

INSTRUCTIONS FOR NASAL/ SALIVA USE – English

Caution: Read all steps before collecting samples.

DEVICE NAME

iSWAB™-Respiratory Tract Sample Collection Media-Extraction-Less (iSWAB™-RC-EL)

INDICATION FOR USE

The iSWAB™-Respiratory Tract Sample Collection Media-Extraction Less collection device is intended for the stabilization and inactivation of upper respiratory and saliva human specimens suspected of containing SARS-CoV-2. This device can be used for the collection, transport, and storage of specimens at ambient temperature. Specimens collected in the iSWAB™-Respiratory Tract Sample Collection Media-Extraction Less collection device are suitable for use with legally marketed molecular diagnostic tests.

CONTENTS

iSWAB™-RC-EL Device
Swabs sold separately*

iSPIT™ funnel sold separately* §

NextSWAB® sold separately* §

*Not included in rack or bag format

§ Item may not be included in certain countries.

STORAGE AND STABILITY

Pre-collection: 15 months from date of manufacture, between 15-30° C. Transport temperature.

Post-collection: Sample stability and storage 15-30° C. 28 days for nasal specimens and 33 days for saliva specimen

Additional information available at www.mawidna.com.

WARNING AND PRECAUTIONS

For external use and single use only. DO NOT drink, touch, or remove the buffer from the device. Do Not use if device is broken, leaking, or visibly damaged. These products should only be used in accordance with the instructions provided. Avoid skin and eye contact with the liquid in the tube. If Ingested Call a POISON CENTER. Rinse mouth. IF IN EYES: Rinse cautiously with water for several minutes. Not a Hazardous Combustion Product. Device cap can be a choking hazard. Do not ingest.

DEVICES

All the iSWAB™-RC-EL family of products consist of one device pre-filled with 800 µL stabilizing buffer.

REF /Catalog Number	Product Name	Stabilizing Buffer
IRC-T-EL	iSWAB™-Respiratory Tract Sample Collection Media-Extraction-Less	800 µL x 500 units
IRC-T-EL-R	iSWAB™-Respiratory Tract Sample Collection Media-Extraction-Less Rack	800 µL x 50 units

PREPARATION FOR USE

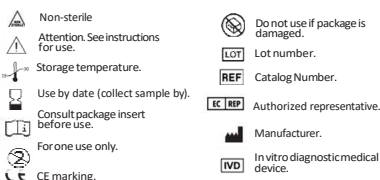
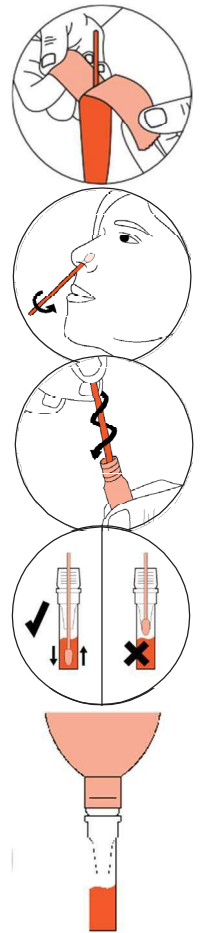
Before sample collection, verify preferred method of collection with your processing lab.

- Note: It is recommended not to eat, drink, or smoke for 30 minutes before collecting your sample.
- Do not touch swab tips or allow contact with any other object.
- For swab collection, use either 1 or 2 swabs depending on the test protocol.
- Tap the device gently 2-3 times before collection to concentrate all liquid to the bottom.

If using saliva collection skip to step number 8

For saliva self-collection, the iSPIT funnel is purchased separately.

