • Filtration performance • Surface characteristics 	Cellulose <ul style="list-style-type: none"> • Properties <ul style="list-style-type: none"> – Grammage: 40–700 gsm (+/- 10%) – Thickness: 80–3000 µm • Paper grades <ul style="list-style-type: none"> – Qualitative – Wet strengthened – Quantitative[‡] – Technical – Hardened paper Glass fibre <ul style="list-style-type: none"> • Grammage: 16–300 gsm (+/- 10%) • Thickness: 80–3000 µm • Particle retention range: 0.7–2.7 µm • Heat resistant to 500°C 	“Parent” reels cut to different widths Cutting <ul style="list-style-type: none"> • Sheet length: 430–790 mm • Sheet width: 460–1500 mm Slitting <ul style="list-style-type: none"> • Slitting: 6–1500 mm • Tolerances up to +/- 0.5 mm • Max rewind diameter: 1300 mm Punching <ul style="list-style-type: none"> • Circles: 10–500 mm diameter • Shapes and patterns possible

* Cotton linter and specialty wood pulps are available

[†] Dependent on instrument

[‡] Accurate ash content quantitation: 0.006%-0.015%

Paper treatment options

Our paper products can be post-treated to your needs with respect to strength, hydrophobicity, and oleophobicity. Definitions of the different techniques are provided below. The table describes the specific post-treatment options that you can request for your customised product.

Controlled impregnation

A surface chemistry is added to a substrate to enhance mechanical properties and/or to capture specific target molecules.

Acid treatment (cellulose paper)

Nitric acid treatment reduces ash content, which hardens the paper and reduces impurities.

Calendering (glass fibre sheets)

Consolidation of sheets by cold or hot pressing smooths the paper product.

Firing (glass sheets)

Firing of glass sheets ensures that a product complies with organic content requirements.

Lamination

A nonchemical process strengthens paper.

Paper treatment

Controlled impregnation

- Max width: 300 mm

On-line

- GF substrates
 - Liquid PVA, acrylic binders, oleophobic and hydrophobic agents

Off-line

- Cellulose and GF substrates
 - Water-based chemicals (e.g., FTA and silicone)

Lamination

- Max width: 100 mm
- Min wet strength: 2N/15 mm

Glass fibre sheets

Calendering

- Sheet width: 500–1020 mm
- Grammage: 20–40 gsm

Firing

- Max sheet size: 550 × 850 mm
- < 1% loss on ignition

Cellulose fibre sheets

- Acid treatment
 - Sheet width: 400–860 mm

Filtration media

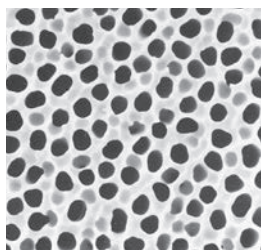
Membranes

GE Healthcare provides a range of Whatman membranes whose advanced technical specifications make them an outstanding choice for a wide range of applications. Use the decision tree on page 15 to select the optimal membrane type for your application. Our true pore and polymer membranes are summarized below. The table on page 15 includes details for specific custom options.

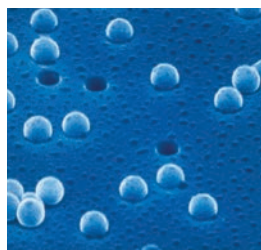
Membrane applications

- Western blotting
- Immunodiagnostics
 - Lateral-flow
 - Flow-through
 - Dipstick (colorimetric)
- Filtration

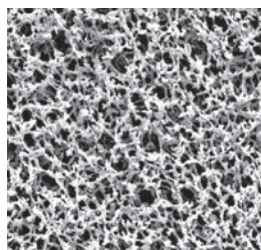
Our true pore matrices offer accurately controlled pore sizes. Our polymer membrane matrices offer controlled pore size distribution.



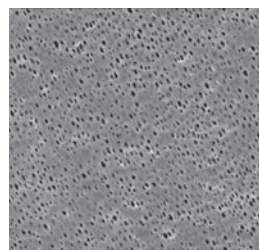
Anopore membrane with true pore honeycomb structure.



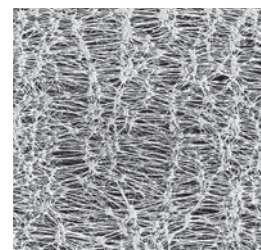
Track-etched membrane with latex beads.



