

DNA Extraction Kits

REF 437501 DNA-1 (Urine/Plasma)

REF 437502 DNA-2 (CSF/Swab)

REF 437503 DNA-3 (Swabs in Transport Medium/UTM)

For use with the BD MAX™ System



INTENDED USE

BD MAX™ DNA Extraction Kits are used with the BD MAX™ System to extract DNA from Gram-negative bacteria and viruses, which may be present in clinical specimens. Purified DNA obtained with the BD MAX™ DNA Extraction Kits may be analyzed using the BD MAX™ System or another commercially available system for nucleic acid amplification and detection. BD MAX™ DNA Extraction Kits have not been validated for use with any specific analytical test method.

PRINCIPLES OF THE PROCEDURE

The specimen is mixed with BD MAX™ Sample Preparation Reagent and processed using the BD MAX™ System. The BD MAX™ System automates DNA 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 cell lysis, DNA extraction and removal of inhibitors. Following cell lysis, by a combination of heat and lytic enzymes, the released nucleic acid is captured by magnetic affinity beads. The beads, with the bound nucleic acids, are washed and the nucleic acid is eluted using ~10 µL of release solution. DNA is neutralized for a final volume of ~20 µL.

REAGENTS

REF	Product Name	Pkg Quantity
437501	DNA Extraction Reagent E1 DNA Sample Preparation Reagent SP2 DNA Unitized Reagent Strips	▽ 24
437502	DNA Extraction Reagent E2 DNA Sample Preparation Reagent SP1 DNA Unitized Reagent Strips	▽ 24
437503	DNA Extraction Reagent E2 DNA Sample Preparation Reagent SP3 DNA Unitized Reagent Strips	▽ 24

EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

- BD MAX™ System
2 channel BD MAX™ System: REF 441769, 441856, 441838 or 441857
Note: DNA-2 (CSF/Swab) has not been validated on the 2 channel BD MAX™ System
6 channel BD MAX™ System: REF 441916 or 441917
- Syringe Filter Assembly REF 437017
- Micropipettors (accurate between 100-1000 µL)
- Aerosol resistant micropipette tips
- Disposable gloves/lab coat
- Specimen Collection Container(s)
- Swabs with Universal Transport Medium (UTM) or viral transport media such as M4

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 may affect product performance.
- Samples which deviate from expected quality (physical or otherwise) may not be suitable for testing.
- Avoid microbial and deoxyribonuclease (DNase) contamination of reagents at all times. The use of sterile 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.

BD MAX™ DNA Extraction Kits are stable at 2-25°C through their stated expiration date. Do not use kits or kit components that have passed their expiration date.

INSTRUCTIONS FOR USE

Specimen Collection

- Collect specimen and label appropriately.
Note: Plasma specimens must be obtained from sodium citrate anticoagulated blood. Other anticoagulants have not been evaluated.
- Proceed to Test Preparation.

Test Preparation

- Urine/Plasma:** Pipette 750 µL of specimen into a Sample Preparation Reagent SP2 tube.
For urine: If the original specimen is observed to be turbid, viscous or contains particulate material, filtration of the diluted specimen (specimen added to SP2 tube) may be necessary. Proceed to Sample Filtration Procedure if filtering is required. If filtering is not required, proceed to BD MAX™ Operation.
- CSF:** Pipette 200 µL of specimen into a Sample Preparation Reagent SP1 tube.
Swab: Insert swab into a Sample Preparation Reagent SP1 tube and swirl at least three times. Lift the swab out of the liquid and press against the side of the SP1 tube to expel residual specimen. Completely remove the swab from the tube and discard appropriately.
Proceed to BD MAX™ Operation.
- Swabs in Transport Medium/UTM:** Pipette 750 µL of specimen into a Sample Preparation Reagent SP3 tube. If the original specimen is observed to be turbid, viscous or contains particulate material, filtration of the diluted specimen (specimen added to SP3 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 (for urine or swabs in transport medium)

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

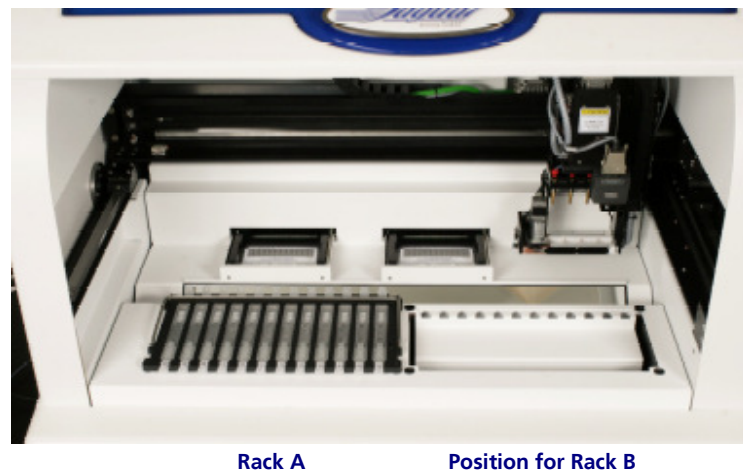
(Refer to BD MAX™ System User's Manual for programming and setup instructions)

1. For each specimen to be extracted, place one (1) DNA Unitized Reagent Strip on the BD MAX™ System Rack(s).
2. Snap Extraction Reagent tube (E1 or E2) into Position 1 of the DNA Unitized Reagent Strip, as shown in Figure 1.
3. Select the 'Work List' tab in the 'Run' screen on the BD MAX™ System monitor.
4. 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).
5. Enter the Sample Preparation Reagent tube barcode corresponding to each patient/specimen using the barcode scanner or manual entry. Start with Position 1 of Rack A and ensure that the patient/specimen and the Sample Preparation Reagent tube are accurately matched.
6. Place the Sample Preparation tube (containing the specimen) on the BD MAX™ System Rack. Start with Position 1 of Rack A.
7. Repeat Steps (1-6) for all specimens. Always move from Position 1 through Position 12 on each Rack, ensuring that no positions are skipped.
8. If the BD MAX™ System is also being used for nucleic acid amplification, include additional reagents and disposables, as required. Refer to the BD MAX™ System User's Manual for detailed instructions.
9. Load Rack(s) into the BD MAX™ System (Figure 2). Ensure that the placement of the Rack(s) corresponds to the 'Work List' definition.
10. Close the BD MAX™ System door to start processing of the test run.

Figure 1. DNA Unitized Reagent Strip



Figure 2. BD MAX™ System



LIMITATIONS OF THE PROCEDURE

1. The BD MAX™ DNA Extraction Kits can only be used on the BD MAX™ System by trained personnel.
2. The BD MAX™ DNA-2 (CSF/Swab) Extraction Kit has not been validated on the 2 channel BD MAX™ System.
3. Use of BD MAX™ DNA Extraction Kits, for clinical specimen types other than those specified, has not been evaluated and performance characteristics are not established.
4. Plasma obtained from blood anticoagulated by methods other than sodium citrate has not been evaluated and performance characteristics are not established.
5. 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.




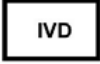




REFERENCES

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 United 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
	<i>In Vitro</i> Diagnostic Use		Temperature limitation
	Use by		Reseal pouch after use
	Contains sufficient for "n" tests		