Request for Information (RFI) – Procurement of commercial end to end solution for Immunocompromised assays to include Parvovirus, HEV, CMV and Entero targets and supply of any CE-marked reagents and consumables

Supplier Name	
Contact Name	
Contact Email Address	
Contact Tel Number	

Instructions:

1. Bristol UKHSA is seeking to modernise its methods for testing for Pathogens which affect Immunocompromised patients by implementing an end to end molecular System. This RFI is seeking to develop Bristol UKHSA's understanding of the feasibility of different contracting models for the provision of a Molecular Immunocompromised service. The issuance of this RFI does not constitute a sourcing exercise but responses provided will help to shape UKHSA's sourcing strategy. UKHSA will not pay any costs incurred by respondents in the preparation of a response to this RFI.

2. The UKHSA's key objectives for this RFI are:
    a. to understand the market's interest in meeting its requirements;
    b. to understand the market's appetite for meeting UKHSA's needs via different contracting models;
    c. estimated costs for delivering the scope of the contract;
    d. the ability for UKHSA to flexibly utilise the platform in public health emergencies for outbreaks;
    e. whether technology refreshes through-life would be possible; and
    f. to understand the technology available to provide the service and the future road map of suppliers in this area.
3. The key dates for this RFI are as follows:
    a. **RFI Published: 13th May 2024**
    b. **RFI Response Deadline: 12pm – 27th May 2024**
4. 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.

5. 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

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.

This requirement is for the procurement of an end-to-end solution incorporating nucleic acid extraction, detection and associated amplification tests and consumables (NAAT) to detect viral targets associated with affecting immunocompromised patients to replace current in-house PCR assays.

The intention is that when fully operational the UKHSA would intend the service to:

- transform the ways vesicular rash viral pathogens are detected by replacing in-house labour-intensive methods with technologically advanced automation;
- significantly reduce the turnaround times for clinical and public health samples and improve patient management, infection control and public health interventions;
- provide superior sensitivity and expected detections rates which will notably assist Health Protection Teams;
- reduce the risk of transcription errors by adopting automated result entry and interpretation;
- provide UKHSA with contingency capacity in the event of surge in workloads.

UKHSA is seeking for the provision and support of this system to be delivered for the full life of the project from installation through to disposal this includes the provision of:

- the equipment/system (inclusive of installation where required);
- reagents and consumables;
- software management and updates;
- training;
- preventative maintenance and repairs and overhauls;
- helpdesk and support capabilities; and
- disposal of the system at end of life.

The System must be capable of testing for the following "Essential" targets, and we would like to be able to deliver as many of the "Desirable" targets as possible, these can be delivered in the way of test panels or as one if suppliers solution is validated for multiple sample types on one test:

Table.1 Essential and Desirable targets

Test	Sample types 'Essential'	Sample types 'Desirable'
Parvovirus PCR	Wholeblood or Plasma Amniotic fluid	Serum
CMV DNA PCR	BAL, Amniotic fluid Urine Buccal swab	
Optional test: CMV RNA PCR	Wholeblood or Plasma	
HEV PCR	Whole blood or Plasma Stool/Faeces	Serum
Entero	Wholeblood or Plasma	Throat swab Stool/Faeces

Volumes

Table 2 below shows test numbers over the last 5 years

Target	Specimen type	2019	2020	2021	2022	2023
Parvovirus	Wholeblood/Plasma	292	294	310	316	276
	Amniotic fluid	1	1	0	0	3
	Serum	68	38	52	44	42
CMV	Amniotic fluid	4	5	5	2	20
	BAL	42	36	43	30	41
	Urine	1201	1145	976	1015	1255
	Buccal swab	0	0	1	0	0
Hepatitis E	Wholeblood/Plasma	181	173	231	311	230
	Serum	4321	3770	3748	3860	3601
	Stool	1288	1168	1264	1271	1371
Enterovirus	Wholeblood/Plasma	151	72	69	55	194
	Throat swab	151	72	69	55	194
	Stool	1288	1168	1264	1271	1371

To note: All HEV PCR requests are currently referred to a reference laboratory

Options for Routes to Market

Bristol UKHSA is in the process of devising its sourcing strategy for its Molecular Immunocompromised test System requirement following a review of the marketplace and various potential routes to market utilising government frameworks. At this stage we have concluded that there are two primary options for purchasing the equipment, consumables and reagents and the requisite through life support:

1. A Managed Equipment Service; and
2. The purchase of a molecular vesicular rash System with a Service Wrapper for the through life support of the system (inclusive of the provision of re-agents).

Questions:

1) Please confirm whether your organisation would have an interest in bidding for the provision of UKHSA's requirement for an end to end solution for Immunocompromised assays to include Parvovirus, HEV, CMV and Entero targets and supply of any CE-marked reagents and consumables

2) Please confirm whether you have (or can supply) a Molecular system which can test for all the targets marked as "Essential" in Table One and which of the targets marked as "Desirable" in Table One it is capable of testing for.

3) Please confirm whether your organisation would have an interest in bidding for the provision of UKHSA's requirement, based upon each of the following contracting models:
   a) A Managed Equipment Service?
   b) A Turnkey System with Service Wrapper?
   c) Other suggestions, please give details?

4) Please provide a price per test (including all IFU required reagents and consumables) for testing of all essential targets. In your response describe if single or multiple assay panels are used to achieve this. If multiple assay panels are used, also describe the targets contained in each panel and state the price per test for that panel only. Please also make it clear if the prices would be as part of an MES, Turnkey System with Service Wrapper or other suggested route (if put forward to 3)c)).

   EXAMPLE 1: Solution is one single panel for all essential targets: £XX per test or £YY per test.

   EXAMPLE 2: Panel A for essential bacterial and parasitic targets only, price: £XX per test

   Panel B for essential viral targets only, price: YY per test

   Total price to run panel A and B: £ZZ per test

5) Based upon the volumes outlined above in table 2, please can you provide an estimated cost for a 5-year contract for:
   a) A Managed Equipment Service.
   b) A Turnkey System with Service Wrapper, inclusive of the costs of the equipment at the outset.
   c) Any other suggestions, please give details?

6) Noting UKHSA's role as the UK's Public Health Agency would your organisation anticipate imposing any restrictions under either of the contracting models for employing the equipment provided for non-enteric related testing when Public Health needs require UKHSA to do so?

7) Please can you confirm whether or not on a Managed Equipment Service contract, you would be willing to undertake technology refreshes during the contract?

8) Please can you confirm if you would be willing to provide upgrades of the entire system (i.e., System model version one to system model version two) where the equipment is purchased

outright at reduced costs. If so, would the system upgrade be free of charge, discounted or fully chargeable? Please provide estimated prices if possible.

9) Please provide your organisations future delivery plan for your technology development for the Molecular Systems?

10) Please can you confirm whether as part of your proposal whether you would be able to provide Third Party regular (daily/weekly depending on your proposed solution) Independent Quality Control Material for the duration of the term of the contract?

11) Please can you provide the technical/system performance information for products your organisation would propose to meet our requirements. Including but not limited to:
    a) Specificity and sensitivity ratings for the targets the system can identify; and
    b) the maximum achievable volumes per day.