EN

Instructions for Use

ViroQ® SC2 Variant 1

Test kit for the detection of specific variants of SARS-CoV-2 RNA

Electronic instructions for use see www.bag-diagnostics.com

RUO

For research use only – do not use for diagnostic purpose.

REF 728272 ViroQ® SC2 Variant 1 RUO 96 Test

For use with		
Specimen Types	**RNA extraction kits / automated extraction instruments**	**Real-time PCR instruments**
Nasopharyngeal (NP) swabs	QIAGEN QIAamp Viral RNA Mini QIAcube Kit / QIAcube Roche Roche MagNA Pure 96 DNA and Viral NA Small Volume Kit / MagNA Pure 96 Instrument Thermo KingFisher Thermo Fisher MagMAX Viral/PathogenNucleic Acid Isolation Kit	Bio-Rad CFX96 Touch™ Real-Time PCR Detection System Roche LightCycler® 480 System II
Oropharyngeal (OP) swabs		
Nasal swabs		
Anterior nasal swabs		
Mid-turbinate nasal swabs		

Version: 3/2021 / Issued: 2021-03

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1. APPLICATION

The ViroQ® SC2 Variant 1 Kit is used for qualitative detection of SARS-CoV-2 RNA variants (UK B.1.1.7; ZA B.1.351; BR P.1; BR P.2; BR B.1.1.28; according to RKI B.1.1.7, B.1.351 and P.1 are worrying SARS-CoV-2 virus variants (17.02.2021). RKI - Coronavirus SARS-CoV-2 - Übersicht und Empfehlungen zu besorgniserregenden SARS-CoV-2-Virusvarianten (VOC).) and the correcsponding spike protein mutation in respiratory specimens such as nasopharyngeal (NP), oropharyngeal (OP), nasal, anterior nasal and mid-turbinate nasal swab based on reverse transcription of the RNA and subsequent amplification in real-time PCR.

For research use only – not for diagnostic purposes.

2. PRODUCT DESCRIPTION

The ViroQ® SC2 Variant 1 kit is based on a one step reaction with real-time PCR technology with a compromised PCR protocol (≤ 1h). An efficient cDNA synthesis from RNA coupled with a real-time PCR the ViroQ® SC2 Variant 1 Kit makes it possible to perform the test in one tube. The kit is containing primers and fluorescent probes to amplify and detect gene fragments for SARS-CoV-2 and its variants.

3. TEST PRINCPLE

The test is performed with RNA as starting material. The RNA is converted into cDNA with a reverse transcriptase enzyme and afterwards amplified in a PCR. The primers were designed for the generic amplification of the trancripted cDNA of the viral RNA. The SARS-CoV-2 variants are detected with likewise specific fluorescent dye-labelled hydrolysis probes (TaqMan® probes) (https://dx.doi.org/10.15585%2Fmmwr.mm7003e2).

The specific probes are hydrolyzed by the Taq polymerase and a fluorescence signal is generated that increases proportionally to the amount of the PCR product. The fluorescence signals are measured by the optical detection unit of the RT-PCR-Cycler.

The test is performed in one PCR reaction that detects the different present variant with different flourescent colors.

4. MATERIAL

4.1 Content of the ViroQ® SC2 Variant 1 kit

- **ViroQ|ENZYME** **ViroQ® Enzyme**, lyophilized, contains Reverse Transcriptase, Taq Polymerase, dNTPs
- **ViroQ|SOLV** **ViroQ® Solvent,** ready to use, contains reconstitution buffer for the ViroQ® Enzyme
- **ViroQ|MIX** **ViroQ® Mix V1**, ready to use, contains, Primers, Probes, Storage buffer
- **IFU** **or** **eIFU** **Instructions for use or electronic instructions for use**

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4.2 Additionally required reagents and devices

