Rev. date: 09/2024

EU rev. HCG2-020924

ST AIA-PACK HCGII SAMPLE DILUTING SOLUTION

The ST AIA-PACK HCGII SAMPLE DILUTING SOLUTION is intended for IN VITRO DIAGNOSTIC USE ONLY to dilute patient samples.

CONTENTS

Cat. No.	0025519
4 x 4 mL	ST AIA-PACK HCGII SAMPLE DILUTING SOLUTION Human serum containing no detectable concentration of human chorionic gonadotropin (hCG) with sodium azide as a preservative.

WARNINGS AND PRECAUTIONS

1. The ST AIA-PACK HCGII SAMPLE DILUTING SOLUTION is intended for in vitro diagnostic use only.
2. Inspect the packaging and the exterior of the vials 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. The sample diluting solution has been tested by FDA-approved method and found negative for the presence of HBsAg and antibody to HIV-1 and HCV. Because no test method can offer complete assurance that the products derived from human origin will not transmit infectious agents, it is recommended that this product be handled with the same precautions as used for patient samples.
5. Do not use beyond the expiry date.
6. For safe waste disposal, it is recommended that each laboratory complies with established laboratory procedures and local, state, and federal regulations.
7. After opening, the vial of the sample diluting solution should be kept tightly sealed with a clean rubber cap. Sealing with dirty material may cause deterioration of the reagent.
8. The remaining sample diluting solution after use should not be mixed with another vial but be discarded to avoid contamination.

PREPARATION OF REAGENTS

The ST AIA-PACK HCGII SAMPLE DILUTING SOLUTION is provided ready for use. The sample diluting solution should be used after equilibrating to 18°-25°C for about 30 minutes.

STORAGE AND STABILITY

- Always store the ST AIA-PACK HCGII SAMPLE DILUTING SOLUTION in an upright position.
- When stored unopened and refrigerated at 2°-8°C, the sample diluting solution will remain stable until the expiry date on the label. After opening, the sample diluting solution can be left on-board of the TOSOH AIA System Analyzers (18°-25°C) for a maximum of 3 days (3 x 24 hours). When stored over night at 2°-8°C, the sample diluting solution can be used for up to 9 days (9 cycles of 8 hours on board and 16 hours in the refrigerator). The sample diluting solution should not be used beyond 90 days after opening, even if it is sealed and stored in the refrigerator.

PROCEDURE

Refer to the TOSOH AIA System Operators' manual for additional procedural instructions regarding sample dilution.

1. Serum or heparinised plasma specimens do not require dilution before analysis. Urine specimens should be diluted by more than 5 fold with the ST AIA-PACK HCGII SAMPLE DILUTING SOLUTION before analysis.
2. If a specimen hCG concentration is found to be greater than 2,000 mIU/mL in serum or heparinised plasma or 10,000 mIU/mL in urine, the specimen should be diluted with the sample diluting solution and assayed according to the PROCEDURE in the insert sheet of the ST AIA-PACK HCGII.
3. The AIA Nex•IA / AIA-21, AIA-600 II, AIA-900, AIA-1800 and AIA-2000 will perform dilutions automatically if the dilution factors are entered into the software before assaying the diluted sample.
4. The recommended dilution for specimens containing greater than 2,000 mIU/mL (serum or heparinised plasma) or 10,000 mIU/mL (urine) is 10 or 100 fold dilution. It is desirable to dilute the specimen so that the diluted specimen reads between 0.5 and 2,000 mIU/mL in serum or heparinised plasma, and 2.5 and 10,000 mIU/mL in urine.

RESULTS

When an auto-dilution is performed, the TOSOH AIA System Analyzers will calculate the final result.

LIMITATIONS

The ST AIA-PACK HCGII SAMPLE DILUTING SOLUTION is designed solely for use with ST AIA-PACK HCGII assay procedures.

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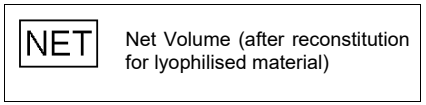
EC REP

UK RP

CH REP


NET
Net Volume (after reconstitution
for lyophilised material)