RCloud Tasking Form – Part B: Statement of Requirement (SoR)

Title of Requirement	DNA, RNA and antigen isolation using fluidic technologies
Requisition No.	As stated in the RCloud Portal
SoR Version	**0.1**

1.	**Statement of Requirements**	
1.1	**Summary and Background Information**	
	Summary: A re-usable, low-burden micro-/fluidics system is to be developed for the isolation of DNA, RNA and native Proteins from a single small volume, aqueous sample. A prototype system shall be supplied and training shall be provided to enable Dstl to be able to fully use the system to allow for isolation from multiple biological agents. The supplier shall work closely with Dstl during all phases of contract delivery. **Background:** Microfluidic devices have been designed in recent years for the extraction of single application RNA, DNA or Proteins from varying sample sources. However there is no reported devices for extracting all three from a crude sample (primarily outdoor environmental aerosol samples). Advances in commercial kits have allowed for extraction of all three using column-based, centrifugal methods. With small-scale and rapid applications now being required, a micro/fluidic based system is of particular interest for extracting samples in a timely manner for downstream detection assays. A rapid low-burden micro-/fluidic device is required to prepare samples for downstream analysis technique(s). Dstl is interested in sample processing to enhance the low burden sensing/detection of hazardous microorganisms and biological materials that may be present in environmental aerosol samples. Therefore a re-usable, portable / low Size, Weight and Power (SWaP) micro-/fluidic based device is required, to isolate DNA, RNA and non-denatured antigen (typically but not exclusively protein) from an un-purified aerosol sample. The areas of research that need to be combined for this work shall include microfluidics, molecular biology, engineering and sample flow through the chip. There is an expectation for engineering	

	and life science departments to work closely during this project. If the supplier needs time to hire a suitable candidate to conduct the work, an estimated timescale shall be supplied. Dstl will provide a concentrated stock of bacterial spores, bacteria, particulates, phage, protein and nucleic acids. The supplier will dilute the stock to 10 cfu/mL and benchmark the microfluidic capability of the prototype system. We expect the supplier to apply molecular biological assays to determine the quantity and quality of the system output namely nanodrop, Q-bit, bioanalyser chip, ELISA and PCR. Following testing, the system will be supplied and subsequent training provided to enable Dstl to fully use the system to allow use of biological agents.	
1.2	**Requirement**	
	This is a two year project, which aims to utilise research in the area of micro-/fluidic technology to demonstrate that such a re-usable device can be utilised for the isolation of DNA, RNA and native antigens/epitopes from a crude sample. The supplier shall design, create prototypes and complete molecular analysis of outputs and waste products. The requirement of the device are as follows: The sample will be pipetted/injected into an inlet with a volume of 10-50 µL and waste and isolated fractions will be deposited in collection tubes. The process is to take less than twenty minutes and the output of the device must produce sufficient purity for SPR immunoassay applications with the parameters of sample loss to be at a minimum to be comparable or better than commercial off the shelf kits. The prototype system and any peripheral equipment should ideally be portable but if this is unachievable then evidence is to be provided to demonstrate how the prototype can be miniaturised in a more refined form. The equipment should be fully automated but if unachievable then evidence is to be provided to demonstrate the potential for full automation with future work. The device should perform as specified in section 1.2 before handover and is to overcome external factors which have the potential for sample interference such as salt concentrations, pH and pollutants such as pollen, diesel fumes and signal smoke. The output shall be of sufficient purity and for proteins they remain in their native conformation to enable binding or hybridisation assays such as Surface Plasmon Resonance (SPR) and immunoassays. A minimum of two fractions of nucleic acids and proteins/antigens should be isolated from the sample, however nucleic acids could be separated further into DNA and RNA fractions. The Authority will consider proposals that aim to develop larger SWaP prototypes provided there is clear evidence to demonstrate the potential for future miniaturisation (hand-held or suitable for integration into a low SWaP sensor) of the solution. The solution shall remove or obviate the effects of interfering substances (e.g. military signal smokes or diesel exhaust) or conditions (e.g. pH extremes) from each of the parallel outputs. The outputs shall be compatible	

with assays including PCR, RT-PCR, isothermal amplification, CRISPR-Cas detection systems and antibody-based sandwich immunoassays using fluorescence or electrochemistry.

As part of this project Dstl require the supplier to investigate the following key areas and linking them to microfluidic systems:

1. The supplier is to liaise with life science areas such as Molecular biology to determine the quantity and quality of DNA, RNA and protein produced.
2. The supplier must evaluate microfluidic flows for reagent minimisation and safety.
3. The supplier must develop and optimise isolations using a pre-prepared stock mix provided by Dstl as described in Section 1.1 and shall be supplied as needed by the supplier. The supplier is free to use their own samples for additional testing.
4. The supplier will transfer the technology to Dstl which will include the prototype system and methodology required to perform the sample preparation and optimisation. The prototype microfluidics system transferred to Dstl will not be returned to the contractor at the conclusion of the project.
5. The supplier must understand how to maintain the system by the end of the project to effectively mentor Dstl staff in said maintenance, determine the high risk areas where contamination may collect and how to effectively clean these areas.

