1009972001-089C
Rev. 08/09

Attention

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AIA-PACK
DETECTOR STANDARDIZATION
TEST CUP

INTENDED USE
The AIA-PACK DETECTOR STANDARDIZATION TEST CUP is intended for IN VITRO DIAGNOSTIC USE ONLY.
The AIA-PACK DETECTOR STANDARDIZATION TEST CUP is used to measure the substrate background on the TOSOH AIA System Analyzers except AIA-1200 series and AIA-600.

DESCRIPTION
Catalog # 0020970
10 trays x 20 DETECTOR STANDARDIZATION TEST CUPs

WARNINGS AND PRECAUTIONS
The AIA-PACK DETECTOR STANDARDIZATION TEST CUP is for in vitro diagnostic use.

PREPARATION AND STORAGE
The AIA-PACK DETECTOR STANDARDIZATION TEST CUP is provided ready for use. Store at 1-30°C.

STABILITY
The AIA-PACK DETECTOR STANDARDIZATION TEST CUP is stable until the expiration date on the label.

PROCEDURAL NOTE
For additional procedural instructions regarding substrate background measurement, refer to the TOSOH AIA System Operator's Manual.

1. Load one DETECTOR STANDARDIZATION TEST CUP in the appropriate position on the instrument.
2. Place the bottle of the reconstituted AIA-PACK SUBSTRATE REAGENT II in the appropriate position on the instrument.
3. Select OK button in the Material Setting Dialogue of the Daily Maintenance to start the automatic measurement of substrate background.

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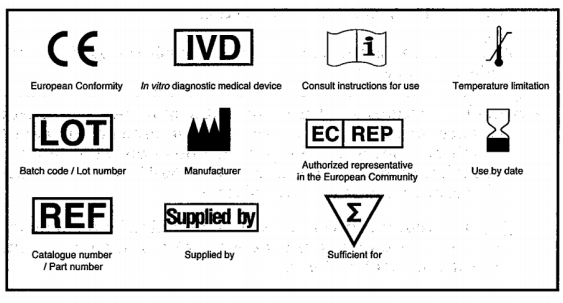

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AIA-PACK
SAMPLE TREATMENT CUP

INTENDED USE
The AIA-PACK SAMPLE TREATMENT CUP is intended for IN VITRO DIAGNOSTIC USE ONLY. The AIA-PACK SAMPLE TREATMENT CUP can be used for automatic sample dilution and automatic sample pretreatment with any AIA-PACK assay on the TOSOH AIA System Analyzers except AIA-1200 series, AIA-600 and AIA-360.

DESCRIPTION
Catalog # 0020971
10 trays x 20 SAMPLE TREATMENT CUPs

WARNINGS AND PRECAUTIONS
The AIA-PACK SAMPLE TREATMENT CUP is for in vitro diagnostic use.

PREPARATION AND STORAGE
The AIA-PACK SAMPLE TREATMENT CUP is provided ready for use. Store at 1-30°C.

STABILITY
The AIA-PACK SAMPLE TREATMENT CUP is stable until the expiration date on the label.

DILUTION PROCEDURE
For additional procedural instructions regarding automatic sample dilution, refer to the TOSOH AIA System Operator's Manual.

1. Add a sufficient quantity of SAMPLE TREATMENT CUPs to the appropriate position on the instrument.
2. Place the appropriate AIA-PACK SAMPLE DILUTING SOLUTION in a reagent cassette and place the cassette on the instrument.
3. Place the sample to be diluted in the sample rack and place the rack on the instrument. (Barcoded samples may be placed in any position. Non-barcoded samples should be loaded according to the Worksheet.)
4. Start the assay.

PRETREATMENT PROCEDURE
For additional procedural instructions regarding automatic sample pretreatment, refer to the TOSOH AIA System Operator's Manual.

