

RNA-Nachweis

Anbieter/Assay	Nachweisverfahren	Nachgewiesene Gene/Varianten	Zulassung	s. S.
Abbott Rapid Diagnostics Germany GmbH				
ID NOW™ Instrument	Point-of-Care isothermale NAT		CE-IVD	2
ID NOW™ COVID-19 Kit	Point-of-Care isothermale NAT		CE-IVD	
adico				
GenomEra® SARS-CoV-2	Point-of-Care Real-time Multiplex RT-PCR	E- und RdRP-Gen, (SARS-CoV-2)	CE-IVD	55
GenomEra® SARS-CoV-2, Flu A/B + RSV	Point-of-Care Real-time Multiplex RT-PCR	E- und RdRP-Gen (SARS-CoV-2), Flu A/B, RSV	CE-IVD	
AID Autoimmun Diagnostika GmbH				
AID SARS-CoV-2 Detection Kit	Real-time Multiplex-RT-PCR	ORF1b- und RdRP-Gen	CE-IVD	61
AID SARS-CoV-2 MutaScreen21.3	Reverse Hybridisierung	Alpha, Beta, Gamma, Delta, Omicron BA.1 und Omicron BA.2	CE-IVD	
altona Diagnostics GmbH				
AltoStar® SARS-CoV-2 RT-PCR Kit 1.5	Real-time RT-PCR (paralleler Nachweis)	E- und S-Gen (SARS-CoV-2)	CE-IVD	49
FlexStar® SARS-CoV-2 Type & FLU RT-PCR Detection Mix 1.5	Real-time RT-PCR (paralleler Nachweis)	E- und S-Gen (SARS-CoV-2), Influenza A/B	CE-IVD (3/2022)	
FlexStar® FLU Type & SARS-CoV-2 RT-PCR-Detection Mix 1.5	Real-time RT-PCR (paralleler Nachweis)	E- und S-Gen (SARS-CoV-2), Influenza A/B	RUO	
RealStar® SARS-CoV-2 RT-PCR Kit 1.0	Real-time RT-PCR (paralleler Nachweis)	E- und S-Gen (SARS-CoV-2)	CE-IVD	
AmplexDiagnostics GmbH				
eazyplex® SARS-CoV-2	Isothermale Amplifikation (LAMP)	N-, ORF8-Gen	CE-IVD	49
Becton Dickinson GmbH				
BD® SARS-CoV-2/Flu	Real-time RT-PCR	N-Gen (N1 + N2, SARS-CoV-2), Influenza A/B	CE-IVD	57
VIASURE SARS-CoV-2	Real-time RT-PCR	N1 + N2 (SARS-CoV-2)	CE-IVD	
VIASURE SARS-CoV-2-Varianten I	Real-time RT-PCR	K417N-, K417T-Mutation, del69/70 (SARS-CoV-2)	CE-IVD	
VIASURE SARS-CoV-2-Varianten	Real-time RT-PCR	P681R-, L452R-Mutation (SARS-CoV-2)	CE-IVD	
VIASURE SARS-CoV-2, Flu (A+B) & RSV	Real-time RT-PCR	N1, N2 (SARS-CoV-2), Influenza A/B, RSV	CE-IVD	
bestbion dx GmbH				
VIASURE SARS-CoV-2 qPCR	Real-time Multiplex-RT-PCR	ORF1ab, N-Gen (SARS-CoV-2)	CE-IVD	58
VIASURE SARS-CoV-2, Flu, RSV qPCR	Real-time Multiplex-RT-PCR	N-Gen, M1-Gen, N-Gen (RSV) (SARS-CoV-2, Flu)	CE-IVD	
VIASURE SARS-CoV-2, Flu A, Flu B qPCR	Real-time Multiplex-RT-PCR	N-Gen (Flu A), M1-Gen (Flu B)	CE-IVD	
VIASURE SARS-CoV-2 del 69/70, ORF1ab & N genes qPCR	Real-time Multiplex-RT-PCR	ORF1ab, S-Gen	CE-IVD	
VIASURE SARS-CoV-2 Varianten I qPCR	Real-time Multiplex-RT-PCR	S-Gen (SARS-CoV-2 Beta, Gamma, Verdacht auf Delta)	CE-IVD	
