NRL WORKSHOP ABSTRACTS

WEDNESDAY 11 OCTOBER

2023

Title: SCoPE2: A VALHUDES clinical validation of self-collection and pathway to ISO accreditation for use in Australian National Cervical Screening program.

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Introduction: The World Health Organization's Elimination Strategy includes the target of 70% of eligible people to be screened twice with a high -precision test. HPV-based cervical screening has created the opportunity for self-collection as a tool to increase access. In July 2022 self-collection became available for all routine screening participants in the National Cervical Screening Program.

Methods: The Self-Collection or Practitioner-collection Evaluation 2 (SCoPE2) study recruited 400 participants attending for colposcopy. Participants who gave informed consent self-collected two samples, using a Copan FLOQSwab and a Rovers Viba-brush in random order, before a cervical specimen was practitioner-collected at colposcopy. The self-collected samples were shipped dry, then eluted in 5 ml of Copan MSwab media. Specimens were tested on a range of clinically validated PCR-based HPV assays. Histological outcomes were available through to 6 months after recruitment.

Results: Relative clinical sensitivity was >90% for six PCR-based HPV assays. Relative clinical specificity using concordant clinician-collected specimens as the reference was >95% for five PCR-based assays. Further testing was undertaken for three assays to meet the requirements of an in-house validation. Testing included specimen stability over 28 days, Limit of Detection, inhibition, and reproducibility.

Conclusion: Self-collection using cheap high-quality devices which can be transported dry are needed to increase accessibility both in low and middle-income countries and support screening in traditionally under- and never-screened populations in high-income countries. The method undertaken in the SCoPE2 study has now been validated and accredited under the new ISO 15189:2022 standard which may give other laboratories confidence in utilizing this protocol.

Title: Evaluation and comparison of the Roche cobas 6800, Alinity m and Hologic Panther automated platforms for quantifying CMV DNA in plasma samples

Authors: Jodie D'Costa[1], Doris Chibo[1], Katherine Soloczynskyj[1], Mitchell Batty[1], Rizmina Sameer[1], Elaine Lee[1], Thomas Tran[1], Dimitra Mavroulis[1], Megan Gooey[1], Chuan Kok Lim[1], Kathy Jackson[1]

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Cytomegalovirus (CMV) is a member of the herpes family and infection with this virus has minimal effect on healthy individuals. Complications may arise however for the immunocompromised, including those with congenital CMV infection, solid-organ transplant patients and hematopoietic stem cell transplant patients. In this population, monitoring of CMV load is essential for early detection of infection, prevention of disease progression and optimisation of immunosuppressive therapy.

High-throughput commercial assays are currently available for CMV quantitation, but they are often evaluated independently and performance between assays is unknown. This study aims to evaluate the use of the Roche cobas 6800, Abbott Alinity m and Hologic Panther platforms for quantitation of CMV DNA in patient plasma.

Parallel testing of 136 clinical samples across the three platforms showed similar agreement between each assay with the greatest positive agreement between the Panther and Alinity m assays (95.6%, 95% CI 89-98.6%) and the least agreement between the Panther and cobas 6800 assays (94.1%, 87.4-97.5%). Based on the WHO international standard, linearity for each of the three assays ranged from 98.6% to 99.96%. Precision and limit of quantitation were as expected and showed little variation between platforms.

The functionality of each platform was comparable in terms of workflow and labour time. The Alinity m and Panther are random access instruments, creating ease of use when testing different targets. The Alinity m and 6800 assays offer the advantage of smaller sample requirement – 500µl each compared to 700µl for the Panther assay. All assays were sensitive and accurate when quantifying CMV, and performance across all 3 assays was comparable for monitoring CMV viral loads in patient plasma.

