

HiGargle™ Saline Gargle Kit

With 5ml PBS in self-standing tube, Collection funnel, Alcohol wipe and 250µl TE-Proteinase K Buffer 10X

Each set is individually packed in a zip-lock bag



Based on 'Saline Gargle RT-PCR Test' developed by NEERI, Nagpur & approved by ICMR.

Product Code: MS6760

Intended Use: For collection & transportation of potentially infectious saliva samples containing SARS-CoV-2 virus (Corona Virus) from the collection site to the laboratory and extraction of RNA for RT-PCR test.

Product description:

HiGargle™ Saline Gargle Kit is specially designed to collect gargle samples of COVID-19 suspected patients and isolate RNA from the collected samples for RT-PCR test.

The Phosphate buffered saline pH 7.2 (Product code: TL1031) is a balanced salt solution used for gargling.

The collection funnel fits properly into the tube, thereby helping spill-free collection.

The Tris-EDTA-Proteinase K buffer (Product code: TL1161) is a 10X buffer solution that solubilizes RNA while protecting it from degradation. Proteinase K helps in extraction of viral RNA by gently lysing the cells while maintaining integrity of RNA.

Alcohol wipe is used for surface disinfection of the tube after gargle sample collection.

Kit Contents:

1. Self-standing saliva collection tube with PBS, pH 7.2 (TL1031) -1No.
2. Collection funnel -1No.
3. Alcohol wipe -1No.
4. HiViral™ TE-Proteinase K Buffer 10X (TL1161) -250µl.

Note: This kit consists of 50 zip lock pouches, each containing 1No. PBS Tube, 1No. Funnel & 1No. Alcohol wipe supplied at room temperature.

A vial containing 10X TEP Buffer is supplied separately at 2-8°C.

Note: 250µl of 10X TEP Buffer is sufficient for processing of 50 gargle samples (5µl per sample). Users are advised to strictly maintain its temperature of 2-8°C while storage & sample processing.

Procedure:

A. Collection precautions

1. DO NOT eat, drink, smoke, brush teeth, or chew gum for 30 minutes before collecting saliva sample .

B. Collection of Samples

1. Unscrew the lid of the saliva collection tube
2. Gently take 5 mL of PBS solution in mouth, rinse the mouth completely for **15 seconds** followed by gargling for **15 seconds**. (Total time: 30 Seconds)
3. Put the funnel into the collection tube.
4. Gently spit the saline solution from mouth into the same collection tube, through funnel.
5. Properly seal the collection tube with the cap.
6. Label the tube with patient ID & patient name.
7. Maintain the collected samples tubes in cold chain (at 4°C) for transportation to the testing centre

C. Transportation of the Samples:

Samples should be transported to the laboratory as soon as possible.

Samples can be transported at room temperature.

However, it is preferable to transport the sample at 2-8° C.

If a long delay is expected in transit and processing, samples should be transported on dry ice and should be frozen at -70° C.

D.Sample processing:

1. Add 5µl of 10X Tris-EDTA Proteinase K (TE-P) buffer (TL1161) to each well of sterile nuclease free 96-well PCR plate. Properly cover the plate with aluminum foil.
Note: To be strictly operated in clean room.
2. Transfer the 96-well PCR plate containing 5µl of TE-P buffer to BSL-2/BSL-3 facility.
3. Open the collection tube containing the patient's saline gargle sample and transfer 45µl to 96-well PCR plate containing 5µl of TE-P buffer.
Note: To be strictly operated inside BSL- 2/BSL-3 facility.
4. Seal the plate properly with non-optical adhesive seals.
5. Vortex the PCR plate for 15 seconds.
6. Quick spin the PCR plate at 1500 rpm to bring down the droplets.
7. Incubate the PCR plate containing the sample and TE-P buffer at room temperature for 30 minutes inside BSL-2/BSL-3 facility.
8. After incubation heat the PCR plate at 98°C for 6 minutes in Thermocycler (PCR / RT-PCR Machine/Dry bath).
9. Remove the PCR plate from the Thermocycler and let it cool to room temperature.
10. Quick spin the PCR plate at 1500 rpm to bring down the droplets.
11. The PCR plate contains RNA extract which can be used as template directly. Open the PCR plate seal very carefully avoiding any spillage inside laminar air flow cabinet.
12. Prepare the RT-PCR master mix in clean room and add to sterile nuclease free 96-well PCR plate. Properly cover the plate with aluminum foil. Shift the master mix RT-PCR plate from clean room to the template addition area.
13. Add the template (as per the kit requirement) from the RNA extract PCR plate to the corresponding master mix RT-PCR plate inside laminar air flow cabinet.
To be strictly operated inside template addition area.
14. Seal the plate properly with optical adhesive seal.
15. Quick spin the PCR plate at 1500 rpm to bring down the droplets.
16. Proceed with RT-PCR as per the ICMR approved kit's manufacturer recommendation.

Caution:

Do not swallow the PBS solution. In case swallowed accidentally, Note that this is a neutral & safe solution, that is harmless for the body.

Precautions:

1. Isolation of viruses will largely depend on proper specimen collection, timing of sample collection and processing of samples.
2. Specimen collection should be done in the acute phase of illness.
3. To maintain infectivity of viruses, it is important that temperature be properly maintained for sample collection to processing.
4. Avoid repeated freeze-thaw of collected samples.
5. It is recommended to refer to standard procedures and published protocols for sample collection and processing.

Quality control:

Appearance

TL1031: Clear colourless solution

TL1161: Clear colourless solution

pH

TL1031 : 7.10 - 7.30

TL1161 : 7.00 - 7.40

Sterility

No bacterial or fungal growth is observed after 14 days of incubation as per USP specification

Performance Test

Complies

Storage and shelf life:

Store PBS,pH 7.2, collection funnel & alcohol wipe at 15-30°C.

Store TE-Proteinase K Buffer at 2-8°C.

Use before expiry date given on the product label.

Advantages:

1. Nasal and oral sample collection by swabs not required.
2. No skilled healthcare worker required for sample collection.
3. Self-sampling possible.
4. RNA extraction kit not required.
5. Cost-effective & user-friendly technique, especially useful in rural and tribal areas.
6. Significantly reduced sampling time

Disposal Instruction:

1. Wash the funnel with mild detergent (soap) or disinfectant (hand sanitizer) for 30 seconds.
2. Rinse with water and dispose off appropriately.



In vitro diagnostic medical device



CE Marking



Consult instructions for use



Do not use if package is damaged



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Single use.
Not intended to be
reprocessed and/or used on
another patient

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