

COULTER®
diff A^c•T Pak™ Reagent
Kit

[REF] 8547134

PN 772249-AA



For In Vitro Diagnostic Use

INTENDED USE

For use on COULTER A^c•T diff™ and A^c•T diff 2™ hematology analyzers only. Refer to your instrument product manuals.

REAGENT 1 - COULTER Balanced Electrolyte Solution

For use as an isotonic buffered diluent for counting and sizing blood cells.

REAGENT 2 - COULTER Lytic Reagent

For use as a lytic agent for the quantitative determination of hemoglobin and for leukocyte counting and sizing.

SUMMARY

Blood cell analysis comprises diluting a whole-blood sample with a solution that functions as a diluent. The diluent (Reagent 1) provides the ability to analyze portions of the diluted blood sample for different blood cell types, such as red blood cells and platelets. When combined with the lytic reagent (Reagent 2), the diluent (Reagent 1) is useful in the quantitative determination of hemoglobin, the enumeration of leukocytes (white blood cells), and the derivation of leukocyte subpopulations.

PRINCIPLES

The diluent (Reagent 1) is a chemical composition of organic buffers, anesthetics, and germicides in an osmotically balanced neutral solution that includes the following:

- Sodium chloride allows the diluent to become an electrolyte capable of conducting electrical current in an electronic analyzer and, along with Sodium Sulfate and Procaine Hydrochloric Acid, provides buffer for pH balance and cell component stabilization (that is, becoming an isotonic solution, stabilizing blood cell volume, and reducing turbidity in the measurement of hemoglobin).
- Dimethylolurea, an antiseptic, is for product preservation against microbial growth.

In this capacity, the diluent (Reagent 1) is useful for the determination of red blood cell and platelet measurements. Combined with the lytic reagent (Reagent 2), the diluent is useful in the determination of hemoglobin, the enumeration of leukocytes (white blood cells), and their differentiation into three populations (lymphocytes, mononuclear cells, and granulocytes).

The lytic reagent (Reagent 2) consists of quaternary ammonium salts whose surface active properties destroy the red cell membrane, thus lysing the red blood cells (stromatolysis) and reducing the size of cellular debris to a level that does not interfere with leukocyte counts. The lytic reagent also causes a differential shrinkage of the leukocytes into predictable volume components, thus enabling the histogram differential (that is, lymphocytes, mononuclear cells, and granulocytes). Additionally, the

reaction of the quaternary ammonium salts functions to reduce the amount of protein buildup in the sensing orifices of the instrument. Potassium cyanide is used to form a suitable chromagen for hemoglobin determination.

REACTIVE INGREDIENTS

The COULTER diff A^c•T Pak Reagent Kit contains the following:

REAGENT 1 - COULTER Balanced Electrolyte Solution

Sodium Sulfate	9.72 g/L
Sodium Chloride	4.0 g/L
Dimethylolurea.....	1.0 g/L
Procaine HCL	0.11 g/L

REAGENT 2 - COULTER Lytic Reagent

Quaternary Ammonium Salts	19-26 g/L
Isopropanol.....	1-2%
Potassium Cyanide	0.15-0.5 g/L

WARNINGS

- Product contains <2% Isopropyl Alcohol and <2% Quaternary Ammonium Salts. Irritating to eyes.
- Do not inhale and/or ingest.
- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- Keep package intact for proper performance. This is a single unit package and is to be used as such.
- DO NOT REUSE CONTAINERS.

STORAGE, STABILITY, AND DISPOSAL

- Store COULTER diff A^c•T Pak Reagent Kit at 2-30°C.
- Do not use product past expiration date.
- Use product at temperatures stated in the instrument product manuals. If the operating environment of your laboratory is 16-25°C, discard opened container after 60 days. If the operating environment of your laboratory is 26-35°C, discard opened container after 30 days.
- Dispose of waste product, unused product, and contaminated packaging in compliance with federal, state, and local regulations.

PREPARATION

Reagents in the COULTER diff A^c•T Pak Reagent Kit are ready to use. For instructions regarding reagent replacement or use of the enclosed management card, refer to your instrument product manuals.

To avoid cross contamination when replacing the COULTER diff A^c•T Pak Reagent Kit, transfer pickup tubes one at a time beginning with Reagent 1 (diluent) and then Reagent 2 (lytic reagent).

IMPORTANT: If product has been partially or completely frozen, allow product to warm to room temperature. Mix product by gentle inversion prior to placement on the instrument. Install and prime the reagent kit as directed in your instrument product manuals. Verify background counts are acceptable before analyzing patient samples.

PRODUCT AVAILABILITY

COULTER diff A^c•T Pak Reagent Kit

[REF] 8547134

(Contains 1 x 15 L Reagent 1 and 1 x 300 mL Reagent 2)

TRADEMARKS

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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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