RapidQ

Quality, Simplified

Product Catalogue

NRL

Science of Quality

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RapidQ ensures reliable results, **anytime, anywhere**

What is Point-of-Care Testing?

Point-of-Care Testing (PoCT) enables diagnostic testing close to the patient, providing immediate results that directly impact clinical decisions. This rapid result availability is crucial in settings where follow-up care is difficult due to geographic, social, economic, or environmental challenges.

PoCT's versatility is evident in its use of rapid diagnostic tests (RDTs) and portable molecular testing (NATs) for infectious diseases like SARS-CoV-2. These technologies are easy to use and don't require specialised laboratory equipment, making PoCT ideal for non-traditional settings such as schools, airports, and workplaces.

However, PoCT, like all diagnostic testing, is regulated and requires regular performance reviews. These checks are often harder to conduct in non-laboratory environments, especially when tests are performed by non-laboratory professionals. Testing failures can result in poor patient outcomes, resource waste, inaccurate epidemiological data, and the spread of infections, underscoring the need for robust quality assurance (QA) programs.

Current QA programs are tailored for well-resourced laboratories and are often cost-prohibitive for resource-limited settings. To address this gap, **NRL has developed a specialised QA model for infectious disease PoCT, designed specifically for these environments.**

RapidQ Model

The RapidQ program is comprised of two key components:

Competency Panels (CP):

Competency Panels consist of known positive and negative samples. The positive sample exhibits moderate reactivity across most PoCT methods. These panels are tested periodically to assess assay performance and user competence.

External Quality Assessment Panels (EQA):

EQA panels follow the same structure as NRL traditional programs, consisting of four vials with varying reactivity, unknown to the operator. The operator tests and reports results as if from real patient samples, with immediate feedback provided upon submission.

RapidQ Program Design:

The RapidQ program supports PoCT sites in meeting quality standards. Sites should regularly participate in competency assessments and use EQA to confirm the detection of various analytes. While participation frequency is flexible, NRL recommends specific intervals for each site, as outlined *below.*

Minimum quality testing for sites	Optimal quality testing for sites
CP testing **once** per month	CP testing **once** per week
EQAS testing **twice** per year	EQAS testing **three** times per year

RapidQ Programs are designed for analyte specific testing. Please contact NRL to determine availability in your region or if you would like to partner with us to develop other PoCT QA programs.

Our Features

RapidQ Management

The RapidQ model is delivered through Implementing Partners, not directly to individual test sites. NRL partners with organisations like the World Health Organization (WHO), ministries of health, IVD manufacturers, and major procurement bodies (e.g., the Global Fund, the Clinton Foundation, FIND) to manage networks of test sites. Regulatory authorities reviewing IVD performance may also act as Implementation Partners.

Logistics

Implementing Partners order RapidQ panels for 6-12 months to supply their test site networks. The panels are shipped ambient, requiring no UN3373 compliance. Local regulations must be followed, though importation permits may not be necessary. The panels are stored at a centralised warehouse under NRL's specified conditions before being distributed to test sites, where they can be stored at 2-8°C or room temperature.

Samples

The RapidQ competency and EQAS panels contain non-infectious, well-characterised clinical or biological materials, such as whole viruses or bacteria. These samples are validated for most PoCT devices and are not extracted nucleic acids or recombinant materials.

Storage

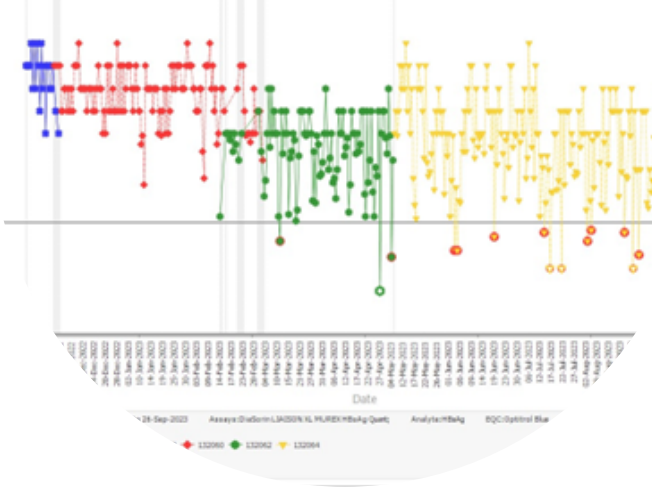
RapidQ panel samples are stable for **24 months** when frozen *(select panels)*, **6-8 months** at 2-8°C, and **3 months** at room temperature.

