

# **AIA-PACK**

## **Wash Concentrate Set**

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### **Intended Use**

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

### **Material Provided (Cat. No. 0020955)**

4 x 100 mL      Wash Concentrate

Buffer solution with detergent and bacteriostatic agent.

### **Warnings and Precautions**

- The AIA-PACK Wash Concentrate set is intended for in vitro diagnostic use only.
- Do not use beyond the expiration date.

### **Preparation and Storage**

- Add the entire contents of the AIA-PACK Wash Concentrate (100 mL) to approximately 2.0 L of CAP Class I water or clinical laboratory reagent water, mix well, and adjust the final volume to 2.5L
- Always store the AIA-PACK Wash Concentrate Set at 2° - 8° C when not in use.

### **Stability**

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

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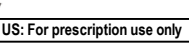
### Procedural Notes

Ligand assays performed by the Tosoh AIA System Analyzer require that the laboratory use water designated by the CAP Class I or by the clinical laboratory 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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| <br>European Conformity               | <br>In vitro diagnostic medical device | <br>Consult instructions for use                           | <br>Temperature limitation        |
| <br>Batch code / Lot number           | <br>Manufacturer                       | <br>Authorized representative<br>in the European Community | <br>Use by date                   |
| <br>Catalogue number<br>/ Part number | <br>Supplied by                        | <br>Sufficient for                                         | <br>US: For prescription use only |