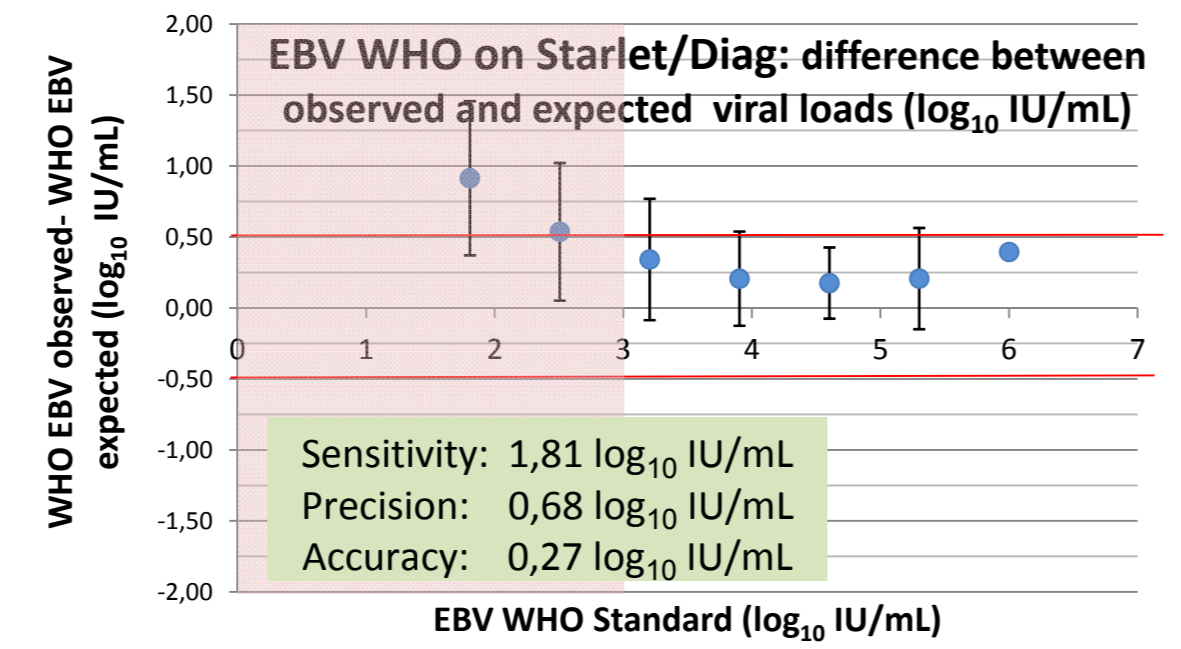