Management and Milestones:

6. The work will be communicated by monthly updates between Dstl and the supplier via e-mails, supplier site visits every 6 months and teleconferences as required or a minimum of per monthly basis to coincide with reports.
7. Dstl scientists are to have the opportunity for visits to the supplier to build awareness of technical hurdles and limitations of the device whilst in development once every 6 months, with exact dates of visits to be decided upon project start.
8. The supplier shall provide quarterly progress reports to be emailed to Dstl to update on prototype progress. Quarterly progress reports on the progress of the work carried out can be conducted in conjunction with Dstl visits to the supplier or by teleconference.
9. Full training in use, maintenance, routine cleaning and troubleshooting of the device is required at 24 months.
10. At 24 months, a technical report shall be provided following the analysis of the pre-prepared mixture supplied by Dstl.
11. At 12 months an annual report shall be conducted by the supplier and at 24 months, a summary report is required outlining details indicated in Section 1.6.
12. At 24 months the supplier shall transfer a complete prototype microfluidics system and supporting user-guide to Dstl.

1.3	**Options or follow on work** *(if none, write 'Not applicable')*	
	Not Applicable	
1.4	**Contract Management Activities**	
	1. The work will be communicated by monthly updates between Dstl and the supplier via e-mails, supplier site visits every 6 months and teleconferences as required or a minimum of per monthly basis to coincide with reports. 2. The supplier will provide quarterly progress reports to be emailed to Dstl to update on prototype progress. Quarterly presentations on the progress of the work carried out can be conducted in conjunction with Dstl visits to the supplier or by teleconference.	
1.5	**Health & Safety, Environmental, Social, Ethical, Regulatory or Legislative aspects of the requirement**	
	Work will conducted under health and safety and ethical assessments conducted by the contractor prior to work commencement. All work will comply with the Health and Safety at work act 1974, Management of Health and Safety at Work Act 1999, Control of Substances Hazardous to Health Regulations 2002, Personal Protective Equipment Regulations 1992, Provision and Use of Work Equipment Regulations 1998 and Hazardous Waste Regulations 2005.	

1.6	Deliverables & Intellectual Property Rights (IPR)					
Ref.	**Title**	**Due by**	**Format**	**Expected classification (subject to change)**	**What information is required in the deliverable**	**IPR Condition**
D – 1	Quarterly Progress and Technical Review Presentations (QPTR 1)	T0+3 Months Every 3 months thereafter	Presentation (.pptx)	UK OFFICIAL	Presentation pack to include but not limited to: • Update on technical progress • Progress report against project schedule. • Review of risk management plan. • Commercial aspects. • Review of deliverables. • Risks/issues. • GFA and supplier performance	DEFCON 705
D - 2	Annual Summary Report	T0+12 Months	Report (.docx)	UK OFFICIAL	Report to include but not limited to: • Progress on project thus far • Review of yearly testing and results • Update on technical progress • Progress report against project schedule. • Risks/issues • Description of technical difficulties	DEFCON 705

D - 3	Final Technical Report	T0 + 24 Months	Report (.docx)	UK OFFICIAL	Following analysis of the pre-prepared test mixture supplied by Dstl, a technical report will be conducted including but not limited to methods used, demonstrating prototype capabilities, outputs, advantages and disadvantages of the prototype, data analysis, quality metrics and statistics, improvements and recommendations.	DEFCON 705
D – 4	Training	T 21 Month	In Person training	UK OFFICIAL	In person training to be given to two Dstl staff members at the supplier site on how to operate the model, cleaning, troubleshooting to enable use following handover. This shall be done throughout the course of the project to develop capabilities within Dstl.	DEFCON 705
D - 5	Summary Report	Month 24	Report (.docx)	UK OFFICIAL	Report to include but not limited to: • Overall progress of the project, including all significant milestones • Complete workings of the device including cleaning instructions and identification of areas of contamination • Troubleshooting	DEFCON 705

					• Summary of output of the device, expected yield loss. • Recommendations for the model	
	Complete handover and delivery of a full working device	Month 24	In person	UK OFFICIAL	Following completion, the supplier will transfer a complete prototype microfluidics system and supporting user-guide including details of the analytical techniques to be used with the system to Dstl.	DEFCON 705

1.7	**Deliverable Acceptance Criteria**
	The full working prototype isolation system must be shown to and handed to Dstl along with full training to Dstl staff on how to operate the device, troubleshooting and running an isolation, methods of cleaning and troubleshooting the apparatus. The device is to adhere to the requirements set out by the criteria outlined in section 1.2 and be in full working order; the device shall produce extracted analytes that meet the stated concentration and volume requirements, are sufficiently pure for downstream molecular assays, and allows waste products to be collected at the time of handover. All technical report shall contain information as outlined in Section 1.6.

2	**Evaluation Criteria**
2.1	Method Explanation
	Most economically advantageous tender (MEAT) methodologies will be applied using a Value For Money index which assesses and assigns scores based on the cost, technical quality and maximum investment return of the tender.
2.2	Technical Evaluation Criteria
	See attached Evaluation Criteria
2.3	Commercial Evaluation Criteria
	See attached Evaluation Criteria