1. Add a sufficient quantity of SAMPLE TREATMENT CUPs to the appropriate position on the instrument.
2. Place the appropriate AIA-PACK pretreatment reagents in a reagent cassette and place the cassette on the instrument.
3. Place the sample to be pretreated in the sample rack and place the rack on the instrument. (Barcoded samples may be placed in any position. Non-barcoded samples should be loaded according to the Worksheet.)
4. Start the assay.

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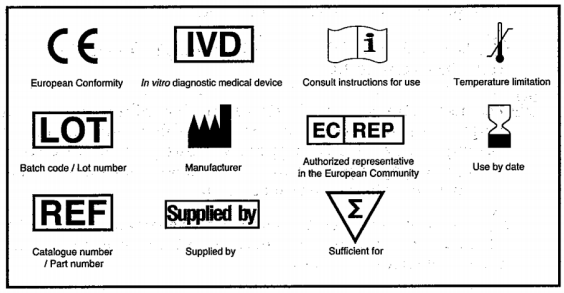

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Rev. 08/15

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AIA-PACK
WASH CONCENTRATE

The AIA-PACK WASH CONCENTRATE is intended for IN VITRO DIAGNOSTIC USE ONLY for the AIA-PACK or the ST AIA-PACK assay.

CONTENTS

Cat. No. 0020955
4 x 100 mL AIA-PACK WASH CONCENTRATE
Buffer solution with detergent and bacteriostatic agent.

WARNINGS AND PRECAUTIONS

1. The AIA-PACK WASH CONCENTRATE is intended for in vitro diagnostic use only.
2. Inspect the packaging and the exterior of the bottles for any sign of damage before use. If any damages are visible, contact your local TOSOH sales representative.
3. Do not use beyond the expiration date.
4. For safe waste disposal, it is recommended that each laboratory complies with established laboratory procedures and local, state, and federal regulations.

PREPARATION OF REAGENTS

Add the entire contents of the AIA-PACK WASH CONCENTRATE (100 mL) to approximately 2.0 L of CAP Class I water or the clinical laboratory reagent water (formerly NCCLS Type I) defined by CLSI C3-A4 guideline, mix well, and adjust the final volume to 2.5 L.

STORAGE AND STABILITY

Always store the AIA-PACK WASH CONCENTRATE in an upright position at 2-8 °C when not in use. When stored unopened and refrigerated at 2-8 °C, the AIA-PACK WASH CONCENTRATE is stable until the expiration date on the label. The diluted wash solution is stable for 30 days at 18-25 °C.

PROCEDURE

Refer to the insert sheet of the AIA-PACK or the ST AIA-PACK and the TOSOH AIA System Operator's Manual for detailed instructions.

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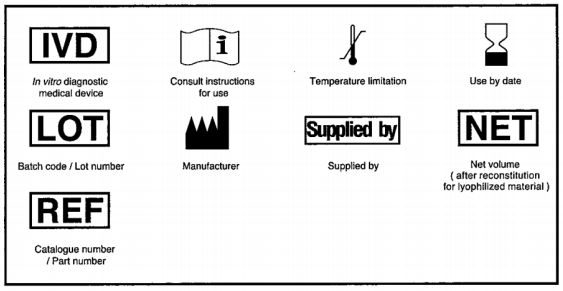

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AIA-PACK DILUENT CONCENTRATE

The AIA-PACK DILUENT CONCENTRATE is intended for IN VITRO DIAGNOSTIC USE ONLY for the AIA-PACK or the ST AIA-PACK assay.

CONTENTS

Cat. No. 0020956
4 x 100 mL AIA-PACK DILUENT CONCENTRATE
Buffer solution with detergent.

WARNINGS AND PRECAUTIONS

1. The AIA-PACK DILUENT CONCENTRATE is intended for in vitro diagnostic use only.
2. Inspect the packaging and the exterior of the bottles for any sign of damage before use. If any damages are visible, contact your local TOSOH sales representative.
3. This material contains sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
4. Do not use beyond the expiration date.
5. For safe waste disposal, it is recommended that each laboratory complies with established laboratory procedures and local, state, and federal regulations.