Software

NRL has developed an informatics system, built on EDCNet™, for result entry and data analysis via QR code mobile technology. This system supports PoCT sites that lack regular computer-based internet access, as most individuals have smartphones. This innovative approach facilitates participation in QA without time and software restrictions.

Result Analysis

All data are stored in a central database and analysed periodically. Any unusual variations in test performance are reported to the test site, Implementing Partner, and IVD manufacturer. Critical issues may be escalated to the WHO and regulatory authorities



EDCNet™

First developed by NRL in 2001, EDCNet™ has been a cornerstone of our international quality control programs for over two decades. As a global leader in infectious disease testing monitoring, NRL has consistently advanced quality control practices beyond traditional methods. Now, this expertise is powering RapidQ, with EDCNet™ enhanced to support both qualitative and quantitative data monitoring.

What is EDCNet?

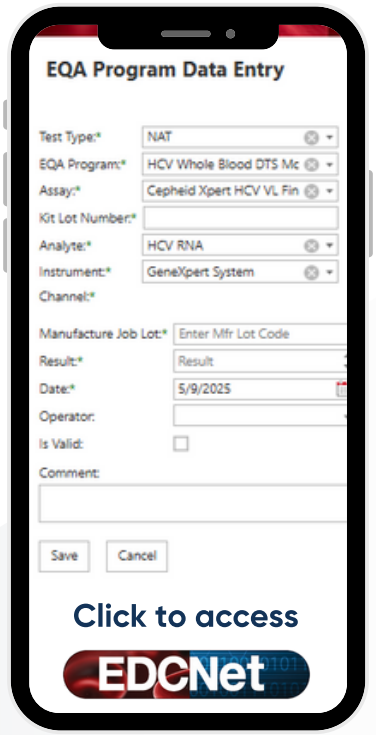
- A virtual, cloud-based database- accessible from anywhere with internet access.
- No software installation required- just enrol and log in.
- Fully GDPR compliant (EU 2016/679).
- Six languages - English, French, German, Italian, Spanish and Polish

How it Works

1. **Enrolment:** Each test site joins EDCNet™ and is issued unique user logins.
2. **Registration:** Sites register their test kits and instrumentation in the system.
3. **Panel Access:** When Competency or EQAS panels are received, users simply scan the QR code on the box.
4. **Auto-Fill:** The system pre-fills key fields (e.g., test kits, panel names, instrument details).
5. **Data Entry:** Users select the sample, reagent lot number, operator name, and testing date.
6. **Instant Feedback:** Once submitted, the results are analysed and immediate performance feedback is provided.

What Happens to the Data?

- All results are securely stored in a central database.
- Data are analysed by NRL staff in real time.
- Unusual or unexpected results are investigated, ensuring accuracy and reliability.
- Reports are generated and shared with the test site, Implementing Partner, and/or IVD manufacturer, depending on the context.



READY-TO-ORDER PRODUCTS

HBV

1. HBV SEROLOGY RDT COMPETENCY

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative **SAMPLE TYPE:** Synthetic Whole Blood-like Sample

PROGRAM CODES	FORMAT	COMPATIBILITY
SC11058 **SC11052** **SC11053**	**2** vial; **0.5mL** each (1 x POS, 1 x NEG) **2** vial; **0.5mL** each (2 x NEG) **2** vial; **0.5mL** each (2 x POS)	HBV rapid diagnostic tests (RDTs) testing serum, plasma or capillary whole blood.

