

AIA-PACK

Diluent Concentrate Set

Intended Use

The AIA-PACK Diluent Concentrate Set is intended for IN VITRO DIAGNOSTIC USE ONLY. The AIA-PACK Diluent Concentrate Set can be used with any AIA-PACK or ST AIA-PACK Assay.

Material Provided (Cat. No. 0020956)

4 x 100 mL Diluent Concentrate

Buffer solution with detergent and 0.5% sodium azide as a preservative.

Warnings and Precautions

- The AIA-PACK Diluent Concentrate Set 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.

Preparation and Storage

- 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, mix well, and adjust the final volume to 5.0 L.
- Always store the AIA-PACK Diluent Concentrate Set refrigerated at 2° - 8° C.

Stability

- When stored unopened and refrigerated at 2° - 8° C, the Diluent Concentrate is stable until the expiration date on the Diluent Concentrate Set box label.
- Once prepared, the diluent solution is stable for 30 days at room temperature (18° - 25° C).

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Procedural Note

Ligand assays performed by the Tosoh AIA System Analyzer require that the laboratory use water designated by the CAP as Class I or by the clinical laboratory as reagent water. Water should be tested at least once per month and should be free of particulate matter including bacteria. The pH of the water should also be routinely tested. For further information, consult the CLSI document GP40-A4-AMD, Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline - Fourth Edition.

References

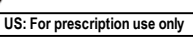
1. AIA Analyte Application Manual (AAM). Tosoh Bioscience, Inc., Grove City, OH.
2. AIA System Operator's Manual. Tosoh Bioscience, Inc., Grove City, OH.



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 European Conformity	 In vitro 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