PerkinElmer® SARS-CoV-2 Solutions for Nucleic Acid Detection

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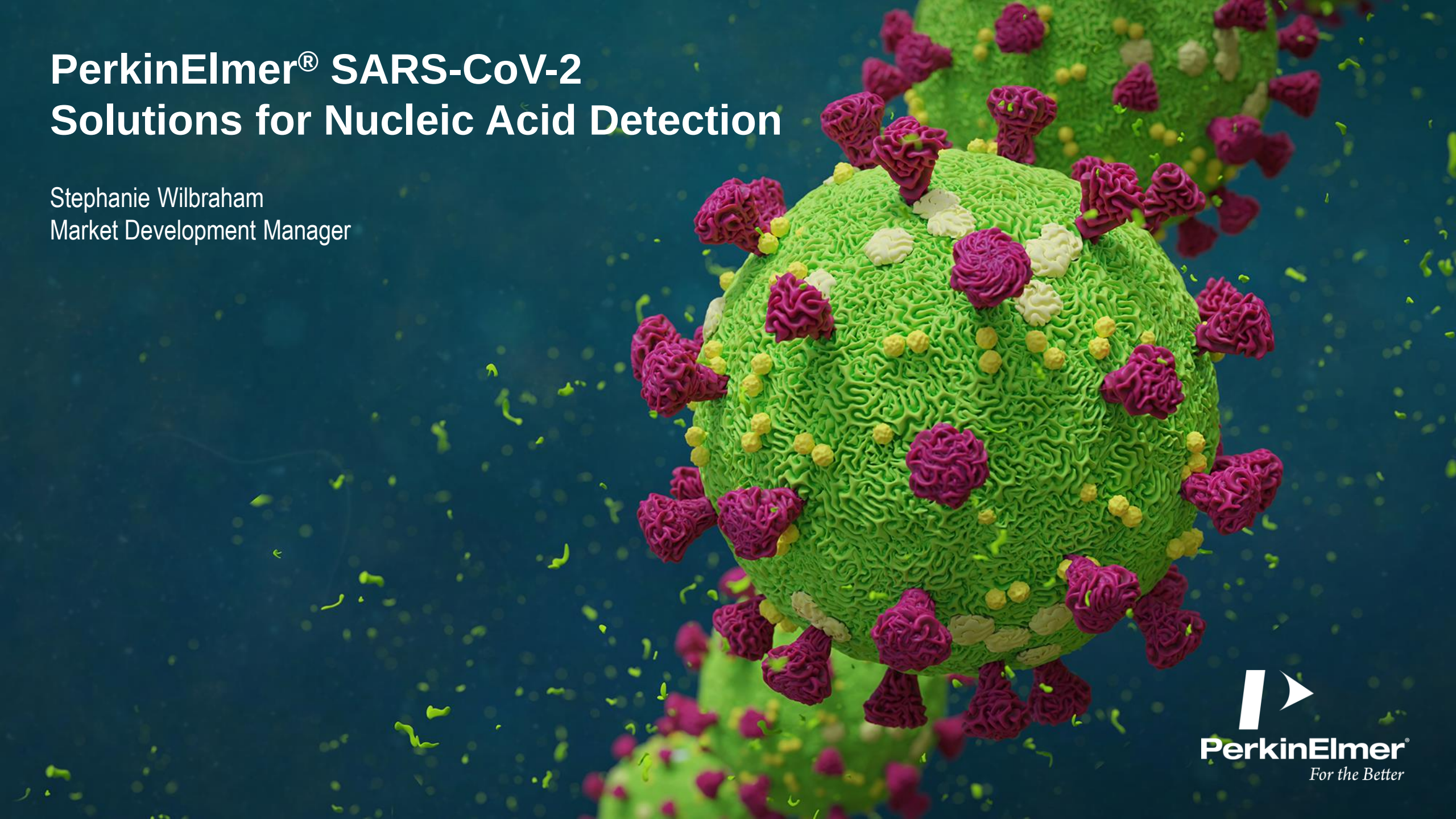
Market Development Manager



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SARS-CoV-2 Identification Methods