VIASURE SARS-CoV-2 Varianten II qPCR	Real-time Multiplex-RT-PCR	S-Gen (SARS-CoV-2 Delta-Variante)	CE-IVD	
VIASURE SARS-CoV-2 Varianten III qPCR	Real-time Multiplex-RT-PCR	ORF 1ab, S-Gen (SARS-CoV-2 Omikron-Variante)	CE-IVD	
VIASURE SARS-CoV-2 Triplex	Real-time Multiplex-RT-PCR	ORF1ab, E- und N-Gen	CE-IVD	
Bioneer Corp.				
AccuPower® SARS-CoV-2 Multiplex Real-Time RT-PCR	Real-time RT-PCR	E-Gen, RdRP-/N-Gen, delHV69/70, N501Y; K417N, L452R, P681R	CE-IVD	50
AccuPower® RV1 Multiplex Kit	Real-time RT-PCR	E-, RdRg-/N-Gen (SARS-CoV-2), Influenza A/B	CE-IVD	
AccuPower® SARS-CoV-2 Variant ID Real-Time PCR Kit	Real-time RT-PCR	Alpha, Beta, Gamma	CE-IVD	
AccuPower® SARS-CoV-2 Variants ID2 Kit A und Kit B	Real-time RT-PCR	Alpha, Delta, Delta Plus	CD-IVD	
AccuPower® SARS-CoV-2 Variants ID3	Real-time RT-PCR	Delta, Omikron	CD-IVD	
AccuPower® COVID-19 Multiplex Real-Time RT-PCR Kit	Real-time RT-PCR	E-, RdRP-/N-Gen	CE-IVD	
AccuPower® RV1 Real-Time RT-PCR Kit	Real-time RT-PCR	E-, RdRP-/N-Gen (SARS-CoV-2), Influenza A/B	CE-IVD	
AccuPower® SARS-CoV-2 Variant ID Real-Time PCR Kit	Real-time RT-PCR	Alpha, Beta, Gamma	CE-IVD	
AccuPower® SARS-CoV-2 Variants ID2 Real-Time PCR Kit	Real-time RT-PCR	Alpha, Delta, Delta Plus	CE-IVD	
Bio-Rad Laboratories GmbH				
Reliance SARS-CoV-2 Flu A Flu B RT-PCR Assay Kit	Real-time RT-PCR		CE-IVD	61
Reliance SARS-CoV-2 RT-PCR Assay Kit	Real-time RT-PCR		CE-IVD	
SARS-CoV-2 ddPCR Kit	RT droplet digital PCR (RT-ddPCR)		RUO	
SARS-CoV-2 Variant assays	Real-time RT-PCR & RT-ddPCR		RUO	
Cepheid GmbH				
Xpert® Xpress SARS-CoV-2	Real-time Multiplex-RT-PCR	E-, N2-Gen	CE-IVD	52
Xpert® Xpress CoV-2/Flu/RSV plus	Real-time Multiplex-RT-PCR	N2-, E-, RdRP-Gen (SARS-CoV-2), Flu A, Flu B, RSV	CE-IVD	
DiaSorin Molecular				
Simplexa™ COVID-19 Direct	Real-time Multiplex-PCR	VoC Alpha, Beta, Gamma, Delta, Omikron und Voi	CE-IVD	53
Simplexa™ COVID-19 & Flu A/B Direct	Real-time Multiplex-PCR	VoC Alpha, Beta, Gamma, Delta, Omikron und Voi, Flu A/B	CE-IVD	
Simplexa™ SARS-CoV-2 Variants Direct	Real-time Multiplex-PCR	VoC Alpha, Beta, Gamma, Delta, Omikron und Voi	RUO	
ELITechGroup GmbH				
SARS-CoV-2 ELITe MGB® Kit	Real-time RT-PCR	RdRP- und ORF8-Gen	CE-IVD	48
SARS-CoV-2 PLUS ELITe MGB® Kit	Real-time Multiplex-RT-PCR	ORF8- und ORF1ab-Gen (SARS-CoV-2), Flu A, Flu B, hRSV	CE-IVD	
SARS-CoV-2 Extended ELITe MGB® Kit	Real-time Multiplex-RT-PCR (inkl. HRM)	Alle VoC, besonders: Beta, Gamma, Delta, Lambda, My, Omikron	RUO	

