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REPORT OF AN INTERNATIONAL COLLABORATIVE STUDY TO EVALUATE A WHO HIV-1 RNA GENOTYPE REFERENCE PANEL

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Summary

Twenty-eight laboratories from 16 countries participated in a collaborative study to evaluate an HIV-1 RNA Genotype Reference Panel (NIBSC Code 01/466) for use with nucleic acid-based tests (NAT). The Reference Panel consisted of 11 coded samples representing different HIV-1 genotypes (subtypes A, B, C, D, AE, F, G, AG-GH, groups N and O) as well as a negative diluent control. Each laboratory assayed the eleven panel members concurrently with the 1st International Standard for HIV-1 RNA (NIBSC Code 97/656) on at least three separate occasions and the data collated and analysed at NIBSC. Twenty-nine sets of data were received, 19 from quantitative and 10 from qualitative assays, with six different commercial assays and five “in-house” assays represented. The results showed that subtypes A-E were detected consistently by most assays, although there were minor discrepancies between assays. However, a variety of problems occurred with the detection and quantitation of the other subtypes and groups. In particular the Nuclisens assay had difficulty in the detection of subtypes F, G, AG-GH and group N. Most assays failed to detect the group O representative. The study highlighted the shortcomings of some molecular assays particularly in detection of some of the non-B genotypes, which are important viruses in the global AIDS pandemic and illustrated the value of a well-characterized genotype panel. It was proposed that the HIV-1 RNA Genotype Reference Panel be established as a WHO Reference Reagent.

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