Mixed cellulose ester membrane.



Polyamide (nylon) membrane.



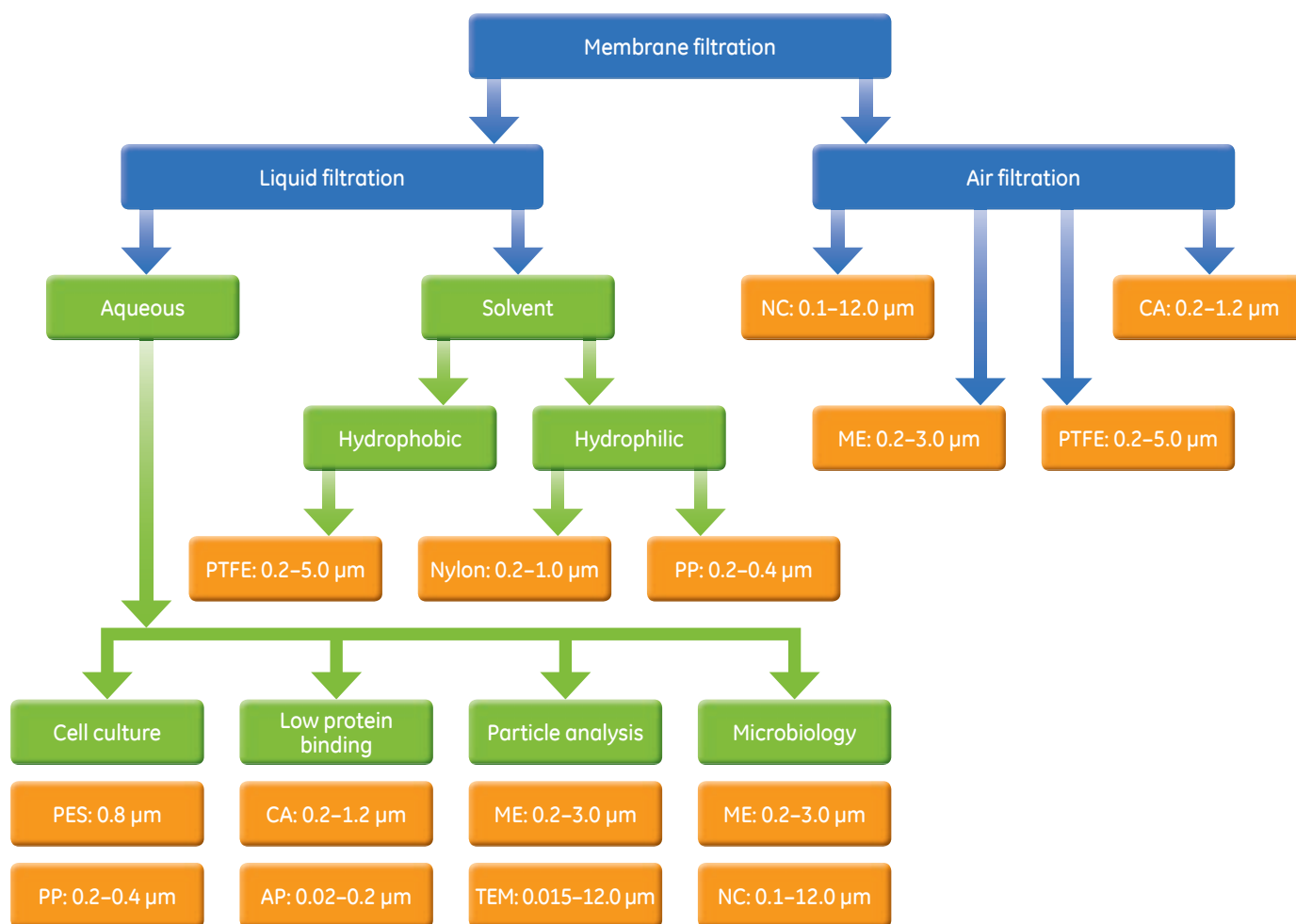
Teflon™ PTFE membrane.