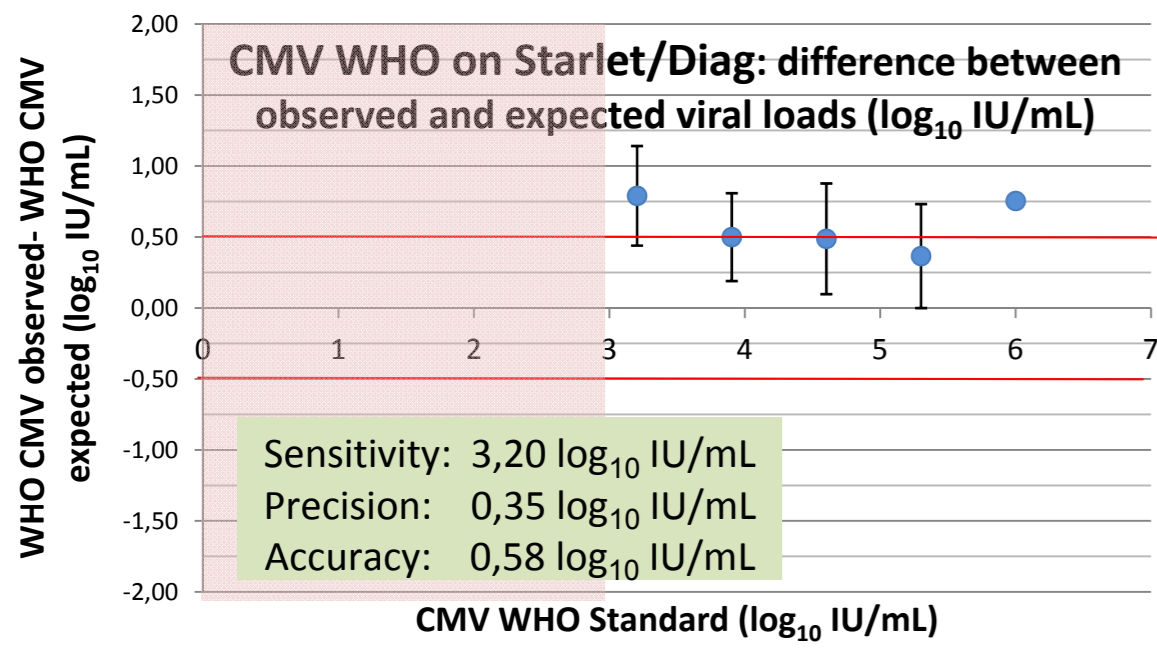
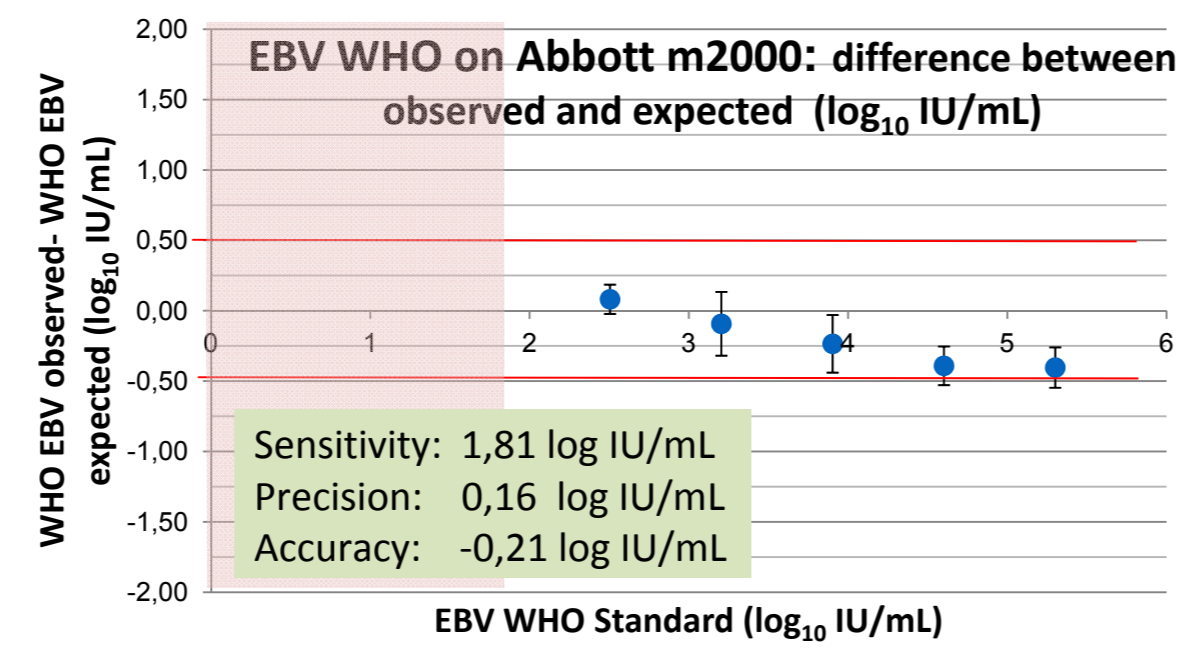