HBsAg

DESCRIPTION

The positive vial consists of human whole blood-like sample known to be positive for HBsAg at a known reactivity. The negative sample is uninfected human whole blood-like sample.

2. HBV SEROLOGY RDT POC EQA

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative **SAMPLE TYPE:** Synthetic Whole Blood-like Sample

PROGRAM CODES	FORMAT	COMPATIBILITY
HBSR4	**4** vial; **0.5mL** each	Rapid diagnostic tests (RDTs) testing serum, plasma or capillary whole blood.

HBsAg

DESCRIPTION

Each vial consists of human whole blood-like sample, positive or negative for HBsAg of various genotypes and concentrations.

3. HBV DRIED PLASMA MOLECULAR COMPETENCY

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative & Quantitative **SAMPLE TYPE:** Dried Human Plasma Matrix

PROGRAM CODES	FORMAT	COMPATIBILITY
MC11058 **MC11052** **MC11053**	**4** vial: **2** vials dry (1 x POS, 1 x NEG), **2** vials **1.2mL** (PBS) **4** vial: **2** vials dry (2 x NEG), **2** vials **1.2mL** each (PBS) **4** vial: **2** vials dry (2 x POS), **2** vials **1.2mL** each (PBS)	HBV molecular tests that use serum or plasma.

HBV DNA

DESCRIPTION

The positive vial consists of dried human plasma known to be infected with HBV DNA at a specified concentration. The negative sample is dried uninfected human plasma. The reconstitution buffer is phosphate buffered saline (PBS).

4. HBV DRIED PLASMA MOLECULAR POC EQA

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative & Quantitative **SAMPLE TYPE:** Dried Human Plasma Matrix

PROGRAM CODE	FORMAT	COMPATIBILITY
DPBR4	**8** vial: **4** vials dry, **4** vials **1.2mL** each (PBS)	HBV molecular tests that use serum or plasma.

HBV DNA

DESCRIPTION

Each vial consists of dried human plasma either uninfected or infected with HBV DNA of various genotypes and concentrations. The reconstitution buffer is phosphate buffered saline (PBS).

HCV

1. HCV SEROLOGY RDT COMPETENCY

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative **SAMPLE TYPE:** Synthetic Whole Blood-like Sample

PROGRAM CODES	FORMAT	COMPATIBILITY
SC11028 **SC11022** **SC11023**	**2** vial; **0.5mL** each (1 x POS, 1 x NEG) **2** vial; **0.5mL** each (2 x NEG) **2** vial; **0.5mL** each (2 x POS)	HCV rapid diagnostic tests (RDTs) testing serum, plasma or capillary whole blood.

anti-HCV

DESCRIPTION

The positive vial consists of human whole blood-like sample known to be positive for anti-HCV at a known reactivity. The negative sample is uninfected human whole blood-like sample.

2. HCV SEROLOGY RDT POC EQA

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative **SAMPLE TYPE:** Synthetic Whole Blood-like Sample

PROGRAM CODE	FORMAT	COMPATIBILITY
HCSR4	**4** vial; **0.5mL** each	HCV rapid diagnostic tests (RDTs) testing serum, plasma or capillary whole blood.

anti-HCV

DESCRIPTION

Each vial consists of human whole blood-like sample, positive or negative for anti-HCV of various genotypes and concentrations.

3. HCV WHOLE BLOOD MOLECULAR COMPETENCY

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative & Quantitative **SAMPLE TYPE:** Dried Human Whole-Blood Matrix

PROGRAM CODES	FORMAT	COMPATIBILITY
MC20028 **MC20022** **MC20023**	**4** vial: **2** vials dry (1 x POS, 1 x NEG), **2** vials **0.25mL** (PBS) **4** vial: **2** vials dry (2 x NEG), **2** vials **0.25mL** each (PBS) **4** vial: **2** vials dry (2 x POS), **2** vials **0.25mL** each (PBS)	HCV molecular tests that use fingerstick whole blood.

