NRL EQAS

Science Architect

External Quality Assessment Schemes

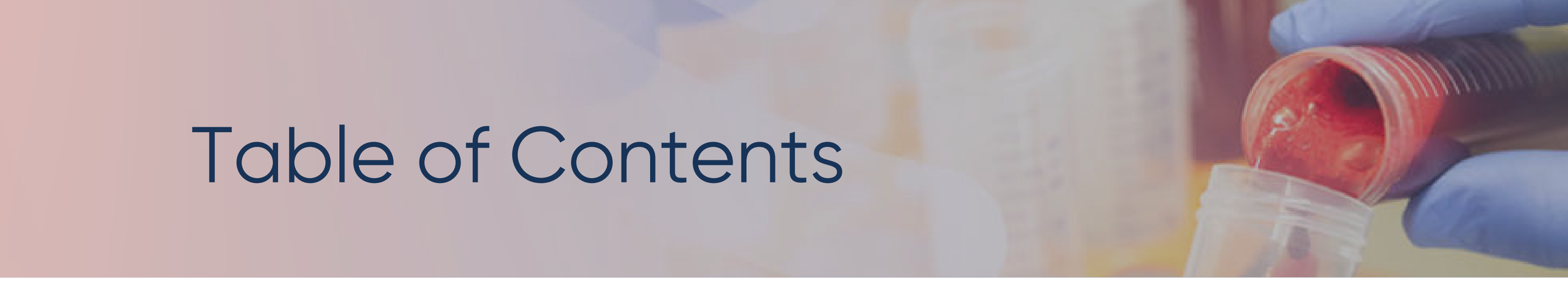
Catalogue

2024

Science of Quality

In Partnership with

oneworld ACCURACY®



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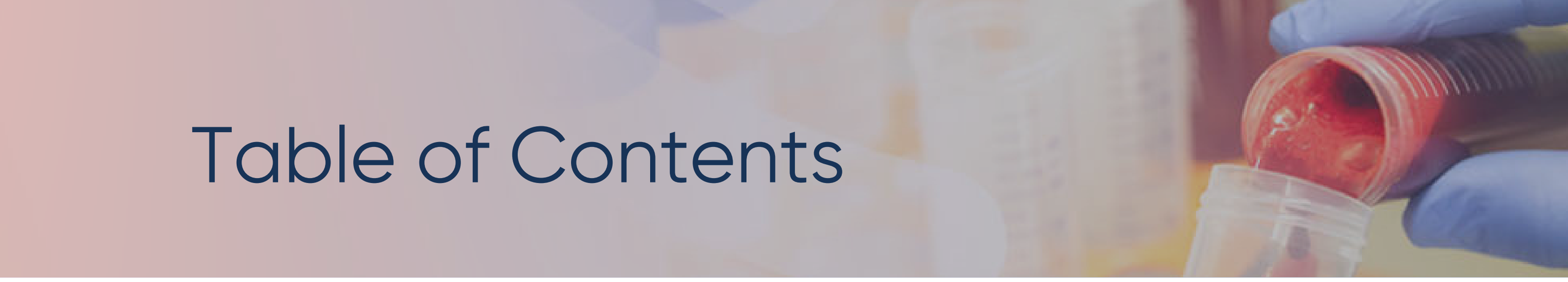

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NRL- About Us

NRL, a World Health Organization (WHO) Collaborating Centre, is a Melbourne based scientific organisation that exists to promote the quality of tests and testing for infectious diseases globally.

Accreditations

NRL is accredited for compliance with ISO/IEC 17043 as a proficiency testing provider
Accreditation Number 14253

NRL is certified to ISO 9001, Quality Management Systems
Certification number FS 60505

NRL EQAS Offering

NRL EQAS are distributed to testing facilities in over 50 countries, enabling monitoring and peer comparison for a range of test kits and instrumentation. Our programs incorporate genuine and diverse samples, and are intended to assess the integrity of the entire testing process.

