

EX-TROL™ PLUS

Hematology Control

CE IVD

REF EXA-3+ (L,N,H)/ EXA-339+/ EXA-3327+

LOT XP0518



2018-07-05

Quality Control Months: May, June

DREW	LOT XP0518-Low				LOT XP0518-Normal				LOT XP0518-High			
	Mean	Limits	Range		Mean	Limits	Range		Mean	Limits	Range	
EXCELL 22 / 2280												
WBC K/uL	3.3	± 0.5	2.8	3.8	7.5	± 0.8	6.7	8.3	21.4	± 2.2	19.2	23.6
Neut K/uL	1.5	± 0.3	1.2	1.8	4.9	± 0.6	4.3	5.5	15.7	± 1.8	13.9	17.5
Neut %	44.0	± 7.0	37.0	51.0	65.5	± 8.0	57.5	73.5	73.5	± 8.0	65.5	81.5
Lymp K/uL	1.4	± 0.2	1.2	1.6	1.8	± 0.6	1.2	2.4	3.3	± 1.3	2.0	4.6
Lymp %	42.5	± 6.0	36.5	48.5	24.5	± 7.0	17.5	31.5	15.5	± 6.0	9.5	21.5
Mono K/uL	0.3	± 0.3	0.0	0.6	0.4	± 0.4	0.0	0.8	0.7	± 0.7	0.0	1.4
Mono %	8.5	± 6.0	2.5	14.5	5.5	± 5.0	0.5	10.5	3.5	± 3.5	0.0	7.0
Eos K/uL	0.1	± 0.1	0.0	0.2	0.3	± 0.3	0.0	0.6	1.4	± 1.4	0.0	2.8
Eos %	3.5	± 3.5	0.0	7.0	3.5	± 3.5	0.0	7.0	6.5	± 6.5	0.0	13.0
Baso K/uL	0.1	± 0.1	0.0	0.2	0.1	± 0.1	0.0	0.2	0.2	± 0.2	0.0	0.4
Baso %	1.5	± 1.5	0.0	3.0	1.0	± 1.0	0.0	2.0	1.0	± 1.0	0.0	2.0
RBC M/uL	2.10	± 0.15	1.95	2.25	4.59	± 0.20	4.39	4.79	5.10	± 0.24	4.86	5.34
HGB g/dL	5.7	± 0.4	5.3	6.1	13.4	± 0.6	12.8	14.0	16.4	± 0.8	15.6	17.2
HCT %	17.9	± 2.0	15.9	19.9	42.7	± 2.4	40.3	45.1	50.0	± 2.8	47.2	52.8
MCV fL	85.0	± 5.0	80.0	90.0	93.0	± 5.0	88.0	98.0	98.0	± 5.0	93.0	103.0
MCH pg	27.1	± 2.4	24.7	29.5	29.2	± 2.8	26.4	32.0	32.2	± 2.8	29.4	35.0
MCHC g/dL	31.9	± 3.0	28.9	34.9	31.4	± 3.0	28.4	34.4	32.8	± 3.0	29.8	35.8
RDW %	14.8	± 4.0	10.8	18.8	14.0	± 4.0	10.0	18.0	13.0	± 4.0	9.0	17.0
PLT K/uL	80	± 20	60	100	235	± 30	205	265	485	± 60	425	545
MPV fL	9.0	± 2.0	7.0	11.0	9.1	± 2.0	7.1	11.1	8.5	± 2.0	6.5	10.5

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For in vitro diagnostics use only.

Intended Use

This product is for use in monitoring parameters for the specific instrument models identified on the assay value tables.

Summary and Principle

The routine use of Control materials is recommended for the long term monitoring of the accuracy, precision and linearity of the Hematology Analyzers.

Contents

EX-TROL™ PLUS is a reagent composed of stabilized human erythrocytes, simulated and mammalian leukocytes, and simulated platelets suspended in a plasma-like fluid.

Storage

Store up-right at 2°C to 10°C (35°F to 46°F) when not in use. DO NOT FREEZE. The expiration date is given on the reverse of this sheet. After opening, vials are stable for at least 16 days with proper handling. Avoid cycles of warming and cooling. Avoid prolonged exposure to room temperature. EX-TROL™ PLUS is similar in appearance to fresh whole blood. Discoloration of the supernatant fluid or visible hemolysis may indicate deterioration. Inability to recover expected ranges may also indicate deterioration. Incomplete mixing, instrument malfunction or differences in calibration may also cause unacceptable results. DO NOT USE the product if deterioration is suspected. Contact your Distributor or Drew Scientific Technical Services.

Procedure

Remove only the necessary number of vials for use. Check that the Lot Number on the vial matches the Assay Sheet. Values for instruments not listed must be established by the user. Allow vials to stand at room temperature for 20 minutes before mixing.

1. Mix by rolling between palms of hand and occasionally inverting the vial. DO NOT SHAKE OR MIX MECHANICALLY.
2. Mix the contents of the vial until the cells are completely suspended. Tubes stored for a long time may require extra mixing. Improper mixing invalidates the sample withdrawn and the portion remaining in the vial.
3. Select the correct Quality Control file on your instrument.
4. Gently invert the vial 8 to 10 times immediately prior to use.
5. Sample the vial using the same technique as with a patient sample.
6. After sampling, carefully wipe 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. Overtightening will cause the stopper to leak causing blood to dry inside the cap and possibly affecting results of the individual vial.
7. Return vial to the refrigerator as soon as possible but within 45 minutes after removal from the refrigerator.
8. Verify results are satisfactory according to individual laboratory performance standards before using the analyzer to report patient results.

Performance Characteristics

Assigned values are presented as a Mean and Range. The Mean is calculated from replicate testing on instruments operated and maintained according to the manufacturer's instructions. Instruments are whole blood calibrated to values obtained by reference methods. The Range is an estimate of variation between laboratories and takes into account differences of the methodology, techniques and expected biological variability of the control material.

Whether you use Drew Scientific EX-TROL™ PLUS assigned values or assign your own laboratories mean, the instrument is considered well maintained and operating correctly if:

- At least 95 percent of results are within the expected ranges of the published Drew Scientific Assigned Values or the assigned values calculated by the laboratory.
- Recovered values do not Trend outside the expected range

Assay values on new lots of controls should be established and confirmed before the new lot is put into routine use. Test the new lot when the instrument is in good working order and quality control results on the old lot of control are acceptable to current assay. Before the current lot expires:

- Confirm that recovered results are within the published Assay Results Table
OR
- Establish your own individual laboratory mean.

Limitations

The components used to simulate white blood cells are not suitable for microscopic differential analysis.

Safety Information

All of the blood donor lots used to prepare this material were tested by FDA approved methods and found to be non-reactive for hepatitis B surface antigen (HbsAG), hepatitis C (HCV), HIV-1 and HIV-2. No test methods can offer complete assurance that these materials are free from infective agents. Handle, use and dispose of these control materials as if they were human specimens and potentially infective. EX-TROL™ PLUS should not be injected, consumed or pipetted by mouth. Adulteration by dilution or addition of any materials invalidates the diagnostic use of the product. Dispose of the product with infectious medical waste in accordance with local and state regulatory requirements.



Manufactured for Drew Scientific
14100 NW 57th Court, Miami Lakes, FL 33014, USA, +1 305 418 2320

EC REP Erba Lachema s.r.o., Karásek 1d, 621 00 Brno, Czech Republic, +420 517 077 111

AISD106-004 Rev. 02/17