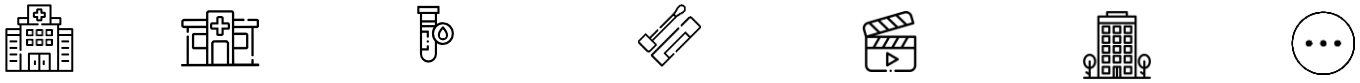
TAAG CS11 COVID-19

SARS-CoV-2 detection service for healthcare providers and institutions by RT-qPCR in respiratory samples

INTENDED USE

SARS-CoV-2 detection for institutions, companies, laboratories and healthcare facilities that want to outsource the analysis of COVID-19 in nasopharyngeal, oropharyngeal, oral, nasal, saliva, environmental, or surface samples.

MAIN INDUSTRIES



Hospitals | Healthcare facilities | Clinical laboratories | Environmental | Entertainment | Work environments | Others

PRINCIPLE

Viral RNA is isolated from the sample and transcribed to cDNA. Then, E and N1 SARS-CoV-2 genes, and the human RP gene (RNAase P) are amplified by RT-qPCR. Viral cDNA is detected using fluorescent probes for the specific recognition of each gene. Results are automatically published in a web platform which is linkeable to external platforms through API connection.

TECHNICAL SPECIFICATIONS

Targets	SARS-CoV-2 genes E (Envelope), N1 (Nucleocapsid) and Human RP gene (RNAse P)
Performance	Limit of detection: 10 genomic copies/µL Specificity: 100% Sensitivity in nasopharyngeal samples: 100% Sensitivity in saliva samples: 91,5%
Validated samples	Nasopharyngeal, oropharyngeal, oral, nasal, saliva, environmental and surface samples
Time for results	24 hours
Technology	Multiplex Reverse-transcription quantitative PCR
Detection chemistry	Intercalant fluorophores (FAM Channel)

SCOPE OF THE SERVICE

- SARS-CoV-2 detection by RT-qPCR
- Automatic publication of results in web platform, linkeable to external platforms through API connection
- Post sale customers service

AWARDS AND CERTIDICATIONS

- CLIA certified laboratory

CUSTOMER RESPONSABILITIES FOR OPTIMAL PERFORMANCE

All samples to be analyzed in our facilities must comply with the following:

- Samples must be properly refrigerated
- Samples must be properly identified
- Samples must be properly sealed and contained according to local protocols for transport of clinical samples

SCIENTIFIC VALIDATION

Experimental sensitivity was determined using quantified SARS-CoV-2 RNA (BEI resources, catalog #NR-52285). Detection limit was obtained by serial dilutions in a negative SARS-CoV-2 composite of samples followed by real-time PCR. The lowest concentration of SARS-CoV-2 RNA that yielded a detection rate of ≥95% was 10 genomic copies/µl.

Inclusivity analysis was performed aligning each of the primer and probe sequences to all complete sequences of SARS-CoV-2 (>29kb) available on GISAID genomic database (https://www.gisaid.org/) as of June 15, 2020. Primers and probes have 100% identity to the 56,172 sequences, for N1 region and 57,318 sequences for E gene.

Operational validation for SARS-CoV-2 detection in nasopharyngeal samples was performed analyzing 330 samples by a reference method (CDC 2019-nCoV RT-qPCR diagnosis panel) and TAAG CS11 COVID-19 method, reporting a sensitivity of 100%. Results are summarized in the following table:

		CDC 2019-nCoV RT-qPCR diagnosis panel			
		Positives	Negatives	Indeterminate	Total
TAAG CS11 COVID-19	Positives	49	0	0	49
	Negatives	0	281	0	281
	Indeterminate	0	0	0	0
	Total	49	281	0	330

Operational validation for SARS-CoV-2 detection in saliva samples was performed comparing results of 144 nasopharyngeal and saliva samples collected from same patients. There was 97.9% positive and 100% negative agreement between the results obtained from testing of saliva and those obtained from nasopharyngeal swab. The results of the evaluation with paired nasopharyngeal swabs and saliva were therefore considered acceptable.

		Nasopharyngeal Diagnosis			
		Positives	Negatives	Indeterminate	Total
Saliva Diagnosis	Positives	92	0	0	92
	Negatives	2	50	0	52
	Indeterminate	0	0	0	0
	Total	94	50	0	144

ORDER INFORMATION

Catalog #	Service
S-CR01-1	TAAG CS11 COVID-19

TAAG Genetics Corp.
3710 Illinois Avenue, St. Charles, IL. 60174 United States
Phone: 1-630-246-7777
Email: contact_US@taag-genetics.com
Web: www.taag-genetics.com