True pore membranes	Material	Pore sizes (µm)
Anopore (AP)	Aluminium oxide	0.02, 0.1, 0.2 [†]
Track-etched membranes (TEM)	Polycarbonate (PC)* • Clear PC, PVP-treated, PVP-free; also available gold-coated, black-stained Polyester (PET)* • Clear PVP-treated	0.02 to 14

Polymer membranes	Material	Pore sizes (µm)
Cellulose Acetate (CA)	Pure CA	0.2, 0.45, 1.0 [†]
Mixed Cellulose Ester (ME)	Nitrocellulose • Added cellulose acetate enhances mechanical strength	0.2 to 3.0 [†]
Nitrocellulose (NC)	Pure NC • Also available with reinforcing polyester-fleece	0.1 to 12.0 [†]
Regenerated Cellulose (RC)	Pure cellulose • No wetting agents	0.2, 0.45, 1.0 [†]
Nylon	Polyamide Hexamethylenediamine	0.2, 0.45, 0.8, 1.0
Polyethersulfone (PES)	PES	0.8
Polypropylene (PP)	PP	0.2, 0.45
Teflon (PTFE)	Polytetrafluoroethylene (PTFE) • Hydrophobic, hydrophilic, and oleophobic	0.2 to 5
Hydrophobic PVDF	Polyvinylidene fluoride (PVDF)	0.2, 0.45

* Both PC and PET membranes are available in different pore densities ranging from 1×10^5 to 6×10^8 pores/cm²

[†] Other pore sizes possible



Capabilities (manufacturing)	Capabilities (membranes)*	Capabilities (conversion)†	Treatments (membranes)
Casting <ul style="list-style-type: none"> • Dry • Wet 	Manufacturing specifications <ul style="list-style-type: none"> • Pore size • Thickness • Water flow rate • Capillary rise/flow time • Burst strength • Porosity • Protein binding • Leachables • Autoclavable • Bubble point (unbacked only) • Flow-through (unbacked only) • Scanning electron microscope use 	Sheet cutting Dimensions <ul style="list-style-type: none"> • Min: 10 × 10 mm • Max: 640 × 1200 mm Slitting <ul style="list-style-type: none"> • Precision slitting: 6–1500 mm • Tolerances: up to +/- 0.5 mm • Max rewind diameter: 1200 mm Punching <ul style="list-style-type: none"> • Circles: 6–500 mm diameter • Shapes and patterns possible 	Backing <ul style="list-style-type: none"> • Unbacked • Foil-backed • PTFE-backed <ul style="list-style-type: none"> – Polyester, polypropylene, or Halar™ Supported Impregnation Lamination Colouring Printing Sterilisation Functionalise membranes <ul style="list-style-type: none"> • For specific diagnostic applications

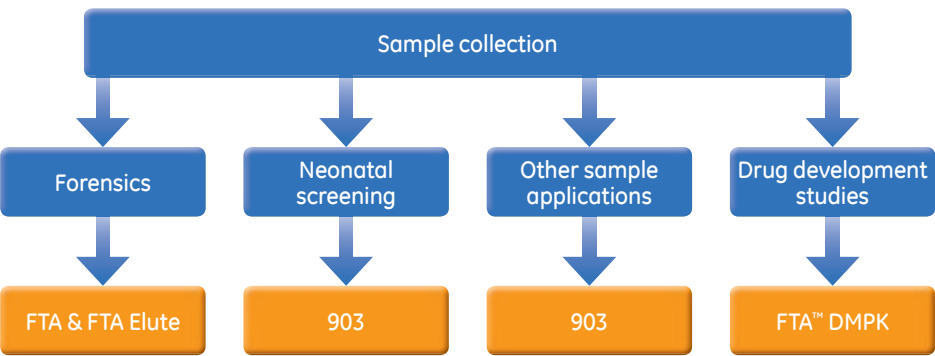
* General manufacturing limits may differ for membrane grades as limiting factor is master reel width

† Dependent on membrane grade

Custom sample collection

Customised ready-to-use kits

GE Healthcare configures and manufactures customised ready-to-use kits for specific sample collection applications, ensuring that all the tools you need for optimal sample collection are ready for immediate use.



Dried Blood Spot (DBS) sample collection

- Reduces required blood volume
- Eliminates freezing of blood samples
- Enables remote sample collection
- Simplifies handling

Forensics and FTA

Each custom kit features Whatman FTA technology. FTA enables you to collect, transport, archive, and purify DNA samples with ease and confidence. Whether you are collecting specimens from suspects, adding samples to a convicted offender database, or conducting epidemiological studies, FTA technology makes the whole process easy, reliable, and convenient.

