The T-COR 8™ System for Point-of-Care Multiplex Real Time Polymerase Chain Reaction (RT-PCR) Assays Directly from Patient Samples

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The T-COR 8 thermocycler is field deployable, CLIA waivable, and designed for use in field forward primary care settings as well as laboratories, and is currently commercially available with a CE mark. It is battery operated, 4.5 Kg, and data is accessible remotely through cloud ready software. The assay dependent consumables (optimized for each target sample / analyte) include, an easy to use integrated "collect-to-test" (C2T™) sample-processing device (figure 1a) is used for sample collection at the point-of-care; the processed sample is then tested in a C2T cartridge (a single use, barcoded, cartridge with dried down multiplex RT-PCR reagents (figure 1a)). The dried down reagents for multiplex (rt)RT-PCR assays were developed at Tetracore, and work in both laboratories and remote/low resource areas. The T-COR 8 user experience has been designed to be easy to operate C2T cartridge, no pipetting or specialized fluid handling operations are necessary. A bar code is read directly from the C2T cartridge. The software automatically selects the assay protocol and data analysis parameters based on the bar code. All of the buffers necessary for sample processing are stored in the snap-valve bulb of the C2T sample processing device, and all of the reaction components necessary to run PCR are dried down in the C2T cartridge (stable for 12 months at room temperature). To collect a sample the user swabs the affected area (oral, NP, or nasal) or collects blood from a finger-stick, cracks the snap-valve, and squeezes the bulb, which combines the sample appropriate proprietary sample processing buffers with the sample. The user then drops between 4-6 drops into the C2T cartridge (it has been designed to automatically meter the correct volume regardless of the number of drops added to the sample reservoir) the C2T cartridge is then closed and the run start. During the run, the data for each channel is automatically analysed as detected or not detected by proprietary Smart C_T™ algorithm. At the end of the run, the individual Smart C_T analysis results are interpreted into an automatically generated report table (figure 1c). All results are stored on the T-COR 8 and both the most recent results and previous results are always accessible to the user. An operator may only see the truth tables (figure 1c) and/or amplification curves (figure 1d). The T-COR 8 software is cloud-ready, giving the user flexibility in accessing the PCR results. T-COR8 can be accessed by various users at any location using a VPN Client, once the user has logged into a VPN server via LAN or, portable 3G / 4G hotspot or cell phone.

The T-COR 8 and C2T integrated system for the direct detection of dengue virus, chikungunya virus, and zika virus in a Tetracore developed triplex has been evaluated in the laboratory setting using serum samples sent in to a central/reference laboratory. This was a comparison between traditional RNA extraction methods with direct sample preparation using C2T sample processing device. Dengue virus had been previously evaluated by spiking cell culture derived DENV in normal human blood samples[1] (both finger prick and venous puncture for blood collection were tested in this system) the testing performed using the direct C2T and T-COR 8 integrated system gave similar or better results as with laboratory extraction methods on the T-COR 8 and ABI 7500 instrument.

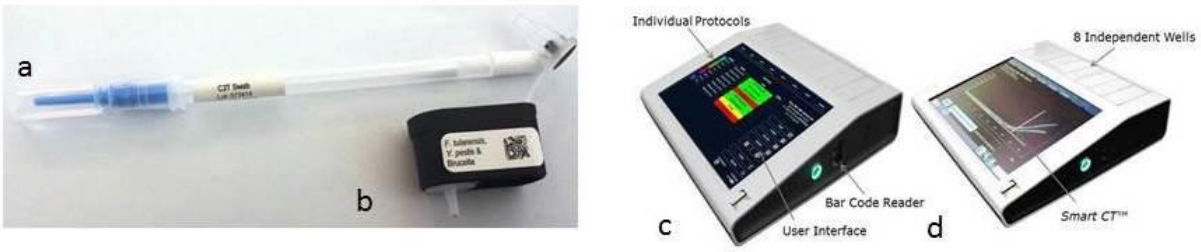

Figure 1: a) C2T collection/ processing device; b)C2T nucleic acid amplification cartridge; c) Results displayed as table on T-COR 8; d) Amplification curves displayed on T-COR 8

1) William Nelson, Tracy Fecteau, et al, Rapid direct detection of dengue virus in blood samples by real time - polymerase chain reaction (rt-pcr) using a portable point-of-care device, abstract # 1229, 30th Annual Clinical Virology Symposium, April 27– 30 in Daytona Beach, FL