SARS-CoV-2 RT-PCR Test Kit Package Insert

REF P131-1591	English

An *in vitro* multiplex real-time RT-PCR test for qualitative detection of nucleic acid from SARS-CoV-2 in oropharyngeal swab, nasopharyngeal swab or deep cough sputum specimens.

For professional in vitro diagnostic use only.

INTENDED USE

The *Promotor*® SARS-CoV-2 RT-PCR Test Kit is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in oropharyngeal swab, nasopharyngeal swab and deep cough sputum specimens collected from individuals suspected of SARS-CoV-2 by their healthcare provider.

The test utilizes amplification of target RNA by reverse transcription polymerase chain reaction (RT-PCR) to assess the presence or absence of SARS-CoV-2.

Positive results are indicative of the presence of SARS-CoV-2 RNA but do not rule out bacterial infection or co-infection with other viruses. The pathogen detected may not be the definite cause of disease; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The *Promotor*® SARS-CoV-2 RT-PCR Test Kit is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures.

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

The *Promotor*® SARS-CoV-2 RT-PCR Test targets specific genomic regions of SARS-CoV-2: nucleocapsid (N) gene, Envelope protein (E) gene, ORF1ab gene. The TaqMan probes for the three amplicons are labeled with FAM, VIC and ROX fluorescent dyes respectively to generate target-specific signal. Human RNase P gene is used as an internal control to monitor the processes from nucleic acid extraction to fluorescent detection. The IC probe is labeled with CY5 fluorescent dye to differentiate its fluorescent signal from SARS-CoV-2 targets. UNG enzyme and dUTP are used to avoid contamination.

In the reaction process, the RNA of SARS-CoV-2 is converted to cDNA by the reverse transcriptase, and then cDNA was used as template for amplification. In the PCR cycle, the probe anneals to a specific target sequence located between forward and reverse primers; during the extension phase, the 5'→3' polymerase activity and exo-nuclease activity of Taq DNA polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal.

WARNING AND PRECAUTIONS

The *Promotor*® SARS-CoV-2 RT-PCR Test Kit work flow should be performed by qualified and trained staff to avoid the risk of erroneous results.

Strictly separate sample preparation area used for specimens and controls, and reagent preparation area used for reagents, to prevent false positive results. Specimens, controls and reagents must be handled under a laminar airflow hood or biological safety cabinet. This package insert should be read carefully prior to use. Strictly follow the instructions in the package insert. Reliability of array results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Handling Precautions

- For professional *in vitro* diagnostic use only. Do not use reagents after the expiration date.
- The procedures should be performed in separated areas to aid in preventing contamination. The areas should include Reagents Preparation Area, Sample Preparation Area and Detection Area. All supplies for a particular procedure should be stored in the area where that procedure is performed and should not be moved between areas.
- Follow necessary precautions when handling specimens. Use personal protective equipment (PPE) for the handling of potentially infectious samples.
- Do not use reagents from different lots in the same test.
- Avoid cross contamination between reagents to ensure valid test results.
- All the equipment should be used with care, calibrated and maintained regularly according to the manufacturers' instructions.

Laboratory Procedures

- Wear personal protective gloves, protective coats, and medical protective masks, and eye protection when handling clinical specimens and reagents. The protective equipment such as masks must be worn correctly, and wash hands thoroughly after handling specimens，controls and kit reagents.
- All clinical specimens should be considered potentially infectious. Handle all samples, controls and reagents according to good laboratory practice. Refer to CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with SARS-CoV-2.
- The operation of the respiratory tract samples potentially containing SARS-CoV-2 should be carried out in a biosafety cabinet，and the operating procedures should be followed.
- Thoroughly clean and disinfect all laboratory work surfaces with a freshly prepared solution of 0.5% sodium hypochlorite in distilled or deionized water (dilute household bleach 1:10). Follow by wiping the surface with 70% ethanol.
- Do not pipette by mouth. Do not eat, drink or smoke in laboratory areas.
- Use a new pipet tip for each specimen assayed.