- Reagents for RNA isolation (validated RNA isolation kits see 6.2)
- Real-time PCR-Cycler (validated cyclers see 4.3)
- RT-PCR reaction tubes with caps or foils (validated products see 4.3)
- RNase free H_2O
- Piston pipettes (0,5 – 1000 µl) and tips
- Color Compensation kit for LightCycler® 480 I+II, 2.0 (REF 728258 ViroQ CC Light Cycler®, provided by BAG Diagnostics)

4.3 Validated cyclers and reaction tubes

Cycler	real-time-PCR reaction tubes	real-time-PCR closing system
CFX96 Touch™ Real-Time PCR Detection System Comp. Bio-Rad	Vari-Strip™ 8 Well PCR Tube Strips Product No. 4ti-0753 Comp. 4titude / Brooks Life Sciences	Crystal Strips™ Product No. 4ti-0755/120 Comp. 4titude / Brooks Life Sciences
	FrameStar® Break-A-Way PCR Plate, Low Profile, 96 white wells, black frame Product No. 4ti-1201 Comp. 4titude / Brooks Life Sciences	qPCR Seal Product No. 4ti-0560 Comp. 4titude / Brooks Life Sciences
LightCycler® 480 System II Comp. Roche	LightCycler® 480 Multiwell Plate 96, white Product No. 04729692001 Comp. Roche	qPCR Seal Product No. 4ti-0560 Comp. 4titude / Brooks Life Sciences
	Vari-Strip™ 8 Well PCR Tube Strips Product No. 4ti-0753 Comp. 4titude / Brooks Life Sciences	Crystal Strips™ Product No. 4ti-0755/120 Comp. 4titude / Brooks Life Sciences

Special Note: If other realtime cyclers, reactions tubes and closing systems are used they must be validated by the user.

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5. STORAGE AND STABILITY

The kits are shipped without cooling. Upon receipt store all reagents in temperature monitored devices at ≤ -20 °C. The expiry date is indicated on the label of each reagent. The reagents ViroQ® Enzyme and ViroQ® Solvent can be stored at room temperature until expiry date, as long as the enzyme lyophilisate is not solved with the reconstitution buffer. After solving it can be used upon 12 month. Repeated thawing and freezing of reagents (more than twice) should be avoided, as this might affect the performance of the assay. In terms of intermittent use the reagents should be aliquoted.

6. TEST PROCEDURE

6.1 Safety conditions and special remarks

Molecular genetic techniques are particularly sensitive and should be performed by well trained personnel experienced in molecular genetic techniques.

Special safety conditions must be observed in order to avoid contamination and thus false reactions:

- ♦ Wear gloves during work (powder-free, if possible).
- ♦ Use new tips with each pipetting step (with integrated filter).
- ♦ If possible, use separate working areas for pre-amplification (RNA isolation and PCR set up) and post-amplification (detection).
- ♦ Use devices and other materials only at the respective places and do not exchange them.

6.2 RNA Isolation

The sample material for the isolation of RNA must be sent in appropriate cell collection systems.
For RNA isolation use appropriate RNA isolation kits.

Validated RNA isolation kit:

- QIAamp® Viral RNA Mini QIAcube Kit
- Roche MagNA Pure 96 DNA und Viral NA Small Volume Kit
- Thermo KingFisher Thermo Fisher, MagMAX Viral/PathogenNucleic Acid Isolation Kit

If the established standard method of the lab is used for RNA isolation and this is not the above mentioned kit, it must be validated by the user.

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6.3 Reagent preparation

ViroQ® Enzyme

The enzyme mix reagent ViroQ® Enzyme is lyophilized. Before use dissolve ViroQ® Enzyme with 400 µl ViroQ® Solvent by pipetting up and down.

6.4 Amplification

Reaction tubes recommended by the manufacturer of the realtime cycler or the materials recommended in chapter 4.3 should be used.

For each sample the following reagents are pipetted into a reaction tube:

Reaction	
4 µl	ViroQ® Enzyme
2 µl	ViroQ® Mix V1
5 µl*	RNA sample
5 µl	RNase free H_2O

*In case of very low expected concentration of virus copies the volume of the sample can be increased, while decreasing the amount of water.