PREPARATION OF REAGENTS

Add the entire contents of the AIA-PACK DILUENT CONCENTRATE (100 mL) to approximately 4.0 L of CAP Class I water or the clinical laboratory reagent water (formerly NCCLS Type I) defined by CLSI C3-A4 guideline, mix well, and adjust the final volume to 5.0 L.

STORAGE AND STABILITY

Always store the AIA-PACK DILUENT CONCENTRATE in an upright position at 2-8 °C when not in use. When stored unopened and refrigerated at 2-8 °C, the AIA-PACK DILUENT CONCENTRATE is stable until the expiration date on the label. The diluted diluent solution is stable for 30 days at 18-25 °C.

PROCEDURE

Refer to the insert sheet of the AIA-PACK or the ST AIA-PACK and the TOSOH AIA System Operator's Manual for detailed instructions.

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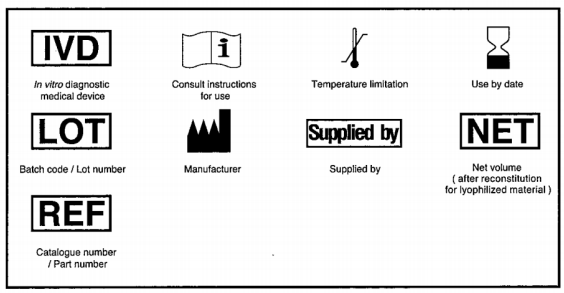

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AIA-PACK SUBSTRATE SET II

The AIA-PACK SUBSTRATE SET II is intended for IN VITRO DIAGNOSTIC USE ONLY for the AIA-PACK or the ST AIA-PACK assay.

CONTENTS

Cat. No.	0020968
2 bottles	AIA-PACK SUBSTRATE REAGENT II 4-methylumbelliferyl phosphate, stabilizers and sodium azide as a preservative. (Lyophilized)
2 x 100 mL	AIA-PACK SUBSTRATE RECONSTITUENT II Buffer containing sodium azide as a preservative. (Liquid)

WARNINGS AND PRECAUTIONS

1. The AIA-PACK SUBSTRATE SET II is intended for in vitro diagnostic use only.
2. Inspect the packaging and the exterior of the bottles for any sign of damage before use. If any damages are visible, contact your local TOSOH sales representative.
3. These materials contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
4. Do not use beyond the expiration date.
5. For safe waste disposal, it is recommended that each laboratory complies with established laboratory procedures and local, state, and federal regulations.

PREPARATION OF REAGENTS

1. Bring all reagents to 18-25 °C before preparing the working substrate solution.
2. Add one bottle of the AIA-PACK SUBSTRATE RECONSTITUENT II to the lyophilized AIA-PACK SUBSTRATE REAGENT II and mix thoroughly to dissolve all solid materials.
3. Each bottle of the AIA-PACK SUBSTRATE REAGENT II, when reconstituted, provides sufficient reagent for approximately 400 tests on the TOSOH AIA System Analyzers.

STORAGE AND STABILITY

Always store the AIA-PACK SUBSTRATE SET II in an upright position at 2-8 °C when not in use. Protect it from light. When stored unopened and refrigerated at 2-8 °C, the AIA-PACK SUBSTRATE SET II is stable until the expiration date on the label. The reconstituted substrate solution is stable for 3 days at 18-25 °C or 30 days at 2-8 °C. Serum, dust, metal, or microorganism contamination may cause degradation of reconstituted substrate solution. Store in a clean environment, away from direct sunlight and ultraviolet light.

PROCEDURE

Refer to the insert sheet of the AIA-PACK or the ST AIA-PACK and the TOSOH AIA System Operator's Manual for detailed instructions.

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CE European Conformity	IVD *In vitro* diagnostic medical device	Consult instructions for use	Temperature limitation
LOT Batch code / Lot number	Manufacturer	EC REP Authorized representative in the European Community	Use by date
REF Catalogue number / Part number	Supplied by Supplied by	NET Net volume (after reconstitution for lyophilized material)	