Blood collection requires only one or two drops of blood on an FTA card. For buccal cell collection, EasiCollect™ allows you to uniformly collect and apply cells to the surface of an FTA card for subsequent DNA analysis.

Field-based sample collection often requires the use of multiple products such as data collection forms, gloves, sterile wipes, lancets, foam swabs plus the sample collection cards or swabs. We can provide these products in a convenient kit custom-made to your specifications.



EasiCollect for buccal collection.



Customised FTA kit for human identification.

CAPABILITIES

Custom design and printing of collection cards

- Colour coding
- Sample covers
- OCR compatible

Sequential numbering

- For tracking, identification, and storage

Barcode sample tracking

- Cards with barcoding
- Removable adhesive barcodes
- Barcode strips

Transfer/mailing envelopes

- For mailing of samples to a central laboratory
- Breathable or moisture resistant (dried)

Procedure packs

- Can include data collection forms and instructions for use (IFU), foam swabs, gloves, sterile wipes, lancets, desiccants, and 903 cards

Translation services

- IFU in appropriate language

903 specimen collection paper

Whatman 903 specimen collection paper from GE Healthcare is a globally known high-quality paper used to collect blood samples for neonatal screening and other sample applications.

903 blood collection cards provide an efficient method for sample collection, identification, and transport.

903 paper is manufactured from 100% pure cotton linters with no wet strength additives. Since it is a medical device in the US, 903 paper has to be manufactured under controls compliant with the FDA Quality System Regulations. In addition, serum uptake analysis is conducted for each lot of 903 paper by an independent testing laboratory and by the Centers for Disease Control Newborn Screening Quality Assurance Program. Only when all test results confirm that a batch of 903 paper meets the aforementioned specifications can that lot be released and used for specimen collection.

903 cards for neonatal screening:

- Product performances comply with the CLSI LA4-A5 standard, which is an FDA consensus standard
- Are US FDA Class II Medical Devices
- Are CE marked in Europe as *in vitro* diagnostic medical devices, as required by the IVD Directive 98/79/EC
- Are manufactured under controls compliant with the FDA Quality System Regulations and ISO 13485:2003
- Multiple-part cards can be customised to the needs of each newborn screening program

903 cards for other sample applications

- Enable blood sample collection for diagnostic applications
- Are CE marked for use by health care professionals
- Can be provided alone or as part of a procedure pack containing all the necessary components for efficient sample collection

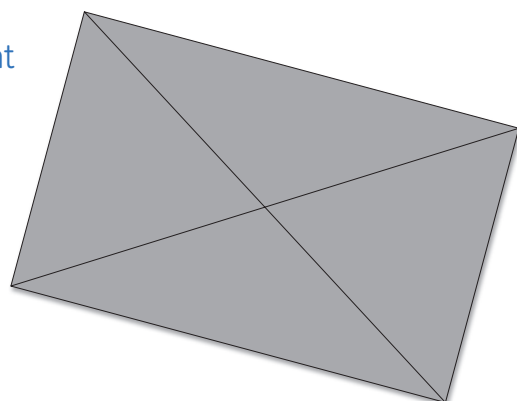


DMPK for drug discovery and development

Pharmacokinetic (PK) and toxicokinetic (TK) studies provide insight into how drug candidates behave in the body. Therefore, they are critical steps in drug development.

Our FTA DMPK portfolio, including DMPK A, DMPK B, and DMPK C cards, is routinely used for dried blood collection in PK/TK studies. Our FTA DMPK products provide:

- Precision and accuracy for a variety of compounds
- Simple sample processing
- Room temperature stability to enable easy storage and transportation



