2022 NRL External Quality Assessment Schemes

INDEX

NRL - ABOUT US

NRL is a Melbourne-based scientific organisation that exists to promote the quality of testing for infectious diseases, globally.

As a World Health Organization (WHO) Collaborating Centre and a fully accredited proficiency testing provider under ISO 17043, NRL offers the following two major types of External Quality Assessment Schemes (EQAS):

Comprehensive EQAS: designed for sophisticated laboratory-based testing as well as testing in low/middle-income countries who utilise high throughput automated testing platforms.

Point-of-Care (POC) EQAS: designed for near-patient molecular and rapid serology tests often utilised by low-income countries, remote and regional communities, and primary care testing sites.

In partnership with Oneworld Accuracy (www.oneworldaccuracy.com) and its extensive network of collaborators, all EQA schemes are supported by OASYS, an internet-based software management system. NRL schemes are distributed to testing facilities in over 60 countries, enabling monitoring and peer comparison for a range of test kits and instrumentation. NRL EQAS incorporates genuine and diverse samples and are intended to assess the integrity of the entire testing process.

The design and analysis of both Comprehensive and POC EQAS draw upon NRL's extensive experience and scientific methods to ensure maximum scope for error detection. NRL staff detect and review unexpected EQAS submitted results and work with the participants and corresponding test kit manufacturers (as applicable) to determine and resolve the root cause of any issues that would have otherwise potentially resulted in mis-diagnosis.

WHAT'S NEW IN 2022?

NEW

- NRL now offers a **SARS-CoV-2 Antigen** Program (COVA432) and a **SARS-CoV-2 Serology** Program (COVS434) for SARS-CoV-2 Antigen and Antibody serology testing respectively. These two EQA program is part of our unique, comprehensive quality solution to support SARS-CoV-2 serology and molecular testing.

- The **Sexually-Transmitted Infections Molecular** program (STIC435) now includes testing for Drug Resistant strains (***Mycoplasma genitalium* Fluoroquinolone resistant, *Mycoplasma genitalium* Macrolide resistant** and ***Neisseria gonorrhoeae* CFT resistant**).

- **Dried Tube Whole Blood HCV Molecular POC** (DWBC435) - This is the only international ISO 17043 accredited Dried Tube EQAS for HCV molecular testing on **finger stick whole blood** samples. This program features inactivated dried human whole blood samples, optimised and validated for POC platforms such as the **Cepheid GeneXpert HCV FS assay.**

- **HTLV DNA program** (HTLD435) is incorporated in the 2022 catalogue. NRL has been offering this unique EQA for the detection of proviral HTLV DNA. The program assesses linearity, reproducibility and limit of detection of the assay in use.

What are the major differences between the Comprehensive and POC schemes?

Comprehensive schemes:

- Accommodate laboratory-based testing facilities and those with algorithms that may include screening, supplemental and confirmatory testing
- Tabular and graphical reports
- Annual written scientific reports
- Incorporation of samples calibrated against the WHO international standards in the HIV, HBV and HCV molecular programs allowing determination of testing accuracy
- Genuine samples
    - plasma samples for serology (undiluted)
    - molecular samples derived from infected plasma, viral culture or clinical samples

POC schemes:

- Suitable for testing facilities that have limited infrastructure and/or resourcing
- Inactivated samples
- Shipped at ambient temperature
- Ease of importation
- Two or five sample panel format options
- Low cost

For any additional queries, we are here to answer your questions:

E: **oneworldaccuracy@nrlquality.org.au**

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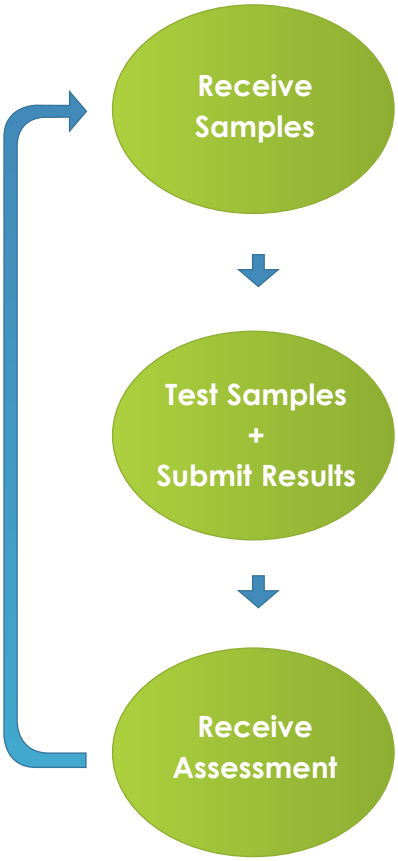
SYSTEM OVERVIEW

Getting started

Programs are listed by discipline. To order programs, please use the Order Form or Request for Quote provided by NRL.

