

Creative Diagnostics®는 새로운 코로나 바이러스 및 항체의 직접 검출을 위한 SARS-CoV-2 면역 분석 키트를 제공합니다.

CD Creative Diagnostics®

SARS-CoV-2 Immunoassay Kits

2019 년 말 중국에서 중증 급성 호흡기 증후군 (SARS-CoV-2, 2019-nCoV) 이 발생하여 전 세계적인 유행병이 되었으며 이로 인해 전례없는 공중 보건 문제가 대두 되고 있습니다.

Creative Diagnostics는 발병이 알려진 직후 새로운 테스트 키트를 개발하기 시작하여 불과 몇 주 후 IgM 및 IgG class의 Anti-SARS-CoV-2 항체 검출을 위한 2 개의 ELISA와 SARS-CoV-2 NP 항원 검출을위한 1 개의 ELISA kit를 만들어냈습니다. 현재 이 두 키트는 연구 전용으로만 판매 가능하며 CE registration 을 위한 준비가 진행 중입니다.

Product List

DEIASL019	SARS-CoV-2 IgG ELISA Kit
DEIASL020	SARS-CoV-2 IgM ELISA Kit
DEIA2020	SARS-CoV-2 Antigen ELISA Kit
DEIASL024	SARS-CoV-2 Total Antibody ELISA Kit
DEIASL019Q	NEW SARS-CoV-2 IgG ELISA Kit
DEIASL020Q	NEW SARS-CoV-2 IgM ELISA Kit
DEIA-WZ021	SARS-CoV-2 Inhibitor Screening ELISA Kit

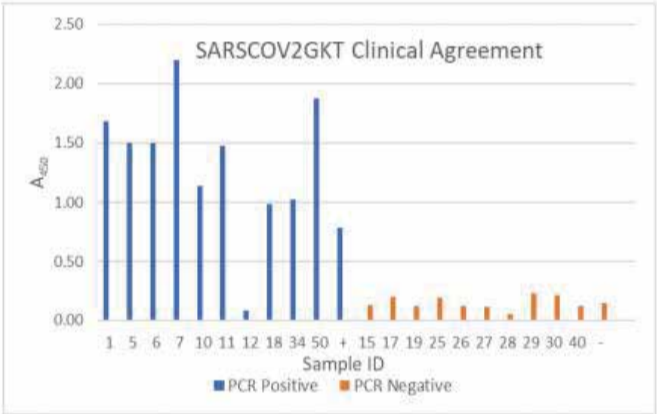
* For research use only, not for use in diagnostic procedures.



Technical Specifications

DEIASL019 SARS-CoV-2 IgG ELISA Kit

Size	96T
Sample	Serum
Species Reactivity	Human
Storage	Storage at 4°C
Precision	Variability: A total of 136 samples were evaluated in duplicate yielding a median CV of 4.2% (95% CI 2.9-5.2%). Clinical Agreement: Human serum samples from patients with PCR confirmed COVID-19 infection status were evaluated in the assay.



Sensitivity

SARSCOV2GKT	PCR	
	Positive	Negative
	9	0
	Positive	Negative
	1	10

Sensitivity: 90
Specificity: 100
Positive Percent Agreement: 100
Negative Percent Agreement: 91

DEIASL020 SARS-CoV-2 IgM ELISA Kit

Size	96T									
Sample	Serum, plasma									
Storage	Storage at 2 - 8 °C									
Precision	<table><tr><th></th><th>Test Positive</th><th>Test Negative</th></tr><tr><td>Confirmed Positive</td><td>16</td><td>0</td></tr><tr><td>Confirmed Negative</td><td>0</td><td>30</td></tr></table> <p>Sensitivity: 90 Specificity: 100</p>		Test Positive	Test Negative	Confirmed Positive	16	0	Confirmed Negative	0	30
	Test Positive	Test Negative								
Confirmed Positive	16	0								
Confirmed Negative	0	30								

DEIA2020 SARS-CoV-2 Antigen ELISA Kit

Size	96T																								
Sample	Serum																								
Storage	Storage at 2 - 8 °C																								
Sensitivity	Three samples of known concentration were tested twelve times on one plate to assess intra-assay precision and were tested in five separate assays to assess inter-assay precision, to evaluate the precision in the kit batch: <div><div>Intra-assay Precision</div><table><tr><th>Sample (ng/mL)</th><th>n</th><th>CV (%)</th></tr><tr><td>80 ng/mL</td><td>12</td><td>4.25</td></tr><tr><td>20 ng/mL</td><td>12</td><td>6.64</td></tr><tr><td>5 ng/mL</td><td>12</td><td>8.44</td></tr></table><div>Inter-assay Precision</div><table><tr><th>Sample (ng/mL)</th><th>n</th><th>CV (%)</th></tr><tr><td>80 ng/mL</td><td>6</td><td>4.13</td></tr><tr><td>20 ng/mL</td><td>6</td><td>7.25</td></tr><tr><td>5 ng/mL</td><td>6</td><td>13.44</td></tr></table></div>	Sample (ng/mL)	n	CV (%)	80 ng/mL	12	4.25	20 ng/mL	12	6.64	5 ng/mL	12	8.44	Sample (ng/mL)	n	CV (%)	80 ng/mL	6	4.13	20 ng/mL	6	7.25	5 ng/mL	6	13.44
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