

Characterisation study of the candidate reference materials EURM-017 and EURM-018 with GenScript SARS-CoV-2 surrogate virus neutralisation test (sVNT)

Test Report - Front Page
Coordinates of the participating laboratory

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Customer

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Directorate F - Health, Consumers and Reference Materials
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Test Report

Results of measurements

General info about the measurements

The 8 units of EURM-017 and EURM-018 must be measured with the GenScript SARS-CoV-2 surrogate virus neutralisation assay as described below and in the most recent technical manual from the manufacturer.

Short description of the measurements

On measurement day 1 the first 2 samples of EURM-017 and the first 2 samples of EURM-018 must be measured on the same assay plate. The 2 remaining samples of both RMs must be measured on the second measurement day also together on one plate. From each sample three dilutions must be made and each dilution should be measured in 3 replicates (wells). In total, 9 measurement wells must be used for each RM sample.

Measurements on Day 1	
Date of the measurement	10/26/2020
Lot number(s) of the kit/reagents used	
A200705	
<p>addition, also report the cut-off value used for the interpretation of the results.</p>	
<p>OD values negative control: 0.885/0.921 - OD values of positive control: 0.063/0.061. Interpretation <20% = negative / ≥ 20% = positive. Inhibition calculated by $(1 - \text{average OD triplicate} / \text{average OD NC } 0.903) * 100$</p>	

EURM-017																																			
Sample 1	Unit number 0772																																		
Results																																			
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th>OD 450 value</th> <th>Inhibition rate (%)</th> <th>Interpretation (Pos/neg)</th> </tr> </thead> <tbody> <tr> <td rowspan="3" style="text-align: center;">Dilution 1</td> <td style="text-align: center;">replicate 1</td> <td style="text-align: center;">0.252</td> <td style="text-align: center;">72.09 pos</td> </tr> <tr> <td style="text-align: center;">replicate 2</td> <td style="text-align: center;">0.246</td> <td style="text-align: center;">72.76 pos</td> </tr> <tr> <td style="text-align: center;">replicate 3</td> <td style="text-align: center;">0.237</td> <td style="text-align: center;">73.75 pos</td> </tr> <tr> <td rowspan="3" style="text-align: center;">Dilution 2</td> <td style="text-align: center;">replicate 4</td> <td style="text-align: center;">0.376</td> <td style="text-align: center;">58.36 pos</td> </tr> <tr> <td style="text-align: center;">replicate 5</td> <td style="text-align: center;">0.329</td> <td style="text-align: center;">63.57 pos</td> </tr> <tr> <td style="text-align: center;">replicate 6</td> <td style="text-align: center;">0.353</td> <td style="text-align: center;">60.91 pos</td> </tr> <tr> <td rowspan="3" style="text-align: center;">Dilution 3</td> <td style="text-align: center;">replicate 7</td> <td style="text-align: center;">0.508</td> <td style="text-align: center;">43.74 pos</td> </tr> <tr> <td style="text-align: center;">replicate 8</td> <td style="text-align: center;">0.518</td> <td style="text-align: center;">42.64 pos</td> </tr> <tr> <td style="text-align: center;">replicate 9</td> <td style="text-align: center;">0.518</td> <td style="text-align: center;">42.64 pos</td> </tr> </tbody> </table>		OD 450 value	Inhibition rate (%)	Interpretation (Pos/neg)	Dilution 1	replicate 1	0.252	72.09 pos	replicate 2	0.246	72.76 pos	replicate 3	0.237	73.75 pos	Dilution 2	replicate 4	0.376	58.36 pos	replicate 5	0.329	63.57 pos	replicate 6	0.353	60.91 pos	Dilution 3	replicate 7	0.508	43.74 pos	replicate 8	0.518	42.64 pos	replicate 9	0.518	42.64 pos
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EURM-017				
Sample 2		Unit number	1261	
Results				
		OD 450 value	Inhibition rate (%)	Interpretation (Pos/neg)
Dilution 1	replicate 1	0.229	74.64	pos
	replicate 2	0.238	73.64	pos
	replicate 3	0.226	74.97	pos
Dilution 2	replicate 4	0.334	63.01	pos
	replicate 5	0.345	61.79	pos
	replicate 6	0.384	57.48	pos
Dilution 3	replicate 7	0.54	40.20	pos
	replicate 8	0.521	42.30	pos
	replicate 9	0.546	39.53	pos
EURM-018				
Sample 1		Unit number	0353	
Results				
		OD 450 value	Inhibition rate (%)	Interpretation (Pos/neg)
Dilution 1	replicate 1	0.214	76.30	pos
	replicate 2	0.201	77.74	pos
	replicate 3	0.196	78.29	pos
Dilution 2	replicate 4	0.347	61.57	pos
	replicate 5	0.327	63.79	pos
	replicate 6	0.353	60.91	pos
Dilution 3	replicate 7	0.5	44.63	pos
	replicate 8	0.478	47.07	pos
	replicate 9	0.491	45.63	pos
EURM-018				
Sample 2		Unit number	0657	
Results				
		OD 450 value	Inhibition rate (%)	Interpretation (Pos/neg)
Dilution 1	replicate 1	0.22	75.64	pos
	replicate 2	0.205	77.30	pos
	replicate 3	0.209	76.85	pos
Dilution 2	replicate 4	0.335	62.90	pos
	replicate 5	0.321	64.45	pos
	replicate 6	0.322	64.34	pos
Dilution 3	replicate 7	0.477	47.18	pos
	replicate 8	0.492	45.51	pos
	replicate 9	0.507	43.85	pos