- Place device standing up on a flat surface. Peel open bags containing swabs and remove a swab. Unscrew device cap before collecting sample.
- For nasal mid-turbinate collection:** Insert the swab head into your nostril no more than 3/4" (1.5cm) in. Slowly rotate at least 3 times, gently pressing against the inside of your nostril. Gently remove the swab and repeat this step in your other nostril.
- Pick up tube and hold steady in one hand. Slowly twist swab into iSWAB™ tube with a corkscrew motion. There will be resistance but push swab to the bottom of tube.
- Hold tube steady and move swab up and down rapidly inside the tube 10-15 times without moving the swab out of the liquid.
- At this point remove the swab. Hold tube firmly and remove swab by slowly twisting out with a corkscrew motion.
- For a more concentrated sample, a second sample may be collected by repeating steps 2-5 with another swab. Skip this step if unnecessary.
- After all samples have been taken, replace cap tightly. Properly dispose used swabs in the appropriate biohazard waste in accordance with federal, state, and local regulations. The sample is now ready for further testing.
- Steps For Saliva Collection (Ignore if using swabs for collection):**
(1) Remove cap from device and place on a clean surface. (2) Place iSPIT™ funnel onto the tube so that it is resting upright as shown in the picture. (3) Stimulate saliva production in your mouth. (4) Spit 1 or 2 times directly into the funnel. (5) Allow several seconds for all saliva to pass through the iSPIT™ funnel into the tube. (6) Remove funnel and discard in the appropriate biohazard waste in accordance with federal, state, and local regulations. (7) Replace cap securely onto tube. (8) Gently shake the device 5-10x to allow mixing. (9) The sample is now ready for further testing.
- For Lab or onsite collection:** Proceed with sample processing or storage.



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iSWAB™-RC-EL Package Insert

Device Classification Name: Microbial Nucleic Acid Storage and Stabilization Device

Type of Device: Device for stabilization of viral nucleic acids

Device Name: iSWAB-Respiratory Tract Sample Collection Media-Extraction Less (iSWAB™-RC-EL)

For invitro diagnostic use only: Rx

Indications For Use: The **iSWAB-Respiratory Tract Sample Collection Media-Extraction Less (iSWAB™-RC-EL)** collection device is intended for the stabilization and inactivation of upper respiratory and saliva human specimens suspected of containing SARS-CoV-2. This device can be used for the collection, transport, and storage of specimens at ambient temperature. Specimens collected in the **iSWAB-Respiratory Tract Sample Collection Media-Extraction Less** collection device are suitable for use with legally marketed molecular diagnostic tests.

Background: iSWAB™-RC-EL was developed to inactivate and stabilize SARS-CoV-2 RNA. The stabilized and inactivated RNA keeps its integrity for downstream molecular-based detection and analysis.

SUMMARY AND EXPLANATION

To conduct molecular testing and receive reliable test findings, proper specimen collection and transportation are crucial. Nasal swab and Saliva samples can be stabilized and transported from the collection site to the processing facility at room temperature using the iSWAB™-RC-EL device.

DEVICE DESCRIPTION

The iSWAB™-RC-EL device consists of a collection tube that is pre-filled with 800 µL of the iSWAB™-RC-EL non-toxic, stabilizing buffer and fitted with a proprietary insert. The insert is designed to optimize the release of specimens collected with swabs into the stabilizing buffer, creating a minimal footprint and allowing for swab-free transport of specimens. The iSWAB™-RC-EL collection device eliminates the costly and time-consuming RNA isolation step from diagnostic workflows.

Materials Provided:

Component	Cat No.	Quantity	Description
iSWAB™-RC-EL	IRC-T-EL	800 µL x 500 units	iSWAB™-RC-EL Collection Device, Bag
	IRC-T-EL-R	800 µL x 50 units	iSWAB™-RC-EL Collection Device, Rack

Materials Required (to be supplied by the customer): Swabs and iSPIT funnel are accessories, which are sold separately.

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WARNINGS AND PRECAUTIONS

Special precautions must be taken when handling the **iSWAB™-RC-EL** device.

