Egoo SARS-CoV-2 Lysis Buffer

REF e70464 Egoo SARS-CoV-2 Lysis Buffer IVD CE

Read and follow this 'Instructions for Use' as second, and when mentioned in the 'Instructions for Use' for the Egoo Capsule, to prepare a sample for analysis. Before this, however, make sure you have an overview of the full process by reading the Egoo Health System user manual.

INTENDED USE

Egoo SARS-CoV-2 Lysis Buffer system is intended for the dilution and preparation of the sample to be used on Egoo Health System to detect nucleic acids for SARS-CoV-2 in oropharyngeal swab samples.

BACKGROUND

The sample is to be used for Egoo SARS-CoV-2 system, a qualitative measurement for detection of SARS-CoV-2 in oropharyngeal swab.
Egoo SARS-CoV-2 Lysis Buffer contains SIBA R1 buffer which is used for breaking down the virus particles and releasing the viral genome prior to analysis.

MATERIAL INCLUDED

- 50 Lysis Buffer vials each containing 180 µL SIBA R1 buffer
- 1 Pipette (multiple use) REF e93138
- Rack (multiple use)

The enclosed pipette is for multiple use and is to be used with a disposable pipette tip. The pipette is designed to collect exactly 20 microliters in the pipette tip.

MATERIAL REQUIRED BUT NOT INCLUDED

- Personal protective equipment (gloves)
- Equipment for performing oropharyngeal swab.
- Transport media (PBS/UTM/VTM) to be used for the collection and transport of the clinical samples containing SARS-CoV-2 from the collection site to the testing laboratory.
  NOTE: *Do not use transport media that contains guanidinium thio-cyanate (GITC) or other guanidine compounds. Use transport media that preserves and not inactivates the virus.*
- Egoo SARS-CoV-2 Capsule REF e48364
- Egoo Instrument REF e78852
- Egoo Clinical Application installed on a PC
- Barcode and QR-code reader

WARNING AND PRECAUTIONS

- All sample material must be considered potentially infectious and handled in accordance with country, state and local regulation.
- Disposable gloves should be worn.
- Discard gloves as biohazard material.
- Do not use the system after expiry date. Expiry date can be found on labels.
- Do not reuse consumables.
- Discard sample material as biological waste.

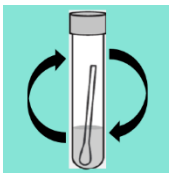
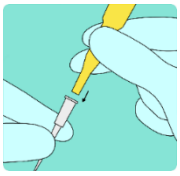
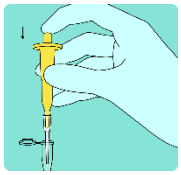
STORAGE AND STABILITY

- The Egoo Lysis Buffer system must be stored at 2-8° C.
- See expiry date on labels on the package of the Egoo Lysis Buffer.
- Oropharyngeal swab diluted in Lysis Buffer can be stored at 15-30 °C up to 6 hours or at 2-8 °C up to 32 hours.

PROCEDURE

IT IS RECOMMENDED TO READ THIS INSTRUCTION BEFORE USE

- Put on gloves.

STEP 2: PREPARE THE PATIENT SAMPLE  Figure 1	**Step 1 is to be found in the Egoo SARS-CoV-2 Capsule IFU** • Take the patient sample containing oropharyngeal material in the transport medium (PBS, UTM or VTM). Leave the swab in. • Mix the sample by either inverting the vial a minimum of 10 times (figure 1) or by using a vortex. • **Place the vial** containing oropharyngeal material **in the rack.** • NOTE: *Make sure to have sample traceability e.g., by using labels or lists*.
STEP 3: COLLECT PATIENT SAMPLE WITH PIPETTE  Figure 2  Figure 3	• Apply a pipette tip to the yellow pipette. There is a single-use pipette tip enclosed in the Egoo Capsule package which can be used for this. • Make sure the pipette tip is tightly placed on the pipette. • Take the vial containing the lysis buffer and place it in the rack. Be aware which is which. • NOTE: *Make sure to have sample traceability e.g., by using labels or lists*. • Push down the piston fully, before immersing the pipette tip into the vial. containing oropharyngeal material. NOTE: *Only the pipette tip is to be immersed into the sample (figure 3).* • Collect 20 microliter sample from the vial with oropharyngeal material by slowly letting go of the piston, while in the sample.
STEP 4: TRANSFER PATIENT SAMPLE TO LYSIS BUFFER AND MIX  Figure 4	• Release the collected sample material into the vial containing the lysis buffer (figure 4). • Mix the liquids by keeping the pipette immersed in the material and pressing the piston minimum 5 times. • Lift the pipette while holding the piston down, to prevent withdrawing of sample. Then hold the pipette in your hand, so the tip does not touch any surface. **See the Egoo SARS-CoV-2 Capsule 'Instructions for Use' for next step and on how to apply the sample in the capsule.**

QUALITY CONTROL

The Egoo SARS-CoV-2 uses positive and negative controls. Procedures for running control capsules must follow current laboratory procedures applicable for the context in which the Egoo Health System is used.
It is recommended to run a positive and negative control once daily and according to national guidelines. We recommend using the COV019CE SARS-CoV-2 Positive Run Control (BioRad) and the COV000CE SARS CoV-2 Negative Run Control (BioRad)

LIMITATIONS

The Egoo SARS-CoV-2 Lysis Buffer is only for dilution of oropharyngeal swab material for detection of SARS-CoV-2.
The Egoo SARS-CoV-2 Lysis Buffer is only for healthcare professional use.
TheEgoo SARS-CoV-2 Lysis Buffer is only to be used with the Egoo Health System and Egoo SARS-CoV-2 Capsule. If the Egoo SARS-CoV-2 Lysis Buffer is passed on to a third party, this information for use must be included.

