

STANDARD M10

Stool Pretreatment Kit

STANDARD™ M10 Stool Pretreatment Kit

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST



EXPLANATION AND SUMMARY

■ Introduction

Unformed stool specimens collected from patients for molecular diagnosis often contain fiber or mucous material, making it difficult to process downstream nucleic acid extraction efficiently. STANDARD™ M10 Stool Pretreatment Kit allows easy liquefaction of unformed stool specimens prior to downstream nucleic acid extraction and increased the efficiency of molecular testing by removing potential PCR inhibitors.

■ Intended Use

STANDARD™ M10 Stool Pretreatment Kit is used to pretreat the unformed stool before processing for downstream nucleic acid extraction and molecular diagnostic testing.

■ Test principle

Molecular diagnostic testing requires purified nucleic acids from stool specimens that have high levels of PCR inhibitors. So it is necessary to remove potential inhibitors. The pretreatment solution included in STANDARD M10 Stool pretreatment kit denatures proteins to help remove potential PCR inhibitors and lyse pathogens.

KIT CONTENTS

Contents	Quantity
Stool Pretreatment solution	10
Disposable Sampling Swab	10
Tube cap	10
STANDARD™ Disposable dropper (1.4 ml)	10
Stool Pretreatment tool	10
Instructions for use	1

WARNINGS AND PRECAUTIONS

1. This product is a reagent for *In vitro* diagnostic (IVD) use.
2. When handling biologically hazardous reagents and clinical specimens, wear gloves and masks.
3. Perform experiments using a sterile filter pipette tip.
4. Store clinical samples at 2 ~ 8°C, protected from light. For long-term storage of samples, samples are aliquoted and stored at -20°C.
5. Do not use the test kit if the kit or the components of it is damaged.
6. Do not use the test kit beyond its expiration date.
7. This kit is designed for use by trained clinical diagnostic staff who have the necessary skills to handle and manipulate clinical specimens correctly and appropriately. Users should have a basic understanding of experimental techniques to perform the experiments described in the instructions for use accurately.
8. Any serious incident that has occurred in relation to the device shall be reported to the manufacturer (TS team : ts@sdbiosensor.com) and the competent authority of the Member State where the user and/or the patient are established.
9. Dispose of used kit components in the appropriate sample waste containers according to your institution's standard practices.
10. Each single-use M10 Stool Pretreatment Kit is used to process one test. Do not reuse used contents.

STORAGE AND HANDLING

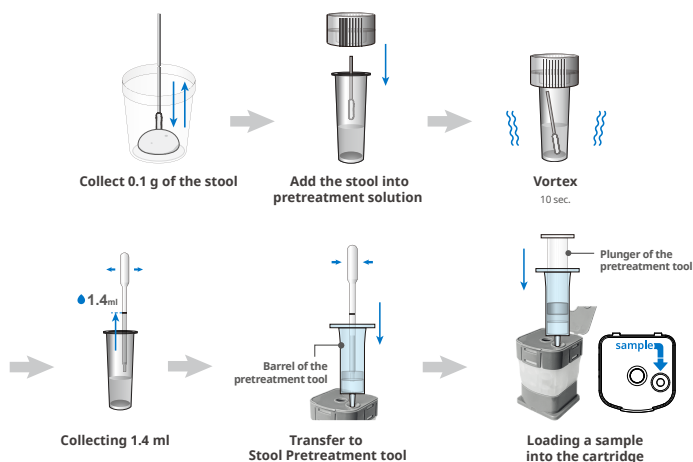
Store STANDARD™ M10 Stool Pretreatment Kit at 2 ~ 28°C. Do not freeze and keep away from light sources. Do not use the kit that has leaked or is wet. Under these conditions, the kit can be stored until the expiration date printed on the packaging label.

SPECIMEN COLLECTION AND PREPARATION

Collect unformed stool following your institution's standard protocol for sample collection and testing.

ASSAY PROTOCOL

■ Stool



1. Prepare the stool in the specimen collection container.
2. Open carefully the lid of the specimen collection container and avoid solid particles that may affect the test.
3. Using the Disposable Sampling Swab, collect 0.1 g of the stool and put it in the stool pretreatment solution.

4. After closing the tube cap, vortex the tube for 10 seconds to ensure that the stool and stool pretreatment solution are thoroughly mixed.
5. Insert the barrel of the Stool pretreatment tool into the sample loading hole of the cartridge.
6. Collect 1.4 ml up to the marked line on the dropper and transfer it to the barrel of the stool pretreatment tool.
7. Load the entire amount into the cartridge using the plunger of the stool pretreatment tool.

SYMBOL

	Reference number		Consult Instructions for use
	Batch code		Note
	Manufacturer		Date of manufacture
	Contains Sufficient for <n> Tests		Temperature limit
	Use-by date		Caution
	Do not re-use		Authorized representative in the European community
	This product fulfills the requirements of the European Regulation 2017/746		<i>In vitro</i> Diagnostics



Manufactured by SD Biosensor, Inc.

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Any inquiries regarding the instructions provided should be addressed to: ts@sdbiosensor.com or you can also contact us through www.sdbiosensor.com