Waste Handling

- The waste liquid and pipette tips generated during the experiment should be placed in a waste liquid tank containing 0.5% -1% chlorine-containing disinfectant.
- Discard unused reagents, contaminated materials, specimens and waste in accordance with national and local regulations.

STORAGE AND STABILITY

- All reagents should be stored at -20 ± 5°C. All unopened reagents are stable until the expiration date printed on the box if stored at -20 ± 5°C.
- After opening, the reagents could be stored at -20 ± 5°C up to 3 months.
- Check the expiration date prior to use. Do not use expired reagents.
- Unused reagents should be stored at -20 ± 5°C, avoid freezing and thawing more than six times.

APPLICABLE INSTRUMENT

The kit has been validated with the *Applied Biosystems*® 7500 Real-Time PCR System manufactured by Thermo Fisher Scientific Inc.

Note: Refer to manufacturers' operating instructions for use of the Applied *Biosystems*® 7500.

The setting of Probe, Reporter Dye: FAM/VIC/ROX/CY5, Quencher Dye: None, Passive Reference: None

SPECIMEN COLLECTION AND PREPARATION

- **Specimen:** oropharyngeal swab, nasopharyngeal swab and deep cough sputum.
- **Specimen collection:**

Oropharyngeal swab: Wipe the bilateral pharyngeal tonsils and the posterior pharyngeal wall at the same time using plastic rod swab with polypropylene fiber tip.

Nasopharyngeal swab: Hold the swab close to the nasal septum slowly and deeply to the back of the nasopharynx, rotate it several times to obtain secretions using plastic rod swab with polypropylene fiber tip

The swabs should be placed immediately into a sterile transport tube containing either viral transport medium (VTM), Amies transport medium or sterile saline. Discard the tail of plastic rod swab, and tighten the tube cover.

Deep cough sputum: Cough up the sputum in the deep part of the respiratory tract and collect it in the container. Liquefying method: add equal volume of acetylcysteine (10g/L) or phosphate solution (containing proteinase K) into the sputum sample, shake at room temperature for 30 minutes, and then carry out RNA extraction after sufficient liquefying.

- **Specimen storage:** Specimens should be tested as soon as possible after collection. If immediate testing is not possible, the specimens may be stored at 2°C to 8°C for up to 24 hours, at -20±5℃ for up to 4 days; it is recommended to freeze the specimens at -70°C or colder for long-term storage.
- **Specimen transportation:** Specimen should be shipped in low temperature using sealed foam box with ice.

Note: Dispose of all material that has come into contact with specimens and reagents in accordance with applicable international, national and regional regulations.

REAGENTS AND COMPONENTS

Materials Provided

Component	Composition	Specification
Reaction Mix	Tris, $(NH_4)_2SO_4$, KCl, $MgCl_2$, primers and fluorescent probes of SARS-CoV-2, primers and fluorescent probes of RNase P	1×630 µL
Enzyme Mix	*Taq* polymerase, RT- polymerase, RNase inhibitor, TS-UNG and dNTPs	1×70 µL
Positive Control	Armored RNA containing target gene fragment	1×200 µL
Negative Control	0.9% NaCl	1×200 µL

Note: 1. Do not mix components from different kit lots.
2. Pipette tips should be change between different reaction mix and specimen.

Materials Required But Not Provided

- Applied *Biosystems*® 7500 Real-Time PCR System
- Vortex Shaker
- Centrifuge
- 0.5% -1% chlorine-containing disinfectant
- 70% ethanol
- Pipettes with disposable tips
- Anhydrous Ethanol
- 1.5 mL centrifuge tubes
- Disposable gloves, disposable protective clothing, goggles, medical protective masks, protective boot
- Nucleic acid extraction reagent

DIRECTIONS FOR USE

1. Specimen Preparation (Sample Preparation Area)

It is recommended to use *Promotor*® Nucleic Acid Extraction Kit manufactured by ACON or *QIAamp*® Viral RNA Mini Kit manufactured by QIAGEN Gmbh to extract nucleic acids.

Note: Frozen specimens should be thawed at room temperature and mixed well before use.

2. Controls Preparation (Sample Preparation Area)

Positive and negative controls should be processed with the same procedure as specimen.

