



For In Vitro Diagnostic Use

INTENDED USE

For use as a leukocyte reagent to differentiate subpopulations of white blood cells on COULTER A[®]T[™] 5diff hematology analyzers. Intended for use only with specific A[®]T[™] 5diff reagents. Refer to your instrument product manuals and/or online help, as applicable.

SUMMARY

COULTER A[®]T[™] 5diff Fix reagent, a deep blue aqueous solution, is used to lyse erythrocytes (red blood cells), fix leukocytes (white blood cells), and differentially stain the granules of lymphocytes, monocytes, neutrophils, and eosinophils.

PRINCIPLES

COULTER A[®]T[™] 5diff Fix reagent is an alcohol solution that includes propylene-glycol, a formic dye, buffers, alkaline salts, wetting agents, and an aldehyde preservative.

When an aliquot of whole blood is mixed with the A[®]T[™] 5diff Fix reagent, the alkaline salts in the reagent serve as a lytic reagent to stromatolyse the erythrocytes either reducing them to very small particles or causing membrane solubilization. As the A[®]T[™] 5diff Fix reagent is destroying the red cell membranes, it preserves the leukocytes at their original size and differentially stains the lymphocytes, monocytes, neutrophils, and eosinophils. The eosinophils stain the most intensely.

The lymphocytes, monocytes, neutrophils, and eosinophils each have a unique nuclear and morphologic structure and staining intensity; therefore, each absorbs light differently. A specialized hydrodynamic focusing process (Dual Focused Flow or DFF) uses A[®]V (Absorbance Cytochemistry and Volume) Technology to develop a DiffPlot from which four of the five leukocyte populations are determined — lymphocytes, monocytes, neutrophils, and eosinophils.

REACTIVE INGREDIENTS

Propane-1, 2 diol.....	<3.00%
Formic Dye.....	<0.004%

WARNINGS

- Product contains >1% Propylene Glycol.
- Do not inhale and/or ingest.
- Avoid eye contact. If product is splashed in eyes, wash eyes gently under running water for 15 minutes or longer.
- Avoid skin contact. In case of skin contact, wash area with soap and water. Rinse well with water.
- DO NOT REUSE CONTAINER.

STORAGE, STABILITY, AND DISPOSAL

- Store and use COULTER A[®]T[™] 5diff Fix at 18-25°C.
- Do not use product past expiration date.
- Opened containers are stable for 3 months when used at 18-25°C. Stability only applies to the reagent when connected to the instrument with an approved reagent pickup tube and cap.
- Dispose of waste product, unused product, and contaminated packaging in compliance with federal, state, and local regulations.
- DISCARD PRODUCT IF FROZEN.

PREPARATION

COULTER A[®]T[™] 5diff Fix reagent is ready to use. Replace the reagent container as directed in your instrument product manuals and/or online help.

IMPORTANT: DO NOT USE this product if it has been partially or completely frozen. Dispose of product in compliance with federal, state, and local regulations.

PRODUCT AVAILABILITY

COULTER A[®]T[™] 5diff Fix - 1 x 1 L
REF 8547171

TRADEMARKS

A[®]T[™], Beckman Coulter Logo, and COULTER are trademarks of Beckman Coulter, Inc.

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For additional information or if damaged product is received, call Beckman Coulter Customer Service at 800-526-7694 (USA or Canada) or contact your local Beckman Coulter Representative.

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