

COULTER® diff A^c•T Tainer™ Reagent Kit

REF 8547135

PN 772247-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.

REAGENT 3 - COULTER Shutdown Diluent

For use as a shutdown diluent for hematology analyzer components that come in contact with blood samples, including apertures.

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. The biodegradable shutdown diluent (Reagent 3) aids in the removal of protein buildup in the sensing orifices of the hematology analyzer.

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 (stromatolization) 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.

Blood proteins flowing through blood counting orifices (apertures) in a hematology analyzer over time accumulate around these openings to a point that the size of the orifices are minimized and eventually blocked. The proteolytic enzyme in the shutdown diluent (Reagent 3) reacts with and dissolves the protein in and around the apertures.¹

REACTIVE INGREDIENTS

The COULTER diff A^c•T Tainer 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

REAGENT 3 - COULTER Shutdown Diluent

A solution of a proteolytic enzyme

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 Tainer Reagent Kit at 2-25°C.
- Do not use product past expiration date.
- Use product at temperatures stated in the instrument product manuals.
- Opened containers are stable for 30 days when used at 16-25°C.
- 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 Tainer 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 Tainer Reagent Kit, transfer pickup tubes one at a time beginning with Reagent 1 (diluent), then Reagent 2 (lytic reagent), and finally Reagent 3 (shutdown diluent).

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.

REFERENCES

1. Lin Y, Means GE, and Feeney RE. 1969. Action of proteolytic enzymes on N,N-dimethyl proteins. Basis for a microassay for proteolytic enzymes. *J Biol Chem*, 244(3):789-793.

PRODUCT AVAILABILITY

COULTER diff A^c•T Tainer Reagent Kit

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(Contains 1 x 4 L Reagent 1; 1 x 190 mL Reagent 2; and 1 x 250 mL Reagent 3)

TRADEMARKS

A^c•T diff, A^c•T diff 2, A^c•T Tainer, 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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