

Complete intra-laboratory validation of a LAL assay for bacterial endotoxin determination in EBV-specific cytotoxic T lymphocytes

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In the originally published version of this article, Table 3 had some errors. In particular, the authors became aware of these errors when they prepared a webinar presentation in which they presented their validation work. The original Table 3 reported values for the tests performed by operator # 1, for dilutions G and H, different from the original raw data. Furthermore, by reanalyzing all the data in this table, we noticed that all the standard deviation measurements were calculated incorrectly. These have now been corrected online. The authors regret this error.

Table 3. Operational/Performance Qualification results

| Operator | RSE dilution suspension | Spike Rxn Time CV ³ | Spike Recovery | Expected value | Measured value | Average | Standard Deviation | RSE Recovery % |
|--------------|-------------------------|--------------------------------|----------------|----------------|----------------|--------------------|-----------------------|----------------|
| QC manager | F | 1.2% pass | 83% pass | <0.02 EU/mL | 0.016 EU/mL | 0.015 | 1×10^{-3} | 80 |
| | | 1.2% pass | 88% pass | <0.02 EU/mL | 0.014 EU/mL | | | 70 |
| | | 2.4% pass | 59% pass | <0.02 EU/mL | 0.015 EU/mL | | | 75 |
| | G | 1.3% pass | 84% pass | <0.05 EU/mL | 0.039 EU/mL | 0.033 | 5.29×10^{-3} | 78 |
| | | 4.7% pass | 97% pass | <0.05 EU/mL | 0.029 EU/mL | | | 58 |
| | | 1.8% pass | 83% pass | <0.05 EU/mL | 0.031 EU/mL | | | 62 |
| H | 6.3% pass | 97% pass | <0.01 EU/mL | 0.013 EU/mL | 0.013 | 1×10^{-3} | 130 | |
| | 0.3% pass | 81% pass | <0.01 EU/mL | 0.014 EU/mL | | | 140 | |
| | 4.1% pass | 93% pass | <0.01 EU/mL | 0.012 EU/mL | | | 120 | |
| Operator # 1 | F | 10.5% pass | 114% pass | <0.02 EU/mL | 0.018 EU/mL | 0.018 | 5.77×10^{-4} | 90 |
| | | 0.6% pass | 121% pass | <0.02 EU/mL | 0.019 EU/mL | | | 95 |
| | | 3.2% pass | 116% pass | <0.02 EU/mL | 0.018 EU/mL | | | 90 |
| | G | 4.9% pass | 90% pass | <0.05 EU/mL | 0.039 EU/mL | 0.044 | 8.96×10^{-3} | 78 |
| | | 14.4% pass | 142% pass | <0.05 EU/mL | 0.038 EU/mL | | | 76 |
| | | 9.5% pass | 72% pass | <0.05 EU/mL | 0.054 EU/mL | | | 108 |
| H | 11.0% pass | 100% pass | <0.01 EU/mL | 0.009 EU/mL | 0.009 | 0 | 90 | |
| | 0.9% pass | 98% pass | <0.01 EU/mL | 0.009 EU/mL | | | 90 | |
| | | 6.4% pass | 88% pass | <0.01 EU/mL | 0.009 EU/mL | | | 90 |

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Table 3. Continued

| Operator | RSE dilution suspension | Spike Rxn Time CV ^a | Spike Recovery | Expected value | Measured value | Average | Standard Deviation | RSE Recovery % |
|--------------|-------------------------|--------------------------------|----------------|----------------|----------------|-----------------------|-----------------------|----------------|
| Operator # 2 | F | 2.2% pass | 104% pass | <0.02 EU/mL | 0.017 EU/mL | 0.017 | 5.77×10^{-4} | 85 |
| | | 0.3% pass | 92% pass | <0.02 EU/mL | 0.017 EU/mL | | | 85 |
| | | 0.0% pass | 93% pass | <0.02 EU/mL | 0.016 EU/mL | | | 80 |
| | G | 0.3% pass | 92% pass | <0.05 EU/mL | 0.055 EU/mL | 0.049 | 6.51×10^{-3} | 110 |
| | | 3.3% pass | 107% pass | <0.05 EU/mL | 0.042 EU/mL | | | 84 |
| | | 1.6% pass | 133% pass | <0.05 EU/mL | 0.049 EU/mL | | | 98 |
| H | 4.5% pass | 83% pass | <0.01 EU/mL | 0.008 EU/mL | 0.010 | 1.53×10^{-3} | 80 | |
| | 1.6% pass | 105% pass | <0.01 EU/mL | 0.010 EU/mL | | | 100 | |
| | 0.6% pass | 158% pass | <0.01 EU/mL | 0.011 EU/mL | | | 110 | |
| Operator # 3 | F | 8.1% pass | 71% pass | <0.02 EU/mL | 0.015 EU/mL | 0.021 | 6.03×10^{-3} | 75 |
| | | 7.4% pass | 78% pass | <0.02 EU/mL | 0.027 EU/mL | | | 135 |
| | | 2.6% pass | 113% pass | <0.02 EU/mL | 0.020 EU/mL | | | 100 |
| | G | 7.0% pass | 82% pass | <0.05 EU/mL | 0.046 EU/mL | 0.042 | 4.04×10^{-3} | 92 |
| | | 11.2% pass | 106% pass | <0.05 EU/mL | 0.043 EU/mL | | | 86 |
| | | 7.8% pass | 105% pass | <0.05 EU/mL | 0.038 EU/mL | | | 76 |
| | H | 4.9% pass | 60% pass | <0.01 EU/mL | 0.007 EU/mL | 0.010 | 3×10^{-3} | 70 |
| | | 3.8% pass | 95% pass | <0.01 EU/mL | 0.013 EU/mL | | | 130 |
| | | 13.2% pass | 72% pass | <0.01 EU/mL | 0.010 EU/mL | | | 100 |

^aSpike Rxn Time CV, spike reaction time coefficient of variation