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P1900 Delayed plasma separation may contribute to false identification of low-level viraemia In HIV-1 viral-load monitoring

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Background: High accuracy of plasma viral load (VL) determination in the low range is crucial for patient management. We investigated the potential impact of delayed plasma separation in clinical routine using specimens from patients with specific characteristics of VL response to treatment over time by direct comparison of the more recently introduced Cobas 6800 HIV-1 assay to RealTi*m*e HIV-1.

Materials/methods: Excess sample materials from routinely tested patients on ART were selected retrospectively based on the actual VL and the course of VL history (RealTi*m*e) during the past two years: Group-A (N=30): successful long-term suppression ("undetectable") for ≥2 years (median treatment 14 years), Group-B (N=50): short-term suppression ("detected" <50 copies/ml) for ≥6 months (median treatment 5 year) and Group-C (N=20): consistent low-level viremia of 50-200 copies/ml (median treatment 2 years). Plasma separation was performed within 4 (T1), after 24 (T2) and after 48 (T3) hours from blood-collection.

Results: Group-A: VLs observed with both tests were <50 copies/ml, regardless of the time between blood-collection and plasma separation. Group-B: 10/50 (20%) samples tested with Cobas exceeded the clinical threshold of 50 copies/ml at T2 (median: 68 copies/ml). At T3, VLs from 8 of the 10 samples further increased (median: 112 copies/ml) and 4 samples exceeded 200 copies/ml. Increased VLs were found with RealTi*m*e in 4/50 samples (8%) at T2 (median: 74 copies/ml), two further elevated to VLs of 66 and 102 copies/ml at T3, respectively. Group-C: At T2, 5/20 (25%) samples quantified >200 copies/ml with Cobas and 2/20 (10%) with RealTi*m*e, respectively and remained above this threshold at T3.

Conclusions: Our data suggest that delaying plasma separation beyond the manufacturers´ recommendations (24 h) may increase the risk of false identification of low-level viremia above the clinical threshold of 50 copies/ml and might contribute to false patient management, particularly in samples from patients with a history of detectable VL <50 copies/ml. RealTi*m*e appears to be less affected by delayed plasma separation compared to Cobas 6800, which might be associated with the size of the intracellular HIV reservoir and potential release of proviral DNA from host cells disintegrating upon extended storage of whole blood.