Immunodiagnosics

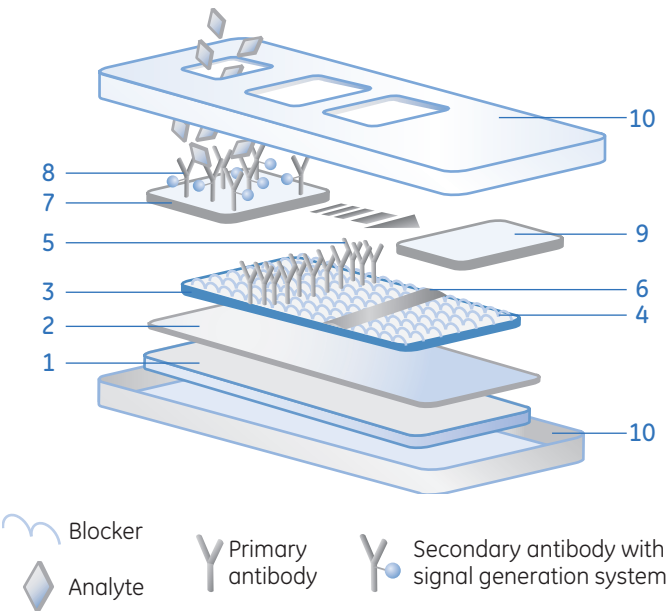
GE Healthcare is an established and proven technology component provider for immunodiagnostic assays; specifically lateral-flow, flow-through, and dipstick diagnostic assays. We have an extensive capability to produce a vast array of cellulose and glass fibre substrates and nitrocellulose membranes to an assured quality, ensuring accurate and reproducible results.

Lateral-flow assay

A typical single-step, lateral-flow immunoassay, shown on the right, requires only the addition of a sample. The sample flows along the housing by capillary action, where it passes through a pretreated area of antibody or antigen. A positive test is typically indicated with a coloured band.

As shown in the figure, multiple components of membrane and paper comprise such a test. Please see the table on page 21 for appropriate GE Healthcare products, from our wide range of novel conjugate release products that improve performance, to Whatman FUSION 5, which can perform five functions of a lateral-flow test.

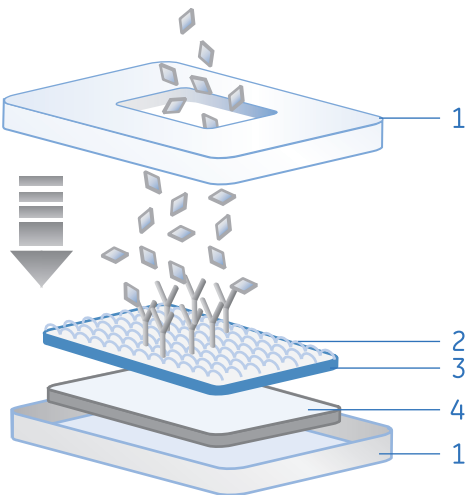
Key to illustration		
1. Plastic backing	4. Blocking agent	pad
2. Adhesive	5. Test line	8. Labeled conjugate
3. Reaction membrane	6. Control line	9. Absorbent
	7. Conjugate release	10. Housing



Flow-through assay

Sample is applied directly to the reactive membrane and is allowed to wick through into an absorbent paper below. The membrane of choice for flow-through tests is a paper cast nitrocellulose, such as the FT family (please see the table on page 21).

Key to illustration		
1. Plastic housing	3. Nitrocellulose membrane	4. Absorbent
2. Blocking agent		



Dipstick assay

Dipstick colorimetric assays, in which a cellulose pad is impregnated with a colour reagent, are widely used in everything from urine testing to environmental assays. The base cellulose is a key part of the system, and the correct choice of absorbancy, wicking rate, and wet strength is critical to producing a working assay.

The GE Healthcare range of cellulose materials for colorimetric assays offers highly consistent and inert substrates for absorption of the active chemicals required for development of dipstick tests. Please see the table on page 21 for appropriate choices of materials.