Comprehensive EQAS:
Designed for sophisticated laboratory-based testing, as well as testing in low/middle-income countries using high throughput automated testing platforms and Point-of-Care (POC)/Rapid Tests.

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

OASYS

In partnership with Oneworld Accuracy, Vancouver Canada, (www.oneworldaccuracy.com) and its extensive network of collaborators, all NRL EQAS are supported by OASYS, an Internet-based software management system.

What's New in 2024? NEW

Introduction of new EQAS for Transplant-Transmitted Infections Molecular Testing

This program, Transplant-Transmitted Infections Molecular (TTIM435), is designed for laboratories that monitor post-transplantation infections and laboratories that perform qualitative and/or quantitative molecular testing of EBV, BKV, JCV and HHV6.

New Ordering Processes coming in 2024

NRL is committed to continuous improvement and ease of customer experience. As such, we will be introducing a new online portal in 2024. This portal will provide a more interactive experience and will facilitate easier access to pricing, ordering processes and faster service.

Test Event Date Streamlining

In order to simplify the EQAS Processes for 2024, the Test Event dates for all Serology, Molecular, POC & Specialised programs now follow the same schedule. Please see the new calendar on page 9.

Introduction of additional Programs

In 2024, we hope to provide a more comprehensive EQA offering for infectious diseases. Details on this additional offering will be shared as soon as they are available.

Any questions? Get in contact with us.

+61 (03) 9418 1111
eqas@nrlquality.org.au

System Overview

Getting started

Programs are listed by category and can be purchased using the Order Form on NRL's website **nrlquality.org.au**, or via the QR code. To obtain a quotation please email: **eqas@nrlquality.org.au**

SCAN ME

How does NRL support quality of testing for EQAS participants?

Test Event Cycle

1 Receive Samples

2 Test Samples & Submit Results

3 Receive Assessment

Annual Certificates of Participation will be provided listing all subscribed programs.

Shipment Notice
Reminder for shipments arriving soon.

Test Event Reminder
Enable preparation for upcoming test events.

Instructions + Worksheets
Enable appropriate receipt, storage and testing of samples, and recording of submitted results.

Results Deadline Reminders
Assist in timely results submission.

Performance Reports
Summarise laboratory performance.

Our Program Codes Give You Program Details

HEPM435

- HEPM — Program Code
- 4 = EQA
- 3 — Number of Test Events in a year
- 5 — Number of samples

The First Principle

The First Principle describes the requirement for NRL EQAS participants to test and report program samples using the same processes as patient samples.

Our programs are intended to be educational in nature so that if problems are identified, they represent an opportunity for laboratories to improve the quality of testing. We strive to support laboratories to deliver accurate, clinically relevant and timely results.

First Principle Guidelines:

- Test samples in the same manner and number of times as patient samples
- Test samples within the same timeframes as 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 patient results
- Not discuss your results with other participants or send samples for outside testing

Program Samples = Patient Samples

Why do Result Deadlines Matter?

Submitting Results Before the Deadline Signals Your Commitment to the First Principle

For consistency, all Result Deadlines end at 11:59 pm (23:59) local time on the closing date for the Test Event. Submitting on time enables us to evaluate and provide feedback as soon as possible. To ensure sufficient testing time, all programs have Test Event Windows that exceed routine testing times for patient samples. Reminders are sent for missing results and Result Deadlines.

Supporting adherence to Result Deadlines:

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

Shipping and Test Event Information

Comprehensive Serology Programs

3 shipments, shipped Ambient prior to each Test Event.

Comprehensive Molecular and POC & Specialised Programs:

Dependent on program can include:

a) 1 shipment on Dry Ice, shipped prior to Test Event 1.

b) 3 shipments, shipped Ambient prior to each Test Event.

Please refer to individual program details for more information.