Nucleic Acid Detection

EARLIER ID OF LIVE VIRUS | DETECTION

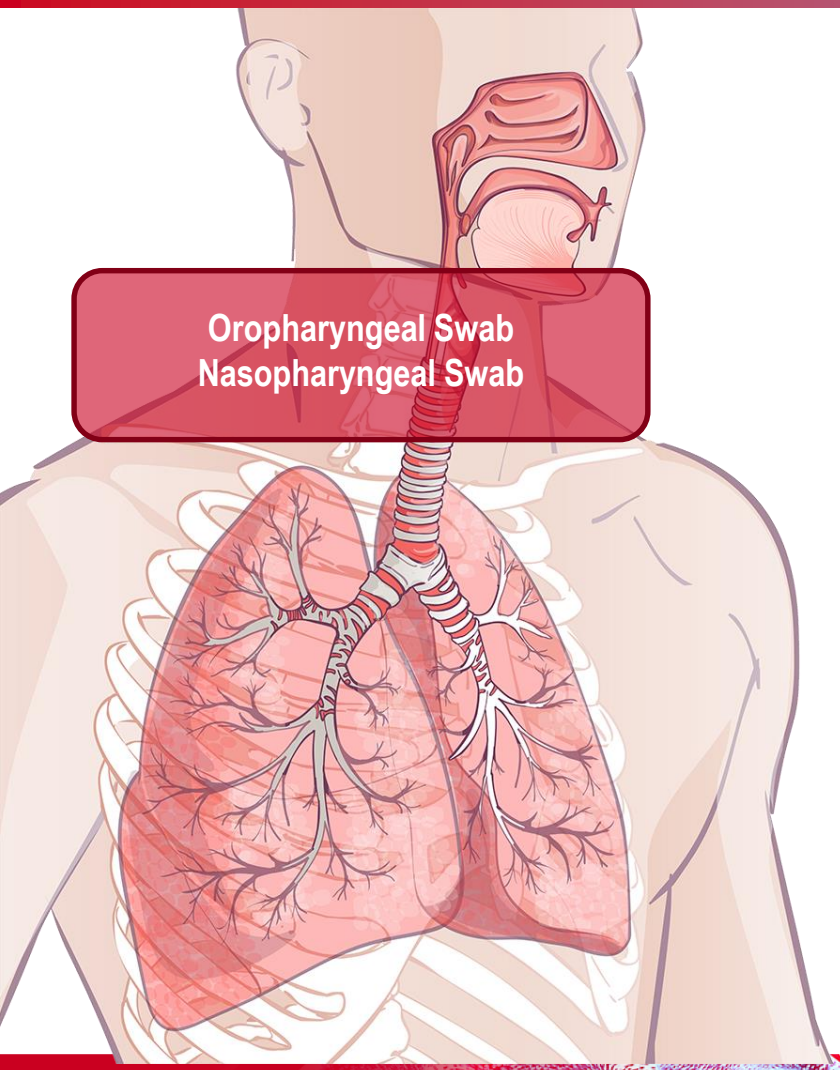
Antibody Detection

LATER ID OF INFECTION | SURVEILLANCE

PerkinElmer® SARS-CoV-2 Nucleic Acid Detection Workflow

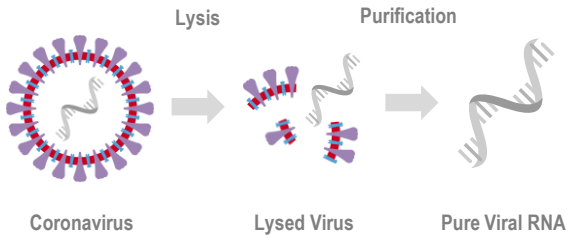
Automated Workflow

1 | SAMPLE COLLECTION



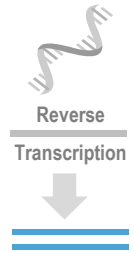
2 | NUCLEIC ACID EXTRACTION

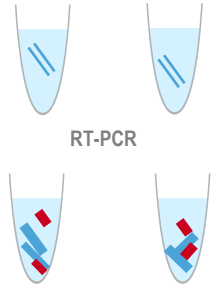
PerkinElmer® chemagic™ Kits on chemagic™ 360 Instruments