The reaction volume for each real-time PCR test is 20 µl.

If a premix of ViroQ® Enzyme, ViroQ® Mix V1 and RNase free H_2O is prepared for more than one sample please allow for a reasonable additional amount for pipetting losses.

To perform a **no template control (NTC)** prepare a PCR reaction and use RNase free H_2O for the negative control instead of RNA.

Close the reaction tubes and briefly spin down the liquid. Ensure that no bubbles are present in the wells. If bubbles are observed, gently tap the reaction tube on the bench to remove the bubbles.

Start the PCR program with the following parameters:

Step	Time	Temperature	No. of cycles
Reverse Transcription	8 min	48°C	1 cycle
Polymerase activation	2 min	96°C	1 cycle
Denaturation	2 sec	95°C	42 cycles
Annealing + Extension	10 sec + reading	60°C	

The following real-time cyclers have been validated for the ViroQ SARS-FluA/B-RSV kit. Please note the cycler-specific settings described under 6.5 Cycler settings:

Biorad: CFX96 Touch™ Real-Time PCR Detection System

Roche: LightCycler® 480 System II

Special Note

• If other realtime cyclers are used they have to be validated by the user.

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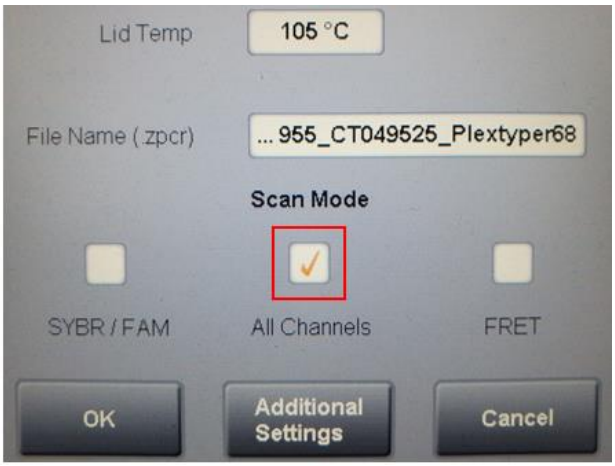
6.5 Cycler settings

Bio-Rad CFX96 Touch™ Real-Time PCR Detection System

For use on the CFX96 Touch™, the following specific settings must be made. Before starting the run, a check mark must be set for “All Channels”. The lid temperature is set to 105°C.The default ramp rate is used.



Roche LightCycler® 480 II

For use on the LightCycler® 480 II, the following specific settings must be made. When programming the PCR program, the corresponding ramp rate must also be set.

Step	Time	Temperature	Ramp rate	No. of cycles
Reverse Transcription	8 min	48°C	4,4°C/s	1 cycle
Polymerase activation	2 min	96°C	4,4°C/s	1 cycle
Denaturation	2 sec	95°C	2,2°C/s	42 cycles
Annealing + Extension	10 sec + reading	60°C	2,2°C/s	

The following filter settings must be made:

Excitation Filter	Emission Filter	Name	Melt Factor	Quant Factor	Max Integration Time (sec)
597	616	Texas Red	1	10	1
495	520	FAM	1	10	1
535	556	HEX	1	10	1
646	669	Cy5	1	10	1

The Max Integration Time can be increased for weak signals.
To get to the filter settings, please carry out the following steps.