2024 Test Event Calendar

Test Event	Panel ID	Test Event Open	Test Event Window	Result Deadline
1	2024-04-10	10 April 2024	21 days	1 May 2024
2	2024-07-03	26 June 2024	21 days	17 July 2024
3	2024-10-16	25 September 2024	21 days	16 October 2024

The Test Event Calendar applies for all EQAS

COMPREHENSIVE SEROLOGY EQAS

Comprehensive Serology EQAS

1. SARS-CoV-2 ANTIBODIES

PROGRAM TYPE: Comprehensive | ANALYSIS: Qualitative | SAMPLE TYPE: Liquid Human Plasma | SHIPPING CODE: UN 3373

PROGRAM CODE	FORMAT	COMPATIBILITY
COVS435	**3** Test Events x **5** samples x **0.5** mL **3** shipments	No known compatibility issues with any method or analyzer.
COVS432	**3** Test Events x **2** samples x **0.5** mL **3** shipments	

SARS-CoV-2 IgG* SARS-CoV-2 IgA* SARS-CoV-2 IgM*

DESCRIPTION

Application – Designed as a comprehensive, cost-effective EQA program for laboratories that perform serology testing for SARS-CoV-2 antibodies using automated testing platforms, manual assays and rapid tests. This program has options for 2 and 5 samples per Test Event.

Science – This EQA program has been designed for participants that perform serology testing for SARS-CoV-2 antibodies and features single donor human plasma samples with IgG, IgA, 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. To improve affordability while maintaining scientific integrity, we offer two panel sizes: 5 samples per Test Event and 2 samples per Test Event. With NRL's scientific foundation and reformatted Test Event assessments, this program meets the highest international clinical standards.
* Accrediated via A2LA under One World Accuracy.

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 – Designed as a comprehensive, cost-effective EQA program for laboratories that perform serology testing for hepatitis markers using automated testing platforms, manual assays and rapid tests.

Science – We created sample sets to cover all serology analytes relevant to hepatitis serology testing. To improve affordability while maintaining scientific integrity, we offer 5 samples per Test Event. To ensure sufficient sample volume for testing for multiple analytes and multiple assays, we offer the volume of 1.8 mL per sample. We use undiluted single human plasma or pooled plasma samples in this program. This program is ISO 17043 accredited and meets the highest international clinical standards.

Comprehensive Serology EQAS

3. 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.

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

DESCRIPTION

Application – Designed as a comprehensive, cost-effective EQA program for laboratories that perform blood and tissue screening serology for infectious diseases.

Science – The MMBS4310 EQA program is the only ISO 17043 accredited infectious disease blood and tissue screening serology program that offers samples representative of those normally tested in blood and tissue screening facilities. To maintain both affordability and scientific integrity, we offer the panel size of 10 samples per Test Event. To ensure sufficient sample volume for testing for multiple analytes and multiple assays, we offer the volume of 1.8 mL per sample. We use undiluted single human plasma or pooled plasma samples in this program. This program meets the highest international quality standards.

4. 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-*Treponema pallidum*	Anti-HTLV
Anti-HIV	Non-Treponemal antibodies	

DESCRIPTION

Application – Designed 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 HTLV, HIVC and TREP and presents excellent value compared to multiple single analyte programs.

Science – Clinicians routinely screen for HIV, HTLV and Syphilis serology together in one test request. We created sample sets to mimic the clinical need, with coverage of these three pathogens. Laboratories can submit results from multiple assays across the entire testing algorithm for multiple analytes. To improve affordability while maintaining scientific integrity, we offer 5 samples per Test Event. To ensure sufficient sample volume for testing for multiple analytes and multiple assays, we offer the volume of 1.8 mL per sample. We use undiluted single human plasma or pooled plasma samples. This program is ISO 17043 accredited and meets the highest international clinical standards.

