ERINHA-Advance TNA project NESARSDia:

A research collaboration on SARS-CoV-2 with QIAGEN, Germany and Medical University of Graz, Austria

The SARS-CoV-2 pandemic led to an unprecedented requirement for diagnostic testing, challenging not only health care workers and laboratories, but also manufacturers. Quantitative RT-PCR for the detection of SARS-CoV-2 from various specimen types is considered as diagnostic gold standard. Broad testing of people is one of the keys for controlling SARS-CoV-2 infections. But the decisive impact of pre-analytical variables on test results is by far not sufficiently known and consequently not built into full diagnostic workflows. The ERINHA-Advance TNA project NESARSDia with the cooperation partners QIAGEN GmbH in Hilden, Germany, and the team of the BSL-3 laboratory at the Medical University Graz, Austria, has been funded to improve SARS-CoV-2 next generation diagnostics for wide use in European and global healthcare systems. This is intended to be achieved by complete sample-to-insight workflows covering all diagnostic workflow steps from dedicated patient specimen collection, stabilization devices, transport, storage and processing until the final RT-PCR assay. The pre-analytical handling of patient specimens is a critical factor to ensure reliable and valid test results, and has not been systematically investigated so far. Therefore, NESARSDia examined the effect of storage duration (up to 96 hours to mimic transport delays) and temperature (20°C and 37°C to simulate not temperature controlled specimen transport during summer) on a selection of the most commonly used naso/oropharyngeal swab and saliva collection devices by spiking with defined SARS-CoV-2 copy numbers. The tested swab devices showed no significant decrease of viral RNA copy numbers when stored at room temperature except one system when stored for 96 hours. At 37°C a significant reduction of SARS-CoV-2 RNA was measured in three out of four swab devices. Viral RNA levels remained unchanged in all seven saliva devices tested as well as in unstabilized saliva when stored for 96 h at room temperature. However, one device showed marked RNA copy number loss at 37°C. All tested

saliva collection devices inhibited the SARS-CoV-2 infectivity immediately, whereas SARS-CoV-2 remained infectious in the examined swab transport systems which are designed to be used for viral or bacterial growth in cell culture systems. Further experimental series and examinations of other relevant respiratory viruses and the evaluation of time and resource saving high-throughput workflows are in progress. These results are planned to be used for one or more new CEN standard documents projects at the European Committee for Standardization for pre-analytic workflows applied to SARS-CoV-2 and other respiratory viruses in vitro diagnostics.

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