

AIA-PACK

Substrate Set II

Intended Use

The AIA-PACK Substrate Set II is intended for IN VITRO DIAGNOSTIC USE ONLY. The AIA- PACK Substrate Set II can be used with any AIA-PACK or ST AIA-PACK Assay on the Tosoh AIA System Analyzers.

Summary and Explanation

The AIA-PACK Substrate Set II contains a fluorogenic substrate, 4-methyl-umbelliferyl phosphate (4MUP).

Material Provided (Cat. No. 0020968)

2 vials Substrate Reagent

4-methylumbelliferyl phosphate, stabilizers and 0.01% sodium azide as a preservative (lyophilized).

2 x 100 mL Substrate Reconstituent

Buffer containing 0.01% sodium azide as a preservative.

Warnings and Precautions

- The AIA-PACK Substrate Set II is intended for in vitro diagnostic use only.
- These materials contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such materials, always flush with large volumes of water to prevent azide build up.
- Do not use beyond the expiration date.

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Preparation and Storage

- Bring all reagents to room temperature (18° - 25° C) before preparing the working reagent.
- Add one vial of Substrate Reconstituent to the lyophilized Substrate Reagent, mix thoroughly to dissolve all solid material. Each vial of Substrate Reagent, when reconstituted, provides sufficient reagent for approximately 400 tests.
- Place the Substrate Reagent bottle directly on the analyzer.
- Always store the AIA-PACK Substrate Set II refrigerated at 2° - 8° C.

Stability

- When stored unopened and refrigerated at 2° - 8° C, the Substrate Reagent and Substrate Reconstituent are stable until the expiration date on the Substrate Set II box label.
- Reconstituted Substrate Reagent is stable for 3 days at room temperature (18° - 25° C) or 30 days when stored in the refrigerator (2° - 8° C).

Procedural Notes

1. Substrate Reagent must be completely dissolved and equilibrated to room temperature prior to use.
2. Do not add freshly reconstituted substrate to working substrate.

References

1. AIA Analyte Application Manual (AAM). Tosoh Bioscience, Inc., Grove City, OH.
2. AIA System Operator's Manual. Tosoh Bioscience, Inc., Grove City, OH.

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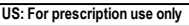
Substrate Set II



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 European Conformity	 <i>In vitro</i> diagnostic medical device	 Consult instructions for use	 Temperature limitation
 Batch code / Lot number	 Manufacturer	 Authorized representative in the European Community	 Use by date
 Catalogue number / Part number	 Supplied by	 Sufficient for	 US: For prescription use only