Comprehensive Serology EQAS

5. 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-Rubella IgG	Anti-Toxoplasma IgG	Anti-HSV-1/2 IgG	Anti-EBV VCA IgG
Anti-CMV IgM	Anti-Rubella IgM	Anti-Toxoplasma IgM	Anti-HSV-1/2 IgM	Anti-EBV VCA IgM
				Anti-EBV-EBNA IgG

DESCRIPTION

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

Science – Clinicians often request testing for a range of Serology analytes to determine cause of illness and facilitate diagnosis of patients. We created sample sets to mimic the clinical needs, 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 testing for multiple analytes and multiple assays, we offer the volume of 1.8 mL per sample. This program is ISO 17043 accredited and meets the highest international clinical standards.

COMPREHENSIVE MOLECULAR EQAS

Comprehensive Molecular EQAS

1. CMV MOLECULAR

PROGRAM TYPE: Comprehensive | **ANALYSIS:** Qualitative and Quantitative | **SAMPLE TYPE:** Frozen Human Plasma | **SHIPPING CODES:** UN 3373 UN 1845

PROGRAM CODE	FORMAT	COMPATIBILITY
CMVN435	**3** Test Events x **5** samples x **1.2** mL **1** shipment	No known compatibility issues with any method or analyzer.

CMV DNA

DESCRIPTION

Application – CMVN is a comprehensive, cost-effective EQA program for laboratories that perform quantitative and/or qualitative molecular testing for CMV in plasma sample type.

Science – CMVN program was discontinued in 2020 and re-introduced in 2023 to accommodate the requirement of laboratories that perform quantitative and/or qualitative molecular testing for CMV in plasma sample type. To maintain both affordability and scientific integrity, we offer the panel size of 5 samples per Test Event. This program is ISO 17043 accredited and meets the highest international clinical standards.

2. HBV MOLECULAR

PROGRAM TYPE: Comprehensive | **ANALYSIS:** Qualitative and Quantitative | **SAMPLE TYPE:** Frozen Human Plasma | **SHIPPING CODES:** UN 3373 UN 1845

PROGRAM CODE	FORMAT	COMPATIBILITY
HBVL435	**3** Test Events x **5** samples x **1.4** mL **1** shipment	No known compatibility issues with any method or analyzer.

HBV DNA

DESCRIPTION

Application – Designed as a comprehensive, cost-effective EQA program for laboratories that perform HBV DNA viral load testing and HBV DNA detection.

Science – We calibrated sample sets to the prevailing WHO international standard to enable laboratories to assess the accuracy of their testing, the Limits of Detection (LOD), the reproducibility and repeatability of their assays, and the coefficient of variation within their laboratories and peer group. We believe this is the only ISO 17043 accredited EQA program of its type globally that uses sample sets derived from a secondary WHO international standard. We offer the panel size of 5 samples with 1.4 mL per sample to accommodate the needs of testing on multiple assays, retesting and troubleshooting. This program is ISO 17043 accredited and meets the highest international clinical standards.

Comprehensive Molecular EQAS

3. 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 **1.4** mL **1** shipment	No known compatibility issues with any method or analyzer.
HCV RNA		

DESCRIPTION

Application – Designed 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 the accuracy of their testing, the Limits of Detection (LOD), the reproducibility and repeatability of their assays, and the coefficient of variation within their laboratories and peer group. We believe this is the only ISO 17043 accredited EQA program of its type globally that uses sample sets derived from a secondary WHO international standard. We offer the panel size of 5 samples with 1.4 mL per sample to accommodate the needs of testing on multiple assays, retesting and troubleshooting. This program is ISO 17043 accredited and meets the highest international clinical standards.

4. HIV MOLECULAR

PROGRAM TYPE: Comprehensive | **ANALYSIS:** Qualitative and Quantitative | **SAMPLE TYPE:** Frozen Human Plasma | **SHIPPING CODES:** UN 3373 UN 1845

PROGRAM CODE	FORMAT	COMPATIBILITY
HIVL435	**3** Test Events x **5** samples x **1.4** mL **1** shipment	No known compatibility issues with any method or analyzer.
HIV RNA		

DESCRIPTION

Application – Designed as a comprehensive, cost-effective EQA program for laboratories that perform HIV RNA viral load testing and HIV RNA detection.