The Test Event Cycle



Shipment Notice
These remind you that a shipment will be arriving soon.

Test Event Reminder
These enable you to prepare for the upcoming Test Event.

Instructions + Worksheets
These enable you to properly receive, store and test your samples and record submitted results.

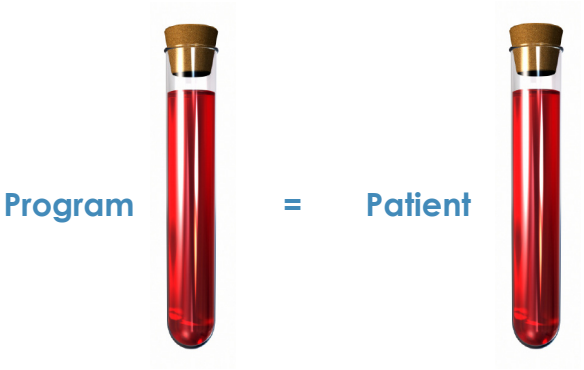
Results Deadline Reminders
These remind you to submit all results before the Results Deadline.

Performance Reports
These summarise your performance.

Here's how we acknowledge your commitment to testing quality

For EQA schemes, we provide an annual Certificate of Participation listing the disciplines of all programs you participated in.

THE FIRST PRINCIPLE



When you participate in NRL EQAS, the First Principle is that you must test program samples and report results exactly as you would patient samples.

Our programs are designed to assess how you test patient samples and report results. They are intended to be educational in nature so that if problems are identified, they represent an opportunity for you to improve the quality of your patient testing. We strive to help you so that all of your patients receive accurate, clinically relevant and timely results.

Your commitment to the First Principle ensures that our programs can be a reliable measure for how you test patient samples and report results. This means you must:

- test samples in the same manner and number of times as you test patient samples;
- test samples within the same timeframes as you test patient samples;
- test samples by the same personnel that routinely test patient samples;
- test samples using the same systems used to routinely test patient samples;
- submit results within the same timeframes as you report patient results; and
- not discuss your results with other participants or send your samples for outside testing.

WHY RESULTS DEADLINES MATTER

Submitting results before the 

signals your commitment to the First Principle.

For consistency, all Results Deadlines are on the Test Event date and end at 11:59 pm (23:59) your local time.

Submitting on time enables us to evaluate and communicate your performance as soon as possible.

To give you ample time, all programs have Test Event Windows that exceed routine testing times for patient samples.

The system reminds you of missing results and Results Deadlines. As well, the system helps you meet Results Deadlines:

- To encourage early submission, the system records when your results are submitted and calculates your Turn-Around-Time measured in days before the Results Deadline.
- To discourage late submission, the system does not accept your results if submitted after the Results Deadline.
- To fix clerical errors, the system accepts all changes to your submitted results anytime before the Results Deadline.

Our Program Codes give you Program Details

name of the program

HEPM435

number of samples

number of test events

4 = EQA

SEROLOGY EQAS

2022 Test Event Calendar

The following Test Event Calendar applies for all Programs in the Serology EQAS section.

Test Event	Test Event Open	Test Event Window	Results Deadline
1	30 March 2022	21 days	20 April 2022
2	29 June 2022	21 days	20 July 2022
3	28 September 2022	21 days	19 October 2022

SEROLOGY EQAS

1. MULTIMARKER BLOOD SCREENING SEROLOGY

PROGRAM TYPE: Comprehensive | **ANALYSIS: Qualitative** | **SAMPLE TYPE: Liquid human plasma** **SHIPPING CODE:** UN 3373

PROGRAM CODE	FORMAT	COMPATIBILITY
MMBS4310	**3** test events x **10** samples x **1.8** mL **3** shipments	Participants can report multiple runs and replicates for multiple analyzers or methods. **Not compatible** with Non-Treponemal detection methods.

HBsAg Anti-HBc Total	HCVAg Anti-HCV	HIV p24 Ag Anti-HIV	Anti-HTLV Anti-*Treponema pallidum*

DESCRIPTION

Application - We designed this as a comprehensive, cost-effective program for laboratories that perform blood and tissue screening serology for infectious diseases.

Science - The MMBS4310 EQA program is the only ISO accredited infectious disease blood and tissue screening serology program that offers samples representative of those normally tested in routine blood screening facilities and now includes anti-HTLV. To maintain both affordability and scientific integrity, we offer sample set size of 10 samples per Test Event. To ensure sufficient sample volume for EQA testing and troubleshooting, we offer the volume of 1.8mL. We use undiluted human plasma or pooled plasma samples. We redesigned our Test Event assessments to shorten the turnaround times and have introduced graphical reports to enhance comparisons within and between peer groups. This program meets the highest international quality standards.