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EUROIMMUN Medizinische Labordiagnostika AG				
EURORealTime SARS-CoV-2	Real-time Multiplex-RT-PCR	ORF1ab-/N-Gen; Alpha, Beta, Gamma, Delta, Lambda, My, Omikron	CE-IVD	60
EURORealTime SARS-CoV-2/Influenza A/B	Real-time Multiplex-RT-PCR	Alpha, Beta, Gamma, Delta, Lambda, My, Omikron, Flu A/B	CE-IVD	
Fujirebio Germany GmbH				
iAMP COVID-19 SANO Assay	Direkte isothermale Amplifikation	ORF1a, N, RdRP	CE-IVD	56
DiaPlexQ™ SARS-CoV-2	Real-time RT-PCR	ORF1a, N, RdRP	CE-IVD	
DiaPlexQ™ Flu A/B & SARS-CoV-2	Real-time RT-PCR	HA (A+B) / ORF1a, N	CE-IVD	
Genetic Signatures Ltd				
EasyScreen™ SARS-CoV-2 Detection Kit	Real-time Multiplex-PCR	M-, N-Gen	CE-IVD	5, 51
EasyScreen™ SARS-CoV-2 Respiratory Plus	Real-time Multiplex-PCR	M-, N-Gen (SARS-CoV-2), Flu A/B, RSV, Rhinovirus, hMPV	CE-IVD	
EasyScreen™ SARS-CoV-2 Variant Detection Kit	Real-time Multiplex-PCR	Alle Varianten inkl. Diskriminierung von Beta, Delta und Omikron	RUO	
HISS Diagnostics GmbH				
Gerbion virellaSARS-CoV-2 mutant 3	Multiplex-PCR	L452R, P681R (S-Gen)	CE-IVD	57
Gerbion virellaSARS-CoV-2 mutant 4	Multiplex-PCR	G142D, Y145H, A222V (S-Gen)	CE-IVD	
Gerbion virellaSARS-CoV-2 seqc real time RT-PCR Kit 2.0	Real-time RT-PCR	SARS-CoV-2 Subgenus Sarbecovirus (SARS-CoV-1, SARS-CoV-2)	CE-IVD	
Gerbion respiraScreen 1 multiplex	Multiplex-PCR	Influenza A und B, RSV A und B, SARS-CoV-2	CE-IVD	
Gerbion respiraScreen 2 Multiplex	Multiplex-PCR	E-, RdRP-, S-Gen (SARS-CoV-2), Flu A, Flu B	CE-IVD	
Gerbion respiraSC2 multi gene	Multiplex-PCR	S-, RdRP-, E-Gen	CE-IVD	
Gerbion respiraSC2-FluA/B seqc	Multiplex-PCR	S-, RdRP-, E-Gen (SARS-CoV-2, Flu A, Flu B)	CE-IVD	
Gerbion virellaSARS-CoV-2 seqc	Multiplex-PCR	SARS-CoV-2 und andere Betacoronavirus-Viren	CE-IVD	
Gerbion virellaSARS-CoV-2 4G seqc	Multiplex-PCR	SARS-CoV-2 + Subgenus Sarbecovirus (SARS-CoV-1, SARS-CoV-2)	CE-IVD	
Hologic Deutschland GmbH				
Aptima® SARS-CoV-2 Assay	TMA	ORF1ab-Gen, alle bekannten Varianten inkl. Beta, Delta, Omikron	CE-IVD	53
Aptima™ SARS-CoV-2/Flu Assay	TMA	Wie Aptima® SARS-CoV-2 Assay, zusätzlich Flu A, Flu B	CE-IVD	
Novodiag® COVID-19 Assay	Real-time RT-PCR	E- und N-Gen	CE-IVD	
Panther Fusion® Open Access™	Real-time RT-PCR	E-Gen	CE-IVD	
Luminex – a DiaSorin Company				
ARIES® SARS CoV 2	Real-time Multiplex-PCR	N-, ORF1ab-Gen, SARS-CoV-2-Varianten inkl. Beta, Delta, Omikron	CE-IVD	53
NxTAG® CoV Extended Panel	Multiplex-PCR	E-, N-, ORF1ab-Gen, SARS-CoV-2-Varianten inkl. Beta, Delta, Omikron; MERS, SARS	EUA/RUO	
NxTAG® Respiratory Pathogen Panel +SARS CoV 2	Multiplex-PCR	M- und ORF1ab, alle bekannten SARS-CoV-2-Varianten; zahlreiche respiratorische Erreger	CE-IVD	
LumiraDx GmbH				
LumiraDx RNA STAR Complete	Qualitative Real-time RT-PCR	ORF1a inkl. aller VoC, Omikron inkl. BA.2	CE-IVD	58
Mast Diagnostica GmbH				
MAST ISOPLEX® SARS-CoV-2	Multiplex RT-LAMP	N-, RdRP-Gen	CE-IVD	60
MIKROGEN GmbH				
ampliCube Coronavirus SARS-CoV-2	Real-time Multiplex-RT-PCR	E- und ORF1a	CE-IVD	61
ampliCube Coronavirus Panel	Real-time Multiplex-RT-PCR	SARS-CoV/SARS-CoV-2, MERS-CoV, HCoV	CE-IVD	
ampliCube Respiratory Flu & SARS-CoV-2	Real-time Multiplex-RT-PCR	Flu A, Flu B, SARS-CoV-2: E-, ORF1a-Gen	CE-IVD	
ampliCube Respiratory Flu & SARS-CoV-2 LC	Real-time Multiplex-RT-PCR	Flu A, Flu B, E-, ORF1a-Gen (SARS-CoV-2)	CE-IVD	
ampliCube Respiratory SARS-CoV-2 Variants	Real-time Multiplex-RT-PCR	Alpha, Beta, Gamma	CE-IVD	
ampliMelt SARS-CoV-2 Variants 1	Real-time Multiplex-RT-PCR, HRM	Alpha, Delta	RUO	
ampliMelt SARS-CoV-2 Variants 2	Real-time Multiplex-RT-PCR, HRM	Beta, Gamma	RUO	
ampliMelt SARS-CoV-2 Variants 3	Real-time Multiplex-RT-PCR, HRM	Delta, Omikron BA.1, Omikron BA.2	RUO	
New England Biolabs GmbH				
Luna® SARS-CoV-2 RT-qPCR Multiplex Assay Kit	Real-time Multiplex-RT-PCR	N1-, N2-Gen	RUO	49
SARS-CoV-2 Rapid Colorimetric LAMP Assay Kit	LAMP	E-, N-Gen	RUO	
Roche Diagnostics Deutschland GmbH				
cobas® 58/68/8800 SARS-CoV-2 Qualitative	Qualitative Real-time RT-PCR		CE-IVD	62 f.
cobas® 58/68/8800 SARS-CoV-2 DUO	Qualitative/quantitative Real-time RT-PCR		CE-IVD (Q2-2022)	
cobas® 58/68/8800 SARS-CoV-2 & Influenza A/B	Qualitative Real-time RT-PCR		CE-IVD	
cobas® 68/8800 SARS-CoV-2 Variant Set 1	Qualitative Real-time RT-PCR		RUO	
cobas® Liat® SARS-CoV-2 Test	Qualitative Real-time RT-PCR		CE-IVD	
cobas® Liat® SARS-CoV-2 & Influenza A/B Test	Qualitative Real-time RT-PCR		CE-IVD	