3 | REAL-TIME PCR

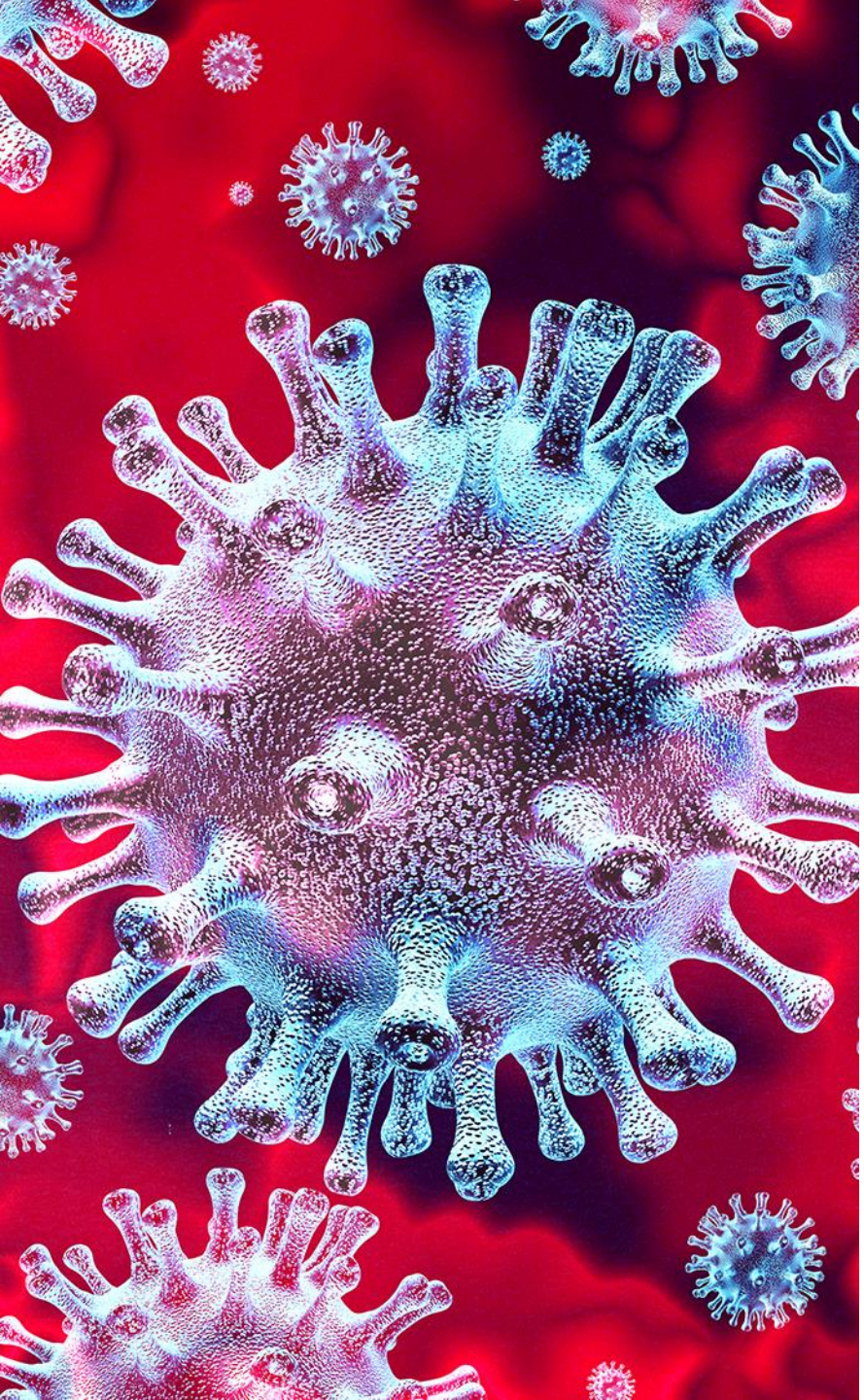
PerkinElmer® RT-PCR Kits on 3rd Party Thermal Cyclers





PerkinElmer® JANUS® G3 Workstation Options for Liquid Handling

PerkinElmer



Extraction Kit Description

chemagic™ Viral DNA/ RNA 300 Kit H96

High throughput | High recovery of pathogens

Input: up to 300 µL

Throughput: 96 samples in 60 minutes

Number of Preps per kit: 960

Sample Types: Oropharyngeal swab, Nasopharyngeal swab, Bronchoalveolar Lavage (BAL), Sputum, Plasma and Serum