Title: Consolidation and standardisation of transplant marker testing

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Viral primary infections and reactivations are a major cause of morbidity and mortality for recipients of solid organ transplantation (SOT) and haematopoietic stem cell transplant recipients (HSCT). Well-known viruses associated with routine clinical management of transplant recipients include BK virus (BKV), Cytomegalovirus (CMV) and Epstein-Barr virus (EBV)1. These viruses are common in healthy individuals, with an approximate prevalence of 80%, 60%, and 90%, respectively2. Primary infection usually occurs during childhood with the virus remaining latent and asymptomatic under normal conditions. Individuals with compromised immune systems are prone to both primary infection and reactivations with clinically relevant symptoms. These reactivations are the most common cause of complications post-transplant. Quantitative PCR methods are the gold standard for the detection and viral load monitoring of BKV, CMV and EBV3. Laboratory-developed methods of viral quantification are limited by the lack of standardised results and can lead to a high degree of inter-laboratory and inter-assay variability. First- and second-generation commercial assays improved inter-laboratory standardisation with many laboratories adopting commercial assays for CMV and EBV in particular. Viral load reporting units have changed over time from assay-specific target copies/mL to WHO international standards, reported in international units (IU) per millilitre. Some assays provide conversion factors from copies/mL to IU/mL, whilst other assays have further improved the level of standardisation with internal assay calibration to IU/mL. As the state-wide reference laboratory for quantitative transplant marker testing, our laboratory has transitioned from in-house to first-, second- and third-generation commercial assays for BKV, CMV and EBV. Here we present method comparisons (correlation, reproducibility, lower limit of detection) for BKV, CMV and EBV, including commutability to WHO standards. We also highlight the consolidation and standardisation of transplant marker testing (including solid organ donor screening) using the cobas 6800 system. The improved test turnaround, reliability and accuracy of viral load monitoring is crucial for the ongoing clinical management of SOT and HSCT recipients.

1. Annaloro, C., Serpenti, F., Saporiti, G., Galassi, G., Cavallaro, F., Grifoni, F., Goldaniga, M., Baldini, L., & Onida, F. (2021). Viral Infections in HSCT: Detection, Monitoring, Clinical Management, and Immunologic Implications. Frontiers in immunology, 11, 569381. https://doi.org/10.3389/fimmu.2020.569381

2. Blazquez-Navarro, A., Dang-Heine, C., Wittenbrink, N., Bauer, C., Wolk, K., Sabat, R., Westhoff, T. H., Sawitzki, B., Reinke, P., Thomusch, O., Hugo, C., Or-Guil, M., & Babel, N. (2018). BKV, CMV, and EBV Interactions and their Effect on Graft Function One Year Post-Renal Transplantation: Results from a Large Multi-Centre Study. EBioMedicine, 34, 113–121. https://doi.org/10.1016/j.ebiom.2018.07.017

3. Pang, X. (2018). Standardisation of Viral Load Determination for Monitoring CMV, EBV, and BK Viruses in Solid Organ Transplant Recipients. In: Tang, YW., Stratton, C. (eds) Advanced Techniques in Diagnostic Microbiology. Springer, Cham. https://doi.org/10.1007/978-3-319-95111-9_28

Title: Clinical and laboratory evaluation of the BioFire Respiratory Panel 2.1 plus compared to SpeeDx PlexPCR

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Background:

Respiratory tract infection is a common cause of visits to the hospital emergency department (ED). Rapid and sensitive sample-to-result multiplex nucleic acid amplification tests (NAATs) have emerged which target multiple respiratory pathogens in a single test1. These sample-to-result assays are clinically useful for managing patient hospital admissions due to the rapid test turnaround (TAT), however these syndromic tests are lower throughput and higher cost compared to conventional molecular methods. Conversely, conventional NAATs have improved throughput and broadened the number of clinically relevant targets available2.

Objectives:

1. Compare BioFire FilmArray Respiratory Panel 2.1 plus (RP; 23 targets) to SpeeDx PlexPCR (Plex; 8 targets) for the detection of pathogenic respiratory viruses.

2. Retrospectively analyse turnaround time (TAT) in the clinical context.

Methods:

Upper respiratory tract swabs were tested prospectively with RP as part of routine testing (n=1915). Samples were retrospectively tested with Plex with discordant analysis by retesting both RP, Plex and GeneXpert.