HCV RNA

DESCRIPTION

The positive vial consists of dried human whole blood known to be infected with HCV RNA at a specified concentration. The negative sample is dried uninfected human whole blood. The reconstitution buffer is phosphate buffered saline (PBS).

4. HCV WHOLE BLOOD MOLECULAR POC EQA

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative & Quantitative **SAMPLE TYPE:** Dried Human Whole-Blood Matrix

PROGRAM CODES	FORMAT	COMPATIBILITY
DBCR4	**8** vial: **4** vials dry, **4** vials **0.25mL** (PBS)	HCV molecular tests that use fingerstick whole blood.

HCV RNA

DESCRIPTION

Each vial consists of dried human whole blood either uninfected or infected with HCV RNA of various genotypes and concentrations. The reconstitution buffer is phosphate buffered saline (PBS).

5. HCV DRIED PLASMA MOLECULAR COMPETENCY

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative & Quantitative **SAMPLE TYPE:** Dried Human Plasma Matrix

PROGRAM CODES	FORMAT	COMPATIBILITY
MC11028 **MC11022** **MC11023**	**4** vial: **2** vials dry (1 x POS, 1 x NEG), **2** vials **1.2mL** (PBS) **4** vial: **2** vials dry (2 x NEG), **2** vials **1.2mL** each (PBS) **4** vial: **2** vials dry (2 x POS), **2** vials **1.2mL** each (PBS)	HCV molecular tests that use serum or plasma.

HCV RNA

DESCRIPTION

The positive vial consists of dried human plasma known to be infected with HCV RNA at a specified concentration. The negative sample is dried uninfected human plasma. The reconstitution buffer is phosphate buffered saline (PBS).

6. HCV DRIED PLASMA MOLECULAR POC EQA

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative & Quantitative **SAMPLE TYPE:** Dried Human Plasma Matrix

PROGRAM CODES	FORMAT	COMPATIBILITY
DPCR4	**8** vial: **4** vials dry, 4 vials **1.2mL** each (PBS)	HCV molecular tests that use serum or plasma.

HCV RNA

DESCRIPTION

Each vial consists of dried human plasma either uninfected or infected with HCV RNA of various genotypes and concentrations. The reconstitution buffer is phosphate buffered saline (PBS).

HIV

1. HIV SEROLOGY RDT COMPETENCY

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative **SAMPLE TYPE:** Synthetic Whole Blood-like sample

PROGRAM CODES	FORMAT	COMPATIBILITY
SC11038 **SC11032** **SC11033**	**2** vial; **0.5mL** each (1 x POS, 1 x NEG) **2** vial; **0.5mL** each (2 x NEG) **2** vial; **0.5mL** each (2 x POS)	HIV rapid diagnostic tests (RDTs) testing serum, plasma or capillary whole blood.

anti-HIV

DESCRIPTION

The positive vial consists of a human whole blood-like sample known to be positive for anti-HIV at a known reactivity. The negative sample is uninfected human whole blood-like sample.

2. HIV SEROLOGY RDT POC EQA

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative **SAMPLE TYPE:** Synthetic Whole Blood-like Sample

PROGRAM CODES	FORMAT	COMPATIBILITY
HISR4	**4** vial; **0.5mL** each	HIV rapid diagnostic tests (RDTs) testing serum, plasma or capillary whole blood.

anti-HIV HIV p24 Ag

DESCRIPTION

Each vial consists of whole blood-like sample, positive or negative for anti-HIV and/or HIV p24 Ag of various genotypes and concentrations.

3. HIV DRIED PLASMA MOLECULAR COMPETENCY

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative & Quantitative **SAMPLE TYPE:** Dried Human Plasma Matrix

PROGRAM CODES	FORMAT	COMPATIBILITY
MC11038 **MC11032** **MC11033**	**4** vial: **2** vials dry (1 x POS, 1 x NEG), **2** vials **1.2mL** (PBS) **4** vial: **2** vials dry (2 x NEG), **2** vials **1.2mL** each (PBS) **4** vial: **2** vials dry (2 x POS), **2** vials **1.2mL** each (PBS)	HIV molecular tests that use serum, plasma and assays used in molecular early infection diagnostics.

