# Request for Information – Lateral Flow Devices for Pandemic Preparation

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| **Supplier Name** |   |
| **Contact Name** |   |
| **Contact Email Address** |   |
| **Contact Tel Number** |   |

**| Instructions:**

* 1. The purpose of this document is to enhance the Authority’s understanding of the marketplace and its options for sourcing for a potential future requirement.
	2. The issuance of this request for information (RFI) does not constitute a sourcing exercise nor will the Authority pay any costs incurred in the preparation of a response to this RFI.

* 1. The UK Health Security Agency’s (UKHSA) key objectives for this RFI are:
	2. understand the ability of the marketplace to fulfil its requirements;
	3. refine the scope of the requirements to best align to the marketplace;
	4. inform the Authority’s chosen route to market to best enable competition;
	5. understand UK’s LFD manufacturing ability and capacity;
	6. understand LFD manufacturing supply chain in regard to what elements are and can be manufactured in the UK ;
	7. to understand the market’s ability of scalable manufacturing capacity in the event pandemic;
	8. To understand resilience of LFD component supply chain to enable this scale of manufacture at a sustained level; and
	9. understand the innovation in the marketplace.
	10. The key dates for this RFI are as follows:
1. **RFI Published: 12th September 2025**
2. **RFI Response Deadline: 17:00 on 10th October 2025**
	1. Should you have any questions or queries relating to this RFI, please use the Atamis portal’s messaging centre to direct your questions to us for a response.
	2. If a response is not received by the RFI response deadline this will have no impact on your ability to tender for the opportunity in the future. UKHSA will not enter into contracts on the basis of replies to this RFI.

**| Description of Scope of Requirements:**

The UK Health Security Agency (UKHSA) is responsible for protecting every member of every community from the impact of infectious diseases, chemical, biological, radiological and nuclear incidents and other health threats. We provide intellectual, scientific and operational leadership at a national and local level, as well as on the global stage, to make the nation's health secure.

**Background**

Lateral flow tests, in particular antigen Lateral flow tests, were a key component of large-scale testing during the response to the COVID-19 outbreak. It is expected that similar tests would form a key part of future pandemic response for clinical sample testing. Challenges to the use of such tests are quality, scale of production, resilience of supply and shelf-life once manufactured as follows:

* The initial quality and performance of many LFDs supplied for evaluation during COVID-19 was poor with a very high failure rate (see Bown *et al* 2025).
* The ability to deliver LFDs at scale to meet demand of mass testing through self-use in the population requires production at a sufficient level, often much higher than that for combined production of tests used for routine testing outside of outbreaks.
* The ability to produce tests at scale for a sustained period of time for the duration of testing needed in the outbreak i.e. the need for resilient supply chain of components.
* The ability to rapidly produce *de novo* tests at scale, but also to develop tests for existing pathogens in pilot studies to confirm performance, to avoid stockpiling of lateral flow tests which will expire in the absence of an outbreak.

**Scope of this request**

To address this UKHSA has been funded by the Cabinet Office Integrated Security Fund to identify and evaluate manufacturers capable of rapidly scalable onshore production of lateral flow tests for pandemic response and increased biosecurity.

To deliver this project we are seeking individual manufacturers or manufacturing partnerships (e.g. Assay development and Assay manufacturing specialists) to respond to this request which will require submission of information on scale of manufacture in the UK and resilience of the component supply chain to manufacture at that scale for the duration of an outbreak, as well as, the usual test performance requirements which the manufacturer will supply.

Following this response from potential manufacturers, we will then review the submissions and where necessary seek further information and assurance through data reviews and audits before selecting suppliers for pilot studies to demonstrate ability to manufacture lateral flow tests for an existing use case e.g. multiplex respiratory antigen lateral flow test by the end of the financial year (31/03/2026).

This intended outcome of this initial project is to identify scalable UK based manufacturing capacity capable of providing lateral flow tests in sufficient volume sustainable for the duration of a pandemic. Following on from this UKHSA would work with selected suppliers identified to develop lateral flow tests for pathogens which could cause pandemics, though not necessarily scale up production, as well as lateral flow tests for routine pathogen testing which would be used at moderate scale for business-as-usual testing.

**Capacity and Scalability**

From the COVID-19 outbreak data and modelling of similar outbreaks with a novel airborne/respiratory pathogen then need for a lateral flow test after 4-6 weeks, preferably sooner, is clear as PCR based testing would be scaled up in that time but demand will exceed capacity. With current modelling projections production capacity >1million tests per day would be required before PCR capacity is exceeded and sustained for >100 days. Not all outbreaks will require such levels of production (e.g. Mpox in 2022 and 2025) but the need for a rapid supply of lateral flow tests is clear, so production capacity needs to be rapidly scalable commensurate with demand.

**Future innovation – for information only**

Lateral Flow Test use during COVID-19 changed the way we think about large-scale testing in the community and healthcare setting. Their use also poses new challenges which we would anticipate the selected manufacturers to address as part of development of the next generation of such devices with UKHSA to be clear though these aren't part of current selection criteria they are areas we expect suppliers to address in the next generation of LFTs. Variability in performance is often due to operator interpretation which can be addressed by use of mobile phone cameras linked to applications software to improve reading of lateral flow test results, reporting of the result and action for the individual receiving the result to take (e.g. isolation, medication or to seek further healthcare support). Use of lateral flow tests can lead to loss of surveillance data on pathogen evolution so compatibility of devices with sequencing of nucleic acid recovered from positive lateral flow tests is a requirement and the means to stabilise nucleic acid and inactivate any infectious agent present will be necessary.

**Questions**

1. Do you produce a UKCA or CE marked LFD test kit i.e. pan –respiratory multiplex LFD which is:
	1. for professional use only; and/or
	2. can be self-administered/does not require a medical professional to administer?

Please confirm which and the pathogens which it is capable of detecting.

1. If you do is this product on any UK government frameworks, dynamic purchasing systems or dynamic markets?
2. If you do not, would you be willing to get your product UKCA marked for this purpose?
3. Do you currently have the capability to manufacture this product within the UK? If not, are there any plans or options to establish UK-based production in the future? Please outline timelines for any future plans.
4. Who is the legal manufacturer?
	1. Where is the product currently manufactured?
	2. And if this is taking place already in the UK, who is the authorised representative?
5. What quality standards do you work to in
	1. your LFD assay development?
	2. and LFD manufacturing processes? Please include your accreditation number
6. What is your current maximum production capacity for this product (e.g., units per day/week/month)?
7. What is your theoretical maximum capacity if all resources were fully mobilised?
8. If required, what would be the estimated timeline to scale up production to meet increased demand to produce up to or beyond 1 million tests per day?
9. Are there any constraints (e.g., staffing, materials, equipment, space) that could affect your ability to scale up?
10. At your maximum capacity how long could you sustain production based on current component stocks which you hold?
11. Please provide a high-level overview of your supply chain for this product, including key component suppliers and their locations.
12. Are there any known risks or dependencies in your supply chain that could impact continuity or lead times?
13. What mitigation do you have in place for supply chain issues?
14. Please provide details of key suppliers, their capacity to supply and alternative options for supplies of the key components.
15. Please confirm you are able, as part of the review process, to host visits from UKHSA representatives to visit your manufacturing facilities and undertake reviews of manufacturing capability and supply chain resilience.