Results:

The overall agreement between RP and Plex was 98.4% (95% CI 97.7-98.9%). The highest percentage of RP results were negative (72%), followed by Rhinovirus/Enterovirus (7%), SARS-CoV-2 (7%), and respiratory syncytial virus (5%). The remaining pathogens (9%) included non-SARS-CoV-2 coronaviruses, human metapneumovirus, parainfluenza virus 1-4, influenza virus A, adenovirus, influenza virus B, and Bordetella parapertussis). Contingency tables for all Plex targets and lower-limit detection studies were performed with comparable results. The median TAT for RP was 1.78h without clinically significant day-to-day variation. ED collected 76% of samples. Pathogen detection rate was higher in ED samples (30%) compared to inpatient wards (17%) although SARS-CoV-2 detection was lower in ED (5%) than inpatients (9%). For ED samples, 89.3% of results were available prior to discharge, including 71.5% of those with an ED visit time under 4h, increasing to 92.5% in positive samples.

Conclusions:

The RP assay is well-suited for rapid respiratory testing in the context of a laboratory operating 24h and servicing a high-turnover ED. Consistently providing TAT of under 2h has clear potential to facilitate appropriate anti-viral prescription and inform bed allocation. We also demonstrate a high degree of concordance comparing RP to Plex. The RP assay has an advantage with a broader range of targets and rapid sample-to-result TAT, whereas the Plex has an advantage in terms of throughput and cost. We envisage a combination of RP and Plex could provide an effective diagnostic strategy to meet the clinical and laboratory demands of respiratory testing. Further work is required to define the optimal testing algorithm.

1. Bouzid D, Hingrat QL, Salipante F, Ferré VM, etal. 2023. Agreement of respiratory viruses' detection between nasopharyngeal swab and bronchoalveolar lavage in adults admitted for pneumonia: a retrospective study. Clinical Microbiology and Infection. 29(7), 942.e1–942.e6. https://doi.org/10.1016/j.cmi.2022.12.024

2. Pryce TM, Haygarth EJ, Bordessa J, Boan PA. 2021. Evaluation of a PlexZyme-Based PCR Assay and Assessment of COVID-19 Surge Testing Throughput Compared to Cobas SARS-CoV-2. Pathogens 10:1088. https://doi.org/10.3390/pathogens10091088

Title: Helicobacter pylori Clarithromycin-resistance detection via formalin-fixed paraffin embedded (FFPE) tissue: Specimen validation and implementation

Author: Steph Howarth

Emerging Helicobacter pylori Clarithromycin resistance continues to pose a significant threat to evolving antimicrobial resistance and available effective treatment options. Current culture-based microbiological techniques utilised in the identification of Clarithromycin resistance have proven laborious, expensive and offering poor sensitivity. Detection of Clarithromycin resistance in H. pylori FFPE gastric biopsy specimens via molecular techniques offers a rapid, highly specific and sensitive testing solution.

Title: Laboratory assessment of a multi-target assay for the rapid detection of viruses causing vesicular diseases.

Authors: Mitchell Batty[1], Georgina Papadakis[1], Changxu Zhang[1], Thomas Tran[1], Julian Druce[1], Chuan Kok Lim[1,2], Deborah A Williamson[1,2]and *Kathy Jackson[1]

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Abstract

Background

The recent mpox outbreak has highlighted the need to rapidly diagnose the causative agents of viral vesicular disease to inform treatment and control measures. Common causes of vesicular disease include Monkeypox virus (MPXV), clades I and II, Herpes simplex viruses Type 1 and Type 2 (HSV-1, HSV-2), human herpes virus 6 (HHV-6), Varicella-zoster virus (VZV) and Enteroviruses (EVs). Here, we assessed a syndromic viral vesicular panel for rapid and simultaneous detection of these 7 targets in a single cartridge.

Objective

The aim of this study was to evaluate the analytical measures of the QIAStat-Dx ® viral vesicular (VV) panel and compare with laboratory developed tests (LDTs). This included limit of detection, inter-run variability, cross-reactivity and specificity. Comparative assessment criteria (assay agreement and correlation) were determined using 124 clinical samples from multiple anatomical sites.

Results

The overall concordance between the QIAstat and LDTs was 96%. Positive percent agreement was 82% for HHV-6, 89% for HSV-1 and 100% for MPXV, HSV-2, EV and VZV. Negative percent agreement was 100% for all targets assessed. There was no cross-reactivity with Vaccinia, Orf, Molluscum contagiosum viruses, and a pooled respiratory panel.

