# Request for Information – Respiratory Multiplex LFD Test Kit

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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.
  3. The UK Health Security Agency’s (UKHSA) key objectives for this RFI are:
  4. understand the ability of the marketplace to fulfil its requirements;
  5. refine the scope of the requirements to best align to the marketplace; and
  6. inform the Authority’s chosen route to market to best enable competition
  7. The key dates for this RFI are as follows:

1. **RFI Published: 03rd September 2025**
2. **RFI Response Deadline: 22nd September 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 national and local level, as well as on the global stage, to make the nation's health secure.

UKHSA uses Lateral Flow Device (LFD) test kits as a critical tool in protecting public health, providing support in outbreak investigations and control measures for SARS-CoV-2 and Influenza A&B.

To provide greater resilience and flexibility across use cases as part of UKHSAs Pandemic Preparedness strategy and support the UK’s contribution to the [100 Days Mission - GOV.UK](https://www.gov.uk/government/publications/100-days-mission-to-respond-to-future-pandemic-threats), which targets deployment of diagnostics within 100 days of identifying a new pandemic threat, it would be beneficial to evaluate the variety of LFD test kits currently on the market and establish the range of respiratory pathogens that can be identified by multiplex LFD kits.

The UKHSA requires a UKCA/CE marked self-test respiratory LFD which as a minimum can detect SARS-CoV-2 and Flu A/ B (including H5N1). The product will need to be evaluated for its performance at Porton Down and will also need to pass relevant QC/QA checks.

UKHSA also intends to publish a further request for information, focusing on onshoring, supply chain resilience, and future product development for LFDs. Additional details will be made available in due course.

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**Questions**

1. Can you supply a complete individual UKCA/CE approved self-test LFD kit, which as a minimum can test for SARS-CoV-2, Influenza A&B & RSV?
2. Please provide full kit and manufacturer details, including brand name (as it appears on label/IFU), manufacturers product code, legal manufacturer and UK representative (if applicable) and date the model was first placed upon the market.
3. Please provide a description of all components that are provided as standard with the test and list any additional items/equipment that need to be purchased to run this test.
4. Please provide the latest Instructions for Use (IFU), including version and revision date, and indicate if a different version was used in regulatory submissions, providing the copy used for regulatory submission.
5. Please provide the intended use statement, and confirm it is manufactured in an ISO 13485 accredited facility?
6. What other certifications or accreditations does your organisation or manufacturing site hold (e.g., ISO 9001, ISO 10993, GMP)?
7. Do you operate a defined batch release process, and has the product been subject to any recalls or Field Safety Notices in the past 3 years?
8. What is the product’s shelf life and stability under various storage conditions aligned to your regulatory approvals, and do you have access to a warehouse temperature controlled or monitored?
9. Which regulatory frameworks apply to the device (e.g., UK MDR 2002 (as amended), EU IVDR), and is the device UKCA/CE marked for its intended use? Please also state if the product has CTDA approval status.
10. Are you able to provide variant assurance evidence and commitment for new and emerging variants or mutations for all pathogens including SARS-CoV-2 as per gov.uk guidance, (Guidance for manufacturers: diagnostic assurance with SARS-CoV-2 variants in circulation - GOV.UK)
11. Please provide regulatory documentation, including CE/EC Declaration of Conformity or UKCA certificate number/UDI, or internal reference if self-declared.
12. Is the product for research use only, and does it have a latex-free declaration?
13. Is your organisation included on any UK government frameworks, DPS, or Dynamic Markets through which UKHSA could procure your LFD test kit?
14. Please provide details regarding your supply chain for materials and/or components related to the LFD test kit, please provide lead times, shipping methods and confirm whether you maintain or could maintain a stockpile of those components/materials and for what quantity of LFD test kit.
15. Please provide commercial and supply details, including country of manufacture, pack size, unit of issue, pallet specification (units and outer boxes per UK standard pallet), indicative unit price (GBP), inclusive of price breaks by volume and weekly supply capacity.
16. What are your current lead times for manufacturing and delivery, and what is your average turnaround time from order receipt to dispatch?
17. What is your fulfilment capacity and scalability, including current daily capacity and your timescales and capability to ramp up to 100,000 consignments per day? Please also confirm how long you would be able to sustain this once the 100,000 consignments per day is met.
18. Are you able to provide temperature monitoring for all kits during all stages of transportation and delivery? And make temperature records available to UKHSA?