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Seegene Inc				
Allplex™ 2019-nCoV Assay	Real-time Multiplex-RT-PCR	E-, N- und RdRP-Gen (SARS-CoV-2)	CE-IVD	54
Allplex™ SARS-CoV-2 Assay	Real-time Multiplex-RT-PCR	E-, N-, RdRP- und S-Gen (SARS-CoV-2)	CE-IVD	
Allplex™ RV Master Assay	Real-time Multiplex-RT-PCR	N-, RdRP- und S-Gen (SARS-CoV-2), FluA, FluB, RSV und weitere	CE-IVD	
Allplex™ SARS-CoV-2/FluA/FluB/RSV Assay	Real-time Multiplex-RT-PCR	N-, RdRP- und S-Gen (SARS-CoV-2), FluA, FluB, RSV	CE-IVD	
Allplex™ SARS-CoV-2 Master Assay	Real-time Multiplex-RT-PCR	E-, N-, RdRP-, S-Gen: delHV69/70, delY144, E484K, N501Y, P681H	CE-IVD	
Allplex™ SARS-CoV-2 fast PCR Assay	Real-time Multiplex-RT-PCR	E-, N- und RdRP-Gen (SARS-CoV-2)	CE-IVD	
Allplex™ SARS-CoV-2 Variants I Assay	Real-time Multiplex-RT-PCR	Alpha, Beta, Gamma, Eta	CE-IVD	
Allplex™ SARS-CoV-2 Variants II Assay	Real-time Multiplex-RT-PCR	Beta, Gamma, Epsilon, Delta	CE-IVD	
Novaplex™ SARS-CoV-2 Variants IV Assay	Real-time Multiplex-RT-PCR	Delta	RUO	
Novaplex™ SARS-CoV-2 Variants V Assay	Real-time Multiplex-RT-PCR	Delta, Lambda	RUO	
Novaplex™ SARS-CoV-2 Variants VI Assay	Real-time Multiplex-RT-PCR	Lambda, My	RUO	
Novaplex™ SARS-CoV-2 Variants VII Assay	Real-time Multiplex-RT-PCR	Omikron BA.1, Omikron BA.2	RUO	
TIB Molbiol Syntheselabor GmbH				
Sarbeco SARS-CoV-2 Kit	Real-time Multiplex-RT-PCR	E- und N-Gen	CE-IVD	62 f.
SARS-CoV-2 RdRP Test	Real-time Multiplex-RT-PCR	Delta, Lambda	RUO	
Omicron VirSNiP SARS-CoV-2 Spike	SARS-CoV-2 Variantentestung inkl. HRM	S371L S373P (S-Gen)	RUO	
Omicron vs. Delta VirSNiP SARS-CoV-2 Spike L452R + S371L S373P	SARS-CoV-2 Variantentestung inkl. HRM	L452R + S371L S373P (S-Gen)	RUO	
Delta VirSNiP SARS-CoV-2 Spike L452R	SARS-CoV-2 Variantentestung inkl. HRM	L452R	RUO	
VirSNiP SARS-CoV-2 Assays	SARS-CoV-2 Variantentestung inkl. HRM	Für alle anderen Varianten erhältlich	RUO	