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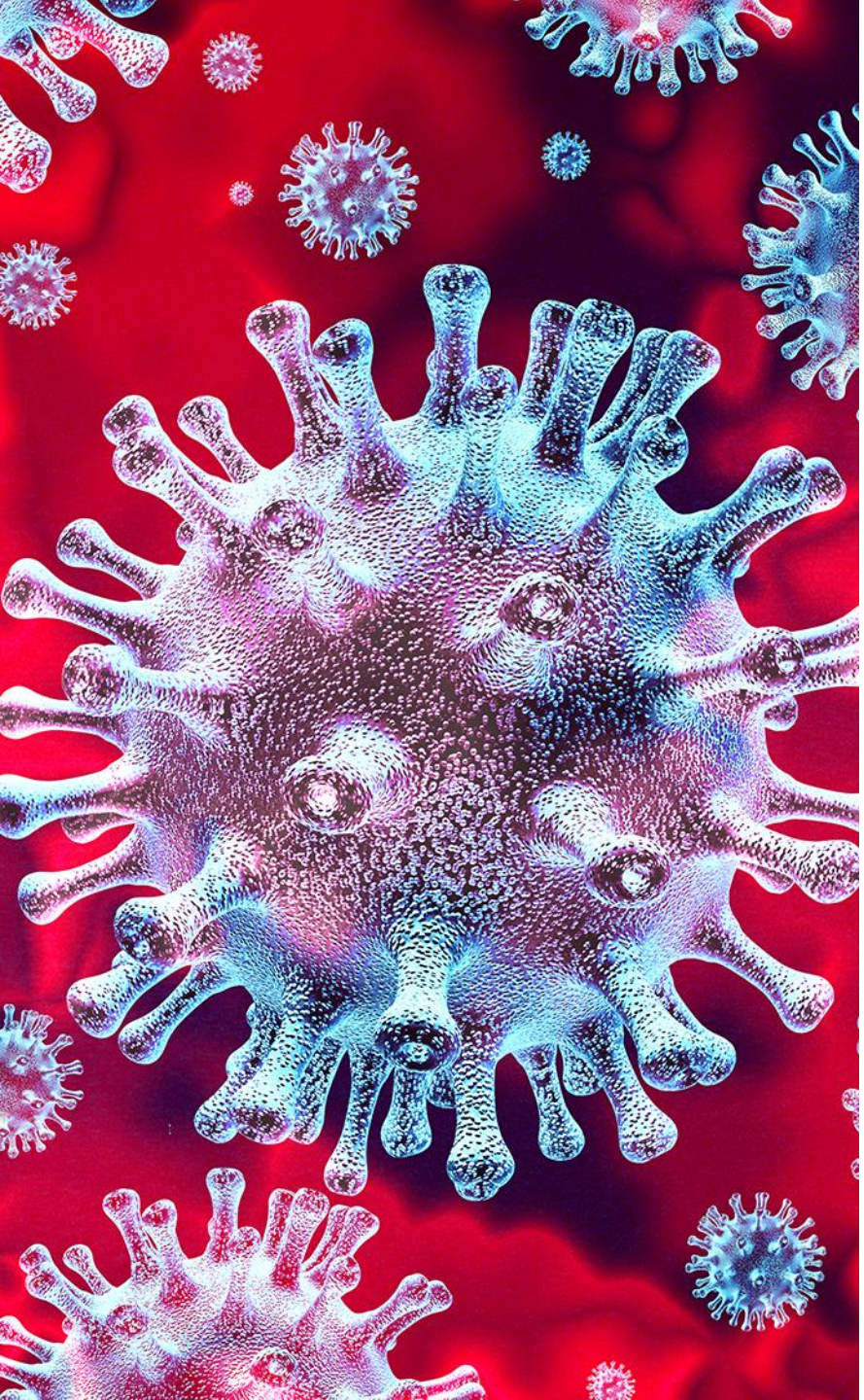
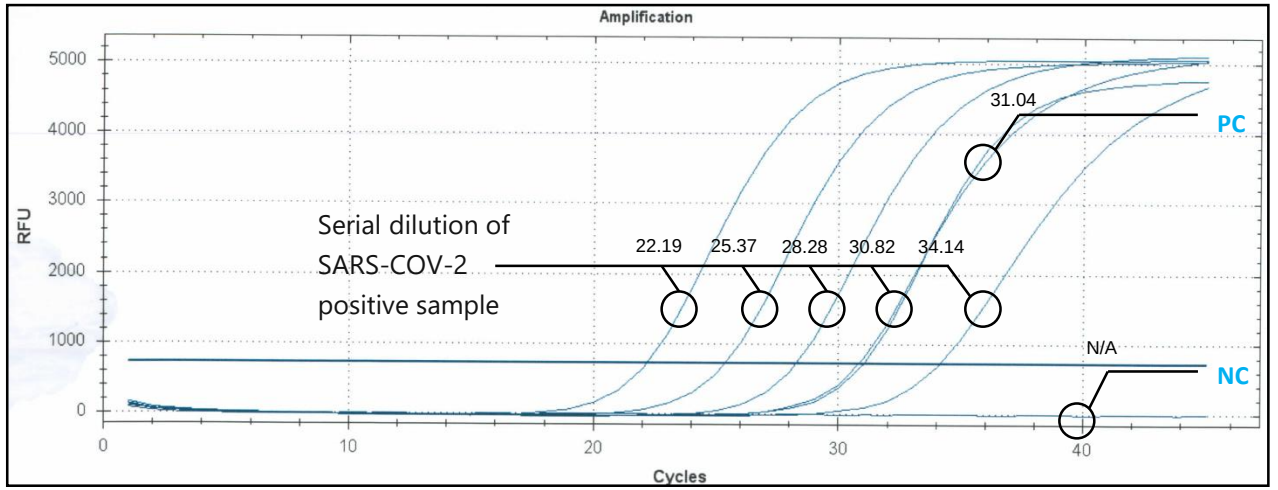