2. HEPATITIS SEROLOGY

PROGRAM TYPE: Comprehensive | **ANALYSIS: Qualitative** | **SAMPLE TYPE: Liquid human plasma** **SHIPPING CODE:** UN 3373

PROGRAM CODE	FORMAT	COMPATIBILITY
HEPM435	**3** test events x **5** samples x **1.8** mL **3** shipments	Participants can report multiple runs and replicates for multiple analyzers or methods.

Anti-HAV IgG Anti-HAV IgM Anti-HAV Total	HBsAg Anti-HBc Total Anti-HBc IgM	Anti-HBs HBeAg Anti-HBe	HCVAg Anti-HCV Anti-HDV

DESCRIPTION

Application - We designed this as a comprehensive, cost-effective EQA program for laboratories that perform testing for hepatitis markers using automated testing platforms.

Science - We created sample sets to cover all serology analytes relevant to hepatitis testing, expanding our analyte offering to include anti-HDV. To improve affordability while maintaining scientific integrity, we offer 5 samples per Test Event. To ensure sufficient sample volume for EQA testing and troubleshooting, we offer the volume of 1.8mL. We use undiluted human plasma or pooled plasma samples. We redesigned our Test Event assessments to shorten the turnaround times and have introduced graphical reports to enhance comparisons within and between peer groups. This program is accredited and meets the highest international clinical standards.

SEROLOGY EQAS

3. RETROVIRUS AND SYPHILIS SEROLOGY

PROGRAM TYPE: Comprehensive | **ANALYSIS: Qualitative** | **SAMPLE TYPE: Liquid human plasma** **SHIPPING CODE:** UN 3373

PROGRAM CODE	FORMAT	COMPATIBILITY
RVSS435	**3** test events x **5** samples x **1.8** mL **3** shipments	Participants can report multiple runs and replicates for multiple analyzers or methods.

HIV p24 Ag
Anti-HIV

Anti-*Treponema pallidum*
Non-Treponemal antibodies

Anti-HTLV

DESCRIPTION

Application – We designed this as a comprehensive, cost-effective EQA program for laboratories that perform serology testing for HIV, HTLV and Syphilis. We combined anti-HIV, HIV p24, anti-HTLV, anti-Treponema and Non-Treponemal antibodies into a single, convenient program. This program replaced single analyte programs HTLV4310, HIVC4310 and TREP435 and presents as excellent value compared to multiple single analyte tests.

Science – Clinicians routinely screen for HIV, HTLV and Syphilis together in one test request. We created sample sets to mimic clinical need, with coverage of these three pathogens. Laboratories submit all results from multiple assays for assessment across the entire testing algorithm. To improve affordability while maintaining scientific integrity, we offer 5 samples per Test Event. To ensure sufficient sample volume for EQA testing and troubleshooting, we offer the volume of 1.8mL. We use undiluted human plasma or pooled plasma samples. We redesigned our Test Event assessments to shorten the turnaround times and have introduced graphical reports to enhance comparisons within and between peer groups. This program is accredited and meets the highest international clinical standards.

4. TORCH AND EBV SEROLOGY

PROGRAM TYPE: Comprehensive | **ANALYSIS: Qualitative** | **SAMPLE TYPE: Liquid human plasma** **SHIPPING CODE:** UN 3373

PROGRAM CODE	FORMAT	COMPATIBILITY
TRCH435	**3** test events x **5** samples x **1.8** mL **3** shipments	Participants can report multiple runs and replicates for multiple analyzers or methods.

Anti-CMV IgG
Anti-CMV IgM
Anti-HSV-1/2 IgG

Anti-HSV-1/2 IgM
Anti-Rubella IgG
Anti-Rubella IgM

Anti-Toxoplasma IgG
Anti-Toxoplasma IgM
Anti-EBV VCA IgG

Anti-EBV VCA IgM
Anti-EBV-EBNA IgG

DESCRIPTION

Application – We designed this as a comprehensive, cost-effective EQA program for laboratories that perform serology testing for Toxoplasma, CMV, Rubella, HSV and EBV.

Science - Clinicians often request testing for a range of serological analytes to determine cause of illness and facilitate diagnosis of patients. We created sample sets to mimic clinical need, with coverage of all serology analytes relevant to ToRCH and EBV screening. To improve affordability while maintaining scientific integrity, we offer 5 samples per Test Event. To ensure sufficient sample volume for EQA testing and troubleshooting, we offer the volume of 1.8mL. We use undiluted human plasma or pooled plasma samples. We redesigned our Test Event assessments to shorten the turnaround times and have introduced graphical reports to enhance comparisons within and between peer groups. This program is accredited and meets the highest international clinical standards.

SEROLOGY EQAS

NEW

5. SARS-CoV-2 ANTIGEN

PROGRAM TYPE: Comprehensive | **ANALYSIS: Qualitative** | **SAMPLE TYPE: FLOQSwab®**

PROGRAM CODE	FORMAT	COMPATIBILITY
COVA432	**3** test events x **2** samples **3** shipments	Immunological assays for the detection of SARS-CoV-2 nucleocapsid protein, from swab based samples.

