REF **100500 NeuMoDx™ Saliva Collection Kit** ℞ only

IVD For prescription use only.
For *in vitro* diagnostic use.
For use with the NeuMoDx™ SARS-CoV-2 Assay.
For use under FDA Emergency Use Authorization only in the United States and its territories.

Electronic version is available at www.neumodx.com/client-resources
Before proceeding to specimen testing, read: NeuMoDx™ SARS-CoV-2 Assay instructions for use (IFU)—document: P/N 40600437 (United States) OR P/N 40600425 (United States Export Only)

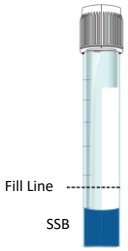
READ ALL INSTRUCTIONS PRIOR TO COLLECTION

INTENDED USE: The NeuMoDx™ Saliva Collection Kit is intended for the collection, stabilization, storage, and transport of saliva specimens from individuals suspected of SARS-CoV-2, collected in a clinical setting and to be tested for the detection of SARS-CoV-2 RNA with the NeuMoDx™ SARS-CoV-2 Assay on the NeuMoDx™ Molecular Systems.

SUMMARY AND EXPLANATION: The NeuMoDx Saliva Collection Kit provides the materials and instructions for collection, transport, and storage of saliva specimens for SARS-CoV-2 testing. The kit contains two vials. The empty Saliva Collection Vial is used for the actual saliva collection. The Specimen Stabilization Tube contains the saliva stabilization buffer and should not be used for direct saliva collection.

Kit Contents: (1) empty **NeuMoDx™ Saliva Collection Vial**, (1) **NeuMoDx™ Specimen Stabilization Tube*** with 1 mL stabilization buffer solution containing guanidine HCl and sodium borate and (1) Disposable **Transfer Pipet**.

Saliva Collection Vial



Specimen Stabilization Tube (SSB)*

Transfer Pipet

* **Warnings:** The Specimen Stabilization Tube and liquid must only be handled by healthcare personnel with specific training on handling hazardous substances. Wash with water if stabilizing liquid comes in contact with eyes or skin. Do NOT ingest. See SDS at www.neumodx.com/client-resources.

Kit Storage: Store at 4-28°C.

Product Deterioration: The NeuMoDx Saliva Collection Kit should not be used if (1) there is evidence of damage or contamination to the product, (2) there is evidence of leakage, (3) the expiration date has passed or (4) there are other signs of deterioration.

WARNINGS AND PRECAUTIONS:

- The NeuMoDx Saliva Collection Kit has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories.
- The NeuMoDx Saliva Collection Kit has been authorized only for the collection and maintenance of saliva as an aid in the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- The emergency use of the NeuMoDx™ SARS-CoV-2 Assay in combination with the authorized NeuMoDx SARS-CoV-2 Assay is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of medical devices for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- **This collection device contains harmful chemicals (Guanidine HCl) in the Specimen Stabilization Tube and is therefore for use only in clinical settings. This collection device must not be used for self-collecting and stabilizing samples at home without the supervision of a trained healthcare professional. The Specimen Stabilizing Tube, the stabilizing liquid and the stabilized saliva sample must only be handled by healthcare personnel with specific training on handling hazardous substances.**
- Do not ingest.
- Do not re-use any kit contents.
- For healthcare providers, wear Personal Protective Equipment (PPE).
- Do not use kit contents if the Specimen Stabilization Tube has leaked or appears otherwise compromised.
- The individual providing the sample must not eat, drink, smoke, chew gum or use oral hygiene products for at least 30 minutes prior to sample collection.
- Discard all used materials to biohazardous waste per local regulations.
- Avoid specimen contamination.
- Do not use the kit beyond its expiration date.

- Do not drop specimen or transfer pipet after collection.
- Small caps and pipet may pose choking hazards.
- Safety data sheet (SDS) is available at www.neumodx.com/client-resources

COLLECTION INSTRUCTIONS

1. Do NOT eat, drink, smoke, chew gum or brush teeth 30 minutes before collecting the saliva sample.
2. Make sure the donor is well hydrated.
3. Have donor rinse mouth with water to remove food residue. Wait at least 10 minutes after rinsing before proceeding to saliva collection.

