2023 NRL External Quality Assessment Schemes

INDEX

NRL - ABOUT US

NRL, as 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.

Accreditation:

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 605059

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 using 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 NRL EQAS are supported by OASYS, an Internet-based software management system. 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.

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 misdiagnosis.

WHAT'S NEW IN 2023?

NEW

- NRL is expanding the **Respiratory Molecular** offering in 2023 and launching two new programs:
  - **Extended Viral Respiratory Molecular** Program (RESV435) and **Bacterial Plus Respiratory Molecular** Program (RESB435).
  - **Influenza A Genotyping** into the existing Viral Respiratory Molecular Program (RESP435).
  - The three programs cover most analytes for respiratory molecular testing.
- **CMV Molecular** Program (CMVN435) is being re-introduced in 2023:
  - The program is designed for laboratories which perform viral load and/or qualitative CMV molecular testing on plasma samples.
- Improved the **SARS-CoV-2 Antibodies** Program (COVS435/432) for 2023 with two panel sizes:
  - This program is now designed and managed by NRL.
  - Unique individual samples from single donors and enhanced assessment.
- **HIV Molecular** Program (HIVL435), **HBV Molecular** Program (HBVL435) and **HCV Molecular** Program (HCVQ435):
  - Now assess both **quantitative** results (Viral Load) and **qualitative** results (Detection).
  - Increase sample volume of all three programs to **1.4 mL**.
- Sexually-Transmitted Infections Molecular Program (STIC435)now includes:
  - An additional Drug Resistant strain: ***Mycoplasma genitalium* Azithromycin Resistant**.

∇ HPV Molecular Program (HPVN435) now:

- Contains **a greater variety of other HPV High Risk Types**.
- Group or individual HPV genotyping results can be reported in the program.

- Mycobacterium Molecular POC Program (MTBN435) now:
  - Contains more **Drug Resistant Strains**.
  - A Variety of TB drug resistant results can be reported in the program.
- SARS-CoV-2 Antigen Program (COVA434) is being discontinued in 2023.
  - Please contact NRL if you need quality assurance programs for SARS-CoV-2 Antigen Testing.

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

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

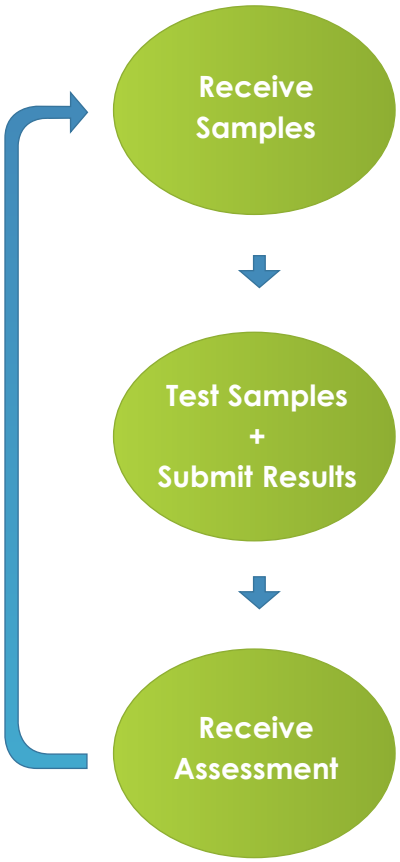
T: +61 3 9418 1124

SYSTEM OVERVIEW

Getting started

Programs are listed by discipline. To order programs, please use the Order Form on NRL's website or contact NRL directly for a quote.

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.

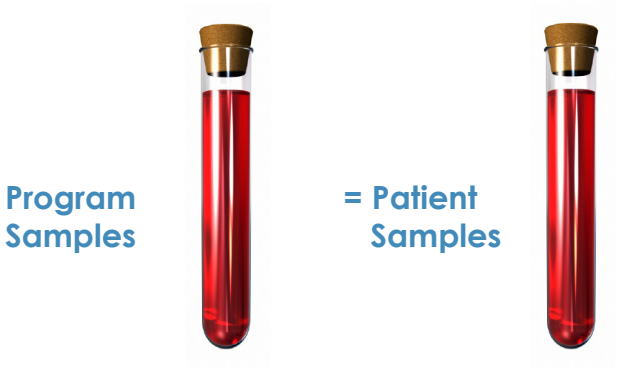
Performance Reports

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

SEROLOGY EQAS

2023 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	29 March 2023	23 days	21 April 2023
2	28 June 2023	21 days	19 July 2023
3	27 September 2023	21 days	18 October 2023

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.

