

EX-TROL™ PLUS



Hematology Control

LOT XP050



2010-07-02

Quality Control Months: May, June

| DREW | XP050-Low | | | | XP050-Normal | | | | XP050-High | | | |
|------------------|-----------|--------|-------|------|--------------|--------|-------|------|------------|--------|-------|-------|
| | Mean | Limits | Range | | Mean | Limits | Range | | Mean | Limits | Range | |
| EXCELL 22 / 2280 | | | | | | | | | | | | |
| WBC K/uL | 3.1 | ± 0.5 | 2.6 | 3.6 | 8.1 | ± 0.8 | 7.3 | 8.9 | 22.3 | ± 2.2 | 20.1 | 24.5 |
| Neut K/uL | 1.7 | ± 0.3 | 1.4 | 2.0 | 5.4 | ± 0.8 | 4.6 | 6.2 | 16.8 | ± 1.8 | 15.0 | 18.6 |
| Neut % | 54.0 | ± 9.0 | 45.0 | 63.0 | 67.2 | ± 9.0 | 58.2 | 76.2 | 75.5 | ± 8.0 | 67.5 | 83.5 |
| Lymp K/uL | 1.1 | ± 0.3 | 0.8 | 1.4 | 1.9 | ± 0.7 | 1.2 | 2.6 | 3.6 | ± 1.6 | 2.0 | 5.2 |
| Lymp % | 35.5 | ± 8.0 | 27.5 | 43.5 | 24.0 | ± 8.0 | 16.0 | 32.0 | 16.0 | ± 7.0 | 9.0 | 23.0 |
| Mono K/uL | 0.1 | ± 0.1 | 0.0 | 0.2 | 0.3 | ± 0.3 | 0.0 | 0.6 | 0.8 | ± 0.8 | 0.0 | 1.6 |
| Mono % | 4.5 | ± 4.5 | 0.0 | 9.0 | 3.8 | ± 3.8 | 0.0 | 7.6 | 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 | 0.8 | ± 0.8 | 0.0 | 1.6 |
| Eos % | 4.5 | ± 4.5 | 0.0 | 9.0 | 3.5 | ± 3.5 | 0.0 | 7.0 | 3.5 | ± 3.5 | 0.0 | 7.0 |
| Baso K/uL | 0.1 | ± 0.1 | 0.0 | 0.2 | 0.1 | ± 0.1 | 0.0 | 0.2 | 0.3 | ± 0.3 | 0.0 | 0.6 |
| Baso % | 1.5 | ± 1.5 | 0.0 | 3.0 | 1.5 | ± 1.5 | 0.0 | 3.0 | 1.5 | ± 1.5 | 0.0 | 3.0 |
| RBC M/uL | 2.18 | ± 0.15 | 2.03 | 2.33 | 4.68 | ± 0.20 | 4.48 | 4.88 | 5.15 | ± 0.24 | 4.91 | 5.39 |
| HGB g/dL | 5.5 | ± 0.4 | 5.1 | 5.9 | 13.5 | ± 0.6 | 12.9 | 14.1 | 16.6 | ± 0.8 | 15.8 | 17.4 |
| HCT % | 17.3 | ± 2.0 | 15.3 | 19.3 | 41.7 | ± 2.4 | 39.3 | 44.1 | 50.0 | ± 2.8 | 47.2 | 52.8 |
| MCV fL | 79.5 | ± 5.0 | 74.5 | 84.5 | 89.0 | ± 5.0 | 84.0 | 94.0 | 97.0 | ± 5.0 | 92.0 | 102.0 |
| MCH pg | 25.2 | ± 2.4 | 22.8 | 27.6 | 28.8 | ± 2.8 | 26.0 | 31.6 | 32.2 | ± 2.8 | 29.4 | 35.0 |
| MCHC g/dL | 31.7 | ± 3.0 | 28.7 | 34.7 | 32.4 | ± 3.0 | 29.4 | 35.4 | 33.2 | ± 3.0 | 30.2 | 36.2 |
| RDW % | 15.0 | ± 4.0 | 11.0 | 19.0 | 14.0 | ± 4.0 | 10.0 | 18.0 | 13.4 | ± 4.0 | 9.4 | 17.4 |
| PLT K/uL | 80 | ± 20 | 60 | 100 | 240 | ± 40 | 200 | 280 | 490 | ± 65 | 425 | 555 |
| MPV fL | 7.8 | ± 2.0 | 5.8 | 9.8 | 7.4 | ± 2.0 | 5.4 | 9.4 | 8.0 | ± 2.0 | 6.0 | 10.0 |

EX-TROL™

Hematology Control



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 performance of Hematology Analyzers.

Contents

EX-TROL™ 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 between 2°C to 8°C (36°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™ 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. Invert the vial 8 to 10 times immediately prior to use.
5. Open vial and observe the vial rim. If there is a bubble present encompassing the rim, it is important to break this bubble. Do so by touching the bubble with a lint free tissue or the edge of the vial cap.
6. Sample the vial using the same technique as with a patient sample.
7. After sampling, carefully wipe the vial rim and cap with lint-free wipe. Re-place 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.
8. Return vial to the refrigerator as soon as possible but within 45 minutes after removal from the refrigerator.
9. 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™ 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™ should not be injected, consumed or pipetted by mouth. Adulteration by dilution or addition of any materials invalidates the diagnostic use of the product. Product should be disposed with infectious medical waste in accordance with local and state regulatory requirements.



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AISD105-007 Rev. 9/09