Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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negative in plasma (3.54 and 3.83 log_{10} IU/ml) and 6 gave the opposite results (mean viral load: 2.73 log_{10} IU/ml). All positive (n = 36) samples were analyzed. Linear regression analysis showed a good correlation between the two methods: r = 0.75, p < 0.0001, (slope of Deming regression 1.299 [CI 95%: 0.900–1.698] and y-intercept 0.49 [CI 95%: –1.908 to 0.919]). The Bland-Altman representation showed that the CMV-DNA quantitation in whole blood gave higher virus loads than did the CMV-DNA quantitation in plasma: the average deviation was ~0.54 log_{10} IU/ml (SD = 0.60).

The influence of the blood compartment was also analyzed by comparing the virus load kinetics for successive samples selected from four immunosuppressed patients (16 samples). Overall results showed similar patterns with variation in the same direction. Whole blood was the only compartment that tested positive in one patient for very low virus loads (2.02–2.78 log_{10} log_{10} IU/ml).

**Conclusion:** The H-DIACMVQ kit® provides precise, reproducible results and it satisfies quality requirements for routine monitoring of DNA-CMV in plasma or whole blood samples.

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**Abstract no: 65**

**Presentation at ESCV 2016: Poster 56**

**Use of recombinant virus technology to produce non-infectious, whole process controls for emerging viruses such as Ebola, Chikungunya, Dengue-2, Norovirus GI, MERS-CoV and Zika**

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**Background:** Outbreaks of viral communicable disease and appearance of new viral strains can represent public health emergencies. As diagnostic laboratories and test developers design, manufacture and validate diagnostic assays to prepare for these threats, positive reference materials are needed. SeraCare has developed AccuPlex™ recombinant virus technology to produce whole process reference materials that mimic clinical samples. They are mammalian virus products and are non-infectious. AccuPlex technology was used to develop quality controls for amplified nucleic acid tests for the emerging viruses Ebola, Chikungunya, Dengue-2, Norovirus GI, MERS-CoV and Zika as well as drug resistant HIV-1. Here we demonstrate the performance of these quality control materials to show that they have an extended stability at 2–8 °C and do not require freezer storage.

**Methods:** AccuPlex™ controls for RNA viruses employ engineered Sindbis virus, and a portion of the Sindbis structural genes are replaced with up to ~4000 bp of the diagnostic targets of interest. Where the diagnostic targets are well defined, those regions were incorporated into one recombinant virus. For example, the recombinant Chikungunya reference material contains portions of the NSP1, NSP2, NSP4, Capsid, E3 and E1 genes, and is based on the sequence of strain IND-06-Guj. The recombinant Dengue reference material contains portions of 3’ UTR, NSP5, Capsid, and E1 genes from serotype 2. Recombinant Norovirus, Ebola, and MERS-CoV reference materials follow a similar design scheme.

However, when diagnostic targets are undefined, as is the case for Zika, a different design scheme is required. The entire Zika genome was divided into four segments and each segment was used to generate an AccuPlex recombinant virus. The Zika reference material therefore is a mixture of four distinct AccuPlex recombinant viruses. Dividing the pathogen’s genome among multiple constructs ensures each recombinant virus is not functional. Additional safety features such as gene truncation, multiple stop codons and frame shifts are also used and the products are heat treated for viral inactivation.

**Results:** Recombinant AccuPlex viruses were diluted in defibrinated plasma or other commutable matrices and characterized by Digital PCR using pathogen specific primers and probes. The target concentration range of the reference materials is from 5E+05 copies/mL for recombinant Ebola, to 5E+06 copies/mL for many of the other viruses. Functional testing of the reference materials on Altona RealStar RT-PCR Kits as well as Primer Design Ltd GeneSig Advanced kits showed positive detection. The recombinant viruses gave cycle threshold values (Ct) on these assays consistent with a low positive control (Ct of 27–31.5). Accelerated stability studies indicate that the product is stable at 4 °C for at least two years. Real time stability data at Room Temperature has been collected through 20 months and updated stability data will be presented.

**Conclusions:** SeraCare has developed stable, well-characterized whole process controls for pathogenic viruses. These reference materials will enable laboratories to validate tests and train technicians to ensure preparedness for outbreaks. These products demonstrate the utility of recombinant virus technology to produce non-infectious controls for select agents and viruses difficult to source or propagate.

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**Characterisation and standardisation of Qnostic products in the absence of higher order standards**

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**Introduction:** Viral load determination plays a critical role in clinical diagnostics and a central role in monitoring patients’ response to treatment and disease progression. However, true transferability of results remains elusive due to the lack of inter-laboratory standardisation. Where available, International Standards have helped to facilitate data comparison but where there is no standard or Certified Reference Material available assay variation obscures meaningful comparison of results at the technology and laboratory level. The use of characterised control materials with known performance characteristics would allow for objective comparisons between laboratories and assays used. In this study we evaluated the use of digital PCR (dPCR) to quantify control materials for four viral targets (Cytomegalovirus (CMV), Epstein-Barr Virus (EBV), JC Virus (JCV) and BK Virus (BKV)), and established performance across the top five available commercial assays in clinical use for each. International Standards are available for CMV and EBV but not for JCV and BKV. Digital PCR permits the characterisation of control materials without the requirement of a standard or certified reference material thereby allowing direct comparison of results between laboratories.

**Methods:** Control materials for each of the 4 viral targets (Cytomegalovirus (CMV), Epstein-Barr Virus (EBV), JC Virus (JCV) and BK Virus (BKV)) were prepared at a single titre in human plasma at a concentration that fell within the linear range for most assays in use. The controls were characterised internally using both an in-house qPCR based method and digital PCR (BioRad QX200). Blind panels were provided to laboratories participating in the study in 2015. Laboratories were asked to treat the materials as they would a clinical sample and to return quantitative data along with information on the assay workflow used to generate the results.