

CERTIFICATE OF ANALYSIS

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Product Description: SARS-CoV-2 Plate 9

Catalog Numbers:N05CA-1Lot Number:Z0056953Expiration Date:31 OCT 2023

Storage Temperature: 2-8°C

Plate Uniformity Testing Results:

Parameter	Precision			Uniformity	Signal
Metric	CV of Intra- plate Averages	Average Intra-plate CV	Max Intra- plate CV	Average Uniformity Metric	Average Signal
RBD (L452R)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (K417N, E484K, N501Y)	≤ 18%	≤ 10%	13.2%	Pass	1,500 – 1,000,000
RBD (E484K)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (K417T, E484K, N501Y)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (S477N)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (N501Y)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (E484K, N501Y)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (L452R, E484Q)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (Q414K, N450K)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 S1 RBD	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000

RBD indicates SARS-CoV-2 Receptor Binding Domain with mutation(s) listed

Coating Confirmation Testing Results:

Spot	Description	Result
1	RBD (L452R)	Pass
2	RBD (K417N, E484K, N501Y)	Pass
3	RBD (E484K)	Pass
4	RBD (K417T, E484K, N501Y)	Pass
5	RBD (S477N)	Pass
6	RBD (N501Y)	Pass
7	RBD (E484K, N501Y)	Pass
8	RBD (L452R, E484Q)	Pass
9	RBD (Q414K, N450K)	Pass
10	SARS-CoV-2 S1 RBD	Pass

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Functional Testing Results:

Sample Type	Calibrator	Controls		Samples	
Metric	Average Signal Ratio Test:Reference	Control Recovery	Control Conc. CV	Average % Difference Test:Reference	Slope Test:Reference
RBD (L452R)	N/A	N/A	N/A	N/A	N/A
RBD (K417N, E484K, N501Y)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 - 1.2
RBD (E484K)	N/A	N/A	N/A	N/A	N/A
RBD (K417T, E484K, N501Y)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 - 1.2
RBD (S477N)	N/A	N/A	N/A	N/A	N/A
RBD (N501Y)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 - 1.2
RBD (E484K, N501Y)	N/A	N/A	N/A	N/A	N/A
RBD (L452R, E484Q)	N/A	N/A	N/A	N/A	N/A
RBD (Q414K, N450K)	N/A	N/A	N/A	N/A	N/A
SARS-CoV-2 S1 RBD	50 – 200%	70 – 130%	< 20%	± 25%	0.80 - 1.2

Additional Comments:

Functional testing was executed using SARS-CoV-2 Plate 9 (Z0056953), SULFO-TAG Anti-Human IgG Antibody (D00V0009), Reference Standard 1 (A0080270), and Serology Controls (A00C0771, A00C0772, A00C0773).

All components were manufactured and tested according to MSD documents. The lots listed meet MSD's specifications.

Statement:

The above product is intended for Research Use Only. Not for use in Diagnostic Procedures.

	Name	Function	Signature	Date
Review/Approval	Karen Hamilla	Quality	Laur Hamille	01 OCT 2021

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