



d. Diagnostics

00176 MULTICENTRE EVALUATION OF THE SIMPLEXA™ COVID-19 DIRECT ASSAY

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Background One of the drawback of most COVID-19 RT-PCR assays is the need for nucleic acid extraction from clinical samples. The Simplexa™ COVID-19 Direct assay is performed directly from nasopharyngeal swab specimens and thus allows rapid testing of up to eight samples simultaneously. The objective of this study was to perform a multicentre evaluation of this assay.

Methods The validation study was organized by the National Virology Laboratory and was performed in the Clinical Microbiology laboratories of the Tel-Aviv Sourasky, Rabin and Poria Medical centers. The Simplexa™ COVID-19 Direct assay is performed on the LIAISON® MDX platform (DiaSorin) and detects the S and the ORF1 genes. The comparator method was the Allplex™ 2019-nCoV Assay (Seegene) that detects the N, E and RdRP genes. The comparison included positive samples with low (<20), medium (20-30) and high (>30) Ct values as well as negative samples.

Results The study included 80 positive samples. The Simplexa™ COVID-19 Direct assay accurately detected 76 of the 80 samples (sensitivity- 95%). The Ct values reported by the Simplexa™ COVID-19 Direct assay were equivalent to the values reported by the Allplex™ 2019-nCoV Assay at the low (n=13) and middle (n=23) Ct ranges. In the high Ct range (n=38), the values were equivalent, higher and lower in 21, 9 and 4 samples, respectively; four samples were not detected by the Simplexa™ COVID-19 Direct assay. All ten negative samples were also tested negative by the Simplexa™ COVID-19 Direct assay.

Conclusions The Simplexa™ COVID-19 Direct assay provides an important tool for rapid testing of COVID-19, albeit caution must be taken if samples with suspected low viral load are tested.

Conflict of interest Nothing to declare.