

 e48364 Egoo SARS-CoV-2 Capsule  

It is recommended to read and follow this 'Instruction for Use' **first**, when preparing SARS-CoV-2 sample analysis. Before this, however, make sure you have an overview of the full process by reading the Egoo Health System user manual, and have the 'Instruction for Use' for the Egoo Lysis Buffer nearby.

INTENDED USE



Egoo SARS-CoV-2 Capsule is an automated in vitro diagnostic test for use on Egoo Health System. It is intended for qualitative detection of SARS-CoV-2 RNA in oropharyngeal swab samples from individuals.

The Egoo SARS-CoV-2 capsule is intended for use by healthcare professionals in laboratory environment.



BACKGROUND

Coronavirus SARS-CoV-2 is the cause of Covid-19 [1].

MATERIALS INCLUDED

- 10 Egoo SARS-CoV-2 Capsule  e86657
- 10 Pipette tips  e23602

MATERIALS REQUIRED BUT NOT INCLUDED

- Egoo Instrument  e78852
- Egoo Clinical application installed on a PC
- Egoo SARS-CoV-2 Lysis Buffer,  e70464
- Barcode and QR-code reader
- Personal protective equipment (gloves)

WARNING AND PRECAUTIONS

- The system is to be used by healthcare professionals only.
- Only oropharyngeal swabs diluted in Egoo Lysis Buffer can be used with the Egoo Health System.
- Gloves must be worn.
- All sample material should be considered potentially infectious and handled in accordance with good laboratory practice [3] and country, state, and local regulation. All sample material, gloves, and pipette tips should be discharged as biohazard material after use.
- Do not use capsule if packaging is broken or damaged.
- The Egoo Capsule cannot be used after date of expiry. The Egoo Health System will tell you if the capsule has expired when you try to use the capsule in the Egoo Health System. Expiry date can also be found on the label of the Egoo SARS-CoV-2 capsule package.
- Do not reuse Egoo SARS-CoV-2 capsule.
- Do not reuse Egoo SARS-CoV-2 Lysis Buffer.
- Do not reuse pipette tip.
- Do not use Egoo SARS-CoV-2 capsule if frozen, defrost prior to use.
- Do not touch the top of the capsule or the pipette entrance hole.

STORAGE AND STABILITY


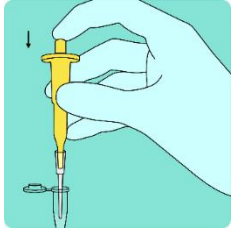

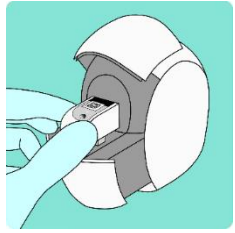
- Egoo SARS-CoV-2 Capsule must be stored at -20 °C.
- See expiry dates on the labels.
- The capsule must be defrosted 15 minutes at room temperature prior to be used for analysis.
- The capsule can, after defrosting, be stored at 15-30°C for 24 hours.

PROCEDURE

IT IS RECOMMENDED TO READ THIS INSTRUCTION BEFORE USE

- Put on gloves

Egoo SARS-CoV-2 Capsule

<p>STEP 1: DEFROST THE CAPSULE</p>  <p>Figure 1</p>	<ul style="list-style-type: none"> • Open the capsule package and take the capsule out to defrost. Leave the capsule in the plastic holder. • Defrost the capsule by placing it at room temperature for minimum 15 mins. • If condensation appears, place the capsule on an absorbent material and gently wipe the underpart (figure 1). • Place the capsule in the holder nearby to be ready for future steps in the process. <p>Before continuing with preparation of the capsule, follow the sample preparation steps in the 'Instructions for Use' of the Egoo SARS-CoV-2 Lysis Buffer.</p>
<p>STEP 5: COLLECT THE SAMPLE</p>  <p>Figure 2</p>	<ul style="list-style-type: none"> • When the preparation of the sample is done (step 2-4 of the Egoo SARS-CoV-2 Lysis Buffer IFU), perform this step 5. • Now collect 20 µl sample from the Egoo SARS-CoV-2 Lysis Buffer in the pipette tip by pressing the piston fully down and immersing the pipette into the vial containing lysis buffer. <p>NOTE: Only the pipette tip is to be immersed into the sample (figure 2).</p>
<p>STEP 6: LOAD THE SAMPLE INTO THE CAPSULE</p>  <p>Figure 3</p>	<ul style="list-style-type: none"> • Place the tip of the pipette in the entrance hole of the capsule without touching the piston of the pipette. • Insert the tip of the pipette until a slight resistance is felt and penetrate the membrane by pushing the tip further inside the capsule (figure 3). • Apply the 20 µl liquid into the capsule by pressing on the piston and then remove the pipette while holding the piston down preventing withdrawing of sample. Release the piston after the pipette tip is out of the capsule. • Discard the pipette tip as biohazard waste, without touching the end of the pipette tip. Keep the yellow pipette (multiple use) for later use. Put the plastic cover back on the capsule holder.
<p>STEP 7: GO TO THE EGGO HEALTH SYSTEM USER MANUAL FOR NEXT STEP</p>  <p>Figure 4</p>	<ul style="list-style-type: none"> • The capsule is now ready to be analysed in the Egoo Instrument. Follow the steps in the Egoo Health System user manual. • Start the analysis within 15 mins of loading 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 capsule is only for detection of SARS-CoV-2 in oropharyngeal swab diluted in Egoo SARS-CoV-2 Lysis Buffer provided. The Egoo SARS-CoV-2 capsule is only for healthcare professional use. The Egoo SARS-CoV-2 capsule is only to be used with the Egoo Health System. If a capsule 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/ μ l based on analyses from three different quantified SARS-CoV-2 virus isolates.

Virus isolate	LoD RNA copies/ μ l
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 \pm SD	$1,8 \pm 0.2$

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

Egoo SARS-CoV-2 Capsule

Neisseria meningitidis	5.31x10 ⁸ genomes/ml
Pseudomonas aeruginosa	1.38x10 ¹⁰ genomes/ml
Staphylococcus epidermis	2.52x10 ⁹ genomes/ml
Streptococcus pneumoniae	7.23x10 ⁹ genomes/ml
Streptococcus pyogenes	6.03x10 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

Parameter	Unit	Number of decimals
SARS-CoV-2	POSITIVE	None
	NEGATIVE	None
	INCONCLUSIVE*	None

*With this result, a re-run of the sample is recommended. If this result keeps occurring, a new sample is needed.

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.







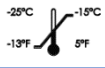




TROUBLE SHOOTING

For trouble shooting, consult the Ego 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		