NGS

Anbieter	Assay	Nachweisverfahren	Zulassung	s. S.
HiSS Diagnostics GmbH – PerkinElmer, Inc.	NEXTFLEX® Variant-Seq™ SARS-CoV-2 kit	amplicon-based whole genome amplification	RUO	57
New England Biolabs GmbH	NEBNext ARTIC SARS-CoV-2 FS Library Prep Kit (Hersteller Illumina)	NGS inkl. VarSkip Short Primer	RUO	49
	NEBNext ARTIC SARS-CoV-2 Companion Kit (Hersteller ONT)	NGS inkl. VarSkip Short Primer	RUO	
	NEBNext ARTIC SARS-CoV-2 RT-PCR Module	NGS inkl. VarSkip Short Primer	RUO	

Kontrollen für den RNA-Nachweis inkl. NGS

Anbieter	Assay	Nachweisverfahren	Zulassung	s. S.
Bio-Rad Laboratories GmbH	SARS-CoV-2 Standard	PCR/ddPCR	RUO	61
	SARS-CoV-2 Negative	PCR/ddPCR	RUO	
	SARS-CoV-2 Positive Run Control	PCR/ddPCR	CE-IVD	
	SARS-CoV-2 Negative Run Control	PCR/ddPCR	CE-IVD	
	SARS-CoV-2, Flu, RSV Positive Control	PCR/ddPCR	CE-IVD	
	SARS-CoV-2, Flu, RSV Negative Control	PCR/ddPCR	CE-IVD	
bestbion dx GmbH	Amplirun SARS-CoV-2 RNA-Kontrolle	Lyophilisierte RNA-Amplifikationskontrolle (Gesamtgenom COVID-19)	RUO	58
	Amplirun SARS-CoV-2 RNA-Kontrolle, Südafrika-Variante		RUO	
	Amplirun SARS-CoV-2 RNA-Kontrolle, del 69/70		RUO	
	Amplirun Total SARS-CoV-2 RNA-Kontrolle	Inaktiviertes SARS-CoV-2-Gesamtgenom für gesamte molekulare Analyse	CE-IVD	
	Amplirun Total SARS-CoV-2/FluA/FluB/RSV RNA-Kontrolle		RUO	
	Amplirun Total SARS-CoV-2 alpha RNA-Kontrolle		RUO	
	Amplirun Total SARS-CoV-2 beta RNA-Kontrolle		RUO	
	Amplirun Total SARS-CoV-2 gamma RNA-Kontrolle		RUO	
	Amplirun Total SARS-CoV-2 delta RNA-Kontrolle		RUO	
Amplirun Total Negativkontrolle respiratorische Tupfer	Respiratorische Negativkontrolle in VTM (SP und NAT)		RUO	
HiSS Diagnostics – LGC Clinical Diagnostics, Inc.	AccuPlex™ SARS-CoV-2 Variant Reference Materials	Rekombinantes Virus mit Proteinhülle & SARS-CoV-2-Genom (WT oder VOCs)	RUO	57
	AccuPlex™ SARS-CoV-2 Reference Materials		CE-IVD	
	AccuPlex™ SARS-CoV-2 Verification Panels	Wie oben, aber 3 verschiedene Konzentrationen	RUO	
	AccuPlex™ SARS-CoV-2, Flu A/B and RSV Reference Materials	Rekomb. Virus mit Proteinhülle (SARS-CoV-2-, Influenza A/B oder RSV-Genom)	RUO	
	AccuPlex™ SARS-CoV-2, Flu A/B and RSV Verification Panels	Wie oben, aber 3 verschiedene Konzentrationen	RUO	
	AccuPlex™ SARS-CoV-2 in Synthetic Oral Fluid	Rekomb. SARS-CoV-2 (Genom m. Proteinhülle) in künstlichem Speichel	RUO	
	Seraseq® SARS-CoV-2 Mutation RNA Mix	82 SARS-CoV-2-Varianten in 3 versch. Allelfrequenzen, für NGS-Assays	RUO	