3. Reagents Preparation (Reagent Preparation Area)

- Thaw the Reaction Mix and Enzyme Mix at room temperature, vortex to mix thoroughly and then centrifuge it at 2000rmp for 10 seconds.
- Calculate the appropriate number of tests (n), (n = specimen number + 2 Controls).
- Calculate the total volume of working solution for all tests.
- Working solution for one test is described as below:

Component	Volume
Reaction Mix	18 µL
Enzyme Mix	2 µL

- Completely vortex the prepared PCR mix, aliquot 20 µL into each PCR tube or each well of a 96-well PCR plate.

4. Amplification Mix (Sample Preparation Area)

Add 20 µL of extracted nucleic acid into each tube or well containing PCR mix, close lids for the PCR tubes or 96-well seal PCR plates with an appropriate film, slightly vortex the tubes and briefly centrifuge them to get rid of bubbles. Transfer them to the Detection Area.

5. Amplification and Detection (Detection Area)

Load the PCR tubes on the Applied *Biosystems*® 7500 Real-Time PCR System.

Edit and run the program as below:

Step	Cycle (s)	Temperature	Time
1	1	50℃	20min
2	1	95℃	5 min
3	45	94℃	15 sec
		60℃	30 sec (Fluorescence detection)

Fluorescence channel selection: Reporter Dye (FAM/VIC/ROX/CY5), Quencher Dye: None, Passive Reference: None

VALIDATION REQUIREMENTS AND QUALITY CONTROL

1. Baseline and threshold setting

View the baseline values, in the Graph Type drop-down list, select Linear. Select the Baseline check box to show the start cycle and end cycle. The horizontal part of the baseline is used for the baseline range, which normally starts from 3-5 cycles and ends at 15-20 cycles. Baseline setting is normally automatically done by instrument. It can also be manually adjusted to choose the horizontal part of the curve.

Select the Threshold check box to show the threshold. Thresholds should be adjusted to fall within exponential phase of the fluorescence curves and above any background signal. The threshold value for different instruments varies due to different signal intensities.

Perform data analysis by clicking "Analyze" button of the software.

2. Quality control

The product provides negative control, positive control to monitor the reliability of the results. All test controls should be examined prior to interpretation of patient results. Positive control, negative control should meet the requirements listed in the below table to ensure valid results. If the controls are not valid, the patient results cannot be interpreted.

Control	Ct Values			
	N (FAM)	E (VIC)	ORF1ab (ROX)	RNase P (CY5)
Positive Control	≤ 36	≤ 36	≤ 36	≤ 36
Negative Control	Not Detected	Not Detected	Not Detected	Not Detected

Note: Amplification curves of positive control above the threshold should be sigmoid curve profile, and no amplification curve observed for negative control.

INTERPRETATION OF RESULTS

Reporter dye	Target	Ct Values and Amplification Curves
FAM	N gene(+)	Ct ≤ 40, and there should be sigmoid amplification curves.
	N gene(-)	Ct ＞40 or no Ct values
VIC	E gene(+)	Ct ≤ 40, and there should be sigmoid amplification curves.
	E gene(-)	Ct ＞40 or no Ct values
ROX	ORF1ab(+)	Ct ≤ 40, and there should be sigmoid amplification curves.
	ORF1ab(-)	Ct ＞40 or no Ct values
CY5	RNase P gene(+)	Ct ≤ 40, and there should be sigmoid amplification curves.
	RNase P gene(-)	Ct ＞40 or no Ct values

Note: If Ct values of FAM, VIC, ROX, Cy5 channels are all greater than 40 or have no Ct values, there are problems with specimens or operation. Recollect specimen and extract nucleic acid to test again.