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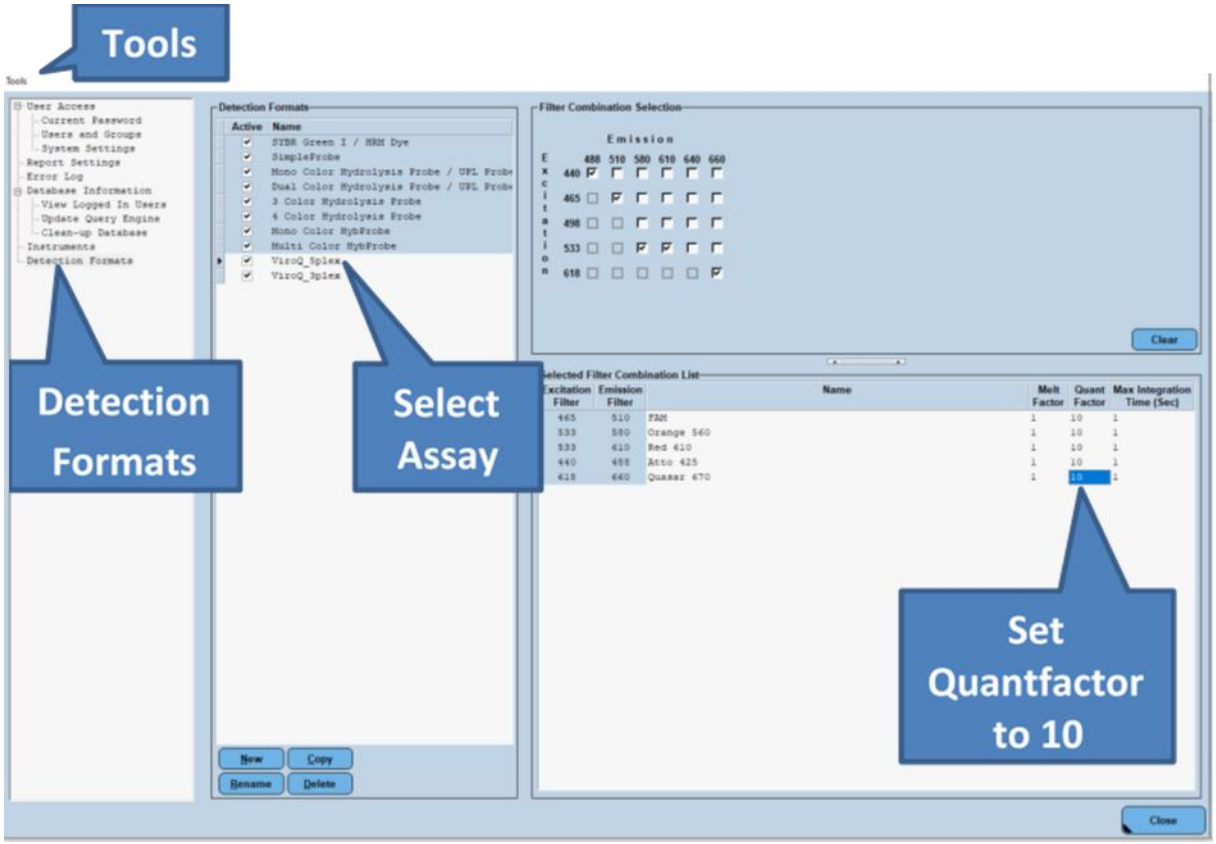
Go to Tools → Detection Formats → Select Assay → set the settings for example Quantfactor to 10
Example image with 5 channels. Only the 4 channels in the table above are used for the ViroQ SC2 Variant Test.



6.6 Interpretation of results

For all reactions in the multiplex PCR mix a Ct cutoff is used to define positive reactions. If the Ct-value is inconclusive it can be helpful to review the fluorescent curves.
The detection reactions in the individual mixes are characterized by a maximum of three reactions in the different color channels. Background reactions may occur in other color channels (see figures at the end of the chapter). In the ViroQ® Mix V1, this was observed in the motifs 484E (Texas Red) vs. 484K (Cy5). Due to the fact that it is the same nucleotide position, only one reaction can be the specific one.The background reaction always appears to be significantly weaker in comparison to the specific reactions. It is recommended to increase the threshold for these reactions to suppress the Ct value. The intensity of the specific reaction of motif 1176F is relatively low compared to the specific reactions of the other motifs (see figures at the end of the chapter). There is no background at all with this motif.

The amplification signals for SARS-CoV-2 negative samples should be outside the defined Ct-values for all channels.

