27th ECCMID Vienna, Austria 22 – 25 April 2017
The congress of ESCMID

Session: EV009 Diagnostic virology

Category: 1g. Diagnostic virology (other than hepatitis & HIV)

22 April 2017, 08:45 - 15:30
EV0100

Monitoring CMV-DNA in whole blood with a highly automated platform

Jean-Michel Mansuy[1], Catherine Hasle[1], Karine Sandres-Saune[2], Jacques Izopet[2]

[1]*Ch Toulouse; Virology*

[2]*Ch Toulouse; Virology, Physiopathology, Unité Inserm U563*

Background: The VERIS™/MDx System CMV Assay® is a fully-automated platform already assessed for monitoring CMV-DNA in plasma samples (Mengelle et al. 2016).
We evaluated its suitability for monitoring CMV-DNA in whole blood samples.

Material/methods: Analytical and clinical performances were evaluated from potassium-EDTA samples collected among hospitalized patients tested prospectively with the in-house technique (limit of detection 74 IU/ml).
After storage at -20°C pending batch analysis the specimens were retested with the routine assay and with the VERIS™/MDx System CMV Assay®.
XL stat 2014.1.09 and GraphPad Prism 5.03 were used for statistical analyses.

Results: The specificity was 98.8 % [CI 95%:93.5-99.9]. Intra and inter-assay reproducibilities were respectively 0.14, 0.15 and 0.16 $\log_{10}$ IU/ml and 0.13, 016 and 0.13 $\log_{10}$ IU/ml for expected values of 4.7, 3.7 and 2.7 $\log_{10}$ IU/ml. The lower limit of detection was 57 IU/ml [CI 95%: 47-75], and the assay was linear from 3.83 to 6.83 $\log_{10}$ IU/ml.
112 whole blood samples that tested positive prospectively in routine use (mean viral load: 3.45 $\log_{10}$ IU/ml, median: 3.35 $\log_{10}$ IU/ml, range: 6.73–1.23 $\log_{10}$ IU/ml) were selected for further analysis.

- 104/112 (92.8%) were positive when retested with the routine technique (mean viral load: 3.62 $\log_{10}$ IU/ml, median: 3.52 $\log_{10}$ IU/ml, range: 7.32–2.68 $\log_{10}$ IU/ml).
- 92/112 (82.1%) were positive with the VERIS™/MDx System CMV Assay® (mean viral load: 3.31 $\log_{10}$ IU/ml, median: 3.23 $\log_{10}$ IU/ml, range: 6.96–1.48 $\log_{10}$ IU/ml), two samples tested negative and 18 samples gave invalid results (internal control negative).
- 88/112 (78.6%) samples gave concordant results between both assays: CMV-DNA was detected in 87 samples and one sample was negative. Six samples gave discrepant results: five samples tested positive with the VERIS™/MDx System CMV Assay® and negative with the in-house method (1.48 to 3.00 $\log_{10}$ IU/ml), and one sample gave the opposite results (2.55 $\log_{10}$ IU/ml). 18 samples gave

invalid results (internal control negative): 16 positives (mean viral load 3.38 log_{10} IU/ml, median: 3.25 log_{10} IU/ml, range: 5.10–2.5 log_{10} IU/ml) and 2 negatives.

- The results for the positive (87) samples were highly concordant (r=0.83, p<0.0001), slope of Deming regression 1.23 [CI 95%: 1.05-1.41] and y-intercept intercept 0.94 [CI 95%: -1.84 to -048].

The viral loads detected by the VERIS™/MDx System CMV Assay® and the home-brew assay were similar (-0.30 log_{10} IU/ml).

Patient monitoring on 22 samples collected from 3 immunosuppressed patients showed similar profiles with overlapping patterns and variations in the same direction. Only one discrepancy was observed on the first sample of one patient's follow-up (positive with the VERIS™/MDx System CMV Assay®).

Conclusions: The VERIS™/MDx System CMV Assay® satisfies quality requirements for routine monitoring of DNA-CMV in whole blood samples. Further investigations are needed for analysis of invalid results.