GE Healthcare products for custom immunodiagnostic components

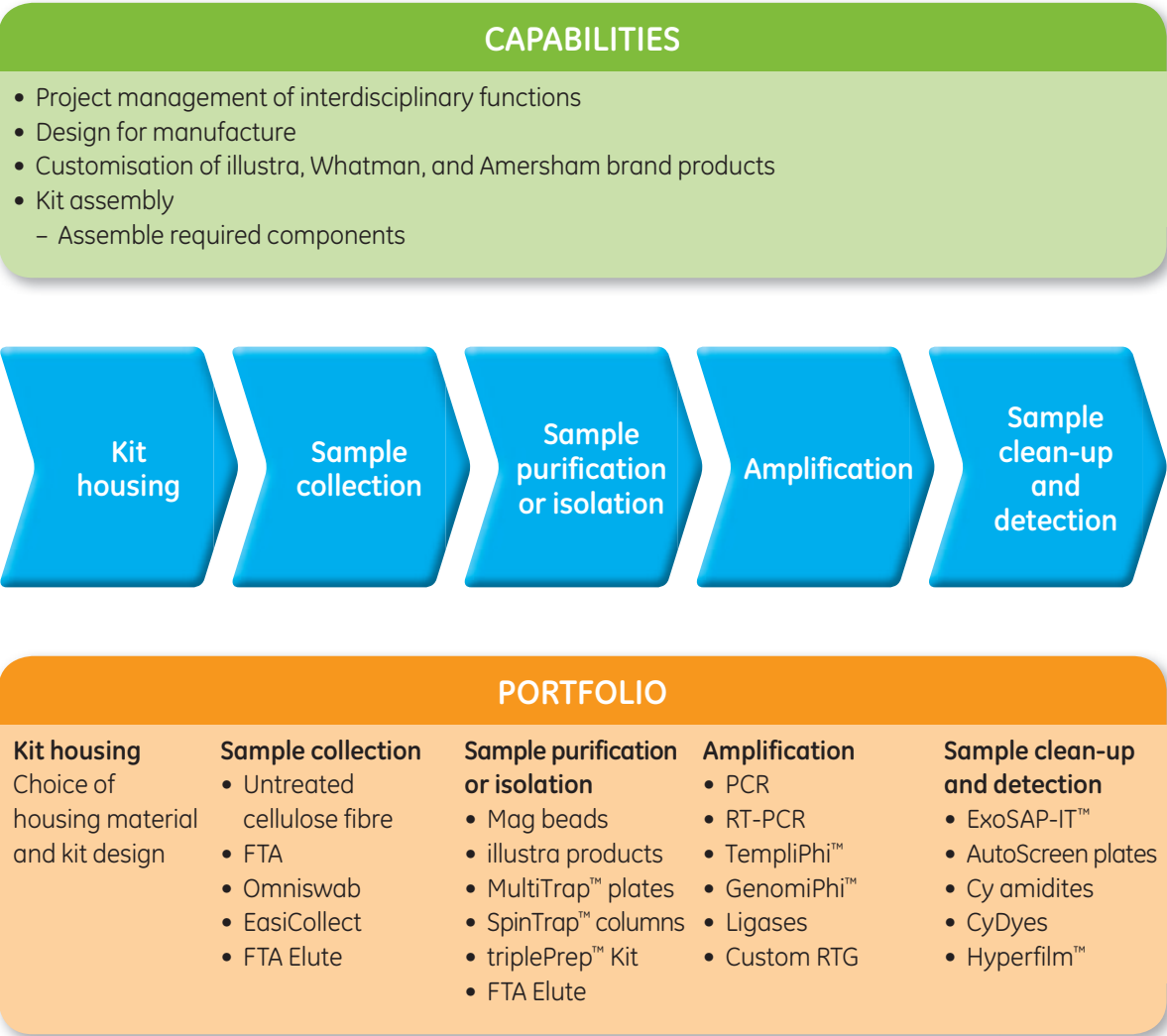
	Lateral Flow					Flow Through			
	Reaction membrane	Blood separation	Conjugate release	Sample wick	Absorbent	Nitrocellulose membrane	Blood separation	Absorbent	Colorimetric assays (dipstick)
CF1				●					●
CF2									●
CF3				●	●				●
CF4				●	●			●	●
470				●	●				●
CF7					●			●	●
CF10					●				●
300					●			●	
900					●			●	
23SL									●
FUSION 5	●	●	●	●	●		●		
VF1		●		●			●		
VF2		●		●			●		
LF1		●		●					
MF1		●		●					
GF/DVA				●					
Standard 14			●	●					
Standard 17			●	●					
PRIMA	●								
AE	●								
FF	●								
FT						●			
BA						●			