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

DESCRIPTION

Application - We designed this 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 routine blood screening facilities and now includes anti-HTLV. 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 human plasma or pooled plasma samples in this program. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and 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	HBsAg	Anti-HBs	HCVAg
Anti-HAV IgM	Anti-HBc Total	HBeAg	Anti-HCV
Anti-HAV Total	Anti-HBc IgM	Anti-HBe	Anti-HDV

DESCRIPTION

Application - We designed this 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 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 testing for multiple analytes and multiple assays, we offer the volume of 1.8 mL per sample. We use undiluted human plasma or pooled plasma samples in this program. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and graphical reports to enhance comparisons within and between peer groups. This program is ISO 17043 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 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 human plasma or pooled plasma samples. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and graphical reports to enhance comparisons within and between peer groups. This program is ISO 17043 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-Rubella IgG
Anti-Rubella IgM

Anti-Toxoplasma IgG
Anti-Toxoplasma IgM

Anti-HSV-1/2 IgG
Anti-HSV-1/2 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 CMV, Rubella, Toxoplasma, 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 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. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and graphical reports to enhance comparisons within and between peer groups. This program is ISO 17043 accredited and meets the highest international clinical standards.

SEROLOGY EQAS

NEW

5. 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 – We designed this as a comprehensive, cost-effective EQA program for laboratories 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. 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. In 2023, this program will be under NRL's serology offering. 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.

*Pending accreditation.

MOLECULAR EQAS

2023 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	8 March 2023	21 days	29 March 2023
2	7 June 2023	21 days	28 June 2023
3	6 September 2023	21 days	27 September 2023

Note: RESP435, RESV435 and RESB435 follow 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 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 to enable laboratories to assess both the precision and the accuracy of their assays. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and graphical reports to enhance comparisons within and between peer groups. This program 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.

HAV RNA Parvovirus B19 DNA HEV RNA CMV DNA

DESCRIPTION

Application - We designed this 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. To maintain both affordability and scientific integrity, we offer the panel size of 10 samples per Test Event. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and graphical reports to enhance comparisons within and between peer groups. This program is ISO 17043 accredited and meets the highest international clinical standards.

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 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 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 testing for patient samples. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and graphical reports to enhance comparisons within and between peer groups. This program is ISO 17043 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 | NEW Influenza A Typing

DESCRIPTION

Application - We designed this comprehensive, cost-effective EQA program for laboratories and Point-of-Care(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 (not synthetic material), which enables monitoring of extraction efficiency as well as detection of analytes. Since the panels of the program can be 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. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and graphical reports to enhance comparisons within and between peer groups. This program is ISO 17043 accredited and meets the highest international clinical standards.

#Follows Point of Care/Specialised EQAS Test Event Calendar.

MOLECULAR EQAS

NEW

5. 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 - We are introducing this brand-new 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 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 covers majority of the clinical testing requirements for viral respiratory infection. The samples feature real inactivated virus (not synthetic material) of various strains, which enables monitoring of extraction efficiency as well as detection of the analytes. The panels of this program can be shipped at ambient temperature. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and 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.
*Pending accreditation.

NEW

6. BACTERIAL PLUS RESPIRATORY MOLECULAR

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

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

DESCRIPTION

Application - We are introducing this brand-new 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 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, inactivated bacteria and fungi (not synthetic material) of various strains, which enables monitoring of extraction efficiency as well as detection of analytes. The panels of this program can be shipped at ambient temperature. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and 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.
*Pending accreditation.