- Do NOT ingest or apply the transport medium directly to skin or mucous membranes. For Information on transport medium components and product safety, request the Safety Data Sheet at info@mawidna.com
- Do NOT insert swab into solution before collecting patient specimen.
- Do NOT leave tubes uncapped for extended periods of time.
- Specimens may be infectious. Follow Universal Precautions when handling specimens.
- Following collection, only trained personnel who are qualified to handle infectious materials in subsequent assays should be processing the specimen.
- For external use and single use only. DO NOT drink, touch, or remove the buffer from the device. Do Not use if device is broken, leaking, or visibly damaged. These products should only be used in accordance with the instructions provided. Avoid skin and eye contact with the liquid in the tube. If Ingested Call a POISON CENTER. Rinse mouth. IF IN EYES: Rinse cautiously with water for several minutes. Not a Hazardous Combustion Product. Device cap can be a choking hazard. Do not ingest.

Storage Requirements: iSWAB™-RC-EL can be stored at room temperature (15°C to 30°C) for 15 months from the date of manufacture, prior to use.

Acceptable Specimen Types to be Used with iSWAB™-RC-EL: Nasal swab and saliva samples suspected of SARS-Co-2 are the permitted specimen types to be collected into the **iSWAB™-RC-EL**.

Specimen Handling: Handle clinical samples carefully to prevent cross-contamination and treat every sample as though it were contagious. To prevent healthcare workers from coming into contact with clinical specimens, maintain industry-standard infection control procedures. Avoid contaminating the tube cap and outer surface, especially when transferring samples. To prevent leakage, make sure the tube caps are properly and securely fastened.

Specimen Collection: Proper sample collection and transportation are necessary for accurate laboratory results. The customer can confirm the desired method of collection with the processing lab prior to sample collection. When collecting the sample, the customer must adhere to the product's IFU, which is included in the packaging insert.

Specimen processing: Samples need to be stored in media for at least 6 hrs to render the virus inactive. The sample maybe added directly into the workflow, skipping the RNA extraction and cDNA synthesis step after laboratory validation of the media with subject assays to ensure not meaningful assay performance is lost.

Pre-Collection Stability: Determined by visual inspection for bacterial and fungal growth in the media along with properties of the media such as appearance, pH, conductivity, and density.

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PREPARATION FOR USE

Before sample collection, verify preferred method of collection with your processing lab.

- Note: It is recommended not to eat, drink, or smoke for 30 minutes before collecting your sample. Do not touch swab tips or allow contact with any other object.
- For swab collection, use either 1 or 2 swabs depending on the test protocol.
- Tap the device gently 2-3 times before collection to concentrate all liquid to the bottom.

If using saliva collection skip to step number 8

For saliva self-collection, the iSPIT funnel is purchased separately.

1. Place device standing up on a flat surface. Peel open bags containing swabs and remove a swab. Unscrew device cap before collecting sample.
2. **For nasal mid-turbinate collection:** Insert the swab head into your nostril no more than 3/4" (1.5cm) in. Slowly rotate at least 3 times, gently pressing against the inside of your nostril. Gently remove the swab and repeat this step in your other nostril.
3. Pick up tube and hold steady in one hand. Slowly twist swab into iSWAB™ tube with a corkscrew motion. There will be resistance but push swab to the bottom of tube.
4. Hold tube steady and move swab up and down rapidly inside the tube 10-15 times without moving the swab out of the liquid.
5. At this point remove the swab. Hold tube firmly and remove swab by slowly twisting out with a corkscrew motion.
6. For a more concentrated sample, a second sample may be collected by repeating steps 2-5 with another swab. Skip this step if unnecessary.
7. After all samples have been taken, replace cap tightly. Properly dispose used swabs in the appropriate biohazard waste in accordance with federal, state, and local regulations. The sample is now ready for further testing.
8. **Steps For Saliva Collection** (Ignore if using swabs for collection):
 - (1) Remove cap from device and place on a clean surface.
 - (2) Place iSPIT™ funnel onto the tube so that it is resting upright as shown in the picture.
 - (3) Stimulate saliva production in your mouth.
 - (4) Spit 1 or 2 times directly into the funnel.
 - (5) Allow several seconds for all saliva to pass through the iSPIT™ funnel into the tube.
 - (6) Remove funnel and discard in the appropriate biohazard waste in accordance with federal, state, and local regulations.
 - (7) Replace cap securely onto tube.
 - (8) Gently shake the device 5-10x to allow mixing.
 - (9) The sample is now ready for further testing.
9. **For Lab or onsite collection:** Proceed with sample processing or storage.

