

RESULTS (continued)

**Table 1
Titer Results**

Sample	Replicate(s)	Contact Time	Titer (Log ₁₀ TCID ₅₀ /mL)	Volume (mL)	Volume Correction ^a	Viral Load (Log ₁₀ TCID ₅₀)
Virus Stock Titer Control (VST)	N/A	N/A	8.05	-	-	-
Cell Viability Control (CVC)			no virus was detected, cells remained viable; media were sterile			
Virus Recovery Control (VRC)	1	10 minutes	7.30	4	2	8.20
	2		7.55	4	2	8.45
	3		7.05	4	2	7.95
VRC - Average	-	-	-	-	-	8.20
FPQM (Lot No. FP206141)	1	15 seconds	≤ 2.83 *	4	2	≤ 3.73
	2		≤ 2.83 *	4	2	≤ 3.73
	3		≤ 2.83 *	4	2	≤ 3.73
	1	60 seconds	≤ 2.83 *	4	2	≤ 3.73
	2		≤ 2.83 *	4	2	≤ 3.73
	3		≤ 2.83 *	4	2	≤ 3.73
	1	10 minutes	≤ 2.83 *	4	2	≤ 3.73
	2		≤ 2.83 *	4	2	≤ 3.73
	3		≤ 2.83 *	4	2	≤ 3.73

**Table 2
Neutralizer Effectiveness and Cytotoxicity Related Controls
FPQM (Lot No. FP206141)**

Dilution***	Neutralization Effectiveness Viral Interference	Cytotoxicity
10 ⁻¹	Virus detected in all 4 wells	Cytotoxicity observed in all 4 wells
10 ⁻²	Virus detected in all 4 wells	No cytotoxicity observed in all 4 wells
10 ⁻³	Virus detected in all 4 wells	No cytotoxicity observed in all 4 wells

*** Dilution refers to the fold of dilution from the neutralized test agent.

RESULTS (continued)

Table 3
Reduction Factor(s)

Test Agent	Replicates	Contact time	Input Load (Log ₁₀ TCID ₅₀)*	Output Load (Log ₁₀ TCID ₅₀)	Reduction (Log ₁₀ TCID ₅₀)	Percent Log ₁₀ Reduction
FPQM (Lot No. FP206141)	1	15 seconds	8.20	≤ 3.73	≥ 4.47	≥ 99.997
	2			≤ 3.73	≥ 4.47	≥ 99.997
	3			≤ 3.73	≥ 4.47	≥ 99.997
	1	60 seconds		≤ 3.73	≥ 4.47	≥ 99.997
	2			≤ 3.73	≥ 4.47	≥ 99.997
	3			≤ 3.73	≥ 4.47	≥ 99.997
	1	10 minutes		≤ 3.73	≥ 4.47	≥ 99.997
	2			≤ 3.73	≥ 4.47	≥ 99.997
	3			≤ 3.73	≥ 4.47	≥ 99.997

CONCLUSIONS

Equibal Lab's FPQM (Lot No. FP206141) was evaluated for the ability to inactivate Herpes Simplex Virus Type 1, Strain HF. FPQM achieved a viral reduction of ≥ 4.47 Log₁₀ (≥ 99.997%) beyond the cytotoxic level for exposure time of 15 seconds, 60 seconds and 10 minutes when tested against Herpes Simplex Virus Type 1.

All of the controls met the criteria for a valid test. These conclusions are based on observed data.