Conclusion

The QIAstat VV multi-target syndromic panel combine ease of use, rapid turnaround, good sensitivity and specificity for enhanced diagnosis, clinical care and public health responses.

HIV NEEDS ATTENTION. THE EVOLVING ROLE OF NAT IN HIV DIAGNOSIS. AN EVALUATION OF THE COBAS® HIV-1/HIV-2 QUAL ON THE COBAS® 5800

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Recently updated laboratory case definitions for children greater than 18 months and adults for the laboratory diagnosis of HIV infection have included for the first time the use of HIV nucleic acid tests (NAT) in samples repeatedly reactive in HIV-1/2 antigen/antibody assays without the requirement for performing other traditional supplementary assays in HIV testing algorithms such as HIV-1 p24 antigen and HIV immunoblots. These changes have recently led to updates to the NPAAC guidelines for HIV testing.

There are now several HIV NAT assays that have claims for the use as HIV confirmation, including HIV-1 viral load assays that have been included on the Australian Register of Therapeutic Goods (ARTG).

The NSW State Reference Laboratory for HIV/AIDS, St Vincent's Hospital, Sydney has used HIV-1 NAT in our HIV confirmatory algorithm for over 20 years. An additional dedicated whole blood sample or neonatal dried blood spot (DBS) sample is requested for discordant HIV serology and tested on HIV-1 NAT qualitative assays that have a claim for HIV-1 confirmation. These assays have proven beneficial in the clarification of results from patients with indeterminate serology including suspected HIV-2 infection, in acute HIV-1 infection, and in early infant diagnosis (EID) More recently these NAT assays have taken further importance in the testing of patients taking anti-retroviral therapy (ART) as pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP) where there can be a delayed serological response to a newly acquired HIV-1 infection.

The benefits and challenges facing laboratories with the implementation of HIV NAT for confirming HIV cases will be discussed.

Data will also be presented on our evaluation of the cobas® HIV-1/HIV-2 on the cobas® 5800 System which is currently in progress. The cobas® HIV-1/HIV-2 is a qualitative assay and is the only NAT assay listed on the ARTG for confirmation of HIV-2 infection. The cobas® 5800 System utilises the same technology as the cobas® 6800/8800 Systems and on-board kits, controls and other reagents can be shared across all three systems and offers smaller run sizes for medium throughput laboratories.

Title: Assessing the Stability of SARS-CoV-2 RNA in Viral Transport Media under various storage conditions

Authors: Chynoweth A, Vandegraaff N, Sahin T

Abstract:

Preserving the viability of Severe Acute Respiratory Syndrome CoV-2 (SARS-CoV-2) in samples until they reach the testing laboratory is essential when conducting SARS-CoV-2 surveillance and testing. Placing samples in Viral Transport Medium (VTM) means that there is a decreased risk of the integrity of the sample being compromised during transport and storage.

The objective of this study was to determine the stability of SARS-CoV-2 RNA in Viral Transport Media (VTM) under real time and accelerated periods of up to 18 months. The transport media tested was comprised of Hanks Balanced Salt Solution (with calcium and magnesium), supplemented with heat inactivated Foetal Bovine Serum (FBS), containing Gentamicin and Amphotericin B.

The suitability of the Roche cobas SARS-CoV-2 test system for assessing virus stability was assessed using serial dilutions of a high-titer, gamma-irradiated SARS-CoV-2 Beta Strain virus and an optimum concentration of virus to use was determined. At defined timepoints, virus was spiked into VTM sample aliquots that had been stored at a reference temperature of 2-8°C or elevated temperatures of 25°C, 37°C, 45°C or 54°C. Samples were then tested in batches using the Roche cobas SARS-CoV-2 test that is designed to detect two SARS-CoV-2 RNA targets (E-gene and ORF1 a/b) on Roche cobas 6800 system. Two different lot numbers of VTM samples were assessed.

The data from this study will supplement existing data obtained in prior real time studies performed by the Project sponsor and will be used to support the assignment of an appropriate shelf life and storage/transport conditions for the VTM product.