LIMITATIONS

- iSWAB™-RC-EL performance characteristics have been demonstrated for only SARS COV-2 using the BGI's "Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV- 2" assay.
- The laboratory is responsible for validating the iSWAB™-RC-EL devices for clinical utilization in their laboratories.
- It is the end user's responsibility to determine the proper assay performance characteristics for nasal and saliva specimen types and to validate viral nucleic acid detection platforms and systems (such as PCR and/or liquid handlers) for extraction-free techniques.
- iSWAB™-RC-EL is a collection, stabilization, transport, and storage system for viral nucleic acids only.
- The iSWAB™-RC-EL is intended for professional use only and not for use in POC or home

QUALITY CONTROL

Every batch of iSWAB™-RC-EL media is verified to inactivate and to preserve RNA from SARS-CoV-2 when stores at 20-25 °C.

PERFORMANCE

The accuracy of molecular testing depends on proper specimen collection, integrity of the nucleic acid, and the PCR amplification kit used for viral nucleic acid detection. The iSWAB™-RC-EL was validated using the performance parameters listed below.

1. Detection Limit:

Nasal samples:

The limit of detection (LoD) of SARS-CoV2 for iSWAB™-RC-EL was confirmed using an EUA authorized assay to determine the lowest concentration of virus that can be repeatedly recovered from the sample tube at the lowest detection concentration with an accuracy greater than 95%. Negative clinical nasal matrix was collected and pooled. 20 individual replicates of matrix were spiked with 25 cp/μL of ATCC VR-1986 and then added to the media.

Samples were assessed using the BGI's "Real-Time Fluorescent RT-PCR Kit for Detecting SARS- CoV-2" assay. 10 μL of sample in media was directly mixed with 20 μL of RT-PCR master mix targeting the ORF1ab region of SARS-CoV-2 genome (FAM channel) and the human housekeeping gene β-Actin (ACTB, VIC/HEX channel) as a sample control.

At 25 cp/μL, 19/20 samples (95%) were positive indicating that the LoD for nasal clinical matrix is 25 cp/μL, table 1 below.

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Table 1. LOD studies at 25 cp/μL with nasal matrix

Replicate #	ORF1ab (average Ct)	SD	ACTB (average Ct)	SD
1	35.00	0.12	27.99	0.02
2	34.27	0.26	27.93	0.06
3	35.02	0.46	27.57	0.20
4	35.07	0.45	27.54	0.01
5	35.36	0.43	28.08	0.01
6	34.96	0.37	27.91	0.17
7	34.93	0.41	27.71	0.10
8	35.16	0.62	27.88	0.12
9	34.91	0.64	28.16	0.03
10	34.91	0.13	28.20	0.02
11	34.96	0.64	28.02	0.16
12	35.31	0.41	28.12	0.11
13	35.19	0.13	28.03	0.02
14	35.20	0.14	26.75	0.91
15	35.78	0.52	27.82	0.03
16	35.23	0.17	27.98	0.24
17	35.27	0.30	28.20	0.02
18*	36.65	1.06	29.21	0.19
19	35.55	0.41	27.17	1.06
20	34.99	0.60	28.16	0.09

* The result was above the Ct cut-off for the assay and is a negative

Saliva samples:

The limit of detection (LoD) of SARS-CoV2 for iSWAB™-RC-EL was confirmed using an EUA authorized assay to determine the lowest concentration of virus that can be repeatedly recovered from the sample tube at the lowest detection concentration with an accuracy greater than 95%. Negative clinical saliva matrix was collected and pooled. 20 individual replicates of matrix were spiked with 30 cp/μL of ATCC VR-1986.