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Measurements on Day 2	
Date of the measurement	10/28/2020
Lot number(s) of the kit/reagents used	
A200705	
<p>addition, also report the cut-off value used for the interpretation of the results.</p>	
<p>OD values negative control: 0.960/0.954 - OD values of positive control: 0.061/0.057. Interpretation <20% = negative / ≥ 20% = positive. Inhibition calculated by $(1 - \text{average OD triplicate} / \text{average OD NC } 0.957) * 100$</p>	

EURM-017				
Sample 3	Unit number	1564		
Results				
		OD 450 value	Inhibition rate (%)	Interpretation (Pos/neg)
Dilution 1	replicate 1	0.248	74.09	pos
	replicate 2	0.245	74.40	pos
	replicate 3	0.261	72.73	pos
Dilution 2	replicate 4	0.44	54.02	pos
	replicate 5	0.364	61.96	pos
	replicate 6	0.38	60.29	pos
Dilution 3	replicate 7	0.558	41.69	pos
	replicate 8	0.546	42.95	pos
	replicate 9	0.563	41.17	pos

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EURM-017				
Sample 4		Unit number	1704	
Results				
		OD 450 value	Inhibition rate (%)	Interpretation (Pos/neg)
Dilution 1	replicate 1	0.246	74.29	pos
	replicate 2	0.247	74.19	pos
	replicate 3	0.247	74.19	pos
Dilution 2	replicate 4	0.406	57.58	pos
	replicate 5	0.388	59.46	pos
	replicate 6	0.393	58.93	pos
Dilution 3	replicate 7	0.598	37.51	pos
	replicate 8	0.561	41.38	pos
	replicate 9	0.606	36.68	pos
EURM-018				
Sample 3		Unit number	0849	
Results				
		OD 450 value	Inhibition rate (%)	Interpretation (Pos/neg)
Dilution 1	replicate 1	0.216	77.43	pos
	replicate 2	0.218	77.22	pos
	replicate 3	0.199	79.21	pos
Dilution 2	replicate 4	0.372	61.13	pos
	replicate 5	0.39	59.25	pos
	replicate 6	0.373	61.02	pos
Dilution 3	replicate 7	0.563	41.17	pos
	replicate 8	0.543	43.26	pos
	replicate 9	0.565	40.96	pos
EURM-018				
Sample 4		Unit number	1174	
Results				
		OD 450 value	Inhibition rate (%)	Interpretation (Pos/neg)
Dilution 1	replicate 1	0.215	77.53	pos
	replicate 2	0.202	78.89	pos
	replicate 3	0.34	64.47	pos
Dilution 2	replicate 4	0.406	57.58	pos
	replicate 5	0.368	61.55	pos
	replicate 6	0.371	61.23	pos
Dilution 3	replicate 7	0.61	36.26	pos
	replicate 8	0.59	38.35	pos
	replicate 9	0.563	41.17	pos