The negative control (NTC) is used as contamination control. If RNA or contaminating amplicon is inadvertently added to the NTC reaction a positive signal will occur. If the Ct is less than 35 it should

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be considered as possible contamination. Amplification signals above Ct 35 in the NTC could be PCR artefacts and can be disregarded taking into consideration the final RFU and the shape of the curve (see also below for interpretation of results between Ct 35 and Ct 42). If PCR contamination is suspected, it is advisable to follow local decontamination guidelines and to exchange the reagents
For valid results all Ct values ≤ 35 are rated as positive (see table below).

ViroQ® Mix V1	Channel	Ct-Level	Inspect	Wave lenght in nm
484E	Red (Texas Red)	≤35	>35-45	Excitation: 597 Emission: 616
1176F	Green (FAM)	≤35	>35-45	Excitation: 495 Emission: 520
501Y	Orange (HEX)	≤35	>35-45	Excitation: 535 Emission: 556
484K	Rot (Cy5)	≤35	>35-45	Excitation: 646 Emission: 669

Regardless of the Ct values a positive reaction should have a sigmoidal curve and a sufficient end RFU. The RFU is cycler dependent – the final RFU of the positive control can be used to get the approximate value that is normal for the final RFU on a given cycler. The positive control can also be used as an example for the correct sigmoidal shape of the curve. Therefore, samples with a Ct value of > 35 and low RFU should be checked for a sigmoidal shape of the curve and the plausibility of the reaction. Samples with a inconclusive result should be repeated. If there are questions regarding the adaptation of the threshold or borderline Ct values please contact the technical support of BAG Diagnostics (phone: +49 (0)6404 925125, email: info@bag-diagnostics.com) or your local sales representative.

The following table shows the interpretation of the amplification results:

ViroQ® Mix	Spike Protein Variation	Dye	UK B.1.1.7 (22,8%)*	ZA B.1.351 (1,3%)*	BR P.1 (0,1%)*	BR P.2 (<1%)**	BR B.1.1.28	Wild type**
1	484K	Cy 5		X	X	X		
	484E	Texas Red	X				X	X
	501Y	HEX	X	X	X			
	1176F	FAM			X	X	X	

* Report RKI 17.02.2021 2. Bericht zu Virusvarianten von SARS-CoV-2 in Deutschland, insbesondere zur Variant of Concern (VOC) B.1.1.7 (rki.de).

**Stated 26.02.2021 PANGO lineages (cov-lineages.org).

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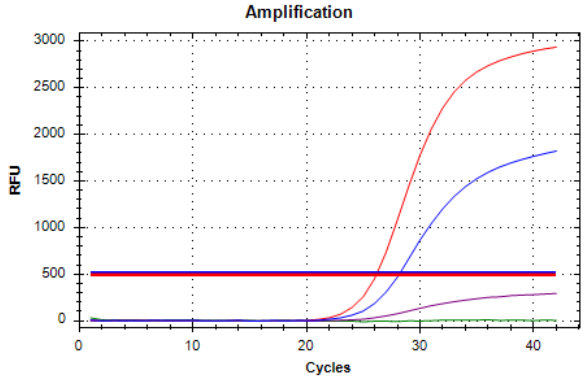
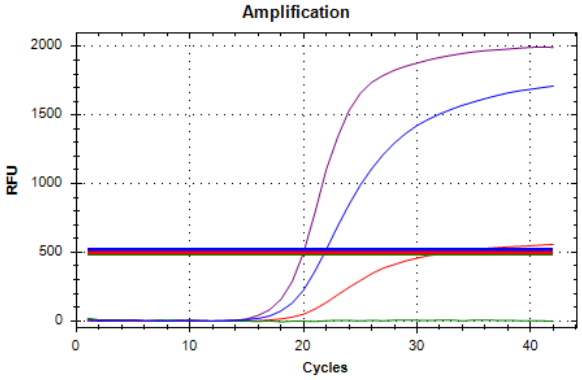
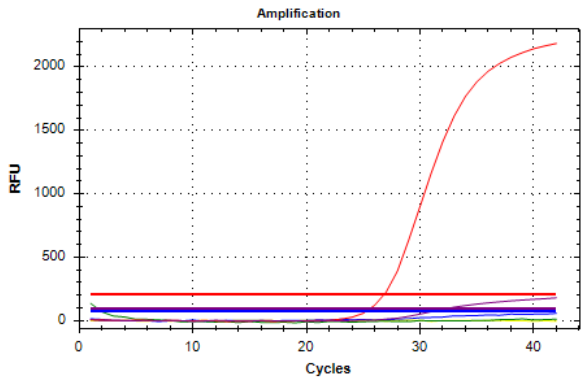
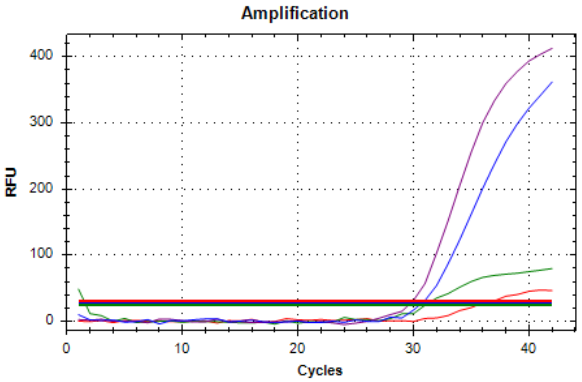
Example pictures on the CFX Cycler