Samples were assessed using the BGI's "Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2" assay. 10 μL of sample in media was directly mixed with 20 μL of RT-PCR master mix targeting the ORF1ab region of SARS- CoV-2 genome (FAM channel) and the

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human housekeeping gene β -Actin (ACTB, VIC/HEX channel) as a sample control.

At 30 cp/ μ L, 20/20 samples were positive, however at 25 cp/ μ L only 13/20 samples were positive, indicating that the LoD for nasal clinical matrix is 30 cp/ μ L table 2 below.

Table 2. LOD studies at 30 cp/ μ L with saliva matrix

Replicate #	ORF1ab (average Ct)	SD	ACTB (average Ct)	SD
1	35.11	0.09	32.30	0.21
2	35.55	0.46	31.24	0.72
3	35.85	0.60	32.08	0.22
4	36.36	0.29	31.05	0.40
5	35.80	0.12	31.29	0.60
6	35.65	0.83	32.32	0.19
7	36.23	0.30	32.39	0.55
8	35.51	0.13	32.13	0.91
9	35.44	0.35	32.76	0.50
10	35.26	0.64	31.21	0.55
11	34.62	0.07	31.79	0.11
12	35.96	0.65	32.14	0.50
13	35.67	0.77	32.19	0.49
14	35.99	1.11	32.57	0.82
15	35.20	0.23	32.73	0.05
16	36.05	0.40	32.76	0.14
17	35.02	0.24	32.50	0.43
18	34.89	0.71	31.72	0.58
19	35.08	0.05	32.14	0.81
20	34.59	0.69	32.51	0.54

Conclusion: the LoD for nasal samples is 25cp/ μ L and for saliva samples is 30 cp/ μ L when tested with 20 replicates.

2. Specimen Stability

Nasal samples:

The specimen stability of SARS-CoV2 virus was determined in iSWAB™-RC-EL media by spiking 110 cp/ μ L of ATCC VR-1986 in iSWAB™-RC-EL media with negative clinical nasal

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matrix. 10 µL of sample was mixed directly without extraction with 20 µL of master mix from BGI Real Time Fluorescent RT-PCR Kit for Detecting SARS-CoV2. A pre-defined acceptance criteria of ± 3 Ct from time zero was used to establish stability after storage at room temperature, 20-25°C. The transport media stabilizes SARS-CoV2 RNA up to 28 days, table 3 below.

Table 3. RT-PCR results for specimen stability in nasal matrix

	Orflab average Ct	Delta Ct from baseline	ACTB average Ct	Delta Ct from baseline
Day 0	33.74	0.00	30.79	0.00
Day1	33.22	-0.52	31.84	1.05
Day 4	32.51	-1.23	28.62	-2.17
Day 7	32.77	-0.97	29.64	-1.15
Day 14	32.75	-0.99	28.59	-2.20
Day 21	33.20	-0.54	29.42	-1.37
Day 28	34.83	1.09	28.59	-2.20

Saliva samples:

The specimen stability of SARS-CoV2 virus was determined in iSWAB™-RC-EL media by spiking 110 cp/µL of ATCC VR-1986 in iSWAB™-RC-EL media with negative clinical saliva matrix. 10 µL of sample was mixed directly without an extraction step with 20 µL of master mix from BGI Real Time Fluorescent RT-PCR Kit for Detecting SARS-CoV2. A pre- defined acceptance criteria of ± 3 Ct from time zero was used to establish stability after storage at room temperature, 20-25°C. The transport media stabilizes SARS-CoV2 RNA up to 33 days, table 4 below.

Table 4. RT-PCR results for specimen stability in saliva matrix

	Orflab average Ct	Delta Ct from baseline	ACTB average Ct	Delta Ct from baseline
Day 0	33.62	0.00	31.34	0.00
Day1	35.00	1.38	29.00	-2.33
Day 8	35.56	1.94	29.02	-2.31
Day 19	32.65	-0.97	29.89	-1.45
Day 26	34.25	0.63	30.80	-0.54
Day 33	34.90	1.29	31.48	0.14

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Conclusion: the specimen stability for nasal samples is 28 days and for saliva samples is 33 days.

