

RNA Extraction Kit

REF 437506 RNA-3 (Swabs in Transport Medium/UTM)

For use with the BD MAX™ System



INTENDED USE

The BD MAX™ RNA Extraction Kit is used with the BD MAX™ System to extract RNA from viruses, which may be present in clinical specimens. Purified RNA obtained with the BD MAX™ RNA Extraction Kit may be analyzed using the BD MAX™ System or another commercially available system for reverse transcription followed by nucleic acid amplification and detection. The BD MAX™ RNA Extraction Kit has not been validated for use with any specific analytical test method.

PRINCIPLES OF THE PROCEDURE

The specimen is mixed with BD MAX™ RNA Sample Preparation Reagent and processed using the BD MAX™ System. The BD MAX™ System automates RNA extraction and concentration. No operator intervention is necessary once the clinical sample is loaded onto the BD MAX™ System.

The BD MAX™ System uses a combination of lytic and extraction reagents to perform viral lysis, RNA extraction and removal of inhibitors. Viral lysis is achieved by the use of heat and detergents present in the RNA Sample Preparation Reagent. The released nucleic acid is captured by magnetic affinity beads and treated with DNase to degrade any DNA present in the sample. The beads with the bound RNA are then washed twice followed by magnetic separation. The RNA bound to the magnetic beads is then eluted and is ready for use in an RT-PCR reaction.

REAGENTS

REF	Product Name	Pkg Quantity
437506	RNA Extraction Reagent E2-R (R2) RNA Sample Preparation Reagent SP2-R DNase Reagent D1 RNA Unitized Reagent Strips	▽24

EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

1. BD MAX™ System
2. Syringe Filter Assembly REF 437017
3. Micropipettors (accurate between 100-1000 µL)
4. Aerosol resistant micropipette tips
5. Disposable gloves/lab coat
6. Swabs with Universal Transport Medium (UTM) or viral transport media such as M4, M5

WARNINGS AND PRECAUTIONS

- This kit is for *in vitro* diagnostic use only.
- Do not use the kit if the packaging is damaged upon arrival.
- Do not use the reagents after their expiration date.
- Do not use reagents if the protective pouch is open or broken upon arrival.
- Protect reagents against heat and humidity. Prolonged exposure to humidity will affect product performance.
- Samples which deviate from expected quality (physical or otherwise) may not be suitable for testing.

- Avoid microbial and nuclease (RNase and DNase) contamination of reagents at all times. The use of sterile RNase/DNase-free disposable filter-blocked or positive displacement pipette tips is recommended. Use a new tip for each specimen.
- Always handle specimens as if they are infectious and in accordance with safe laboratory procedures such as those described in *Biosafety in Microbiological and Biomedical Laboratories*¹ and in CLSI Document M29².
- Wear personal protective equipment and non-powdered disposable gloves while handling all reagents.
- Wash hands thoroughly after performing the test.
- Do not pipette by mouth.
- Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
- Dispose of unused reagents and waste in accordance with country, federal, provincial, state and local regulations.
- Consult the BD MAX™ System User's Manual for additional warnings, precautions and procedures.

STORAGE AND STABILITY

Collected specimens should be kept between 2-30°C during transport. Specimens mixed with Sample Preparation Reagents should be used within 4 hours.

The BD MAX™ RNA Extraction Kit is stable at 2-25°C through its stated expiration date. Do not use kit components that have passed their expiration date.

INSTRUCTIONS FOR USE

Specimen Collection

1. Collect specimen and label appropriately.
2. Proceed to Test Preparation.

Test Preparation

Swabs in Transport Medium/UTM: Pipette 500 µL of specimen into a Sample Preparation Reagent SP2-R tube. If the original specimen is observed to be turbid, viscous or contains particulate material, filtration of the diluted specimen (specimen added to SP2-R tube) may be necessary. Proceed to Sample Filtration Procedure if filtering is required. If filtering is not required, proceed to BD MAX Operation.

Sample Filtration Procedure

Filter the diluted specimen contained in the Sample Preparation Reagent tube using a Syringe Filter Assembly (REF 437017).

1. Draw up the entire volume of diluted specimen through the filter into the syringe.
2. Remove the filter and cannula from the syringe.
3. Dispense the filtered sample back into the original Sample Preparation Reagent tube.
4. Proceed to BD MAX™ Operation.