chemagic™ Viral DNA/ RNA 300 Kit H96

Sensitive Assay with broad working range



Amplification plot for single probe E-Gene real time RT-PCR for a molecular assay developed for RsRP/E-Gene target developed by the customer. Data set includes five fold serial dilution of positive SARS-CoV-2 sample, positive E-Gene control (PC) and negative control (NC).

CT values for the different dilutions are shown. Detailed and regular updated protocol information available on WHO homepage (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance).

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chemagic™ Viral RNA Isolation

Complete Solution for isolation of virus

- chemagic™ 360 instrument
- chemagic™ 96 Rod Head Set
- chemagic™ Viral DNA/RNA 300 Kit H96

- ✓ 96-well plate format for high throughput nucleic acid isolation in 60 minutes
- ✓ Reliable protocols for multiple applications
- ✓ Convenient sample loading and online buffer dispensing

JANUS® G3 Primary Sample Reformatting

Traceable and safe reformatting of primary samples

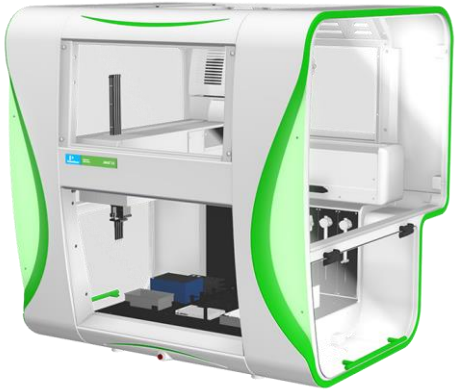
- Automation alternative for a laborious process
- Automated addition of internal standard, enzymes, and lysis buffer
- Automated setup of magnetic bead plates and elution plates
- Optional use of instrument for PCR plate prep

- ✓ Increases efficiency by reformatting 192 samples in 48 minutes
- ✓ Reduces hands-on time with biohazard material
- ✓ Improves sample integrity by reducing manual errors

