

Torino, 12/09/2017

## TO WHOM IT MAY CONCERN

ELITechGroup SpA manufacturer of IVD kits based on Real Time PCR methods hereby declares that use of a wide range of above kits have been validated for IVD purposes in association with nucleic extraction methods from different matrixes performed on the ELITeGALAXY instrument, an automated platform based on the following configuration:

- MICROLAB<sup>®</sup> STARlet IVD workstation
- Microlab<sup>®</sup> ML STAR Software Venus Two IVD
- ELITe GALAXY Consumable Accessories
- ELITe GALAXY Installation Software

Validated assays and matrixes are reported hereafter:

- CMV on Whole Blood and Plasma
- EBV on Whole Blood and Plasma
- BKV on Plasma and Urine
- VZV on Whole Blood, Plasma and CSF
- HSV1 on Whole Blood, Plasma and CSF
- HSV2 on Whole Blood, Plasma and CSF
- HHV6 on Whole Blood, Plasma and CSF
- Enterovirus on CSF and Plasma
- HHV8 on Whole Blood and Plasma
- Parvo B19 on Whole Blood and Plasma
- Adenovirus: on Whole Blood and Plasma
- JCV on Plasma and Urine
- C. difficile on Stool

Quality Assurance & Regulatory Affairs