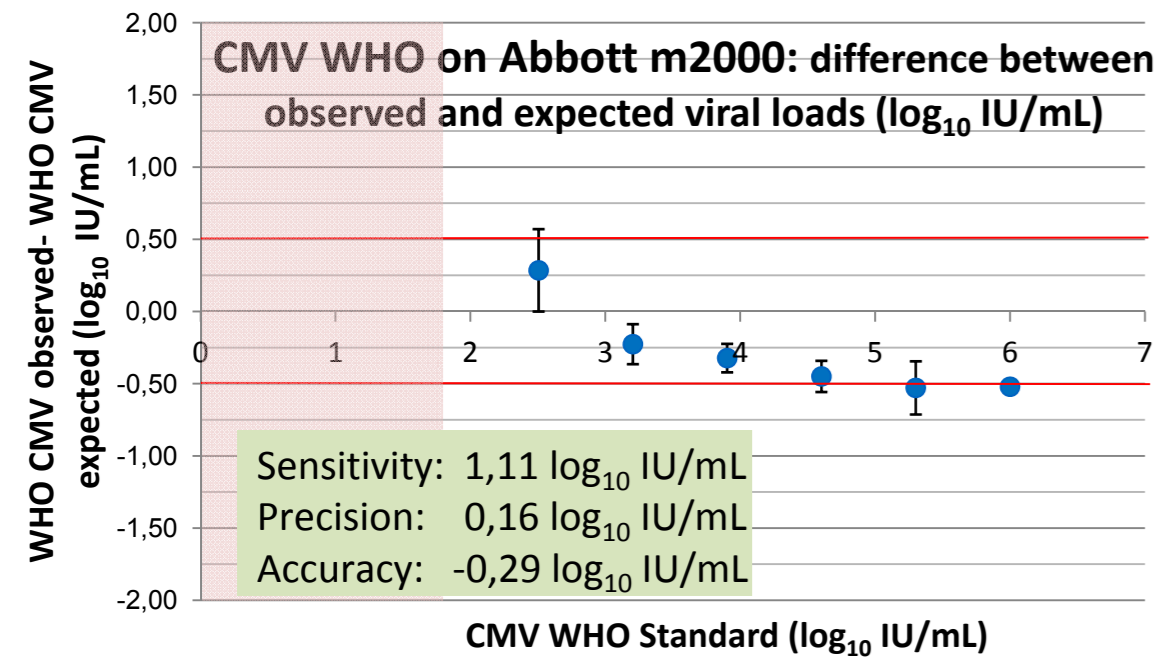


