

LATERAL FLOW ASSAY MANUFACTURE

Robust and Flexible Manufacturing Options

At BBI Solutions, we offer robust and flexible manufacturing options. We cater to routine manufacturing production at a range of production batch sizes and for spiked demand or supply as part of a disaster recovery program.



Outsource to the Experts in Lateral Flow

You may be a start-up company looking for someone to manufacture your developed assay, or a fast growing company under pressure to meet increasing demand for your product. Our flexible manufacturing service will deliver the output you need to fulfill your customer's expectations:

Technical transfer to manufacturing – BBI has extensive experience and expertise in successfully transferring IVD products to manufacturing, including transferring assays into BBI from other sites for routine manufacture.

Competitive product pricing – Using our automation capabilities to manufacture on a large scale will drive production costs down without compromising quality, giving you the opportunity to competitively price your product in the market.

Quality assurance guaranteed – All of our sites are ISO 13485 accredited so we can guarantee that the entire process is executed to the highest quality specifications within the industry.

KEY BENEFITS



+ Quality System Certification

We're certified to the world recognised Quality System for Medical Device and IVD Manufacturers, ISO 13485 and work to a robust design control process



+ Cost Competitive

Using automation to manufacture on a large scale will drive production costs down without compromising quality



+ Flexible Options

From laminated cards to packed kits

BBI'S MANUFACTURING CAPABILITIES – THE FACTS

- + 120,000 sq feet for manufacturing
- + Capacity of 10-15 million assays per annum
- + 5 to 100K+ device batch sizes
- + Facilities located in the UK (Crumlin)
- + ISO13485 certified QMS systems
- + Benchtop and reel-to-reel dispensing systems
- + Manual, semi and fully automated lamination systems
- + Rotary and guillotine strip cutting
- + Manual and automated assembly solutions
- + Manual and semi-automated pouching solutions
- + Buffer dispensing capabilities
- + Dry rooms

FAQs

WHAT RAPID TEST DEVICE ASSEMBLY OPTIONS DO YOU OFFER?

Manual, semi-automated and automated options, including reel-to-reel lamination automation and pick and place automated assembly are available.

WHAT PACKAGING OPTIONS ARE AVAILABLE?

Many options are available for product packing from bulk supply of pouched devices to fully kitted products ready to go to market.

WHAT SAMPLING AND QC METHODS DO YOU USE?

Sampling and QC methods are developed and agreed with the customer to ensure the highest quality product is delivered.

HOW DO YOU ENSURE THE MANUFACTURING PROCESS IS CONSISTENT BEFORE GOING INTO FULL MANUFACTURE?

Typically, three batch validations are produced after a pilot batch manufacture. This reduces risk, ensures robust, stable processes and validates the procedure.

DO YOU ONLY OFFER LARGE SCALE MANUFACTURE?

No, whether a small hand-assembled order or a high volume manufacturing run, BBI can deliver our customers' products to their set QC specifications.

WHAT REAGENT DISPENSING OPTIONS DO YOU OFFER?

We have small scale card based dispensing systems through to high throughput automated dispensing systems that incorporate in-line 100% QC of product quality.

What our customers say

“ BBI’s development experience and certified quality management systems, gave us the confidence we needed to move forward with this critical project”.

Managing Director, European Diagnostic Company

Contact BBI Solutions today to find out how we can help you towards your assay goals

www.bbisolutions.com sales@bbisolutions.com

Int: +44 (0)1495 363 000 USA: 1-800-423-8199 China: +86 021 61042216