BD MAX™ Operation

(Refer to the BD MAX™ System User's Manual for programming and setup instructions)

1. For each specimen to be extracted, place one (1) RNA Unitized Reagent Strip on the BD MAX™ System Rack(s).
2. Snap RNA Extraction Reagent E2-R tube (R2) into Position 1 of the RNA Unitized Reagent Strip, as shown in Figure 1.
3. Snap DNase Reagent tube (D1) into Position 2 of the RNA Unitized Reagent Strip, as shown in Figure 1.
4. Select the 'Work List' tab in the 'Run' screen on the BD MAX™ System monitor.
5. Enter the specimen/patient identification number into the BD MAX™ System, using either the barcode scanner or manual entry. Start with Position 1 of Rack A (Rack A is positioned on the left side of the BD MAX™ System and Rack B is on the right, Figure 2).
6. Enter the barcode from each BD MAX™ Sample Preparation Reagent tube using the barcode scanner or manual entry. Start with Position 1 of Rack A and ensure that each patient/specimen ID and each BD MAX™ Sample Preparation Reagent tube is

accurately matched.

7. Place the BD MAX™ Sample Preparation tube (containing the specimen) on the BD MAX™ System Rack according to the Work List location ensuring that no positions are skipped.
8. Repeat Steps (1-7) for all specimens.
9. If the BD MAX™ System is also being used for reverse transcription and nucleic acid amplification, include additional reagents and disposables, as required. Refer to the BD MAX™ System User's Manual for detailed instructions.
10. Load Rack(s) into the BD MAX™ System (Figure 2). Ensure that the placement of the Rack(s) corresponds to the 'Work List' definition.
11. Close the BD MAX™ System door to start processing of the test run.

Figure 1. RNA Unitized Reagent Strip

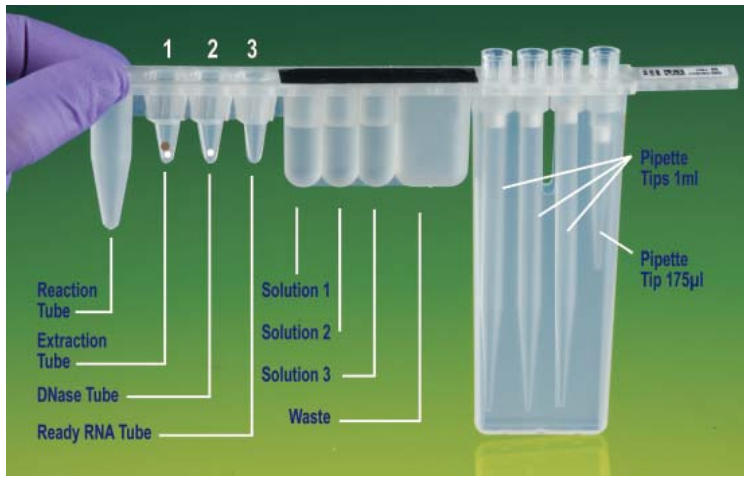
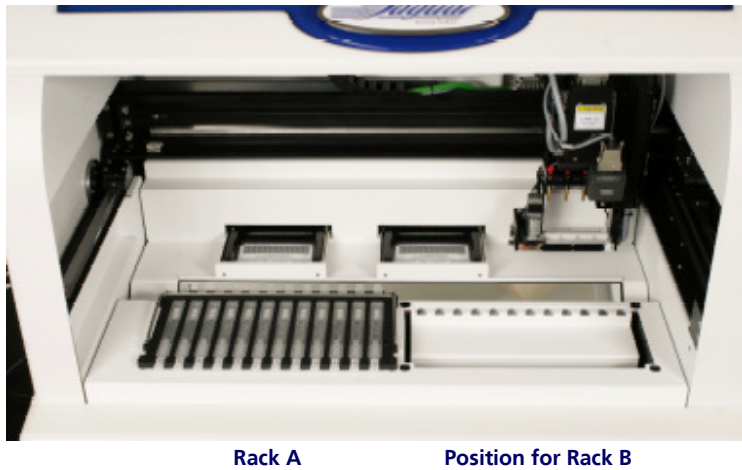


Figure 2. BD MAX™ System



Rack A

Position for Rack B

LIMITATIONS OF THE PROCEDURE

1. BD MAX™ RNA Extraction Kit can only be used on the BD MAX™ System by trained personnel.
2. Use of BD MAX™ RNA Extraction Kit, for clinical specimen types other than those specified, has not been evaluated and performance characteristics are not established.
3. The user must validate the selected application of this product according to country, federal, provincial, state, local and/or accrediting organization guidelines, regulations and standards.

REFERENCES

- 1 Centers for Disease Control and Prevention. *Biosafety in Microbiological and Biomedical Laboratories*. Richmond JY and McKinney RW (eds) (1993). HHS Publication number (CDC) 93-8395.
- 2 Clinical and Laboratory Standards Institute. *Protection of laboratory workers from occupationally acquired infections; Approved Guideline – Document M29* (Refer to the latest edition).



Technical Information: In the Unites States, telephone Technical Services, toll-free (800) 638-8663.

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Symbol	Meaning	Symbol	Meaning
	Manufacturer		Consult instructions for use
REF	Catalog number		Batch code
	In Vitro Diagnostic Use		Temperature limitation
	Use by		Reseal pouch after use
	Contains sufficient for "n" tests		