Kontrollen für den Antikörpernachweis

Anbieter	Assay	Nachweisverfahren	Zulassung	s. S.
Bio-Rad Laboratories GmbH	VIROTROL SARS-CoV-2 Control, positiv	Serologische Tests	CE-IVD	61
	VIROCLEAR SARS-CoV-2 Control, negativ	Serologische Tests	CE-IVD	

Antikörpernachweis

Anbieter	Assay	Nachweisverfahren	Zulassung	s. S.
bestbion dx GmbH	Vircell COVID-19 IgG ELISA	ELISA	CE-IVD	58
	Vircell COVID-19 IgM+IgA ELISA	ELISA	CE-IVD	
	VirClia COVID-19 IgG Monotest	CLIA	CE-IVD	
	VirClia COVID-19 IgM+IgA Monotest	CLIA	CE-IVD	
	STANDARD F COVID-19 IgM/IgG FIA Combo	Immunfluorometrischer Schnelltest	CE-IVD	
	STANDARD Q COVID-19 IgM/IgG Plus	Chromatographischer Immunoassay, Kassettenschnelltest	CE-IVD	
Bio-Rad Laboratories GmbH	Platelia SARS-CoV-2 Total Ab	ELISA	CE-IVD	61
	BioPlex 2200 SARS-CoV-2 IgG Assay	Multiplex-Immunoassay	CE-IVD	
DiaSorin Deutschland GmbH	LIAISON® SARS-CoV-2 IgM	CLIA	CE-IVD	53
	LIAISON® SARS-CoV-2 S1/S2 IgG	CLIA	CE-IVD	
	LIAISON® SARS-CoV-2 TrimericS IgG	CLIA	CE-IVD	
DiaSys Deutschland Vertriebs-GmbH	SARS-CoV-2 UTAB FS	Immunturbidimetrischer Immunoassay	CE-IVD	64
EUROIMMUN Medizinische Labordiagnostika AG	Anti-SARS-CoV-2-QuantiVac-ELISA (IgG)	ELISA, quantitativ	CE-IVD	60
	Anti-SARS-CoV-2-ELISA (IgA, IgG)	ELISA	CE-IVD	
	Anti-SARS-CoV-2-NCP-ELISA (IgM, IgG)	ELISA	CE-IVD	
	EUROLINE Anti-SARS-CoV-2 Profil (IgG)	Immunblot	CE-IVD	
Fujirebio Germany GmbH	Lumipulse® G SARS-CoV-2 N-IgG	CLIA	CE-IVD	56
	Lumipulse® G SARS-CoV-2 S-IgG	CLIA	CE-IVD	
Luminex – a DiaSorin Company	xMAP® SARS-CoV-2 Multi-Antigen IgG	Microsphere-based Suspension Array Technology	EUA/RUO	53
	Guava® SARS-CoV-2 Multi-Antigen Antibody Kit	Durchflusszytometrie	RUO	
LumiraDx GmbH	SARS-CoV-2 Antikörper (Ab) Test	Fluoreszenz-Immunoassay	CE-IVD	58
MIKROGEN GmbH	recomWell SARS-CoV-2 IgA	ELISA	CE-IVD	61
	recomWell SARS-CoV-2 IgG	ELISA	CE-IVD	
	recomLine SARS-CoV-2 IgG	Streifen-Immunoassay	CE-IVD	
Roche Diagnostics Deutschland GmbH	Elecsys® Anti-SARS-CoV-2	ECLIA	CE-IVD	62f.
	Elecsys® Anti-SARS-CoV-2 S	ECLIA	CE-IVD	
	SARS-CoV-2 Rapid Antibody Test	Chromatographischer Immunoassay, Kassettenschnelltest	CE-IVD	

