# MOLECULAR DIAGNOSTIC KIT SOLUTIONS

Gain Confidence in Your Diagnostic Kits with Consumables Committed to Advancing Your Studies



azenta.com

## **Solutions for Molecular Diagnostics**

At Azenta, we design and produce innovative solutions which address the needs of both kit manufacturers and end users, whilst ensuring reproducible results every single time. Our diverse range of products can be handled robotically at the manufacturer's site and later divided into smaller sections to suit the end users specific requirements. Add confidence to your diagnostic kit manufacturing with high-quality products that are:

- ISO 9001 and ISO 13485 certified
- Custom-made or off-the-shelf
- Automation-friendly
- Consistently available

#### **Product Portfolio**

For further details about our products and solutions for advancing Molecular Diagnostics applications, and to learn about our valuable customer collaborations visit <u>https://www.</u> <u>azenta.com/molecular-diagnostics-solutions</u>

#### **Customization for Workflows**

We partner with our customers to provide flexible solutions that improve reproducibility and achieve consistent results. We can provide the complete end-to-end development of custom, premium plastic consumables including PCR plates, strips and tubes, sealing materials and instrumentation. Our completely tailored solutions include custom designs, tool making and contract manufacturing from concept to completion.

- Customizable plates with a broad spectrum of frames and well colors, coatings and treatments
- Customizable seals with a wide array of sizes, printing, material, and chemical compatibility
- Consistently available product
- Highest quality plates and seals
- Expertise in custom kit creation

TECHNICAL NEEDS	1. KIT MANUFACTURING	2. SHIPMENT TO END USER	3. DIAGNOSTIC POINT-OF-CARE
Medical Grade Products	ISO 13485 certified production     Auditing		
Optimal Sealing		• Heat Se • Adhesiv	aling e re-sealing
Error-free Sample Tracking	Color coding, barcoding, and 2D coding options		
Ease of Use	<ul> <li>Dividable 96-well plates</li> <li>Automated work in plate format</li> <li>Cut into strips or sections</li> </ul>		• Tailored kit format

## **Azenta's Promise of Quality Products**

#### MANUFACTURING STANDARD

- ISO 9001 and ISO 13485 certified to manufacture and supply consumables for the life sciences sector
- Process validation and mapping
- Fully document-controlled manufacturing processes
- Statistical analysis of production processes
- Continuous improvement programs
- Injection molding in ISO class 7 cleanrooms
- Virgin, medical grade polymers

#### **QUALITY STANDARD**

- Consumables are certified free from bacterial and human genomic DNA, nucleases, and pyrogens
- Skirted micro- and PCR plates meet the SBS standard footprint
- PCR inhibition tests are performed on all polymers used
- Leak tests are performed on every well of every PCR plate
- White-well plates are checked for low background fluorescence

#### **Featured Customer Favorites**

Category	Product	Coding*	Automation Friendly	Color Options	Features / Treatment Options
	FrameStar <sup>®</sup> 96 well & 384 well PCR plates LEARN MORE →	Coding on Request	$\checkmark$	$\checkmark$	<ul> <li>Fully skirted, upstand, semi-skirted and non-skirted options</li> <li>Thin polypropylene wells optimize thermal efficiency and heat transfer</li> <li>Rigid polycarbonate frame prevents heat distortion</li> <li>Ethylene oxide treatment option available</li> </ul>
	FrameStarbreakable PCR plate range LEARN MORE →	Coding on Request	$\checkmark$	$\checkmark$	<ul> <li>Divisible horizontally, vertically, or both</li> <li>Compatible with standard multichannel pipettes</li> </ul>
	PCR Plates for Removable Tube Strips LEARN MORE →	Coding on Request	$\checkmark$		<ul> <li>Can be used as a complete plate, part plate, or individual strip with an easy-to-handle frame</li> <li>Tube Strips are available with clear or white wells</li> </ul>
	Individual Access 96 Well PCR Plates LEARN MORE →	Coding on Request (options to code individual tubes)	$\checkmark$		<ul> <li>Optional color coding of the individual wells is available</li> <li>Individually removable tubes from the rigid frame</li> </ul>

\*Coding/2D coding options available with eligible products only

### **Other Popular Products and Instruments From Azenta**

#### HEAT SEALS AND ADHESIVE SEALS

- Optically clear and high-strength Heat PCR Seals
- Peelable, pierceable and chemical resistant offerings available; quick and cost effective
- Rolls, sheets, or custom seal formats



#### HEAT SEALING INSTRUMENTS AND DE-SEALING

- Semi and Fully Automated Heat Sealers
- Automated plate seal removal
- Use instruments as stand-alone, or integrated within a robotic setup



Discover how Azenta utilized our automation, coding, and other customization capabilities to support collaborations with infectious disease testing kit manufacturers and other valuable customers.

Visit www.azenta.com/resources/consumable-andinstrument-solutions-human-diagnostic-kit-manufacturers to read our case studies

*We're here to help.* Azenta Life Sciences has locations around the world to help you obtain product information, determine the right combination of technologies for your facility, or access Azenta Global Support. Please contact our regional sales representatives if you have any questions.

# ABOUT AZENTA LIFE SCIENCES

Azenta Life Sciences provides unrivaled sample exploration and management solutions to help our customers accelerate discovery, development, and delivery to bring impactful breakthroughs and therapies to market faster.

Azenta is a market leader in the design and manufacture of consumables and bench top instrumentation for a wide range of life science and medical applications, including research into combatting cancer and infectious diseases, drug development, molecular diagnostics, and forensics. The state-of-the-art manufacturing facility in the UK boasts 25,000 square feet of floor space, producing off-theshelf products including PCR consumables, sealing materials and heat sealing instrumentation, microplates for cell screening and storage, and solutions for sample tracking, including barcodes and 2D datamatrix codes on products.

In addition to these products, Azenta can offer you a complete solution from concept to completion with the capability to offer completely tailored solutions, from custom design of bespoke products, right through to tool making and manufacturing of the parts. Azenta is ISO 9001:2015 & ISO 13485:2016 certified to manufacture and supply consumables for the life sciences sector. Our management systems comply with the requirements to produce medical devices which we sell to diagnostics companies of all sizes including multi-national corporations.

# OUR GLOBAL REACH

Azenta Life Sciences is the global leader in automated compound management for drug discovery, biological storage, and sample processing solutions with 30 locations in seven countries.



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