Result interpretation for patient samples:

N gene	E gene	ORF 1ab	RNase P gene	Status	Result	Action
Negative	Negative	Negative	Negative	Invalid	NA	Repeat test. If the repeat result remains invalid, consider collecting a new specimen.
Negative	Negative	Negative	Positive	Valid	SARS-CoV-2 Negative	SARS-CoV-2 is negative or nucleic acid concentration is below the detection limit of the kit. Report results to healthcare provider. Consider testing for other viruses.
Only N gene or E gene is Positive			Positive or Negative	Valid	SARS-CoV-2 Inconclusive	Repeat test. If the repeat result remains positive, SARS-CoV-2 is negative (May be other near-source coronavirus,such as SARS)
Only ORF1ab gene is Positive			Positive or Negative	Valid		Repeat test. If the repeat result remains positive, SARS-CoV-2 is positive. Report results to healthcare provider and appropriate public health authorities and isolation.
Two or three SARS-CoV-2 targets are positive			Positive or Negative	Valid	SARS-CoV-2 Positive	Report results to healthcare provider and appropriate public health authorities and isolation.

LIMITATIONS

1. For professional *in vitro* diagnostic use only.
2. The *Promotor*® SARS-CoV-2 RT-PCR Test Kit is an *in vitro* assay for the qualitative detection of the nucleic acid from oropharyngeal swab, nasopharyngeal swab or deep cough sputum specimens. Other specimen types have not been evaluated and should not be tested with this assay.
3. Specimens must be collected, transported, and stored using appropriate procedures and conditions. Improper collection, transport, or storage of specimens may hinder the ability of the assay to detect the target sequences.
4. Extraction and amplification of nucleic acid from clinical specimens must be performed according the specified methods listed in this procedure. Other extraction approaches and processing systems have not been evaluated.
5. This kit is intended for detection of SARS-CoV-2. The result is only for clinical reference, and the clinical management of patients should be considered in combination with their symptoms/signs, history, other laboratory tests and treatment responses.
6. False-negative results may arise from:
   - Improper specimen collection
   - Degradation of the SARS-CoV-2 RNA during shipping/storage
   - Using unauthorized extraction or assay reagents
   - The presence of RT-PCR inhibitors
   - Mutation in the SARS-CoV-2 virus
   - Failure to follow instructions for use
7. False-positive results may arise from:
   - Cross contamination during specimen handling or preparation
   - Cross contamination between patient specimens
   - Specimen mix-up
8. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions.

PREFORMANCE CHARACTERISTICS

Limit of Detection

In the LoD determination study, serial dilutions of 5 quantified armored RNA were prepared with negative specimens and 5 levels at target concentrations of 2000, 1000, 500, 250 and 125 copies/mL were tested, each level were tested in 20 replicates. The LoD is determined as the lowest concentration where ≥ 95% (19/20) of the replicates are positive. The study results showed the LoD of the kit is 500 copies/mL.

No.	Specimens	Effective Concentration	Replicate	Mean Ct				% Positive
				N	E	ORF1ab	Internal Reference	
LOT 1	Armored RNA containing target gene fragment	2000copies/mL	20	36.13	35.28	36.95	36.89	100%
		1000copies/mL	20	36.84	36.07	36.62	36.67	100%
		500copies/mL	20	38.67	38.68	38.2	36.26	95%
		250copies/mL	20	38.85	39.56	37.22	36.46	80%
		125copies/mL	20	39.05	39.66	39.91	36.49	70%
LOT 2		2000copies/mL	20	35.42	36.52	35.47	36.97	100%
		1000copies/mL	20	36.81	37.28	36.25	36.66	100%
		500copies/mL	20	38.9	38.18	37.71	36.53	100%
		250copies/mL	20	38.22	37.97	38.66	36.09	95%
		125copies/mL	20	39.51	39.19	40.05	36.35	60%
LOT 3		2000copies/mL	20	35.64	35.22	35.53	36.15	100%
		1000copies/mL	20	37.62	36.28	36.85	36.78	100%
		500copies/mL	20	38.18	38.48	38.77	36.56	100%
		250copies/mL	20	39.33	38.9	39.52	36.31	65%
		125copies/mL	20	39.97	39.95	40.97	36.27	20%

Precision

Precision performance was assessed by testing the same sample under variable conditions. 7 samples (including 2 SARS-CoV-2 positive clinical specimens of oropharyngeal swab and nasopharyngeal swab, 2 SARS-CoV-2 positive clinical specimens of deep cough sputum, 2 armored RNA and 1 negative clinical specimen) were tested for the precision evaluation.