Antigennachweis

Anbieter	Assay	Nachweisverfahren	Zulassung	s. S.
bestbion dx GmbH	Standard F COVID-19 Ag FIA, Nasal	Immunfluorometrischer Schnelltest	CE-IVD	58
	Standard F COVID-19 Ag FIA, NP		CE-IVD	
	Standard F COVID-19/FLU Ag FIA Combo Test		CE-IVD	
	Standard Q COVID-19 Ag, Nasal	Chromatographischer Immunoassay, Kassettenschnelltest	CE-IVD	
	Standard Q COVID-19 Ag, NP		CE-IVD	
Bio-Rad Laboratories GmbH	Coronavirus Ag Rapid Test Cassette (Swab) 12015553	Chromatographischer Immunoassay, Kassettenschnelltest	CE-IVD	61
DiaSorin Deutschland GmbH	LIAISON® SARS-CoV-2 Ag	CLIA	CE-IVD	53
EUROIMMUN AG	SARS-CoV-2 Antigen-ELISA	ELISA	CE-IVD	60
Fujirebio Germany GmbH	Lumipulse G SARS-CoV-2 Antigene	Laborbasierter CLIA	CE-IVD	56
HiSS Diagnostics GmbH – Guangdong WeSail Biotech Co., Ltd.	COVID-19 Ag Test Kit	LFIA Nucleocapsid-Protein (SARS-CoV-2)	CE-IVD	57
LumiraDx GmbH	SARS-CoV-2 Ag-Test	Fluoreszenz-Immunoassay	EUA, CE-IVD	58
	SARS-CoV-2 Ag Pool Test		EUA, CE-IVD	
Roche Diagnostics Deutschland GmbH	Elecsys® SARS-CoV-2 Antigen	ECLIA	CE-IVD	62f.
	SARS-CoV-2 Rapid Antigen Test	Chromatographischer Immunoassay, Kassettenschnelltest	CE-IVD	
	SARS-CoV-2 Rapid Antigen Test Nasal		CE-IVD	
	SARS-CoV-2 Antigen Self Test Nasal		CE-IVD	

Nachweis neutralisierender Antikörper

Anbieter	Assay	Nachweisverfahren	Zulassung	s. S.
bestbion dx GmbH	Standard F SARS-CoV-2 nAb FIA	Immunfluorometrischer Schnelltest	CE-IVD	58
EUROIMMUN AG	SARS-CoV-2 NeutralISA	ELISA (Surrogat-Virusneutralisationstest)	CE-IVD	60

Nachweis reaktiver T-Zellen

Anbieter	Assay	Nachweisverfahren	Zulassung	s. S.
AID Autoimmun Diagnostika GmbH	AID CoV-iSpot SARS-CoV-2 EliSpot	EliSpot	CE-IVD	61
bestbion dx GmbH	STANDARD F Covi-FERON FIA Reagenzienkit	Immunfluorometrischer Schnelltest	CE-IVD	58
EUROIMMUN AG	Quan-T-Cell-System	IGRA	CE-IVD	60
Mikrogen GmbH	T-Track® SARS-CoV-2 Stimulation	Stimulation v. Blutzellen m. SARS-CoV-2-Antigen (S1, NP) (Kit 1) und anschließende Detektion von RNA-Markern mittels RT-qPCR (Kit 2)	RUO	61
	T-Track® SARS-CoV-2 Quant PCR		RUO	
Oxford Immunotec Ltd	T-Spot®.COVID	EliSpot (separate Peptid-Mixe für S & N)	CE-IVD	64, 92
	T-Spot® Discovery SARS-CoV-2	EliSpot (separate Peptid-Mixe für S, N, M & endemische Coronaviren)	RUO	