SARS-CoV-2 Nucleocapsid protein

DESCRIPTION

Application - This program has been designed for participants that perform rapid Antigen testing for SARS-CoV-2 nucleocapsid protein.

Science - This program features swab samples containing a desiccated formulation of SAR-CoV-2 nucleocapsid protein, and is designed for participants that perform rapid Antigen testing for SARS-CoV-2 nucleocapsid protein. The sample type mimics the clinical swab samples. It is recommended the samples are tested using the exact same procedure for unknown clinical swab samples. This EQA program is part of our unique, comprehensive quality solution to support SARS-CoV-2 serology and molecular testing.

This program is accredited by AL2A as compliant with ISO/IEC 17043:2010 under Oneworld Accuracy's scope of accreditation, number 4839.01

NEW

6. SARS-CoV-2 SEROLOGY

PROGRAM TYPE: Comprehensive | **ANALYSIS: Qualitative & Quantitative** | **SAMPLE TYPE: Liquid human plasma**

PROGRAM CODE	FORMAT	COMPATIBILITY
COVS434	**3** test events x **4** samples x **0.5** mL **3** shipments	No known compatibility issues with any method or analyzer.

SARS-CoV-2 IgA | SARS-CoV-2 IgM | SARS-CoV-2 IgG

DESCRIPTION

Application - This program has been designed for participants that perform serology Antibody testing for SARS-CoV-2 and features single donor human plasma samples with IgA, IgG, and/or IgM antibodies against SARS-CoV-2. Single donor samples are particularly clinically relevant as samples are traceable to donor clinical history.

Science - This EQA program has been designed for participants that perform serology testing for SARS-CoV-2 and features single donor human plasma samples with IgA, IgG, and/or IgM antibodies against SARS-CoV-2. Single donor samples are traceable to the donor's clinical history. These samples are compatible with common serology methods including ELISA, rapid lateral-flow assays, immunofluorescence, chemiluminescence and electrochemiluminescence. This EQA program is part of our unique, comprehensive quality solution to support SARS-CoV-2 serology and molecular testing.

This program is accredited by AL2A as compliant with ISO/IEC 17043:2010 under Oneworld Accuracy's scope of accreditation, number 4839.01

MOLECULAR EQAS

2022 Test Event Calendar

The following Test Event Calendar applies for all Programs in the Molecular EQAS section.#

Test Event	Test Event Opens	Test Event Window	Results Deadline
1	9 March 2022	21 days	30 March 2022
2	1 June 2022	21 days	22 June 2022
3	7 September 2022	21 days	28 September 2022

except RESP435 follows the Point of Care/Specialised EQAS Test Event Calendar.

MOLECULAR EQAS

1. MULTIMARKER BLOOD SCREENING MOLECULAR

PROGRAM TYPE: Comprehensive | **ANALYSIS: Qualitative** | **SAMPLE TYPE: Frozen human plasma** **SHIPPING CODES:** UN 3373 UN 1845

PROGRAM CODE	FORMAT	COMPATIBILITY
NATA4310	**3** test events x **10** samples x **4.4** mL **1** shipment	Compatible with Blood Screening NAT assays. No known compatibility issues with any method or analyzer.

HBV DNA | HCV RNA | HIV RNA

DESCRIPTION

Application - We designed this as a comprehensive, cost-effective EQA program for blood screening laboratories that perform routine molecular testing for infectious diseases.

Science - This program is the only ISO accredited infectious disease blood screening molecular EQAS that offers samples representative of those normally tested in blood screening. To maintain both affordability and scientific integrity, we offer sample set size of 10 samples per Test Event. To further enhance this program, we calibrate samples to the prevailing WHO international standard to enable laboratories to assess both the imprecision and the accuracy of their assays. We redesigned our Test Event assessments to shorten the turnaround times and have introduced graphical reports to enhance comparisons within and between peer groups. This meets the highest international quality standards.

2. MULTIMARKER PLASMA FRACTIONATION MOLECULAR

PROGRAM TYPE: Comprehensive | **ANALYSIS: Qualitative and quantitative** | **SAMPLE TYPE: Frozen human plasma** **SHIPPING CODES:** UN 3373 UN 1845

PROGRAM CODE	FORMAT	COMPATIBILITY
MMPF4310	**3** test events x **10** samples x **4.4** mL **1** shipment	No known compatibility issues with any method or analyzer.

CMV DNA | HAV RNA | Parvovirus B19 DNA | HEV RNA

DESCRIPTION

Application - We are introducing this comprehensive, cost-effective EQA program for plasma fractionators and laboratories that perform quantitative and qualitative molecular testing for HAV, Parvovirus B19, CMV and HEV.

