



LabTurbo Nasopharyngeal Swab Collection and Transportation Kit Package Insert

For nasopharyngeal swab collection, transportation, and virus inactivation

INTENDED USE:

The LabTurbo Nasopharyngeal Swab Collection and Transportation Kit (LS0609) is intended for the collection and transportation of nasopharyngeal specimen for nucleic acid testing. The nylon-flocked swab provides the wide-ranging, simple and pain-free sampling for patients to collect nasopharyngeal swab specimens.

SUMMARY AND PRINCIPLES:

Using the LabTurbo LS0609, the collected specimen can be stored at 2-8 °C. The LS0609 consists of lysis buffer containing guanidine hydrochloride, phosphate-buffered saline solution, and nucleic acid stabilizing agents to inactivate and disintegrate the collected virus and preserve the viral nucleic acid.¹ The medium also inhibits overgrowth of bacteria and yeasts, encouraging preservation of nucleic acid for molecular testing. After collection, the samples can be shipped in ambient temperature without direct exposure to sun light. It's recommended that the specimen be stored at 2-8 °C and processed within 5 days.

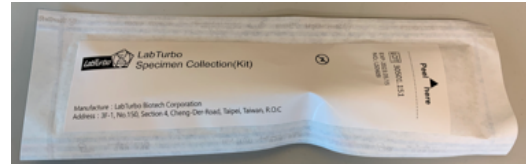
PRODUCT DESCRIPTION

LabTurbo LS0609 is ready to use and requires no further preparation. The package includes a Nasopharyngeal swab and a labeled 7 ml screw cap tube with 2 ml LabTurbo VTM.

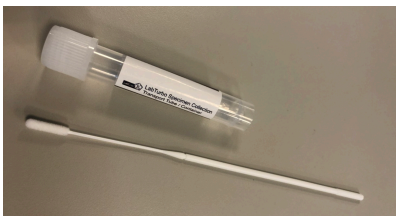
Front view




Back view



Each component



Tube label

 LabTurbo Specimen Collection Transport Tube / Container	
Name _____	<input type="checkbox"/> M <input type="checkbox"/> F
ID No. _____	Date _____
Manufacture : LabTurbo Biotech Corporation	
http://www.labturbo.com.tw	

STORAGE

The product must be stored in its original packaging at room temperature (15 ~ 25°C) until the time of use.

WARNINGS AND PRECAUTIONS

1. LabTurbo LS0609 is intended to be used with the medium tubes and swabs provided in the kit. The use of tubes of medium or swabs from any other source could affect the performance of the product.
2. Only professional healthcare personnel is allowed to operate this kit for sample collection.
3. The sterile swab should be stored at 15 ~ 25°C until use.
4. Do not use the kit if the package is damaged or beyond its expiration date.
5. Do not reuse.

INSTRUCTION FOR USE

1. Open the pouched seal pack and remove the swab and tube from the package.
2. Insert the swab into nasopharynx and spin the swab for at least 10 times. to prevent the risk of contamination, make sure that the swab tip comes into contact with the collection site only
3. After sample collection, place the swab into the Buffer Tube until the breakpoint is level with the test tube opening and bend the swab shaft at a 180 degrees angle to break it off at the breaking point. If needed, gently rotate the swab shaft to complete the breakage and take away the upper part of the swab shaft.
4. Tightly secure the cap onto the tube and transport to the laboratory immediately.
5. Discard the broken handle part of the swab shaft into an approved medical waste disposal container.

DISPOSAL

Waste must be disposed of in compliance with local legislation. Take the appropriate precautions for infected material if necessary.

RESULTS AND PERFORMANCE

Transportation stability test

A series of various temperatures were used to simulate the temperature change during regular shipping condition. The transportation medium with spiked SARS-CoV-2 virus at 2000 copies/ml, 4000 copies/ml and 8000 copies/ml and negative samples were used to evaluate the preservation performance of the LabTurbo LS0609 after the transportation simulation cycle.

Shipping simulation cycle (summer profile)

Cycle Period	Cycle Period (Hours)	Total Time (Hours)	Temperature
1	8	8	40°C
2	4	12	22°C
3	2	14	40°C

Shipping simulation cycle (summer profile)

4	36	50	30°C
5	6	56	40°C

Shipping stability test results

Concentration	2000 RNA copies/ mL	4000 RNA copies/ mL	8000 RNA copies/ mL	Negative 0 RNA copy/mL
Replicate 1	29.97	30.15	29.02	Undetected
Replicate 2	30.61	30.31	28.67	Undetected
Replicate 3	30.62	29.86	28.84	
Replicate 4	30.45	29.84	29.2	
Replicate 5	29.78	29.92	29.81	
Replicate 6	30.45			
Replicate 7	30.74			
Replicate 8	31.06			
Replicate 9	30.67			
Replicate 10	30.93			
Replicate 11	30.16			
Replicate 12	30.29			
Replicate 13	30.16			
Replicate 14	30.65			
Replicate 15	32.61			
Replicate 16	30.36			
Replicate 17	29.99			
Replicate 18	30.45			
Replicate 19	30.39			
Replicate 20	30.78			
Average	30.56	30.02	29.11	
Detection Rate	20/20	5/5	5/5	

All the samples at 2000 copies/ml, 4000 copies/ml and 8000 copies/ml were detected after the shipping simulation cycle, indicating good preservation performance of LabTurbo LS0609 during various shipping conditions.

Preservation stability test

To validate the preservation performance of LabTurbo LS0609, the high and low spiked SARS-CoV-2 positive specimens were extracted and detected by qPCR right after specimen preparation (Hour 0). The prepared high and low positive specimens were incubated at 37 °C in for 150 hours in total. The high and low positive specimens were extracted and detected by qPCR at Hour 50 and Hour 150 to confirm the preservation of SARS-CoV-2 RNA.

Replicate	High positive			Low positive		
	1	2	3	1	2	3
Hour 0	25.31	25.27	25.34	27.99	28.47	28.31
Hour 50	25.25	25.54	25.66	28.50	28.65	28.22
Hour 150	25.15	25.46	25.50	28.51	28.77	28.31

No significant difference was found between Hour 0, Hour 50 and Hour 150, indicating good preservation performance of LabTurbo LS0609.

REFERENCE

1. GENERAL PROCEDURES FOR INACTIVATION OF POTENTIALLY INFECTIOUS SAMPLES WITH EBOLA VIRUS AND OTHER HIGHLY PATHOGENIC VIRAL AGENTS

Inactivation for specific etiological diagnosis by molecular tests (PCR)

“In general, the use of highly denaturing conditions destabilizes the viral envelope, eliminates cellular nucleases, and maintains the structure of RNA for later analyses. Thus, the use of lysis solutions composed with guanidine salts (guanidine thiocyanate, guanidine isothiocyanate) has proven to be efficient for the inactivation of enveloped RNA viruses.”



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