HIV RNA HIV Proviral DNA

DESCRIPTION

The positive vial consists of dried human plasma known to be infected with HIV RNA and/or HIV Proviral DNA at a specified concentration. The negative sample is dried uninfected human plasma. The reconstitution buffer is phosphate buffered saline (PBS).

4. HIV DRIED PLASMA MOLECULAR POC EQA

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative & Quantitative **SAMPLE TYPE:** Dried Human Plasma Matrix

PROGRAM CODES	FORMAT	COMPATIBILITY
DPIR4	**8** vial: **4** vials dry, **4** vials **1.2mL** each (PBS)	HIV molecular tests that use serum, plasma and assays used in molecular early infection diagnostics.

HIV RNA HIV Proviral DNA

DESCRIPTION

Each vial consists of dried human plasma either uninfected or infected with HIV RNA and/or HIV proviral DNA of various genotypes or concentrations. The reconstitution buffer is phosphate buffered saline (PBS).

SARS-CoV-2

1. SARS-COV-2 ANTIGEN RDT COMPETENCY

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative **SAMPLE TYPE:** Clinical Liquid Sample

PROGRAM CODES	FORMAT	COMPATIBILITY
SC18088 **SC18082** **SC18083**	**2** vial; **0.05mL** each (1 x POS, 1 x NEG) **2** vial; **0.05mL** each (2 x NEG) **2** vial; **0.05mL** each (2 x POS)	Most COVID-19 Ag Rapid Diagnostic Tests (RDTs) (Contact NRL for more details).

SARS-CoV-2 Antigen

DESCRIPTION

The positive vial consists of inactivated SARS-CoV-2 virus suspended in a transport medium. The negative vial contains uninoculated transport medium.

2. SARS-COV-2 ANTIGEN RDT POC EQA

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative **SAMPLE TYPE:** Clinical Liquid Sample

PROGRAM CODES	FORMAT	COMPATIBILITY
SCVR4	**4** vial; **0.05mL**	Most COVID-19 Ag Rapid Diagnostic Tests (RDTs) (Contact NRL for more details).

SARS-CoV-2 Antigen

DESCRIPTION

Each vial contains either uninoculated transport medium or inactivated SARS-CoV-2 virus variants of concern at different concentrations.

Serology Multi-Marker

1. MULTI-MARKER SEROLOGY RDT COMPETENCY

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative **SAMPLE TYPE:** Synthetic Whole Blood-like Sample

PROGRAM CODES	FORMAT	COMPATIBILITY
SC11018 **SC11012** **SC11013**	**2** vial; **0.5mL** each (1 x POS, 1 x NEG) **2** vial; **0.5mL** each (2 x NEG) **2** vial; **0.5mL** each (2 x POS)	Rapid Diagnostic Tests (RDTs) testing serum, plasma or capillary whole blood for the target analyte(s).

HBsAg anti-HCV anti-HIV anti-*Treponema pallidum*

DESCRIPTION

The positive vial consists of a human whole blood-like sample known to be positive for HBsAg, anti-HCV, anti-HIV and/or anti-*Treponema pallidum* at a known reactivity. The negative sample is uninfected human whole blood-like sample.

2. MULTI-MARKER SEROLOGY RDT POC EQA

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative **SAMPLE TYPE:** Synthetic Whole Blood-like Sample

PROGRAM CODES	FORMAT	COMPATIBILITY
MMSR4	**4** vial; **0.5mL** each	Rapid Diagnostic Tests (RDTs) testing serum, plasma or capillary whole blood for the target analyte(s).

HBsAg anti-HCV anti-HIV anti-*Treponema pallidum*

DESCRIPTION

Each vial consists of human whole blood-like sample, positive or negative for HBsAg, anti-HIV, anti-HCV and/or anti-*Treponema pallidum* of various concentrations.