PROCEDURE (at healthcare setting)

Most people take 2 to 5 minutes to deliver a saliva sample following Steps 1–4.

Patient

STEP 1 a) Hold *Saliva Collection Vial* upright and remove cap.
b) Bring *Saliva Collection Vial* close to your mouth and press vial beneath your bottom lip.

STEP 2 a) Collect saliva on the floor of your mouth and allow to pool without swallowing. **Do not cough as this may cause mucus rich lower respiratory sputum to be included in the test sample.**
b) Spit into the *Saliva Collection Vial.*
c) Collect enough saliva to reach the top of the cone shaped line (about~ 1-2 mL).
NOTE: Do not spit directly into the Specimen Stabilization Tube.

STEP 3 Replace cap on the *Saliva Collection Vial*.
NOTE: Confirm the cap is on tightly.

STEP 4 **Return** the *Saliva Collection Vial* to healthcare personnel.

Healthcare Personnel

STEP 1 a) Collect the *Saliva Collection Vial* from the patient.
b) Remove cap from *Saliva Collection Vial*.

STEP 2 Hold the *Specimen Stabilization Tube* upright and remove cap.

STEP 3 a) Aspirate saliva from the *Saliva Collection Vial* with the disposable transfer pipet.
b) Transfer saliva to the *Specimen Stabilization Tube* until the saliva reaches the **"Fill" Line.**
NOTE: Avoid transferring air bubbles when using the transfer pipet.

STEP 4 a) Replace cap on the *Specimen Stabilization Tube* and close tight.
b) Invert the *Specimen Stabilization Tube* 5-10 times to mix.

STEP 5 Discard the *Saliva Collection Vial* and the transfer pipet as biohazardous waste.

SPECIMEN STORAGE AND TRANSPORT

- Saliva should be added to the Sample Stabilization Tube within 2 hours of collection. During that time, the untreated saliva can be stored at ambient conditions
- Once added into the Sample Stabilization Tube, the stabilized saliva specimen can be stored up to 48 hours at ambient conditions and up to 7 days at 2-8°C.
- Ship stabilized saliva specimens on icepacks to the testing laboratory.

LIMITATIONS

1. The NeuMoDx™ Saliva Collection Kit has not been FDA cleared or approved.
2. The NeuMoDx™ Saliva Collection Kit has been authorized by FDA under an EUA.
3. The NeuMoDx™ Saliva Collection Kit has been authorized only to collect, stabilize, and maintain during transport, saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA), not for any other viruses or pathogens.
4. This sample collection device is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
5. The NeuMoDx™ Saliva Collection Kit is only for use with the NeuMoDx SARS-CoV-2 Assay processed on NeuMoDx Molecular Systems. Performance characteristics with other tests are unknown.
6. Presence of Crest® Pro-Health Advanced Gum Protection Toothpaste in saliva specimens may interfere with SARS-CoV-2 RNA detection and could lead to a false negative result.
7. Reliable results are dependent on proper specimen collection, handling, and storage.
8. This product is intended for professional use only and not for use in point-of-care (POC) or home.

DISPOSAL

Dispose of waste in accordance with laboratory procedure and local legislation. Take the appropriate precautions for infected material if necessary.

PERFORMANCE DATA

Specimen Stability

The stability of saliva in the NeuMoDx Saliva Stabilizaion Buffer was determined by using a contrived panel of low positive samples prepared by spiking gamma-irradiated SARS-CoV-2 virus in the mixture of pooled saliva specimens with SSB at a ratio of 1:1.67 (v/v), and negative sample panel using the pooled negative saliva with SSB mixture. Enough volume was dispensed into barcoded secondary tubes to allow for a maximum of 4 or 5 tests from each tube.