Example for a positive raction of B.1.1.7	Example for a positive raction of B.1.351
	
Texas Red = Red HEX = Blue Cy5 = Purple → Background reaction	Texas Red = Red → Background reaction HEX = Blue Cy5 = Purple

Example for a psoitive reaction of wild type	Example for a positive raction of P.1
	
Texas Red = Red FAM = Green Cy5 = Purple → Background reaction	Cy5 = Purple HEX = Blue FAM = Green Texas Red = Red → Background reaction

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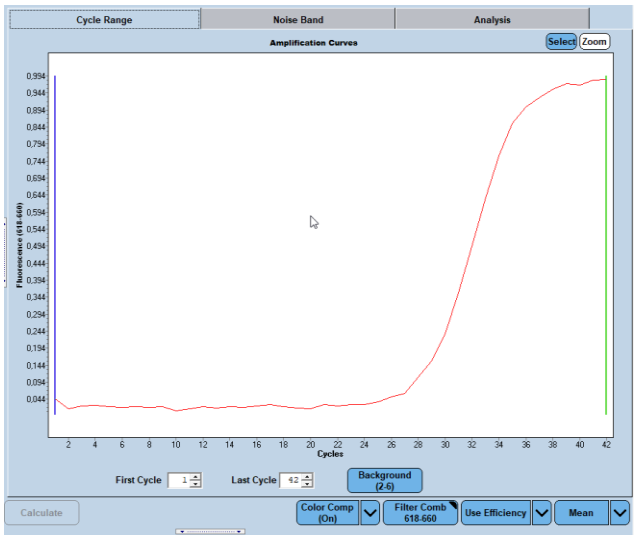
Example pictures on the CFX Cycler

Example for a positive reaction of B.1.1.7

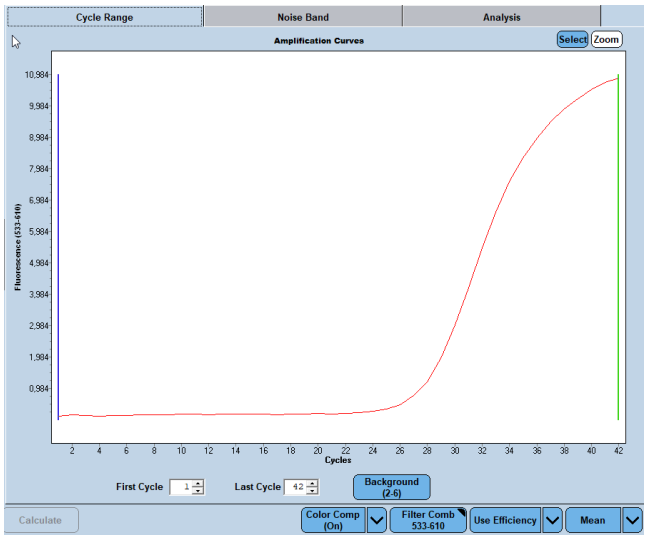
Channel: Cy5

Background (check fluorescence intensity)