Each specimen was tested in 10 replicates across 3 lots of reagents using 2 instruments, 2 operators and 21 days.

Coefficient of Variation(CV,%) of In-batch precision/Batch precision/precision of In-Day/precision of Day/ precision of Operator/precision of instrument were ≤ 5%.

Inclusivity

The *Promotor*® SARS-CoV-2 RT-PCR Test Kit has been designed to detect publicly available SARS-CoV-2 viral RNA sequences. Alignments were performed with the designed oligonucleotide primer and probe sequences of SARS-CoV-2 RT-PCR Test Kit panel with 1119 publicly available sequences of SARA-CoV-2 from NCBI and GISAID as of March 23, 2020 to demonstrate the estimated inclusivity of the SARS-CoV-2 RT-PCR Test Kit. All the alignments exhibited high homology to the available SARS-CoV-2 sequences, suggesting the potential ability of the SARS-CoV-2 RT-PCR Test Kit to detect those SARS-CoV-2 strains.

Specificity

The *Promotor*® SARS-CoV-2 RT-PCR Test Kit has been designed to detect all publicly available SARS-CoV-2 strains. The designed primers and probes were specific to the SARS-CoV-2 virus genome region to ensure the specific detection of the SARS-CoV-2 viral RNA.

In silico analysis of the SARS-CoV-2 assay, common respiratory flora and other viral pathogens were performed with *Promotor*® SARS-CoV-2 RT-PCR Test Kit. All the organisms tested were listed in the below table. The result showed that the *Promotor*® SARS-CoV-2 RT-PCR Test Kit exhibited satisfactory analytical specificity and had no cross-reactivity with virus and microbes tested.