Science – We calibrated sample sets to the prevailing WHO international standard to enable laboratories to assess the accuracy of their testing, the Limits of Detection (LOD), the reproducibility and repeatability of their assays, and the coefficient of variation within their laboratories and peer group. We believe this is the only ISO 17043 accredited EQA program of its type globally that uses samples derived from a secondary WHO international standard. We offer the panel size of 5 samples with 1.4 mL per sample to accommodate the needs of testing on multiple assays, retesting and troubleshooting. This program is ISO 17043 accredited and meets the highest international clinical standards.

Comprehensive Molecular EQAS

5. 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 DNA	HPV Type 16	HPV Type 18	Other High-Risk HPV Types

DESCRIPTION

Application – Designed 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 consist of known HPV genotypes, including HPV high-risk types 16 and 18, and have been extended to include more other high-risk HPV genotypes. Samples are provided in liquid-based cytology fluid suitable for all test systems. Laboratories can submit all results from multiple assays for HPV detection and genotyping. This program is ISO 17043 accredited and meets the highest international clinical standards.

6. 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.

HAV RNA	Parvovirus B19 DNA	HEV RNA	CMV DNA

DESCRIPTION

Application – Designed as a comprehensive, cost-effective EQA program for plasma fractionators and laboratories that perform quantitative and/or qualitative molecular testing for HAV, Parvovirus B19, HEV and CMV.

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 for HAV, Parvovirus B19, HEV and/or CMV. To maintain both affordability and scientific integrity, we offer the panel size of 10 samples per Test Event. This program is ISO 17043 accredited and meets the highest international clinical standards.

Comprehensive Molecular EQAS

7. 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 - Designed as a comprehensive, cost-effective EQA program for blood and tissue screening laboratories that perform routine molecular testing for HBV DNA, HCV RNA and HIV RNA.

Science – This program is the only ISO 17043 accredited infectious disease blood screening molecular EQAS that offers samples representative of those normally tested in blood screening molecular testing. To maintain both affordability and scientific integrity, we offer the panel size of 10 samples per Test Event. To further enhance this program, we calibrate samples to the prevailing WHO international standards for HBV, HCV and HIV, to enable laboratories to assess the precision, the accuracy and the limit of detection of their testing. This program meets the highest international quality standards.

8. 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 – Designed as 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 the syndromic sample sets to meet the 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 testing for patient samples. This program is ISO 17043 accredited and meets the highest international clinical standards.

Comprehensive Molecular EQAS

9. BACTERIAL PLUS RESPIRATORY MOLECULAR

PROGRAM TYPE: Comprehensive | **ANALYSIS:** Qualitative | **SAMPLE TYPE:** Clinical Liquid Samples | **SHIPPING CODE:** UN 3373

PROGRAM CODE	FORMAT	COMPATIBILITY
RESB435	**3** Test Events x **5** samples x **0.8** mL **3** shipments	No known compatibility issues with any method or analyzer.

*Bordetella species**
*Streptococcus species**
*Legionella species**
*Mycoplasma species**
*Chlamydophila species**
*Haemophilus species**
*Pneumocystis species**

DESCRIPTION

Application – Designed as a comprehensive, cost-effective EQA program for laboratories that perform molecular testing for a wide range of bacterial and fungal respiratory analytes.

Science – We created syndromic sample sets for testing of these common respiratory and pneumonia bacteria and fungi, including *Bordetella species, Streptococcus species, Legionella species, Mycoplasma species, Chlamydophila species, Haemophilus species* and *Pneumocystis species.* The samples feature real clinical samples with bacteria and fungi of various strains, which enables monitoring of extraction efficiency as well as detection of analytes on multiplex assays. The panels of this program are shipped at ambient temperature. This program meets the highest international clinical standards.
*Pending accreditation.

