Viral load testing has become a clinical standard of care for monitoring viral infection in patients undergoing anti-viral therapy after solid organ or bone marrow transplantation. The World Health Organization (WHO) has defined biological reference standards to allow comparison of biological measurements worldwide and provide a basis for a uniform reporting system. The International Standard is the reference biological material to calibrate quantitative molecular diagnostic methods in order to present results of molecular analysis as International Units.

ELITechGroup Molecular Diagnostics brings the benefits of WHO Standardization to its industry leading ELITe MGB with the introduction of WHO Conversion Factors for all kits allowing laboratories to report results of quantitative analyses in WHO International Units.
The World Health Organization (WHO) has defined international standards for titration of biological specimens containing specific pathogens including Cytomegalovirus (CMV), Epstein-Barr virus (EBV) and Parvovirus B19. These standards are the primary reference material necessary to calibrate quantitative molecular diagnostic methods to ensure traceability and uniformity. Calibration of ELITe MGB kits to the WHO Standards leads to correct reporting and interpretation of patient results to ensure proper monitoring of disease progression and interventional therapy.

As required by IVD directive, 98/79/EC, ELITechGroup Molecular Diagnostics has determined conversion factor* for Cytomegalovirus, Epstein-Barr virus and Parvovirus B19 Real-Time PCR kits that permits conversion as International Units (I.U.) of quantitative molecular analysis results.

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**International Units - a complete panel**

### CMV

Conversion factor assigned using

“1st WHO International Standard for Human Cytomegalovirus for Nucleic Acid Amplification Techniques”

code09/162, NIBSC, United Kingdom

- **CMV ELITe MGB® Kit**
- **CMV ELITe Standard**

- **RTK015PLD**
- **STD015PLD**

### EBV

Conversion factor assigned using

“1st WHO International Standard for Human Epstein Barr Virus for Nucleic Acid Amplification Techniques”

code09/260, NIBSC, United Kingdom

- **EBV ELITe MGB® Kit**
- **EBV - ELITe Positive Control**
- **EBV ELITe Standard**

- **RTS02OPLD**
- **CTR02OPLD**
- **STD02OPLD**

### Parvovirus B19

Conversion factor assigned using

“2nd WHO International Standard for Parvovirus B19 DNA for Nucleic Acid Amplification (NAT) Assay”

code99/802, NIBSC, United Kingdom

- **Parvovirus B19 ELITe MGB® Kit**
- **Parvovirus B19 - ELITe Pos Con**
- **Parvovirus B19 ELITe Standard**

- **RTS07OPLD**
- **CTR07OPLD**
- **STD07OPLD**

*Conversion factor determined by ELITechGroup Molecular Diagnostics allows the expression of results obtained by use of kit as International Units applying an easy formula reported in the Instructions for Use (IFU).*

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ELITechGroup Molecular Diagnostics has a quality management system certified by BSI in compliance with ISO 9001:2008 and ISO 13485:2012 standard

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