**Aim of this study.** We have evaluated the Abbott RealTime EBV and CMV quantitative assays performed on the fully automated Abbott *m2000* platform. This platform offers the possibility to run both assays for a unique sample in a single run using a double extraction.

**Design.** We have compared the performance of the Abbott system to our currently semi-automated method consisting of a NucleoMag® Blood 200 µL (Macherey-Nagel) DNA extraction automated on a Starlet (Hamilton) platform followed by manually processed real-time PCRs using the CMV and EBV Diagenode assays (H-DiaCMVQ and H-DiaEBVQ™, respectively) on a ABI7500 (=Starlet/Diag). Serial dilutions of CMV and EBV WHO International Standards in negative whole blood were used to test the sensitivity (as 100% of detection rate), the precision (mean of SD) and the accuracy (mean of difference between expected and observed viral loads) of the assays on both platforms.



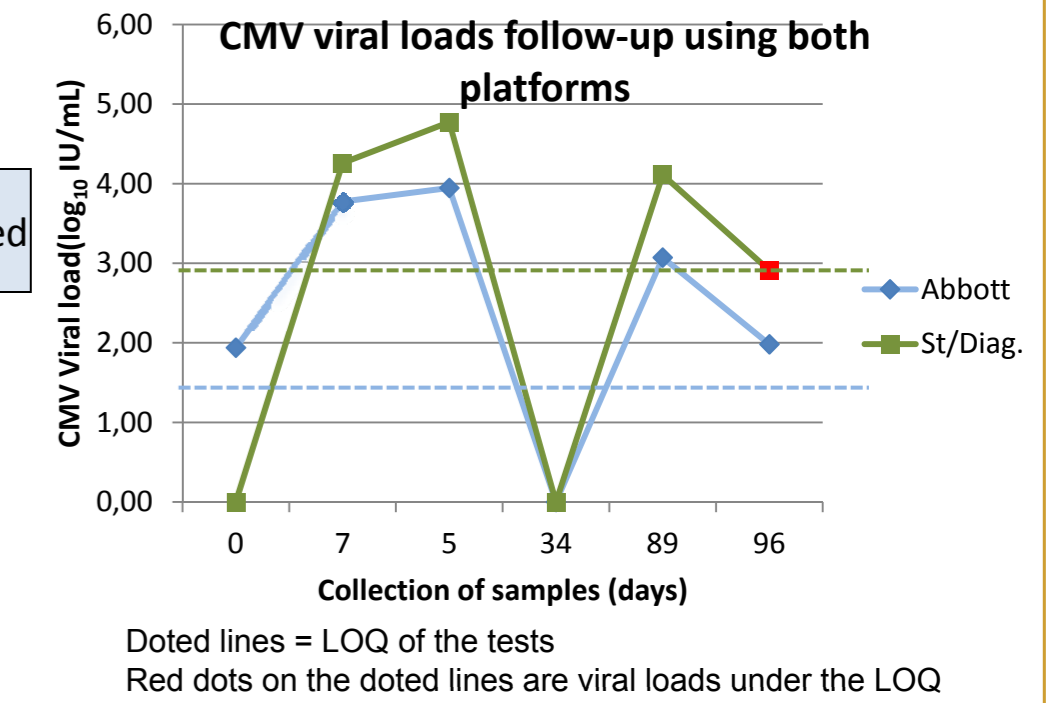
Pink zones = under the announced limit of quantification (LOQ) / Blue dots: quantification rate = 100%

**Results.** The Abbott RealTime CMV assay exhibits a higher sensitivity, precision as well as a higher quantification rate at low viral loads than our routine test while the Abbott RealTime EBV assay performances are similar in terms of sensitivity to those of the Nucleomag/Diagenode EBV test, but is more precise than this late one. The Abbott CMV and EBV assays are more accurate than our routine tests but exhibit a slight underestimation of the viral loads (-0.29 and -0.21 log IU/mL respectively).

Clinical samples were also challenged on both platforms. Among the 86 clinical samples tested, 42 were quantified by the Abbott RealTime CMV assay but only 23 with the Starlet/Diagenode method (including 8 samples undetected). Twenty-two clinical samples were quantified by both methods showing a higher average viral load of 0.79 log<sub>10</sub> IU/mL for the Starlet/Diagenode method as illustrated by the CMV viral load follow-up of a patient.

|                                  |              |                                       |       |              |          |    |          |
|----------------------------------|--------------|---------------------------------------|-------|--------------|----------|----|----------|
|                                  |              | Starlet/Diagenode CMV (nb of samples) |       |              | 42       | 48 | Detected |
|                                  |              | Quantified                            | < LOQ | Not detected |          |    |          |
| Abbott m2000 CMV (nb of samples) | Quantified   | 22                                    | 12    | 8            | 42       | 48 | Detected |
|                                  | < LOQ        | 1                                     | 1     | 4            | 6        |    |          |
|                                  | Not detected | 0                                     | 2     | 36           | 38       |    |          |
|                                  |              | 23                                    | 15    | 48           | 86       |    |          |
|                                  |              | 38                                    |       |              | Detected |    |          |