Science - This program is specially designed for facilities that screen donor samples for plasma fractionation and comprises samples representative of those normally received for screening. To maintain both affordability and scientific integrity, we offer sample set size of 10 samples per Test Event. We redesigned our Test Event assessments to shorten the turnaround times and have introduced graphical reports to enhance comparisons within and between peer groups. This program is accredited and meets the highest international clinical standards for facilities that screen donor samples for plasma fractionation.

MOLECULAR EQAS

3. VIRAL EXANTHEMS MOLECULAR

PROGRAM TYPE: Comprehensive | **ANALYSIS: Qualitative** | **SAMPLE TYPE: Frozen Clinical Liquid Samples** **SHIPPING CODES:** UN 3373 UN 1845

PROGRAM CODE	FORMAT	COMPATIBILITY
RASH435	**3** test events x **5** samples x **1.2** mL **1** shipment	No known compatibility issues with any method or analyzer.

HSV-1 DNA	HSV-2 DNA	VZV DNA	CMV DNA

DESCRIPTION

Application - We designed this to be a comprehensive, cost-effective EQA program for laboratories that perform molecular testing for HSV-1, HSV-2, VZV and CMV.

Science - Clinicians routinely request screening for HSV, VZV and CMV together. We created syndromic sample sets to meet that clinical need with coverage of these three analytes. This program allows laboratories using multiplex molecular assays to test EQA samples in the same manner as patient screening. We redesigned our Test Event assessments to shorten the turnaround times and have introduced graphical reports to enhance comparisons within and between peer groups. This program is accredited and meets the highest international clinical standards.

4. VIRAL RESPIRATORY MOLECULAR

PROGRAM TYPE: Comprehensive | **ANALYSIS: Qualitative** | **SAMPLE TYPE: Clinical Liquid Samples**

PROGRAM CODE	FORMAT	COMPATIBILITY
RESP435	**3** test events# x **5** samples x **1.2** mL **3** shipments	No known compatibility issues with any method or analyzer.

Influenza RNA	RSV RNA	SARS-CoV-2 RNA

DESCRIPTION

Application - We designed this comprehensive, cost-effective EQA program for laboratories and point of care facilities that perform molecular testing for Influenza A and B, RSV and SARS-CoV-2.

Science - We created syndromic sample sets for these common respiratory viruses. Samples feature real, inactivated virus (not synthetic material), which enables monitoring of extraction efficiency as well as detection of analytes. Since sample sets can be shipped at ambient temperature, this program is ideal for both sophisticated laboratories using multiplex molecular assays as well as point of care facilities using platforms such as the Cepheid GeneXpert. We redesigned our Test Event assessments to shorten the turnaround times and have introduced graphical reports to enhance comparisons within and between peer groups. This program meets the highest international clinical standards.

#Follows Point of Care/Specialised EQAS Test Event Calendar

MOLECULAR EQAS

5. SEXUALLY- TRANSMITTED INFECTIONS MOLECULAR

PROGRAM TYPE: Comprehensive | **ANALYSIS:** Qualitative | **SAMPLE TYPE:** Frozen Clinical Liquid Samples | **SHIPPING CODES:** UN 3373 UN 1845

PROGRAM CODE	FORMAT	COMPATIBILITY
STIC435	**3** test events x **5** samples x **1.2** mL **1** shipment	No known compatibility issues with any method or analyzer.

Chlamydia trachomatis
Chlamydia trachomatis serovar
Neisseria gonorrhoeae
Trichomonas vaginalis
Mycoplasma species
Ureaplasma species
Mycoplasma genitalium Fluoroquinolone resistant
Mycoplasma genitalium Macrolide resistant
Neisseria gonorrhoeae CFT resistant

DESCRIPTION

Application - We designed this as a comprehensive, cost-effective EQA program for laboratories that perform molecular testing for *Chlamydia trachomatis* (including LGV), *Neisseria gonorrhoeae*, *Trichomonas vaginalis*, *Ureaplasma species*, *Mycoplasma species* and several drug-resistant strains.

Science - We created sample sets to cover a wide range of sexually-transmitted infections. In 2022, we also introduced several drug-resistant strains, including *Mycoplasma genitalium* Fluoroquinolone resistant, *Mycoplasma genitalium* Macrolide resistant and *Neisseria gonorrhoeae* CFT resistant. This program also assesses the laboratory's ability to differentiate between non-pathogenic and pathogenic *Neisseria species*, different strains of *Chlamydia* including LGV, and mutant organisms known to affect some test systems. Laboratories can submit all results from multiple assays or from their multiplex assay. We redesigned our Test Event assessments to shorten the turnaround times and have introduced graphical reports to enhance comparisons within and between peer groups. This program is accredited and meets the highest international clinical standards.