10. 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
Influenza A Typing

DESCRIPTION

Application – Designed as a comprehensive, cost-effective EQA program for laboratories and POC 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, which enables monitoring of extraction efficiency as well as detection of analytes. Since the panels of the program are shipped at ambient temperature, this program is ideal for both sophisticated laboratories using multiplex molecular assays as well as POC facilities using platforms such as the Cepheid GeneXpert. This program is ISO 17043 accredited and meets the highest international clinical standards.

Comprehensive Molecular EQAS

11. EXTENDED VIRAL RESPIRATORY MOLECULAR

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

PROGRAM CODE	FORMAT	COMPATIBILITY
RESV435	**3** Test Events x **5** samples x **0.8** mL **3** shipments	No known compatibility issues with any method or analyzer.

Adenovirus DNA*	Rhinovirus RNA*	Parainfluenza RNA*	Seasonal Coronavirus RNA*
Enterovirus RNA*	Metapneumovirus RNA*	Parechovirus RNA*	

DESCRIPTION

Application – Designed as a comprehensive, cost-effective EQA program in 2023 for laboratories that perform molecular testing for a wide range of viral respiratory analytes other than Influenza, RSV and SARS-CoV-2.

Science – We created these syndromic sample sets for a wide range of viral respiratory analytes other than Influenza, RSV and SARS-CoV-2, including Human Adenovirus, Enterovirus, Rhinovirus, Metapneumovirus, Parainfluenza, Parechovirus and Seasonal Coronavirus, which cover majority of the clinical testing requirements for viral respiratory infection. The samples feature real inactivated virus of various strains, which enable monitoring of extraction efficiency as well as detection of the analytes on multiplex assays. The panels of this program are shipped at ambient temperature. This program meets the highest international clinical standards.
*Pending accreditation.

12. 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	*Neisseria gonorrhoeae*	*Trichomonas vaginalis*	*M. genitalium* Fluoroquinolone Resistant
Chlamydia trachomatis serovar	*N. gonorrhoeae* CFT Resistant	*Ureaplasma species*	*M. genitalium* Macrolide Resistant
		Mycoplasma species	*M. genitalium* Azithromycin Resistant

DESCRIPTION

Application – Designed as a comprehensive, cost-effective EQA program for laboratories that perform molecular testing for sexually-transmitted infections including *Chlamydia trachomatis* (including LGV and other serovars), *Neisseria gonorrhoeae, Trichomonas vaginalis, Ureaplasma species, Mycoplasma species* and several drug-resistant strains.

Science – We created these syndromic sample sets to cover a wide range of sexually-transmitted infections. This program also assesses the laboratories' ability to differentiate between different serovars of *Chlamydia trachomatis* including LGV, and drug-resistant strains including *Mycoplasma genitalium* Fluoroquinolone resistant, *Mycoplasma genitalium* Macrolide resistant, *Mycoplasma genitalium Azithromycin* resistant and *Neisseria gonorrhoeae* CFT resistant. Laboratories can submit all results for multiple analytes from multiple assays and/or from multiplex assays. This program is ISO 17043 accredited and meets the highest international clinical standards.

Comprehensive Molecular EQAS

13. TRANSPLANT-TRANSMITTED INFECTIONS MOLECULAR NEW

PROGRAM TYPE: Comprehensive | **ANALYSIS:** Qualitative & Quantitative | **SAMPLE TYPE:** Frozen Human Plasma | **SHIPPING CODE:** UN 1845 UN 3373

PROGRAM CODE	FORMAT	COMPATIBILITY
TTIM435	**3** Test Events x **5** samples x **1.4** mL **1** shipment	No known compatibility issues with any method or analyzer.

EBV DNA* | BKV DNA* | JCV DNA* | HHV6 DNA*

DESCRIPTION

Application – We introduced this brand new comprehensive, cost-effective EQA program for laboratories that monitor post-transplantation infections and laboratories that perform quantitative and/or qualitative molecular testing of EBV, BKV, JCV and HHV6.