TEST PRINCIPLE

The Strand Invasion Based Amplification (SIBA) [2] is an isothermal amplification method that relies on a recombinase-coated single-stranded invasion oligonucleotide and a polymerase for the rapid and exponential amplification of nucleic acids. SIBA is an attractive nucleic acid amplification method owing to its short time-to-result and high analytical sensitivity and specificity. For this analysis of SARS-CoV-2 RNA, a SYBR Green dye for nucleic acids optical detection, measured at 525 nm is used.

LIMIT OF DETECTION

LoD (limit of detection) is specified as 1.8 ± 0.2 virus RNA copies/µl based on analyses from three different quantified SARS-CoV-2 virus isolates.

Virus isolate	LoD RNA copies/µl
SARS-CoV-2 USA-WA1/2020	2,0
SARS-CoV-2 Italy-INMI1	1,7
SARS-CoV-2 Hong Kong/VM20001061/2020	1,6
Mean LoD ± SD	1,8 ± 0.2

INTERFERENCE

Interference from the following substances and microorganisms are analysed in SARS-CoV-2 negative and positive samples:

Substance	Concentration
Whole blood	4%
Orifarm Coldy throat spray*	15% v/v
ColdZyme Mouth spray	15% v/v
Strefzap (Fluriprofen)	15% v/v
Zyx citron (Benzydamin)	1.5 mg/ml
Strepsil	1.5 mg/ml
Fisherman´s Friend	1.5 mg/ml

None of the above substances affected the SARS-CoV-2 detection, apart from the Orifarm Coldy throat spray. It is **not** recommended to analyse oropharyngeal swab if Orifarm Coldy throat spray has been used, as the result might be a false negative. Health professionals must ask about the use of Orifarm Coldy throat spray when performing oropharyngeal swab.

Organism	Concentration
Epstein-Barr Virus (EBV)	2.70×10^8 cp/ml
Parainfluenza Virus Type 1 (PIV-1)	9.12×10^8 cp/ml
Adenovirus Type 5 (ADV5)	4.07×10^7 $TCID_{50}$/ml
Respiratory Syncytial Virus Type A (RSV)	5.01×10^5 $TCID_{50}$/ml
Influenza B (Yamagata/16/88)	2.45×10^5 $TCID_{50}$/ml
Influenza A H1N1pdm (NY/02/09)	3.80×10^6 $TCID_{50}$/ml
Human Coronavirus 229E	1.41×10^5 $TCID_{50}$/ml
Human Coronavirus NL63	4.68×10^4 $TCID_{50}$/ml
Human Metapneumovirus 3 Type B1 (hMPV)	3.89×10^4 $TCID_{50}$/ml
Enterovirus Type 68	5.01×10^5 $TCID_{50}$/ml
Bordetella pertussis	2.53×10^{10} genomes/ml
Candida albicans	4.26×10^5 genomes/ml
Chlamydia trachomatis	1.72×10^6 genomes/ml
Corynebacterium diphtheriae	2.02×10^8 genomes/ml
Escherichia coli	1.52×10^{10} genomes/ml
Haemophilus influenzae	2.71×10^9 genomes/ml
Legionella pneumophila	1.69×10^{10} genomes/ml
Moraxella osloensis	ND
Mycoplasma pneumoniae	2.89×10^8 genomes/ml
Neisseria meningitidis	5.31×10^8 genomes/ml
Pseudomonas aeruginosa	1.38×10^{10} genomes/ml
Staphylococcus epidermis	2.52×10^9 genomes/ml
Streptococcus pneumoniae	7.23×10^9 genomes/ml
Streptococcus pyogenes	6.03×10^9 genomes/ml

None of the above microorganisms affected the assay.

PRECISION

The SARS-CoV-2 assay shows a 100% precision at tests repeated for 20 days in a row. The SARS-CoV-2 assay has a reproducibility of 98% at tests repeated for 5 days at 3 different sites and carried out by 6 different persons.

METHOD COMPARISON AND CLINICAL SENSITIVITY AND SPECIFICITY

Comparison was carried out according to the Biorad CFX96Dx with the following result:

Method for comparison	Sensitivity (95%CI)	Specificity
RT-PCR	95.5% (90.4-98.3%)	96.9% (91.3-99.4%)

INTERPRETATION OF RESULTS

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. A negative result should always be combined with clinical observation, patient history, and epidemiological information. Positive results do not rule out bacterial infection or co-infection with other viruses.

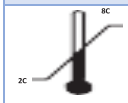
TROUBLE SHOOTING

For trouble shooting, consult the Egoo Health System manual.

REFERENCES

1. Zhe Xu*, Lei Shi*, Yijin Wang et al. Pathological findings of COVID-19 associated with acute respiratory distress syndrome. Lancet Respir Med 2020; 8: 420–22
2. Hoser MJ, Mansukoski HK, Morrical SW, Eboigbodin KE. Strand Invasion Based Amplification (SIBA®): A novel isothermal DNA amplification technology demonstrating high specificity and sensitivity for a single molecule of target analyte. PLoS One. 2014;9(11):1–20.
3. Clinical and Laboratory Standards Institute. Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline – Fourth Edition. CLSI document M29-A4E. 2014.

SYMBOLS

Symbol	Explanation	Symbol	Explanation
	Consult instruction for use		Expiration date
	Batch number		Do not reuse
	Manufacturer		Catalogue number
	Temperature limitations		Do not use if the packaging is broken
	Number		In vitro diagnostic equipment
	European conformity		