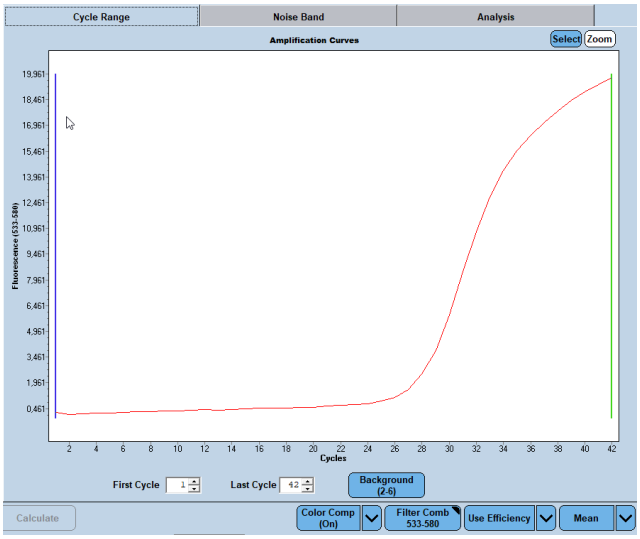


Channel: Texas Red

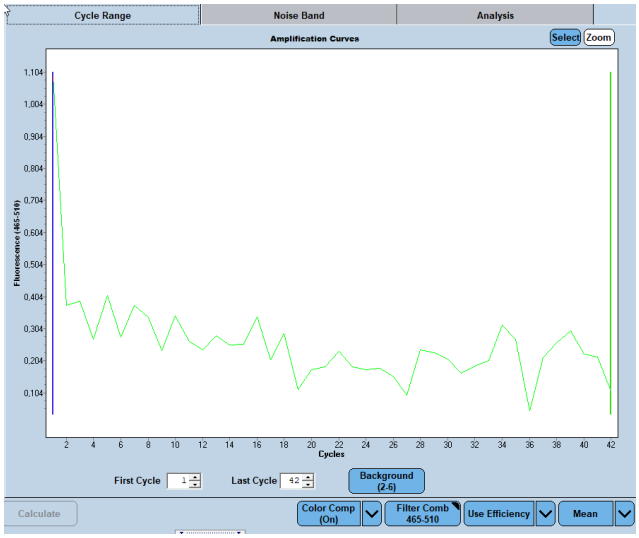
specific signal (check fluorescence intensity)



Channel: HEX



Channel: FAM



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7. WARNINGS AND PRECAUTIONS

ViroQ® SC2 Variant 1 is designed for research use only and should be used by properly trained, qualified staff only. All work should be performed using Good Laboratory Practices.

The reagent ViroQ® Solvent is subject to hazardous substance labeling for **Warning** and **Health hazard**. Please refer to the table in Chapter 12 for more information.

Biological material used for extraction of RNA, e.g. respiratory specimen, should be handled as potentially infectious. When handling biological material appropriate safety precautions are recommended (do not pipet by mouth; wear disposable gloves while handling biological material and performing the test; disinfect hands when finished the test).

Biological material should be inactivated before disposal (e.g. in an autoclave). Disposables should be autoclaved or incinerated after use.

Spillage of potentially infectious materials should be removed immediately with absorbent paper tissue and the contaminated areas swabbed with a suitable standard disinfectant or 70% alcohol.
Material used to clean spills, including gloves, should be inactivated before disposal (e.g. in an autoclave).

Disposal of all samples, unused reagents and waste should be in accordance with country, federal, state and local regulations.