Title: Warts and all – the future of HPV testing in anal cancer screening

Author: Katrina Smith, DHM

Synopsis

The National Cervical Screening (NCS) Program has been in place In Australia since 1991, for many years detecting HPV-associated neoplastic cellular changes by cytologic screening. The treatment of screen-detected premalignant lesions successfully reduced the risk of progression to cancer.

Since 2017 HPV PCR testing has been the primary Cervical Screening Testing (CST) in Australia, and the new paradigm with cytology triage is reported to protect 30% more people than the traditional cytological methods.

Cervical cancer is one of the most preventable cancers, and the results of the NCS program have proven its efficacy. HPV also causes anal cancer (90% of cases*) and in 2022, definitive evidence was published demonstrating that treating anal pre-cancer (anal high-grade squamous intraepithelial lesion: HSIL) prevents anal cancer (the ANCHOR study). Thus, there is increasing evidence supporting screening programs for at-risk populations, to detect the presence and activity of HPV in the anal canal, and to treat premalignant lesions, analogous to the cervical model. This would enable effective clinical management of the patient (potentially reducing the number of high-resolution anoscopies (HRA; a field requiring more trained staff to perform this) and hopefully preventing the development of anal cancers.

DHM is validating the use of the Seegene HPV28 genotyping assay which can detect the specific HPV types present in the samples, including both low risk (wart causing) and high risk (cancer causing) genotypes. This kit is validated for use in cervical samples however our application is using anal samples. The results of this assay, if used as part of routine anal screening is pivotal information for the clinician to identify the presence of specific genotypes (HPV 16 is by far the most oncogenic) and to distinguish between transient and persistent HPV infections with any genotype, as persistent infections carry the greatest risk. The highest-risk individuals could then be selected to undergo high-resolution anoscopy (analogous to cervical colposcopy), enabling biopsy of lesions and subsequent treatment if necessary.

The development of such a screening program is vital. Anal cancer is increasing in incidence in Australia, in some subpopulations (e.g. PLHIV) the incidence is very high and as incidence increases with age, HPV immunisation will not have a significant effect for several decades.

*cancer council website: https://www.cancer.org.au/cancer-information/types-of-cancer/anal-cancer

Title: Advancing Measles, Mumps, and Rubella Testing in Australia for Rapid Diagnosis and Outbreak Prevention

Authors: Tsz Ying Yau, Anna Condylios, Dr Siobhan Hurley, Dr Ana Domazetovska, Prof. William Rawlinson

The Serology and Virology Diagnostic Laboratories (SAViD), NSW Health Pathology, Randwick

Measles, mumps, and rubella (MMR) are highly contagious, vaccine preventable diseases that pose a significant risk of severe complications, particularly among young children. Despite the existence of a safe and cost-effective vaccine, the global toll of measles and rubella is estimated at 351 deaths each day (mostly children) (1, 2). Rubella is also the leading cause of vaccine-preventable birth defects. The MMR vaccine has played a pivotal role in significantly diminishing the prevalence of these diseases. However, outbreaks persist due to incomplete immunity stemming from missed vaccinations, limited vaccine access, vaccine hesitancy, availability of healthcare services, and the movement of individuals from outbreak-affected areas (3).

While the incidence of measles, mumps, and rubella cases in Australia remains notably low and often linked to imported cases (4), the rapid testing of suspected cases and swift public health responses to confirmed MMR infections is critical for effective patient care, and to prevent community outbreaks.

The Serology and Virology Diagnostic Laboratories (SAViD), NSW Health Pathology, Randwick has been a longstanding provider of diagnostic testing for measles, and rubella and has now emerged as one of the limited facilities in Australia offering mumps testing. Recently, SAViD collaborated with Genetic Signatures to develop a simple, real-time PCR diagnostic kit to rapidly screen for MMR in a single test, employing Genetic Signatures' unique 3baseTM technology (5). This diagnostic solution has significantly improved the laboratory's workflow for MMR testing, reduced costs, and drastically expedited result turnaround times.

Notably, this novel multiplex PCR solution for MMR testing has already demonstrated its utility by facilitating the swift diagnosis of several recent MMR cases within Australia, safeguarding patient health and pre-empting potential outbreaks.