The contrived positive saliva panels were stored at ambient temperature for 24 and 48 hours after mixing with SSB. A set of six (6) replicates of the positive and negative panels were processed at each timepoint. Following the initial testing, the saliva panels were stored for 7 days at 2-8°C. One set of six replicates of positive and negative samples was stored at 2-8°C for 7 days immediately after dispensing into secondary tubes. After storage for 7 days, each set of specimens was immediately processed on the NeuMoDx Molecular System before being left onboard the system's worktable for a total of 12 hours. Additional testing was performed after 8 and 12 hours onboard storage. A total of 48 replicates were processed for this study.

Saliva in SSB Stability Results using the NeuMoDx SARS CoV-2 Assay on NeuMoDx Molecular System

Timepoint	SARS-CoV-2 Positive Panel				Negative Panel		
	# Sample Tested	# Valid Result	% Amplified (N gene)	% Amplified (Nsp2 gene)	# Sample Tested	# Valid Result	% Amplified
0 Days (T0)	6	6	100%	100%	6	6	0%
7 Days 2-8°C	6	6	100%	100%	6	6	0%
7 Days 2-8°C + 8h	6	6	100%	100%	6	6	0%
7 Days 2-8°C + 12h	6	6	100%	100%	6	6	0%
24h Ambient	6	5[1]	100%	100%	6	6	0%
24h + 7 Days 2-8°C	6	6	100%	100%	6	5[1]	0%
24h + 7 Days 2-8°C + 8h	6	6	100%	100%	6	6	0%
24h + 7 Days 2-8°C + 12h	6	5[1]	100%	100%	6	6	0%
48h Ambient	6	6	100%	100%	6	6	0%
48h + 7 Days 2-8°C	6	6	100%	100%	6	6	0%
48h + 7 Days 2-8°C + 8h	6	6	100%	100%	6	6	0%
48h + 7 Days 2-8°C + 12h	6	6	100%	100%	6	6	0%

[1]One sample had an UNR result.

As shown in the table above , 100% detection rate was observed from the initial run (Time 0) and at the 24-hour, 48-hour, and 7-day timepoints for saliva samples in SSB. Three samples had Unresolved results.

- All valid SARS-CoV-2 Positive samples correctly reported Positive results after ambient storage and storage at 2-8°C for 7 days.
- Furthermore, 100% detection was observed up to 12 hours onboard the system. All positive samples correctly reported Positive results for valid SARS CoV-2 Positive samples after storage onboard the system for 8 and 12 hours.

This demonstrates that saliva specimens in SSB are stable for at least 48 hours when stored at ambient temperature, 7 days when stored at 2-8°C, and for up to 12 hours when stored onboard the NeuMoDx Molecular System.

For additional performance data please refer to the Performance section of the NeuMoDx SARS-CoV-2 Assay [REF 300800] IFU from www.neumodx.com/client-resources.

Hazards Identification:

Pictograms

Signal Word: Danger

Hazard Statements

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H360	May damage fertility or the unborn child.

Precautionary Statements

P201	Obtain special instructions before use.
P202	Do not handle until all safety precaution have been read and understood.
P264	Wash skin thoroughly after handling.
P270	Do not eat, drink, or smoke when using this product.
P281	Use personal protective equipment as required.
P301 + P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313	IF exposed or concerned: Get medical advice/attention.
P330	Rinse mouth.
P362 + P364	Take off contaminated clothing and wash before reuse.

For further information, refer to the Safety Data Sheet (P/N 40600462) found at www.neumodx.com/client-resources.

TRADEMARKS

NeuMoDx™ is a trademark of NeuMoDx Molecular, Inc.

All other product names, trademarks, and registered trademarks that may appear in this document are property of their respective owners.

SYMBOL KEY

℞ only	**Prescription use only**		**Temperature limit**
	Manufacturer		**Do not re-use**
IVD	***In vitro* diagnostic medical device**		**Consult instructions for use**
EC REP	**Authorized representative in the European Community**		**Caution**
REF	**Catalog number**	CE	**CE Mark**
LOT	**Batch code**		**Use-by date**

PICTOGRAM KEY

Health Hazard (GSH08)

Exclamation Mark (GHS07)

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Patent: www.neumodx.com/patents