JANUS® G3 PCR Workstation

Traceable and reproducible real-time PCR plate prep

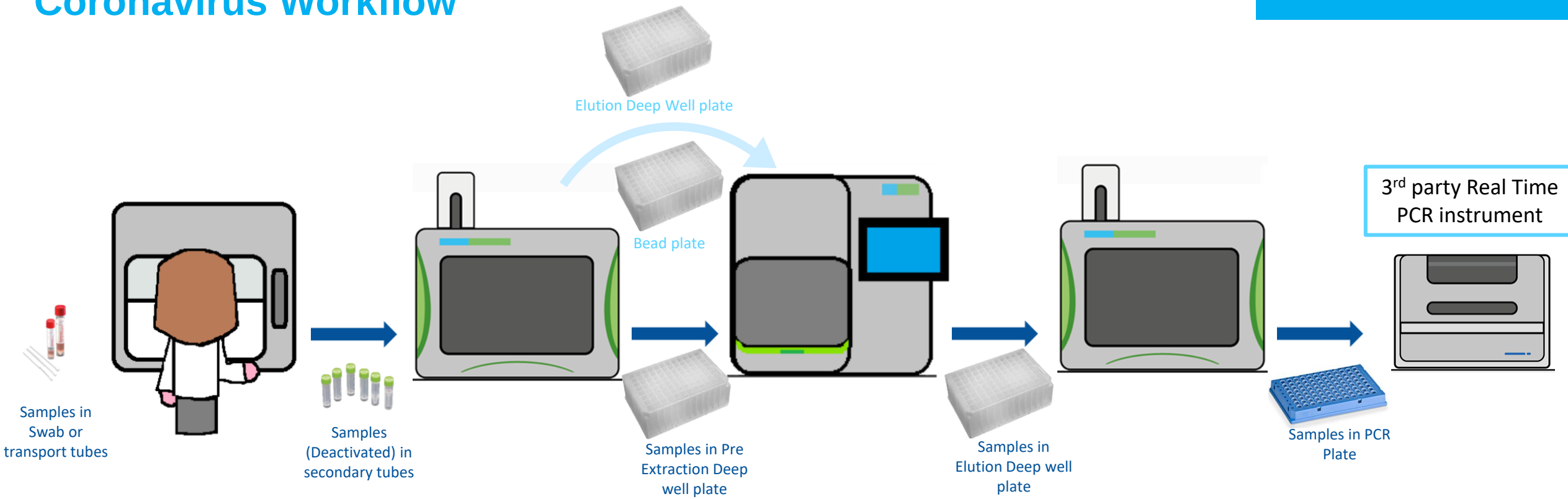
- Automation alternative for a laborious process
- Automated mixing of mastermix and samples
- Optional use of instrument for extraction set up and primary sample reformatting



- ✓ Increases efficiency by preparing two PCR plates in 16 minutes
- ✓ Reduces hands-on time
- ✓ Improves sample integrity by reducing manual errors

Coronavirus Workflow

Workflow Schematic



Scientist deactivates sample and transfers aliquot to secondary tube

JANUS® Workstation 1 reads barcodes of 2ndary tube and gets plate barcodes. It transfers samples and controls to pre extraction plates and adds reagents. It also prepares Elution plate and Bead Plate

chemagic ™360 extracts the samples in 96 well format

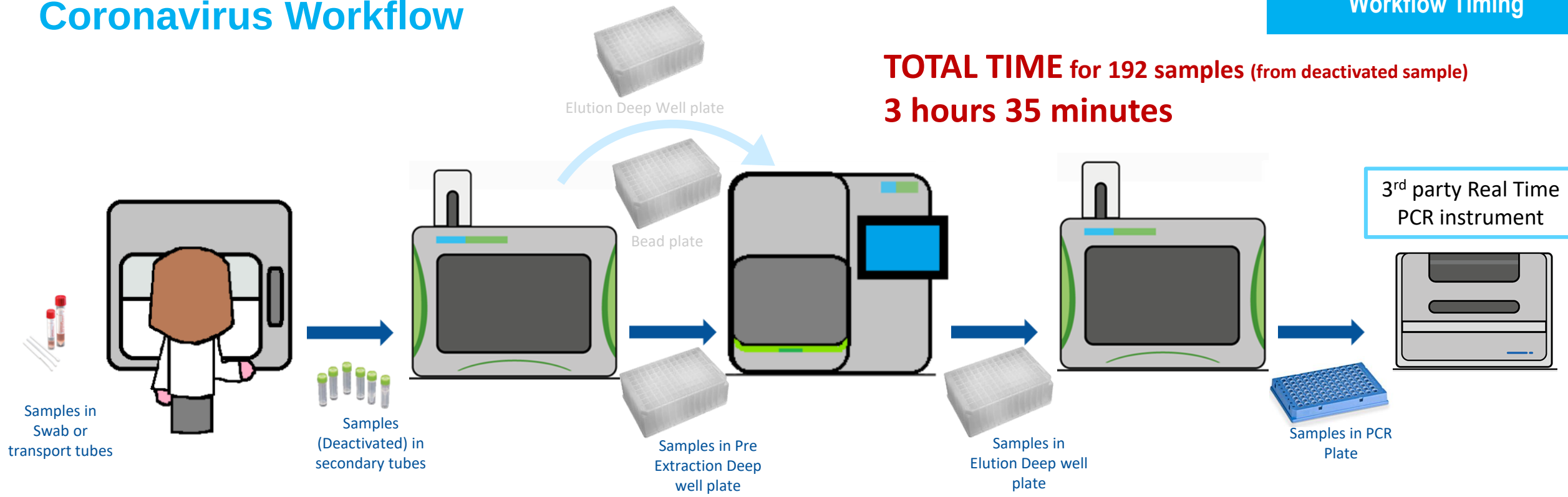
JANUS® Workstation 2 gets the plate barcodes from a user input. It transfers the samples and controls to the PCR plate and adds the mastermix