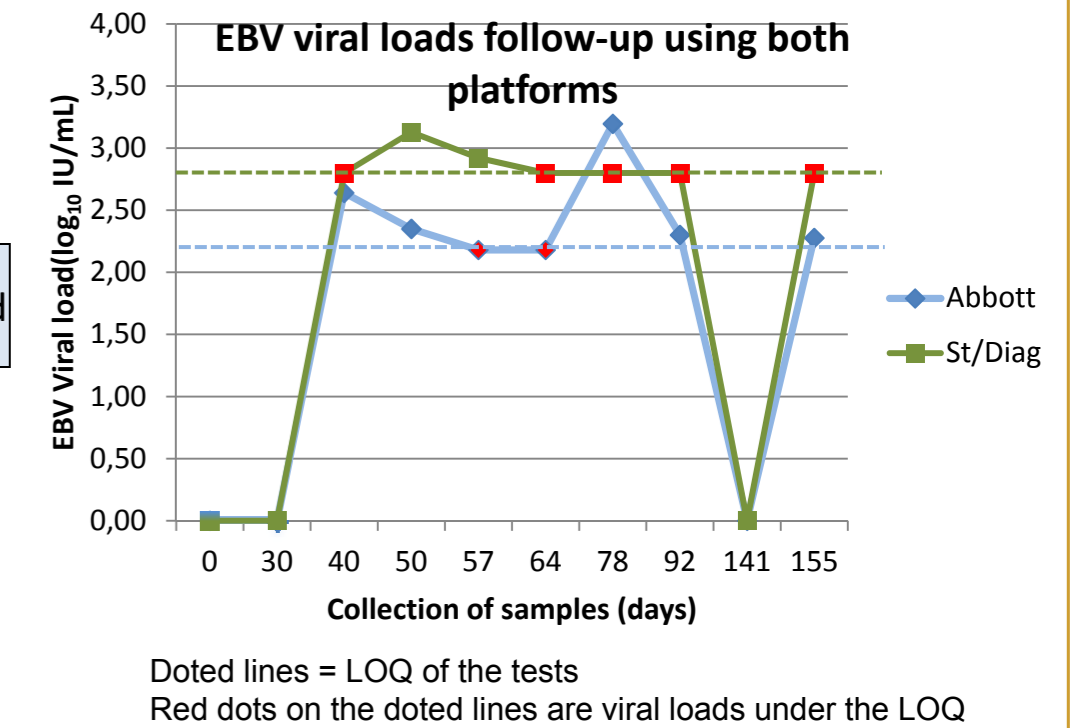
Comparison of CMV detection and quantification in clinical samples using Abbott *m2000* vs Starlet/Diagenode platforms



Among the 86 clinical samples tested, 42 were quantified by the Abbott RealTime EBV assay and 34 with the Starlet/Diagenode method. Thirty-one samples were quantified by both methods with a slightly higher average viral load of 0.18 log<sub>10</sub> IU/mL with the Starlet/Diagenode method as illustrated by the EBV viral load follow-up of a patient.

|                                  |              |                                       |       |              |          |    |          |
|----------------------------------|--------------|---------------------------------------|-------|--------------|----------|----|----------|
|                                  |              | Starlet/Diagenode EBV (nb of samples) |       |              | 42       | 54 | Detected |
|                                  |              | Quantified                            | < LOQ | Not detected |          |    |          |
| Abbott m2000 EBV (nb of samples) | Quantified   | 31                                    | 10    | 1            | 42       | 54 | Detected |
|                                  | < LOQ        | 3                                     | 5     | 4            | 12       |    |          |
|                                  | Not detected | 0                                     | 3     | 29           | 32       |    |          |
|                                  |              | 34                                    | 18    | 34           | 86       |    |          |
|                                  |              | 52                                    |       |              | Detected |    |          |

Comparison of EBV detection and quantification in clinical samples using Abbott *m2000* vs Starlet/Diagenode platforms



**Conclusions.** The Abbott RealTime CMV and EBV quantitative assays performed on the fully automated Abbott *m2000* platform are accurate, sensitive and precise and can be used routinely for the quantification of those viruses in blood. Furthermore, this platform allows the processing of both assays in parallel which is valuable for the management of the workflow in clinical laboratory settings.