

Compatibility of saliva collected using OMNIgene®•ORAL (OM-505) with the Abbott *m*2000*rt* RealTime System for the detection of viral RNA

OMNIgene*•ORAL (OM-505) is designed to collect and stabilize microbial DNA and RNA from saliva. In this document, we demonstrate that saliva collected with this kit is fully compatible with Abbott m2000rt instrument for the detection of RNA from viruses (i.e., HIV and HCV).

Introduction

The detection of human viruses is essential for the effective assessment and treatment of patients. Current systems provide streamlined workflows for nucleic acid extraction from pathogens of interest; followed by their detection using sensitive techniques (i.e., qPCR). These systems can provide qualitative and/or quantitative results as required by practitioners. Proper assessment requires high quality samples to provide diagnostic confidence and to avoid false negatives. The detection of some viruses is particularly challenging due to the labile nature of their nucleic acids and structure. Sample collection of potentially infectious samples is also challenging, as it can cause unintended exposure of medical personal and other patients to pathogens. Infectious agents transmitted through contact with oral fluids (i.e., influenza) are particularly difficult to control because they are easily transmitted from person to person.

OMNIgene•ORAL is an all-in-one system for the collection and ambient temperature stabilization of microbial DNA and RNA present in saliva. This kit allows for the painless and non-invasive collection of high quality samples that facilitate nucleic acid detection from viruses and bacteria. The Abbott *m*2000*rt* instrument is broadly used for the detection of RNA viruses in research and clinical settings. This instrument is recognized for its accuracy and efficient workflow.

This technical bulletin describes the detection of human HCV Armored RNA or Human Immunodeficiency Virus -1 spiked into saliva samples collected with OMNIgene•ORAL and processed using the Abbott *m*2000*rt* RealTi*me* System.

Material and methods

Alcohol was added to the OMNIgene•ORAL/ saliva samples to facilitate integration and detection with the Abbott *m*2000*rt* instrument. This step was validated using control samples spiked with HCV Armored RNA (AsuraGen). All controls were included as per manufacturer protocol.

Saliva samples were collected with OMNIgene•ORAL as per instructions. The samples were spiked with a known amount of HCV Armored RNA (low copy, 2.95 LOG [IU/mL]; medium copy, 4.95 LOG [IU/mL] and high copy, 6.95 LOG [IU/mL] or HIV virus from the plasma of infected patients (low copy, 2.70 LOG [IU/mL]; medium copy, 3.40 LOG [IU/mL] and high copy, 4.18 LOG [IU/mL]). The samples were briefly mixed. Alcohol was added to all samples prior to processing. All samples were processed in triplicate with the Abbott *m*2000*rt* RealTi*me* System for the detection of HCV and HIV.

Results

Preliminary results suggested that the addition of a small amount of alcohol facilitates the integration of OMNIgene•ORAL samples with automated extraction systems such as the Abbot *m*2000*rt*. Alcohol was added to control samples containing known amounts of HCV Armored RNA (low, medium and high copy). Quantitative results of the control with or without alcohol showed equivalent amounts of RNA.

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For research use only, not for use in diagnostic procedures. Not available for clinical diagnostic use in the United States. These results confirmed that the performance of the Abbott instrument is not affected by the presence of alcohol in the sample (Figure 1).



Figure 1: Detection of RNA from HCV Armored RNA using Abbott m2000rt instrument from spiked control samples with our without alcohol. No difference was observed between the control samples. Left – internal control (provided by the manufacturer); center – spiked control samples; right – spiked control samples containing alcohol.

Saliva samples collected using OMNIgene•ORAL were spiked with HCV Armored RNA or HIV virus (low, medium and high viral loads). OMNIgene•ORAL spiked samples were processed as previously described (see above). No differences in the HCV and HIV viral RNA quantification were observed between the spiked OMNIgene•ORAL/ saliva sample and the corresponding controls (Figure 2). These results indicate that saliva samples collected with OMNIgene•ORAL can be reliably used for the detection of viral RNA using the Abbott *m*2000*rt* RealTi*me* System.



Figure 2: Detection of viral RNA from OMNIgene•ORAL/saliva samples using Abbott m2000rt instrument. Samples were spiked using known amounts of HCV Armored RNA (top) or HIV virus (bottom). No differences were observed between saliva samples and the corresponding control samples. Left – internal control; center – spiked control samples; right – spiked OMNIgene•ORAL/saliva samples.

Conclusions

Saliva collected with OMNIgene•ORAL is fully compatible with the Abbott *m*2000*rt* RealTi*me* System for the detection of RNA from human viruses.

Some DNA Genotek products may not be available in all geographic regions.

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