3rd party Real Time PCR instrument to complete PCR reaction

Coronavirus Workflow

Workflow Timing

TOTAL TIME for 192 samples (from deactivated sample)
3 hours 35 minutes



Automated Steps

JANUS® Reformatting 1 plate – 30 mins 2 plates – 60 mins	65 minutes chemagic™ 360 Extraction	Real Time PCR Setup 2 plates – 15mins 6 plates – 60mins	60 min Real Time PCR Run

Manual Steps

Scientist deactivates sample and transfers aliquot to secondary tube	5 min Sample Transfer	10 min Chemagic ™ 360 prep and Sample transfer	10 min JANUS® prep	5 min Sample Transfer	5 min Sample Transfer

PerkinElmer

PerkinElmer® SARS-CoV-2 RT-qPCR Reagent kit

3501-0010 (96 reactions)

SARS-CoV-2 RT-qPCR Reagent kit

Real-time reverse transcriptase polymerase chain reaction

Instructions for use.

Manufacturer:
Wallac Oy,
Mustionkatu 6, FI-20750 Turku, Finland
www.perkinelmer.com

FOR *IN VITRO* DIAGNOSTIC USE

CE

PerkinElmer

SARS-CoV-2 RT-qPCR Reagent kit

INTENDED USE

The kit is intended for the qualitative detection of SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) nucleic acids in RNA extracted from the human oropharyngeal swab and nasopharyngeal swab specimens as an aid in diagnosing patients suspected of COVID-19 (coronavirus disease) by their healthcare provider. Clinical correlation with patient history and other diagnostic information is necessary to determine the patient's infection status.

SUMMARY AND EXPLANATION OF THE ASSAY

SARS-CoV-2 RNA is generally detectable in human oropharyngeal swab and nasopharyngeal swab specimens during the acute phase of SARS-CoV-2 virus infection [1]. Positive results are indicative of presence of SARS-CoV-2 RNA. However, positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not exclude 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 SARS-CoV-2 RT-qPCR Reagent 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.

PRINCIPLES OF THE ASSAY

The SARS-CoV-2 Real-time RT-PCR assay uses TaqMan™ -based real-time PCR technique to conduct in vitro transcription of SARS-CoV-2 RNA, DNA amplification and fluorescence detection.

The assay targets at the specific genomic regions of SARS-CoV-2: nucleocapsid (N) gene and ORF1ab [2]. The TaqMan™ probes for the two amplicons are labeled with FAM™ and HEX™ /VIC™ fluorescent dyes, respectively, to generate target-specific signal.

The assay includes probes for human RNA target that is used as an RNA internal control to monitor the processes from nucleic acid extraction to fluorescence detection. The Internal Control (IC) probe is labeled with Cy5® fluorescent dye to differentiate its fluorescent signal from SARS-CoV-2 targets. The assay also uses a dUTP/UNG carryover prevention system to avoid contamination of PCR products and subsequent false positive results.