Science – This program is specifically designed for facilities that test recipient plasma samples post-transplantation for viral infections and comprises samples representative of those normally received for testing for EBV, BKV, JCV and HHV6. To accommodate the needs of testing on multiple assays, retesting and troubleshooting, we offer a sample volume of 1.4 mL per sample. This program meets the highest international clinical standards.
*Pending accreditation

POINT OF CARE AND SPECIALISED EQAS

Point of Care and Specialised EQAS

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

PROGRAM TYPE: POC | **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 – Designed as a simplified, cost-effective EQA program for POC facilities and laboratories in resource limited settings that perform molecular testing on *Chlamydia trachomatis, Neisseria gonorrhoeae* and *Trichomonas vaginalis* using POC platforms and laboratory platforms. This program has options for 2 and 5 samples per Test Event.

Science – We optimised sample sets for POC testing platforms such as the Cepheid GeneXpert. Samples are dried swabs, and feature inactivated organisms, which means that the panels of this program are stable, non-infectious (UN3373 exempt) and shipped at ambient temperature. This program is ISO 17043 accredited and meets the highest international clinical standards.

2. DRIED TUBE SAMPLE HBV MOLECULAR POC

PROGRAM TYPE: POC | **ANALYSIS:** Qualitative and 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 – Designed as a simplified, cost-effective EQA program for POC facilities and laboratories in resource limited settings that perform molecular testing for HBV DNA Viral Load and HBV DNA detection. 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 and HBV DNA detection. 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. The panels of this program are stable, non-infectious (UN3373 exempt) and shipped at ambient temperature. This program meets the highest international clinical standards.

Point of Care and Specialised EQAS

3. DRIED TUBE SAMPLE HCV MOLECULAR POC

PROGRAM TYPE: POC | **ANALYSIS:** Qualitative and 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 – Designed as a simplified, cost-effective EQA program for POC facilities and laboratories in resource limited settings that perform molecular testing for HCV RNA Viral Load and HCV RNA detection. 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 and HCV RNA detection. 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. The panels of this program are stable, non-infectious (UN3373 exempt) and shipped at ambient temperature. This program meets the highest international clinical standards.

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

PROGRAM TYPE: POC | **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 – Designed as a simplified, cost-effective EQA program for POC facilities and laboratories in resource limited settings that perform molecular testing for HIV Viral Load, HIV RNA detection and also early infant diagnosis (EID) testing for HIV proviral DNA, 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. The panels of this program are stable, non-infectious (UN3373 exempt) and shipped at ambient temperature. This program meets the highest international clinical standards.

Point of Care and Specialised EQAS

5. HTLV MOLECULAR

PROGRAM TYPE: Specialised | **ANALYSIS:** Quantitative and Qualitative | **SAMPLE TYPE:** Human Whole Blood Matrix | **SHIPPING CODE:** UN 1845 UN 3373

PROGRAM CODE	FORMAT	COMPATIBILITY
HTLD435	**3** Test Events x **5** samples x **0.5** mL **1** shipment	No known compatibility issues with any method or analyzer.

Proviral HTLV DNA

DESCRIPTION

Application – This program offers a unique EQA for the molecular testing and 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/panels. Samples contain SP cells diluted with stabilised red cells, creating a matrix designed to mimic whole blood. SP cells are human T cells containing a full-length copy of HTLV-1 DNA. The program assesses linearity, reproducibility and limit of detection of the assay in use.
In 2024, we optimised and validated HTLD435 to be shipped frozen prior to Test Event 1.

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 – Designed 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 sample sets that include a range of Leptospira species to assess the laboratories ability to detect and distinguish between species. The panels of this program are stable, non-infectious (UN3373 exempt) and are shipped at ambient temperature. This program is ISO 17043 accredited and meets the highest international clinical standards.