6. HIV MOLECULAR

PROGRAM TYPE: Comprehensive | **ANALYSIS:** Quantitative | **SAMPLE TYPE:** Frozen human plasma | **SHIPPING CODES:** UN 3373 UN 1845

PROGRAM CODE	FORMAT	COMPATIBILITY
HIVL435	**3** test events x **5** samples x **1.2** mL **1** shipment	No known compatibility issues with any method or analyzer.

HIV RNA

DESCRIPTION

Application - We designed this as a comprehensive, cost-effective EQA program for laboratories that perform HIV viral load testing.

Science - We calibrated sample sets to the prevailing WHO international standard to enable laboratories to assess their Limits of Detection (LOD), the reproducibility and repeatability of their assays, the coefficient of variation within their laboratory and peer group and the accuracy of their testing. We believe this is the only ISO 17043 accredited EQA program of its type globally that uses samples derived from such a secondary standard. We redesigned our Test Event assessments to shorten the turnaround times and have introduced graphical reports to enhance comparisons within and between peer groups. This program is accredited and meets the highest international clinical standards.

MOLECULAR EQAS

7. HBV MOLECULAR

PROGRAM TYPE: Comprehensive | **ANALYSIS:** Quantitative | **SAMPLE TYPE:** Frozen human plasma | **SHIPPING CODES:** UN 3373, UN 1845

PROGRAM CODE	FORMAT	COMPATIBILITY
HBVL435	**3** test events x **5** samples x **1.2** mL **1** shipment	No known compatibility issues with any method or analyzer.

HBV DNA

DESCRIPTION

Application - We designed this as a comprehensive, cost-effective EQA program for laboratories that perform HBV viral load testing.

Science - We calibrated sample sets to the prevailing WHO international standard to enable laboratories to assess their Limits of Detection (LOD), the reproducibility and repeatability of their assays, the coefficient of variation within their laboratory and peer group and the accuracy of their testing. We believe this is the only ISO 17043 accredited EQA program of its type globally that uses sample sets derived from such a secondary standard. We redesigned our Test Event assessments to shorten the turnaround times and have introduced graphical reports to enhance comparisons within and between peer groups. This program is accredited and meets the highest international clinical standards.

8. HCV MOLECULAR

PROGRAM TYPE: Comprehensive | **ANALYSIS:** Qualitative and quantitative | **SAMPLE TYPE:** Frozen human plasma | **SHIPPING CODES:** UN 3373, UN 1845

PROGRAM CODE	FORMAT	COMPATIBILITY
HCVQ435	**3** test events x **5** samples x **1.2** mL **1** shipment	No known compatibility issues with any method or analyzer.

HCV RNA

DESCRIPTION

Application - We designed this as a comprehensive, cost-effective EQA program for laboratories that perform HCV RNA viral load testing and HCV RNA detection.

Science - We calibrated sample sets to the prevailing WHO international standard to enable laboratories to assess their Limits of Detection (LOD), the reproducibility and repeatability of their assays, the coefficient of variation within their laboratory and peer group and the accuracy of their testing. We believe this is the only ISO 17043 accredited EQA program of its type globally that uses sample sets derived from such a secondary standard. We redesigned our Test Event assessments to shorten the turnaround times and have introduced graphical reports to enhance comparisons within and between peer groups. This program is accredited and meets the highest international clinical standards.

9. HPV MOLECULAR

PROGRAM TYPE: Comprehensive | **ANALYSIS:** Qualitative | **SAMPLE TYPE:** Frozen Liquid Based Cytology Medium **SHIPPING CODES:** UN 3373 UN 1845

PROGRAM CODE	FORMAT	COMPATIBILITY
HPVN435	**3** test events x **5** samples x **1.2** mL **1** shipment	No known compatibility issues with any method or analyzer.

HPV High Risk 16 DNA	HPV High Risk 18 DNA	Other High Risk HPV DNA

DESCRIPTION

Application - We designed this as a comprehensive, cost-effective EQA program for laboratories that perform molecular testing for high-risk HPV detection and genotyping.

Science - We created sample sets derived from real patient specimens. Samples are of known HPV genotypes, including various high-risk HPV genotypes. Samples are provided in liquid-based cytology fluid suitable for all test systems. Laboratories submit all results from multiple assays including semiquantitative values and genotypes. We redesigned our Test Event assessments to shorten the turnaround times and have introduced graphical reports to enhance comparisons within and between peer groups. This program is accredited and meets the highest international clinical standards.

POINT OF CARE AND SPECIALISED EQAS

2022 Test Event Calendar

The following Test Event Calendar applies to all Programs in the Point of Care/Specialised EQAS and the RESP435 EQAS.