These case studies will be discussed. (1) World Health Organisation 2023, Measles, viewed 10 August 2023, <https://www.who.int/news-room/fact-sheets/detail/measles>

(2) Centres for Disease Control and Prevention, 23 November 2022, Global Measles and Rubella, viewed 10 August 2023, <https://www.cdc.gov/globalhealth/measles/index.html>

(3) World Health Organization, 27 April 2022, UNICEF and WHO warn of perfect storm of conditions for measles outbreaks, affecting children, viewed on 10 August 2023, <https://www.who.int/news/item/27-04-2022-unicef-and-who-warn-of--perfect-storm--of-conditions-for-measles-outbreaks--affecting-children>

(4) Australian Government Department of Health and Aged Care, National Communicable Disease Surveillance Dashboard, accessed on 10 August 2023, <https://nindss.health.gov.au/pbi-dashboard/ (5) Genetic Signatures, Our Technology, viewed 10 August 2023, <https://geneticsignatures.com/au/about/our-technology/>

Title: Malaria – are molecular methods getting it right?

Authors: DL Byers[1], PJ Santosa[1]

Affiliation(s):
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Introduction:
Malaria is a clinically significant disease with millions of cases each year and is primarily caused by Plasmodium falciparum and P. vivax. The traditional gold standard method for diagnosing malaria is microscopic identification of the parasite in thick and thin blood films, however other diagnostic techniques have since been developed and include rapid diagnostic tests (RDTs), PCR-based methods and isothermal DNA amplification. Molecular-based methods offer speed, sensitivity, specificity and can provide additional information such as parasite load, species differentiation and drug resistance. Furthermore, isothermal DNA amplification methods also remove the need for specialised equipment and are thus more deployable in low-resource settings. As molecular methods for malaria diagnosis continue to expand, it is essential that laboratories are proficient in performing this testing.

Objective:
To assess the detection and reporting of malaria using molecular diagnostics by reviewing an external quality assessment (EQA) program for the molecular detection of malaria introduced by the RCPAQAP in 2022.

Methods:
A review of the EQA surveys was undertaken to assess malaria testing, assays in use, result concordance and appropriate result interpretation.

Results:
In total, eight specimens have been issued for malaria molecular testing over two years, to 49 participants. Up to 88% of participants tested for Plasmodium species and up to 27% tested for specific species including P. falciparum, P. knowlesi, P. malariae, P. ovale and P. vivax. Isothermal DNA amplification was used by the majority of participants, with in-house PCR methods being used for distinguishing the species types. Analysis of three surveys revealed seven discordant results; five falsely identified malaria and two failed to identify malaria. An additional survey is currently underway and findings will be included in the final presentation. These surveys showed that the results of malaria molecular testing is highly concordant. The inclusion of four negative and four positive samples allowed for the identification of contamination and the detection and identification of P. falciparum, respectively.

Conclusions:
Overall, this EQA shows that the detection of malaria by molecular methods is very good. Participants can reliably use these methods and appropriately report and interpret the results, thereby aiding in the diagnosis of malaria.

Title: Direct Detection of Dermatophyte Fungi in Clinical Samples

Speaker: Sarah E Kidd

Institute: National Mycology Reference Centre, Microbiology & Infectious Diseases, SA Pathology, Frome Road, Adelaide, SA 5000.

Abstract: Dermatophyte fungi are a common cause of skin, nail and hair infections globally, ranging in severity from mild to debilitating, and in very rare cases, invasive infections. The gold standard for diagnosis is microscopy and culture, but is labour intensive, has poor sensitivity, long turnaround times and requires significant expertise for identification of the fungi; this makes up a significant proportion of the workload in many mycology laboratories Molecular detection of dermatophytes has the potential to improve diagnostic sensitivity, reduce labour requirements and decrease result turnaround times. Despite these advantages, a PCR-based approach may present some difficulties and disadvantages, most notably its diagnostic range and incompatibility with oral therapy prescribing requirements under the Pharmaceutical Benefits Scheme. The AusDiagnostics 'Dermatophytes and Other Fungi' assay has been used routinely in our laboratory for almost 4 years. The performance of this assay will be discussed, as well as practical aspects of interpreting and reporting results.