Point of Care and Specialised EQAS

7. MYCOBACTERIUM MOLECULAR POC

PROGRAM TYPE: POC/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 – Designed as a simplified, cost-effective EQA program for laboratories performing molecular testing for Mycobacterium tuberculosis and/or its drug resistance typing (Rifampicin resistance and now extended to other resistance types), 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 bacterial samples that include wild type and drug resistant strains (Rifampicin resistance and now extended to other resistance types) of *Mycobacterium tuberculosis.* The panels of this program are stable, non-infectious (UN3373 exempt) and shipped at ambient temperature. This program is ISO 17043 accredited and meets the highest international clinical standards.

Appendix- **Table 1: Serology Program Analytes**

Analytes \ Programs	MMBS	RVSS	HEPM
HIV p24 Ag	✓	✓	
Anti-HIV	✓	✓	
HCV Ag	✓		✓
Anti-HCV	✓		✓
HBsAg	✓		✓
Anti-HBs			✓
Anti-HBc IgG/Total	✓		✓
Anti-HBc IgM			✓
HBeAg			✓
Anti-HBe			✓
Anti-HAV IgG/Total			✓
Anti-HAV IgM			✓
Anti-HDV			✓
Anti-HTLV	✓	✓	
Anti-Treponema Pallidum	✓	✓	
Non-Treponemal Antibodies		✓	

Analytes / Programs	TRCH	COVS
Anti-CMV IgG	✓	
Anti-CMV IgM	✓	
Anti-Rubella IgG	✓	
Anti-Rubella IgM	✓	
Anti-Toxoplasma IgG	✓	
Anti-Toxoplasma IgM	✓	
Anti-HSV-1 IgG	✓	
Anti-HSV-2 IgG	✓	
Anti-HSV-1/2 IgM	✓	
Anti-EBV VCA IgG	✓	
Anti-EBV VCA IgM	✓	
Anti-EBV EBNA IgG	✓	
SARS-COV-2 IgG		✓
SARS-COV-2 IgM		✓
SARS-COV-2 IgA		✓

Appendix- **Table 2: Molecular Program Analytes (Plasma Sample Type)**

Programs / Analytes	HBVL	HCVQ	HIVL	DTSB	DTSC	DTSI	NATA	MMPF	CMVN	TTIM
HBV DNA	✓			✓			✓			
HCV RNA		✓			✓		✓			
HIV RNA			✓			✓	✓			
Proviral HIV DNA						✓				
CMV DNA								✓	✓	
HAV RNA								✓		
HEV RNA								✓		
PVB19 DNA								✓		
BKV DNA										✓
EBV DNA										✓
JCV DNA										✓
HHV6 DNA										✓

Appendix- **Table 3: Molecular Program Analytes (Other Sample Types)**

Analytes \ Programs	STIC	RASH	HPVN	HTLD	CNTP	LEPN	MTBN
Chlamydia trachomatis	✓				✓		
Neisseria gonorrhoeae	✓				✓		
Trichomonas vaginalis	✓				✓		
Mycoplasma species	✓						
Ureaplasma Species	✓						
NG/MG Drug Resistant	✓						
CMV DNA		✓					
HSV-1 DNA		✓					
HSV-2 DNA		✓					
VZV DNA		✓					
HPV DNA			✓				
HPV High-Risk Types			✓				
Proviral HTLV DNA				✓			
Leptospira species						✓	
Mycobacterium species							✓
Mycobacterium Drug Resistant							✓

Appendix- **Table 4: Molecular Respiratory Program Analytes**

Analytes \ Programs	RESP	RESV	RESB
Influenza RNA	✓		
Influenza A Typing	✓		
RSV RNA	✓		
SARS-CoV-2 RNA	✓		
Adenovirus DNA		✓	
Enterovirus RNA		✓	
Metapneumovirus RNA		✓	
Parainfluenza RNA		✓	
Parechovirus RNA		✓	
Rhinovirus RNA		✓	
Seasonal Coronavirus RNA		✓	
Bordetella species			✓
Chlamydophila species			✓
Haemophilus species			✓
Legionella species			✓
Mycoplasma species			✓
Pneumocystis species			✓
Streptococcus species			✓

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