Test Event	Test Event Open	Test Event Window	Results Deadline
1	30 March 2022	21 days	20 April 2022
2	29 June 2022	21 days	20 July 2022
3	28 September 2022	21 days	19 October 2022

POINT OF CARE AND SPECIALISED EQAS

1. *C. TRACHOMATIS, N. GONORRHOEAE & T. VAGINALIS* MOLECULAR POC

PROGRAM TYPE: Point-of-Care | **ANALYSIS: Qualitative** | **SAMPLE TYPE: Clinical Swabs**

PROGRAM CODE	FORMAT	COMPATIBILITY
CNTP435	**3** test events x **5** samples **3** shipments	No known compatibility issues with any method or analyzer.
CNTP432	**3** test events x **2** samples **3** shipments	

Chlamydia trachomatis | *Neisseria gonorrhoeae* | *Trichomonas vaginalis*

DESCRIPTION

Application - We designed this as a simplified, cost-effective EQA program for point of care (POC facilities and laboratories in resource limited economies that perform molecular testing on *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis* using POC platforms such the Cepheid GeneXpert. This program has options for 2 and 5 samples per Test Event.

Science - We created sample sets optimised for POC testing platforms such as the Cepheid GeneXpert. Samples are dried swabs, and feature inactivated organisms, which means that sample sets are stable, non-infectious (UN3373 exempt and are shipped at ambient temperature. We redesigned our Test Event assessments to shorten the turnaround times and have introduced graphical reports to enhance comparisons within and between peer groups. This program meets the highest international clinical standards.

2. DRIED TUBE SAMPLE HIV AND EARLY INFANT DIAGNOSIS MOLECULAR POC

PROGRAM TYPE: Point-of-Care | **ANALYSIS: Qualitative and Quantitative** | **SAMPLE TYPE: Dried human plasma matrix**

PROGRAM CODE	FORMAT	COMPATIBILITY
DTSI435	**3** test events x **5** samples **3** shipments	Not compatible with the Cavidi ExaVir Load Version 3.0 kit. Compatible with proviral DNA assays for testing Early Infant Diagnosis.
DTSI432	**3** test events x **2** samples **3** shipments	

HIV RNA | Proviral HIV DNA

DESCRIPTION

Application - We designed this as a simplified, cost-effective EQA program for point of care (POC facilities and laboratories in resource limited economies that perform molecular testing for HIV Viral Load and RNA detection, particularly those engaged in HIV elimination initiatives. This program has options for 2 and 5 samples per Test Event.

Science - After extensive research, development and validation, we created dried tube samples (DTS suitable for HIV RNA viral load, HIV RNA detection and also early infant diagnosis (EID) testing for HIV proviral DNA. This is the only international ISO 17043 accredited DTS EQAS for HIV molecular testing. This program features inactivated dried human plasma samples, optimised for both POC platforms such as the Cepheid GeneXpert and laboratory platforms. Sample sets are stable, non-infectious (UN3373 exempt and are shipped at ambient temperature. We redesigned our Test Event assessments to shorten the turnaround times and have introduced graphical reports to enhance comparisons within and between peer groups. This program is accredited and meets the highest international clinical standards.

3. DRIED TUBE SAMPLE HBV MOLECULAR POC

PROGRAM TYPE: Point-of-Care | **ANALYSIS:** Quantitative | **SAMPLE TYPE:** Dried human plasma matrix

PROGRAM CODE	FORMAT	COMPATIBILITY
DTSB435	**3** test events x **5** samples **3** shipments	No known compatibility issues.
DTSB432	**3** test events x **2** samples **3** shipments	

HBV DNA

DESCRIPTION

Application - We designed this as a simplified, cost-effective EQA program for point of care (POC facilities and laboratories in resource limited economies that perform molecular testing for HBV Viral Load. This program has options for 2 and 5 samples per Test Event.

Science - After extensive research, development and validation, we created dried tube samples (DTS suitable for HBV DNA viral load. This is the only international ISO 17043 accredited DTS EQAS for HBV molecular testing. This program features inactivated dried human plasma samples, optimised for both POC platforms such as the Cepheid GeneXpert and laboratory platforms. Sample sets are stable, non-infectious (UN3373 exempt and are shipped at ambient temperature. We redesigned our Test Event assessments to shorten the turnaround times and have introduced graphical reports to enhance comparisons within and between peer groups. This program is accredited and meets the highest international clinical standards.

4. DRIED TUBE SAMPLE HCV MOLECULAR POC

PROGRAM TYPE: Point-of-Care | **ANALYSIS:** Quantitative | **SAMPLE TYPE:** Dried human plasma matrix

PROGRAM CODE	FORMAT	COMPATIBILITY
DTSC435	**3** test events x **5** samples **3** shipments	No known compatibility issues.
DTSC432	**3** test events x **2** samples **3** shipments	

HCV RNA

DESCRIPTION

Application - We designed this as a simplified, cost-effective EQA program for point of care (POC facilities and laboratories in resource limited economies that perform molecular testing for HCV Viral Load. This program has options for 2 and 5 samples per Test Event.