Microbial contamination of the reagents while taking aliquots should be avoided. It is recommended to use sterile one way pipettes and tips. Reagents that look cloudy or show any signs of microbial contamination must not be used.

A Material Safety Data Sheet resp. a declaration on Material Safety Data Sheets (MSDS) is available to download at **www.bag-diagnostics.com**.

8. LIMITATIONS OF THE METHOD

Mutations or polymorphisms in the primer and probe binding sites may cause false negative results.
Because of the high susceptibility of the RT-PCR method for cross contaminations special care should be taken during RNA isolation.
The presence of PCR inhibitors may cause invalid results with this product. A negative result does not exclude a possible detection of SARS-CoV-2 RNA and variants, as results are dependent on appropriate specimen collection and the absence of inhibitors.
Extreme care should be taken to prevent contamination of the kit reagents and other laboratory materials and equipment with amplicons, RNA or DNA. Regular wipe tests and negative controls with Aqua dest with each assay are strongly recommended.
In the negative control with Aqua dest. there must not be any fluorescent signal (Ct > N.A.).
In the case of signal development in the negative control please refer to Chapter 6.5 and and if necessary, decontaminate the PCR working place and exchange the reagents.
All instruments (e.g. pipettes, realtime cyclers) must be calibrated according to the manufacturers instructions.

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9. INTERNAL QUALITY CONTROL

Internal quality control of new lots of the ViroQ® SC2 Variant 1 kit can be performed using a combination of RNA samples known to be positive or negative. Negative controls to detect possible contaminations are recommended. Use a PCR reaction with the RNase free water as a NTC for this purpose.

10. TROUBLESHOOTING

Symptom	Possible reason	Potential solution
Bad or no signal	Presence of an inhibitor.	Use fresh reagents.
	No RNA in the reaction.	Repeat test. Take care of correct pipetting.
	Fluorescent probes or primers degraded.	Use fresh Primer-Probe-Mix Avoid exposition to light and frequent thawing and freezing. Observe storage conditions!
	Bubbles in the PCR reaction, remaining liquid at the inner wall of the tube.	Careful pipetting. Spin down PCR plate.
	Incompatible or low quality RT-PCR plastic ware.	Use compatible and high quality plastic ware (see chapter 4.3).
	Evaporation of the reagents due to incorrect closing of the PCR tubes.	Make sure that the PCR tubes are closed properly. Be careful at the edges of sealing foils.
Signal in the negative control	Contamination with RNA or DNA in the negative control	Repeat the negative control. Decontaminate the workplace.

11. TRADEMARKS USED IN THIS DOCUMENT/PRODUCT

TaqMan® is a trademark of Roche Molecular Systems Inc.
Cal Fluor® is a registered trade mark of LGC Biosearch Technologies

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12. EXPLANATION OF SYMBOLS USED ON THE LABELS

	Sufficient for n tests
	Storage temperature / Lower limit of temperature
	Use by
	Consult instructions for use
	Manufacturer
	Date of manufacture
DRY	Dried
CONT	Content, contains
CONTROL | +	Positive control
IFU	Instructions for use
or	or
eIFU	Electronic instructions for use
LOT	Batch code
LYOPH	Lyophilized
REF	Catalogue number
RUO	For Research Use Only
ViroQ | ENZYME	Enzyme mix for ViroQ® products
ViroQ | MIX	Primermix for ViroQ® products
ViroQ | SOLV	Solvent for ViroQ® enzyme mix
	**Warning** H302: Harmful if swallowed. H412: Harmful to aquatic life with long lasting effects.
	**Health hazard** H371: May harm the central nervous system. Route of exposure: Oral

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13. LITERATURE

Emergence of SARS-CoV-2 B.1.1.7 Lineage — United States, December 29, 2020–January 12, 2021 https://dx.doi.org/10.15585%2Fmmwr.mm7003e2

Further information is provided on our website http://www.bag-diagnostics.com.

Instructions for use in other languages see: http://www.bag-diagnostics.com or contact us directly at info@bag-diagnostics.com or phone +49 (0)6404-925-125

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