C. trachomatis, N. gonorrhoeae

1. C. TRACHOMATIS & N. GONORRHOEAE SWAB MOLECULAR COMPETENCY

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative **SAMPLE TYPE:** Clinical Swab

PROGRAM CODES	FORMAT	COMPATIBILITY
MC17098 **MC17092** **MC17093**	**2** dried swabs (1 x POS, 1 x NEG) **2** dried swabs (2 x NEG) **2** dried swabs (2 x POS)	No known compatibility issues with any molecular method or analyser.

C. trachomatis *N. gonorrhoeae*

DESCRIPTION

The positive dried swab contains clinical material known to be positive for C. *trachomatis* and/or N. *gonorrhoeae*. The negative dried swab contains uninoculated buffer.

2. C. TRACHOMATIS & N. GONORRHOEAE SWAB MOLECULAR POC EQA

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative **SAMPLE TYPE:** Clinical Swab

PROGRAM CODES	FORMAT	COMPATIBILITY
CNTR4	**4** dry swabs	No known compatibility issues with any molecular method or analyser.

C. trachomatis *N. gonorrhoeae*

DESCRIPTION

Each swab contains different concentrations of clinical materials known to be positive for C. *trachomatis* and/or N. *gonorrhoeae*. Swabs may be infected with various serovars of Chlamydia or Neisseria spp.

Syphilis

1. SYPHILIS SEROLOGY RDT COMPETENCY

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative **SAMPLE TYPE:** Synthetic Whole Blood-like Sample

PROGRAM CODES	FORMAT	COMPATIBILITY
SC17068 **SC17062** **SC17063**	**2** vial; **0.5mL** each (1 x POS, 1 x NEG) **2** vial; **0.5mL** each (2 x NEG) **2** vial; **0.5mL** each (2 x POS)	Syphilis Rapid Diagnostic Tests (RDTs) testing serum, plasma or capillary whole blood.

anti-*Treponema pallidum*

DESCRIPTION

The positive vial consists of a human whole blood-like sample known to be positive for anti-*Treponema pallidum* at a known reactivity. The negative sample is uninfected human whole blood-like sample.

2. SYPHILIS SEROLOGY RDT POC EQA

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative **SAMPLE TYPE:** Synthetic Whole Blood-like Sample

PROGRAM CODES	FORMAT	COMPATIBILITY
TPSR4	**4** vial; **0.5mL** each	Syphilis Rapid Diagnostic Tests (RDTs) testing serum, plasma or capillary whole blood.

anti-*Treponema pallidum*

DESCRIPTION

Each vial consists of human whole blood-like sample, positive or negative for anti-*Treponema pallidum* of various concentrations.

Tuberculosis

1. TUBERCULOSIS MOLECULAR COMPETENCY

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative **SAMPLE TYPE:** Clinical Liquid Sample

PROGRAM CODES	FORMAT	COMPATIBILITY
MC18118 **MC18112** **MC18113**	**2** vial; **1.2mL** each (1 x POS, 1 x NEG) **2** vial; **1.2mL** each (2 x NEG) **2** vial; **1.2mL** each (2 x POS)	No known compatibility issues with any method or analyser.

M. tuberculosis Complex bacteria

DESCRIPTION

The positive vial consists of inactivated *M. tuberculosis* bacteria suspended in a buffer. The negative vial contains uninoculated buffer.

2. TUBERCULOSIS MOLECULAR POC EQA

SHIPPING CONDITION: Ambient **ANALYSIS:** Qualitative **SAMPLE TYPE:** Clinical Liquid Sample

PROGRAM CODES	FORMAT	COMPATIBILITY
MTBR4	**4** vial; **1.2mL** each	No known compatibility issues with any method or analyser.

M. tuberculosis and drug resistant strains

DESCRIPTION

Each vial contains either uninoculated buffer or inactivated M. tuberculosis bacteria at different concentrations.

IN-DEVELOPMENT

HPV & Group A Strep

The following programs are currently in-development and not yet available for enrolment:

1. **HPV Molecular**

2. **Group A Strep Molecular**

If you are interested in any of these upcoming programs or would like to discuss your laboratory's needs, please get in touch today.

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