Science - After extensive research, development and validation, we created dried tube samples (DTS suitable for HCV RNA viral load. This is the only international ISO 17043 accredited DTS EQAS for HCV molecular testing. This program features inactivated dried human plasma samples, optimised for both POC platforms such as the Cepheid GeneXpert and laboratory platforms. Sample sets are stable, non-infectious (UN3373 exempt and are shipped at ambient temperature. We redesigned our Test Event assessments to shorten the turnaround times and have introduced graphical reports to enhance comparisons within and between peer groups. This program is accredited and meets the highest international clinical standards.

POINT OF CARE AND SPECIALISED EQAS

NEW

5. DRIED TUBE WHOLE BLOOD HCV MOLECULAR POC

PROGRAM TYPE: Point-of-Care | **ANALYSIS:** Quantitative | **SAMPLE TYPE:** Dried whole blood matrix

PROGRAM CODE	FORMAT	COMPATIBILITY
DWBC425	**2** test events x **5** samples **2** shipment	No known compatibility issues with any method or analyzer.

HCV RNA

DESCRIPTION

Application - We designed this as a simplified, cost-effective EQA program specific for point of care (POC facilities that perform molecular testing for HCV Viral Load on fingerstick whole blood samples.

Science - This is the only international ISO 17043 accredited Dried Tube EQAS for HCV molecular testing on fingerstick whole blood samples. This program features inactivated dried human whole blood samples, optimised and validated for POC platforms such as the Cepheid GeneXpert. Sample sets are stable, non-infectious (UN3373 exempt and are shipped at ambient temperature. We redesigned our Test Event assessments to shorten the turnaround times and have introduced graphical reports to enhance comparisons within and between peer groups. This program is accredited and meets the highest international clinical standards.

6. LEPTOSPIROSIS MOLECULAR

PROGRAM TYPE: Specialised | **ANALYSIS:** Qualitative | **SAMPLE TYPE:** Clinical Liquid Samples

PROGRAM CODE	FORMAT	COMPATIBILITY
LEPN435	**3** test events x **5** samples x **1.2** mL **3** shipments	No known compatibility issues with any method or analyzer.

Leptospira species

DESCRIPTION

Application - We designed this as a simplified, cost-effective EQA program for laboratories that perform testing for leptospirosis detection and genotyping.

Science - We collaborated with the International Leptospirosis Society to create inactivated samples that include a range of *Leptospira species* to assess the laboratory's ability to detect and distinguish between species. Sample sets are stable, non-infectious (UN3373 exempt) and are shipped at ambient temperature. We redesigned our Test Event assessments to shorten the turnaround times and have introduced graphical reports to enhance comparisons within and between peer groups. This program is accredited and meets the highest international clinical standards.

7. MYCOBACTERIUM MOLECULAR POC

PROGRAM TYPE: Point-of-Care/Specialised | **ANALYSIS:** Qualitative | **SAMPLE TYPE:** Clinical Liquid Samples

PROGRAM CODE	FORMAT	COMPATIBILITY
MTBN435	**3** test events x **5** samples x **1.2** mL **3** shipments	No known compatibility issues with any method or analyzer.
MTBN432	**3** test events x **2** samples x **1.2** mL **3** shipments	

Mycobacterium species Drug Resistance Typing

DESCRIPTION

Application - We designed this as a simplified, cost-effective EQA program for laboratories performing molecular testing for *Mycobacterium tuberculosis* and particularly optimised for resource limited settings and POC testing sites. This program has options for 2 and 5 samples per Test Event.

Science - We created inactivated bacteria samples that include wild type and drug resistant strains of TB. Sample sets are stable, non-infectious (UN3373 exempt) and are shipped at ambient temperature. We redesigned our Test Event assessments to shorten the turnaround times and have introduced graphical reports to enhance comparisons within and between peer groups. This program is accredited and meets the highest international clinical standards.

NEW

8. HTLV MOLECULAR

PROGRAM TYPE: Specialised | **ANALYSIS:** Qualitative | **SAMPLE TYPE:** Human whole blood matrix | **SHIPPING CODES:** UN 3373

PROGRAM CODE	FORMAT	COMPATIBILITY
HTLD435	**3** test events x **5** samples x **0.5** mL **3** shipments	No known compatibility issues with any method.

Proviral HTLV DNA

DESCRIPTION

Application - This program offers a unique EQA for the detection of proviral HTLV DNA. The program assesses linearity, reproducibility and limit of detection of the assay in use.

Science - We designed the human T-cell lymphotropic virus (HTLV) Molecular EQA program consisting of 5 samples to be sent out three times a year. Samples consist of SP cells diluted with stabilised red cells, creating a matrix designed to mimic whole blood. SP cells are human T cells containing a single full-length copy of HTLV-1 DNA. The program assesses linearity, reproducibility and limit of detection of the assay in use.

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