MOLECULAR EQAS

7. 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
N. gonorrhoeae CFT resistant
Trichomonas vaginalis
Ureaplasma species
Mycoplasma species
M. genitalium Fluoroquinolone resistant
M. genitalium Macrolide resistant
NEW *M. genitalium* Azithromycin Resistant

DESCRIPTION

Application - We designed this 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 sample sets to cover a wide range of sexually-transmitted infections including *Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Ureaplasma species* and *Mycoplasma species*. 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* Azithmycin resistant and *Neisseria gonorrhoeae* CFT resistant. Laboratories can submit all results for multiple analytes from multiple assays and/or from multiplex assays. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and graphical reports to enhance comparisons within and between peer groups. This program is ISO 17043 accredited and meets the highest international clinical standards.

8. 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 NEW **1.4** 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 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. In 2023, we are increasing the volume per sample to 1.4 mL, to accommodate the needs of testing on multiple assays, retesting and troubleshooting. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and graphical reports to enhance comparisons within and between peer groups. This program is ISO 17043 accredited and meets the highest international clinical standards.

MOLECULAR EQAS

9. 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	NEW **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 - We designed this 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. In 2023, we are increasing the volume per sample to 1.4 mL, to accommodate the needs of testing on multiple assays, retesting and troubleshooting. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and graphical reports to enhance comparisons within and between peer groups. This program is ISO 17043 accredited and meets the highest international clinical standards.

10. 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	NEW **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 - 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 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. In 2023, we are increasing the volume per sample to 1.4 mL, to accommodate the needs of testing on multiple assays, retesting and troubleshooting. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and graphical reports to enhance comparisons within and between peer groups. This program is ISO 17043 accredited and meets the highest international clinical standards.

MOLECULAR EQAS

11. 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 consist of known HPV genotypes, including HPV high-risk types 16 and 18, and now are being 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 including HPV detection and genotypes. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and graphical reports to enhance comparisons within and between peer groups. This program is ISO 17043 accredited and meets the highest international clinical standards.

NEW

12. 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 - We are re-introducing CMVN as 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 we are re-introducing this program for 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. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and graphical reports to enhance comparisons within and between peer groups. This program is ISO 17043 accredited and meets the highest international clinical standards.

POINT OF CARE AND SPECIALISED EQAS

2023 Test Event Calendar

The following Test Event Calendar applies to all Programs in the Point-of-Care/Specialised EQAS and RESP435, RESV435 and RESB435 EQAS.

Test Event	Test Event Open	Test Event Window	Results Deadline
1	29 March 2023	23 days	21 April 2023
2	28 June 2023	21 days	19 July 2023
3	27 September 2023	21 days	18 October 2023

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 settings 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 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. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and graphical reports to enhance comparisons within and between peer groups. This program is ISO 17043 accredited and 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 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. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and graphical reports to enhance comparisons within and between peer groups. This program is ISO 17043 accredited and meets the highest international clinical standards.

3. DRIED TUBE SAMPLE HBV MOLECULAR POC

PROGRAM TYPE: Point-of-Care | **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 - We designed this as a simplified, cost-effective EQA program for Point-of-Care (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. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and graphical reports to enhance comparisons within and between peer groups. This program is ISO 17043 accredited and meets the highest international clinical standards.

4. DRIED TUBE SAMPLE HCV MOLECULAR POC

PROGRAM TYPE: Point-of-Care | **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 - We designed this as a simplified, cost-effective EQA program for Point-of-Care (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. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and graphical reports to enhance comparisons within and between peer groups. This program is ISO 17043 accredited and meets the highest international clinical standards.

5. HTLV MOLECULAR

PROGRAM TYPE: Specialised | **ANALYSIS:** Quantitative and Qualitative | **SAMPLE TYPE:** Human whole blood matrix | **SHIPPING CODE:** 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 or analyzer.

Proviral HTLV DNA

DESCRIPTION

Application - This program offers a unique EQA for the molecular testing for 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.

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 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. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and graphical reports to enhance comparisons within and between peer groups. This program is ISO 17043 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/or its drug resistance typing (Rifampicin resistance and now extended to other resistance types), and particularly optimised for resource limited settings and Point-of-Care (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. We redesigned our Test Event assessments to shorten the turnaround times with the inclusion of custom-tailored comments to support troubleshooting and graphical reports to enhance comparisons within and between peer groups. This program is ISO 17043 accredited and meets the highest international clinical standards.

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