3. Inactivation study

Media cytopathic effect:

Cell lines were spiked with iSWAB™-RC-EL media without dilution and no cytopathic effect was observed over 2 hours. As a result, media with virus could be added without dilution to a cell culture monolayer for less than 2 hours before removal and replacement with media for the viral inactivation phase of the inactivation study.

Inactivation time:

The viral inactivation time phase of the study was conducted to assess the time the virus needs to be exposed to the media to render the virus inactive. The iSWAB™-RC-EL was spiked with known concentrations of SARS-Cov2 virus and negative clinical matrix, (table 5. nasal matrix, table 6. saliva matrix), and incubated at room temperature for 30 min, 2 hrs, and 6 hrs.

At each time point 100 µL of the iSWAB™-RC-EL spiked with respective matrix and SARS-Cov2 virus was inoculated onto MDCK II cell culture. The cultures were incubated for up to 48 hours post infection and observed by inverted light microscopy for cytopathic effect (CPE). The Reed and Muench method was used to determine the 50% tissue culture infectious dose per mL (TCID50/mL). In cases where sample showed no sign of any detectable virus, statistical analysis based on the Poisson distribution was carried out to ascertain the theoretical maximum potential titer. Cells spiked with virus without incubation in iSWAB™-RC-EL media showed CPE within 10 min.

Table 5. Inactivation with nasal clinical matrix

Volume (mL)	Replicate	Input Viral Load (Log10TCID50)	Output Viral Load (Log10TCID50)	Reduction (Log10TCID50)
30 minutes	1	5.93 ± 0.28	1.48 ± 0.18	4.45 ± 0.34
	2		1.35 ± 0.16	4.58 ± 0.33
	3		1.35 ± 0.16	4.58 ± 0.33
	Average		1.39 ± 0.17	4.54 ± 0.33
2 hours	1	5.81 ± 0.27	0.60 ± 0.19	5.21 ± 0.33
	2		0.48 ± 0.18	5.33 ± 0.32
	3		0.23 ± 0.12	5.58 ± 0.29
	Average		0.44 ± 0.16	5.37 ± 0.31
6 hours	1	5.81 ± 0.30	0.06 ± 0.02	5.75 ± 0.35
	2		0.05 ± 0.03	5.76 ± 0.35
	3		0.05 ± 0.02	5.76 ± 0.32

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	Average	0.18 ± 0.02	5.76 ± 0.34
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Table 6. Inactivation with saliva clinical matrix

Volume (mL)	Replicate	Input Viral Load (Log ₁₀ TCID ₅₀)	Output Viral Load (Log ₁₀ TCID ₅₀)	Reduction (Log ₁₀ TCID ₅₀)
30 minutes	1	5.93 ± 0.28	1.35 ± 0.16	4.58 ± 0.33
	2		1.35 ± 0.16	4.58 ± 0.33
	3		1.60 ± 0.19	4.33 ± 0.34
	Average		1.43 ± 0.17	4.50 ± 0.33
2 hours	1	5.81 ± 0.27	0.10 ± 0.17	5.71 ± 0.32
	2		0.23 ± 0.12	5.58 ± 0.29
	3		0.35 ± 0.16	5.46 ± 0.31
	Average		0.23 ± 0.15	5.58 ± 0.31
6 hours	1	5.81 ± 0.30	0.05 ± 0.01	5.80 ± 0.34
	2		0.07 ± 0.03	5.80 ± 0.35
	3		0.04 ± 0.03	5.81 ± 0.35
	Average		0.05 ± 0.02	5.80 ± 0.35

Conclusion: the iSWAB™-RC-EL media requires a minimum of 6h to inactivate SARS-CoV2 at room temperature as shown by a >5 log reduction in TCID₅₀/mL values when used with nasal or saliva matrix.

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 Email: support@mawidna.com

For more contact information visit: <https://mawidna.com/>



Biosampling Reinvented™

iSWAB™-RC-EL 510(K) Submission

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