Molecular diagnostics

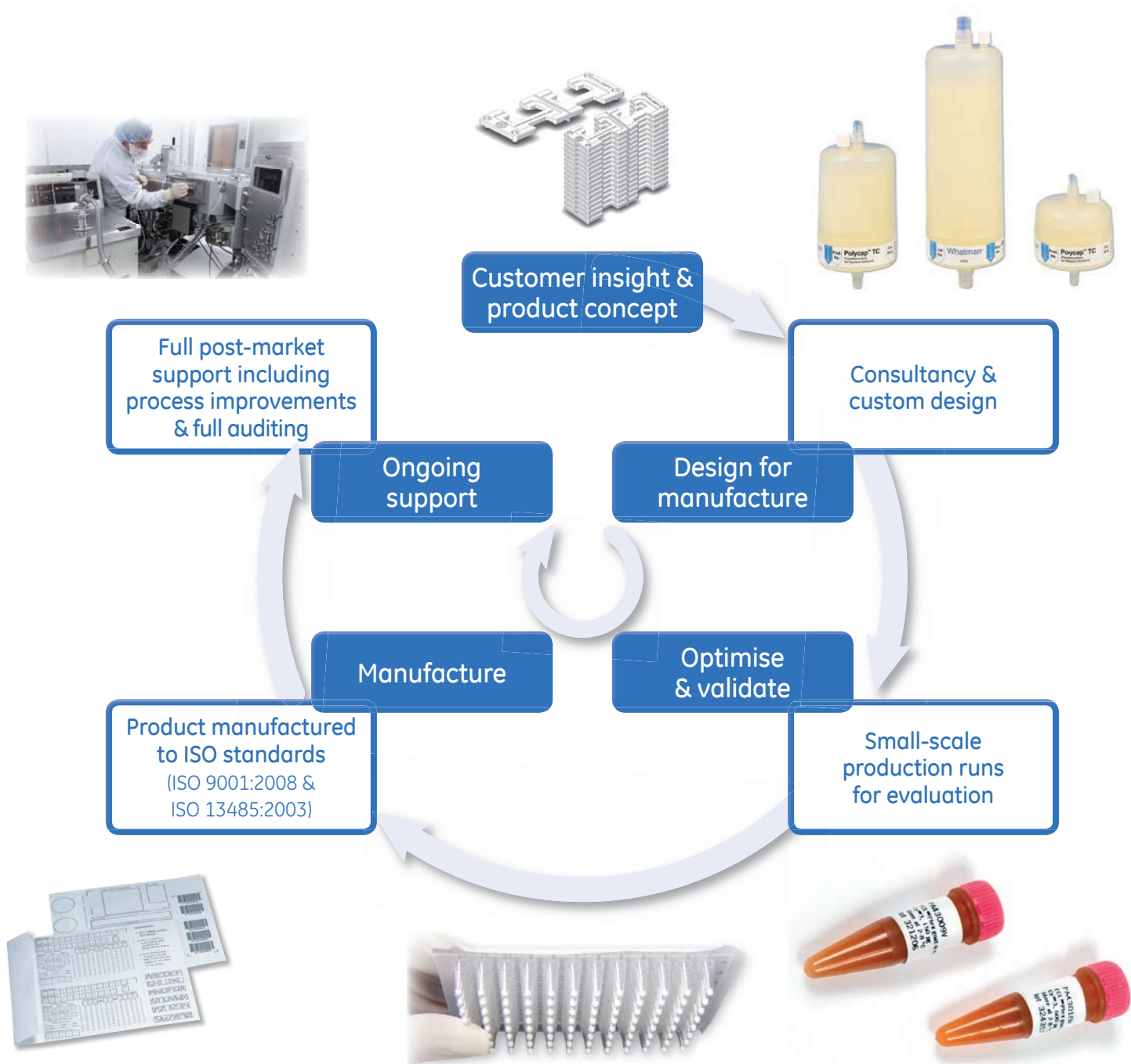
The rapidly growing field of molecular diagnostics, which utilises nucleic acid, protein, or metabolite biomolecules, plays an important role in the identification and early detection of many human conditions and disease states.

The accuracy, sensitivity, and speed of molecular biology techniques are key drivers behind the development of molecular diagnostic tests, for which GE Healthcare has a breadth of capabilities and an in-depth portfolio to support diagnostic kit manufacturers.

A generic nucleic acid-based molecular diagnostic workflow is represented below, with the relevant capabilities and portfolio of GE Healthcare indicated.



Your needs, our capabilities



For local office contact information, visit:

www.gelifesciences.com/contact

For further custom and contract manufacturing information, visit:

www.gelifesciences.com/custom

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