

EX-CAL™ CE IVD

Multiparameter Assayed Hematology Calibrator
For in vitro diagnostic use only.

REF CA-30EX /EXA-339+

Intended Use: This product is for use in the calibration of WBC, RBC, Hgb, MCV, Plt and MPV for Drew hematology analyzers.

Summary and Principle: The routine use of Calibration is recommended. Calibrate according to the instructions in the operators manual. EX-CAL™ is a stable preparation of red blood cells, white blood cells and platelets. Assigned values are derived from replicate analyses on whole blood calibrated hematology analyzers. Users compute calibration factors by comparing recovered values and assigned values. These factors provide the basis for making adjustments to the instruments.

Contents: EX-CAL™ is prepared from human red blood cells, mammalian white blood cells and platelet components in a preservative medium.

Storage: Store up-right at 2°C to 8°C (35°F to 46°F) when not in use. DO NOT FREEZE. Unopened vials are stable until the expiration date shown on the label. Opened vials are stable for 7 days provided they are handled properly. To maintain product integrity, avoid unnecessary cycles of warming and cooling, prolonged exposure to room temperature or vigorous mixing. Darkly colored supernatant fluid due to gross hemolysis may indicate product deterioration or damage. If hemolysis is apparent, contact DREW Technical Service for assistance.

Procedure: CAUTION: Instructions must be followed precisely to ensure accurate calibration. Users must have a thorough understanding of calibration as described in the operators manual. If problems are encountered during this procedure, do not calibrate your instrument.

1. Perform start-up and cleaning procedures according to the operator manual.
 - a. After cleaning, run a background count and check results against the acceptable values for your instrument.
2. Verify that the reagent supply is sufficient to complete calibration.
3. Mix a vial of EX-CAL™ as follows:
 - a. Remove vial from refrigerator and allow to stand at room temperature for 20 minutes before mixing.
 - b. Mix by rolling the vial between palms of hand and occasionally inverting the vial. Continue to mix the vial in this manner until the cells are completely suspended. DO NOT USE A MECHANICAL BLOOD MIXER.
 - c. Improper mixing invalidates the sample withdrawn and the portion remaining in the vial.
4. Analyze EX-CAL™ as recommended in the Instrument's Operators Manual.
 - a. After sampling, carefully wipe the threads of the vial rim and cap with lint-free wipe. Replace the cap immediately. Tighten cap until rubber stopper makes contact and turn the cap another 1/8 of a turn. Over tightening will cause the stopper to leak causing blood to dry inside the cap and possibly affecting results of the individual vial.
 - b. Gently invert the vial 2 or 3 times between analyses.
5. For auto-calibration or manual calibration, refer to procedure in operator's manual. Calibration may not be required for all parameters.
6. After calibration is completed, verify by processing the DREW Controls to ensure accuracy over a complete range. Values obtained should fall within the expected range.
7. For further assistance, contact your Distributor or DREW Technical Service.
8. Return vial to refrigeration within 45 minutes after removal from the refrigerator for maximum open-vial stability.

Limitations: A manual differential analysis of white blood cells cannot be accomplished with EX-CAL™. The white blood cell components are of mammalian origin. These components are representative of the size of human cells but are not morphologically suitable for microscopic analysis.

Safety Information :

WARNING: Potentially Biohazardous Material.

1. All human source material used to manufacture this product was non-reactive for Hepatitis B (HbsAg) and negative by tests for antibodies to HIV (HIV-1/HIV-2) and Hepatitis C (HCV) using techniques specified by the FDA. Because no known test method can assure complete absence of human pathogens, this product should be handled with appropriate precautions.
2. EX-CAL™ should not be injected, consumed or pipetted by mouth.
3. This product should be disposed of with infectious medical waste in accordance with local and state regulatory requirements.
4. This product is intended for use as supplied. Adulteration by dilution or addition of any materials invalidates the diagnostic use.

LOT EX0718-CAL
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Table of Assigned Values

Instrument	WBC K/uL	RBC M/uL	HGB g/dL	MCV fL	PLT K/uL	MPV fL
EXCELL 16/18/10Vet	9.0	4.56	13.9	88.5	245	8.8
EXCELL 22 / 2280	8.8	4.62	13.9	89.5	250	8.5
DREW-3	9.0	4.55	13.9	88.0	250	8.6
EVOLUTION	9.1	4.58	13.8	89.5	253	8.8
LIMITS +/-	0.2	0.08	0.2	1.0	10	0.5

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