Part No.: H-020-000707-00



# MGIEasy

Saliva Sample Collection Kit

**Instructions for Use** 

Version: 1.0

# **Leading Life Science Innovation**

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## About the instructions for use

This instructions for use is applicable to MGIEasy Saliva Sample Collection Kit. The version of the instructions for use is 1.0 and the kit version is 1.0.

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# **Revision history**

Version	Date	Description
1.0	May 15, 2023	Initial release

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Introduction Instructions for use

# **Chapter 1 Introduction**

#### 1.1 Product name

MGIEasy Saliva Sample Collection Kit

## 1.2 Specification

Cat. No.	Model	Name	Specification
940-001262-00	SSC02	MGIEasy Saliva Sample Collection Kit	1 Prep / Kit

## 1.3 Intended use

This product is used to collect, transport and store human saliva.

## 1.4 working principle

The saliva sample preservative in this product lyses cells in human saliva samples and releases nucleic acid. The preservative inhabits enzyme activity to keep the nucleic acid stable. Collected samples with the saliva sample preservative can be stored at room temperature for a long time.

## 1.5 Main components

Tips It is not recommended to mixedly use reagent components from different batches of kit.

Table 1 MGIEasy Saliva sample collection kit Cat. No.: 940-001262-00

Component	Main ingredients	Specification
Saliva sample preservative	Denaturing reagent (1% to 2%)	1 mL/tube×1
Collection funnel	/	1 EA
Collection tube	/	1 EA
Storage bag	/	1 EA
Сар	/	1 EA

## 1.6 Storage condition and validity period

- This product can be stored at 2 °C to 30 °C for 24 months.
- This product can be transported at 2 °C to 40 °C with the transportation time no more than 15 days.
- For the actual manufacturing date and use-by date, please refer to the label.

# Chapter 2 Sample requirements

## 2.1 Applicable sample

This kit is applicable to collect fresh saliva samples.

## 2.2 Sample storage

Freshly collected saliva samples with the preservative are stable for 24 months at 2  $^{\circ}\text{C}$  to 30  $^{\circ}\text{C}$  .

## 2.3 Sample safety

All samples should be considered potentially infectious and should be handled in accordance with relevant national regulations.

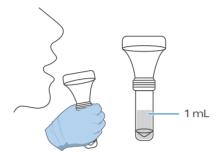
# **Chapter 3 Operation**

Perform the following steps:

1. Rinse your mouth with cool water and keep it clean 30 minutes before saliva sample collection. Do not eat, drink, smoke, or chew gum until you complete collection.



- 2. Gently rub your cheeks from the outside (pressing them against your teeth and gums) or chew to produce saliva.
- 3. Spit the saliva into the tube until your saliva (not bubbles) reaches the 1 mL mark.



4. Remove the collection funnel from the tube, open the cap of the saliva preservative, and carefully pour the saliva preservative into the collected saliva sample.



- 5. Cap the collection tube and twist the cap tightly. Invert the tube for 30 seconds to mix it thoroughly.
- 6. Cap the saliva preservative tube, twist the cap tightly, and dispose of the tube and funnel.

# Chapter 4 Warnings and precautions

- This product is for research use only and should not be used for clinical diagnosis.
- Please read the instructions for use carefully before use, master the operating method, and get familiar with the warnings and precautions.
- Do not swallow any samples or reagents. Avoid direct contact with skin and eyes. If this happens, rinse them immediately with plenty of fresh water and seek medical advice immediately.
- The collected saliva (not bubbles) must reach the 1 mL mark.

- Do not eat, drink, smoke, or chew gum 30 minutes before collecting saliva samples.
- During experiment, the collection kit should be used according to the instructions for use within the expiration date and below 40 °C.
- Avoid cross contamination among different specimens or samples.
- All samples should be considered potentially infectious and should be handled in accordance with relevant national regulations.
- Please only submit saliva and avoid mucous from coughing, expectoration or nasal secretions (sneezing).
- This product is for a single use only and cannot be reused.
- Contact with the manufacturer for the safety data sheet (SDS).
- Any serious incident that has occurred in relation to the kit shall be reported
  to the manufacturer and the competent authority of the Member State in
  which the user and/or the patient is established.

# **Appendix 1 Manufacturer information**

Manufacturer	Wuhan MGI Tech Co., Ltd.
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