Kit Components

Kit components for 96 reactions

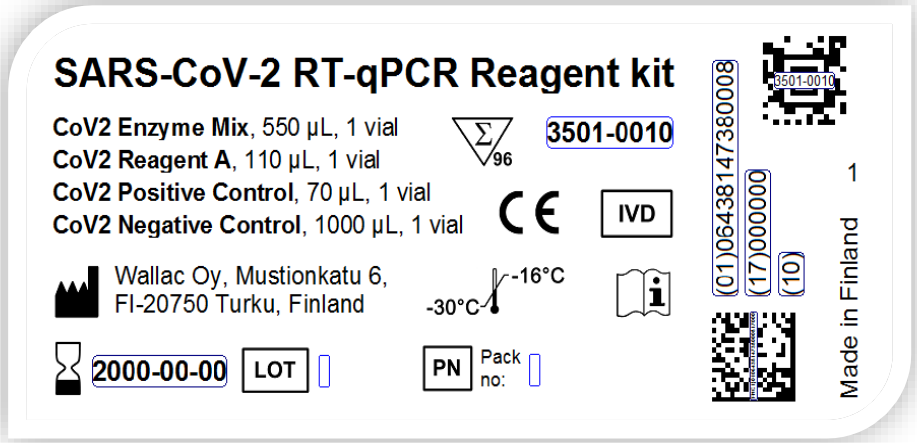
- 1x110 µL **CoV2 Reagent A**;
  - Primers and Probes for virus targets (N & ORF1ab)
- 1x550 µL **CoV2 Enzyme Mix**;
  - DNA polymerase, MMLV Reverse transcriptase, dNTPs, RNase inhibitor, UNG/dUTP
- 1x70 µL **CoV2 Positive Control**;
  - plasmid including virus target regions
- 1x1000 µL **CoV2 Negative Control**;
  - nuclease-free water

Labels:

N = FAM

ORF1ab = HEX/VIC

IC = Cy5



- Kit can be run in 4 parts within 30 days of opening
- Kit needs to be storaged in -30°C to -16°C

None of the components include any hazardous or infectious material

Assay Protocol

VIRUS TARGETS (N & ORF1ab) and TARGET SEQUENCES recommended by China CDC

Reaction mix:

- Reagent A + Enzyme Mix = 6 µL
- Sample or Pos./Neg. Control = 14 µL
- **Total Reaction volume = 20 µL**

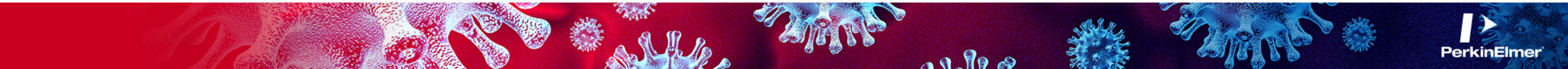
3501-0010 cycle program

Step	Temperature	Time	Number of Cycles
1	+25°C *	2 minutes	1
2	+50°C	15 minutes	1
3	+95°C	2 minutes	1
4	+95°C	3 seconds	45
	+60°C **	30 seconds	

* If the temperature cannot be set to 25°C in the cycler (e.g. Roche® LightCycler® 480 instrument), keep the PCR plate at room temperature for two minutes before starting the amplification run.
** Detect fluorescence signal during the final +60°C step.

- Tested on following qPCR instruments: LightCycler® 480 (Roche) instrument,QuantStudio ™ instrument (Thermo) and Bio-Rad CFX96 system.
  - Cycle program duration = ~1 hour

- Tested on following RNA extraction methods: chemagic™ 360 system (PerkinElmer), nucliSENS® easyMag® system (BioMerieux) or MagNA® Pure 96 system (Roche)



Analytical Performance

- LoD: 1.0 copies/µL (20 copies/reaction)
- Precision (CV%): ≤ 6%
  - over 40 replicates using 2 lots, 2 instruments, 2 operators, in 10 runs
- Cross-Reactivity: primers and probes are not cross-reacting with ~30 different viruses

- Clinical Validation Study (performed in Turku University Hospital):
  - 100% agreement with reference method (WHO/Corman et al, Berlin Charite institute) on positive samples (n=25) and 99% with negative samples (n=100, 1 sample guided to retest).
- In addition, independent test in a customer lab with 5 known positive and 5 known negative samples were detcted correctly (Samples confirmed by Finnish institute for health and welfare). Finally, sample run in same lab with 88 samples analysed with 3501-0010 identified same 2 samples positive as PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay (TAI/AUS). Second samples from the same patients were analysed also at Seoul Clinical Laboratories (SCL) in South-Korea and they found the same 2 samples positive.

PerkinElmer® SARS-CoV-2 Solutions for Nucleic Acid Detection

Summary

- PerkinElmer® SARS-CoV-2 nucleic acid detection workflow
  - Isolate **96 samples in 60 minutes** with chemagic™ 360 and chemagic™ viral RNA kit
  - Reformat **192 samples in 48 minutes** | Set up **2 PCR plates in 16 minutes** with JANUS® workstations
  - Test **94 samples per RT-PCR run** with PerkinElmer® SARS-CoV-2 RT-qPCR Reagent kit

For more information please contact our local African representatives or see our website:

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www.PerkinElmer-AppliedGenomics.com