For In Vitro Diagnostic Use

INTENDED USE
For use as an isotonic buffered diluent in conjunction with a lytic reagent for counting and sizing blood cells on COULTER HmX hematology analyzers. Use with only COULTER LYSE S III diff lytic reagent. Refer to your instrument product manuals and/or online help, as applicable.

SUMMARY
Blood cell analysis comprises diluting a whole-blood sample with a solution that functions as a diluent. The diluent 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 a lytic reagent, the diluent is useful in the determination of hemoglobin, the enumeration of leukocytes (white blood cells), and the derivation of leukocyte subpopulations.

PRINCIPLES
COULTER ISOTON III Diluent 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 is useful for the determination of red blood cell and platelet measurements. When combined with COULTER LYSE S III diff lytic reagent, the diluent is useful in the determination of hemoglobin and the enumeration of leukocytes (white blood cells). In conjunction with differential PAK reagents on instruments using impedance, radio frequency, and laser light scatter (VCS technology), it is useful in the differentiation of leukocytes into five subpopulations — neutrophils, lymphocytes, monocytes, eosinophils, and basophils.

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

WARNINGS
- Do not inhale and/or ingest.
- Avoid eye and skin contact. In case of eye or skin contact, flush affected area with copious amounts of water for at least 15 minutes.
- DO NOT REUSE CONTAINERS.

STORAGE, STABILITY, AND DISPOSAL
- Store COULTER ISOTON III Diluent at 2-30°C.
- Do not use product past expiration date.
- Use product at temperatures stated in the instrument product manuals and/or online help.
- Dispose of waste product, unused product, and contaminated packaging in compliance with federal, state, and local regulations.

PREPARATION
COULTER ISOTON III Diluent is ready to use. Replace the reagent container as directed in your instrument product manuals and/or online help.

IMPORTANT: If product has been partially or completely frozen, allow product to warm to room temperature. Invert the container 16 times to ensure complete mixing prior to placement on the instrument. Install and prime the diluent as directed in your instrument product manuals and/or online help. Verify background counts are acceptable before analyzing patient samples.

PRODUCT AVAILABILITY
COULTER ISOTON III Diluent - 1 x 20 L

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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