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P1340 Comparison of Zika virus detection assays from Abbott, Life River and AITbiotech

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Background: To compare the performance of Abbott, Liferiver and AITbiotech kits for the detection of Zika virus.

Materials/methods: 204 sequential samples submitted for clinical diagnosis from an outbreak in Singapore in 2016 were recovered from storage at -80degC in March 2017: 90 were positive (50 serum/plasma; 40 urine) and 114 negative (53 serum/plasma; 59 urine) as defined by the original in house PCR performed in the 2016 outbreak on RNA extracted with an EasyMag instrument (Biomerieux).

Thawed samples were re-extracted on the Abbott m2000sp system and this RNA used for all three systems on the same day. The Abbott RealTime ZIKA RT-PCR kit was run on an Abbott m2000rt instrument. The Liferiver Zika Virus（ZIKV）Real Time RT-PCR Kit and the AITbiotech Zika Virus (ZIKV）Real Time RT-PCR Kit were run on a Biorad CFX-96 IVD instrument. Sample deterioration was anticipated as the evaluation was performed six months after the outbreak; for this comparison, a true positive was defined as any sample positive by two kits.

Results: Of the 204 samples, 119 were designated true negatives, 84 as true positives (41%) and one was inhibited.

Sensitivity and specificity of the three systems were; Abbott 89% and 94%, Life River 93% and 95% and AITbiotech 96% and 98%.

Ten of the samples originally designated as ‘negative‘ were positive, by at least two kits, after re-extraction with the Abbott system.

Conclusions: The high proportion of positives reflects sample collection during an outbreak. The higher sensitivity and specificity of the AITbiotech kit, made in Singapore, may reflect local reagent design that benefited from knowledge of the sequences of the Singapore Zika Virus. The ability to quickly adjust primers/probes to match new strains is an advantage, especially with RNA viral targets. Laborious regulatory requirements may hinder manufacturers from updating reagents to match emerging strains, especially for minor markets. This has implications for assays designed at one time and then marketed at a later time or in another location. The data suggested RNA extracted by the Abbott system gave better sensitivity than the original RNA preps; this aspect needs more formal evaluation.