Specimen	Source/Specimens type	Concentration	Result
Coronavirus NL63	ShenZhen CDC	＞1×10^{5}copies/mL	Negative
Coronavirus HKU1	ShenZhen CDC	＞1×10^{5}copies/mL	Negative
Coronavirus 229E	ShenZhen CDC	＞1×10^{5}copies/mL	Negative
Coronavirus OC43	ShenZhen CDC	＞1×10^{5}copies/mL	Negative
SARS Coronavirus	Armored RNA	＞1×10^{6}copies/mL	Negative
MERS Coronavirus	Armored RNA	＞1×10^{6}copies/mL	Negative
Influenza A virus, H1N1	Patient Specimens	＞1×10^{5}copies/mL	Negative
H3N2	ShenZhen CDC	＞1×10^{5}copies/mL	Negative
H5N1	Patient Specimens	＞1×10^{5}copies/mL	Negative
H7N9	Patient Specimens	＞1×10^{5}copies/mL	Negative
Influenza B(Victoria)	ShenZhen CDC	＞1×10^{5}copies/mL	Negative
Influenza B(Yamagata)	ShenZhen CDC	＞1×10^{5}copies/mL	Negative
Respiratory syncytial virus A	ShenZhen CDC	＞1×10^{5}copies/mL	Negative
Respiratory syncytial virus B	ShenZhen CDC	＞1×10^{5}copies/mL	Negative
Parainfluenza virus type 1	ShenZhen CDC	＞1×10^{5}copies/mL	Negative
Parainfluenza virus type 2	ShenZhen CDC	＞1×10^{5}copies/mL	Negative
Parainfluenza virus type 3	ShenZhen CDC	＞1×10^{5}copies/mL	Negative
Parainfluenza virus type 4	ShenZhen CDC	＞1×10^{5}copies/mL	Negative
Rhinovirus A	ShenZhen CDC	＞1×10^{5}copies/mL	Negative
Rhinovirus B	ShenZhen CDC	＞1×10^{5}copies/mL	Negative
Adenovirus type 3	ShenZhen CDC	＞1×10^{5}copies/mL	Negative
Adenovirus type 4	ShenZhen CDC	＞1×10^{5}copies/mL	Negative
Adenovirus type 7	Patient Specimens	＞1×10^{5}copies/mL	Negative
Adenovirus type 55	Patient Specimens	＞1×10^{5}copies/mL	Negative
Adenovirus type 1	Patient Specimens	＞1×10^{5}copies/mL	Negative
Adenovirus type 2	Patient Specimens	＞1×10^{5}copies/mL	Negative
Adenovirus type 5	Patient Specimens	＞1×10^{5}copies/mL	Negative
Enterovirus EV71	Patient Specimens	＞1×10^{6}copies/mL	Negative
Enterovirus CA16	Patient Specimens	＞1×10^{6}copies/mL	Negative
Enterovirus CA10	Patient Specimens	＞1×10^{6}copies/mL	Negative
Enterovirus CA6	Patient Specimens	＞1×10^{6}copies/mL	Negative
Human metapneumovirus	ShenZhen CDC	≥1×10^{6}copies /mL	Negative
EB	Patient Specimens	1.15×10^{5}copies/mL	Negative
Human cytomegalovirus	Patient Specimens	1×10^{5}copies /mL	Negative
Mycoplasma pneumoniae	Patient Specimens	≥1×10^{5}copies /mL	Negative
Chlamydia pneumoniae	Patient Specimens	≥1×10^{5}copies /mL	Negative
Pertussis	ATCC/Standard Strain	＞1×10^{5}copies/mL	Negative
Haemophilus influenzae	Clinical Hospital	＞10^{6}cfu/mL	Negative
Staphylococcus aureus	Clinical Hospital	＞10^{6}cfu/mL	Negative
Streptococcus pneumoniae	Clinical Hospital	＞10^{6}cfu/mL	Negative
Streptococcus pyogenes	Clinical Hospital	＞10^{6}cfu/mL	Negative
Klebsiella pneumoniae	Clinical Hospital	＞10^{6}cfu/mL	Negative
Mycobacterium tuberculosis	Clinical Hospital	＞1×10^{5}copies/mL	Negative
Aspergillus fumigatus	Clinical Hospital	＞10^{6}cfu/mL	Negative
Cryptococcus neoformans	Clinical Hospital	＞10^{6}cfu/mL	Negative
Candida albicans	ATCC/Standard Strain	＞1×10^{5}copies/mL	Negative
Candida glabrata	ATCC/Standard Strain	＞1×10^{5}copies/mL	Negative

Interfering substances

The potential interference, whole blood, common antiviral drugs oseltamivir, amantadine, ribavirin and antibiotic azithromycin were tested with *Promotor*® SARS-CoV-2 RT-PCR Test Kit in this study. The substances were tested at the concentration as: 0.5 microliter whole blood, 0.025 g/mL azithromycin, 1.5 mg/mL oseltamivir, 5 mg/mL ribavirin, 2 mg/mL amantadine. The results show that the PCR was not affected by these potential inferring substances.

Clinical Evaluation

The clinical evaluation study was conducted using 118 positive specimens and 172 negative clinical specimens. All 290 specimens were obtained from a clinical hospital, and the specimens were already confirmed with commercial RT-PCR product by clinical hospital.

Clinical Performance for SARS-CoV-2 RT-PCR Test Kit

Method		Comparator Kit		Total Results
	Results	Positive	Negative	
Promotor® SARS-CoV-2 RT-PCR Test Kit	Positive	115	3	118
	Negative	3	169	172
Total Results		118	172	290

Relative Sensitivity: 97.46% (92.75%-99.47%)*
Relative Specificity: 98.26% (94.99%-99.64%)*
Accuracy: 97.93% (95.56%-99.24%)*
*95% Confidence Intervals

Index of Symbols

	Consult instructions for use
IVD	*In vitro* diagnostic medical device
LOT	Batch code
Σ	Contains sufficient for *<n>* tests
REF	Catalogue number
	Use-by date
Reaction Mix	Reaction Mix
Package Insert	Package Insert

	Manufacturer
EC REP	Authorized representative in the European Community
	Temperature limit
Enzyme Mix	Enzyme Mix
CONTROL -	Negative Control
CONTROL +	Positive Control
	Do not reuse

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