



CONTROL BLOOD, UNIVERSAL - INSTRUBLOOD CLASSIC

MULTI PARAMETER HAEMATOLOGY CONTROL FOR CELL COUNTERS

- Contains human blood cells and simulated white blood cells.
- In vials with screwcaps and/or closed tubes
- Expiration date: max. 3 months
- The following parameters can be measured:
- WBC, RBC, Hb, Hct, MCV, MCH, MCHC, RDW, PLT, MPV, PDW, PCT.
- Independent quality control program



Products	Product no.	Quantity
INstrublood Classic normal level assayed	2448	10 x 3 ml
INstrublood Classic abnormal level assayed	2449	10 x 3 ml

SUMMARY

ESTABLISHED NAME

INstrublood Classic; normal and abnormal levels.

INTENDED USE

Whole blood quality control material for haematology in the determination of complete blood count.

SUMMARY

The use of whole blood quality control material to monitor determination of blood cell values is an established procedure. Stabilized whole blood quality control materials provide a useful means of ascertaining the accuracy and precision of measurements and is used in the same manner as patient specimens.

PRINCIPLE

INstrublood Classic is a stabilized suspension of human blood cells standardized for use as a haematology control for techniques and equipment in automated and manual Red Blood Cell Count (RBC), White Blood Cell Count (WBC), Haemoglobin (Hb), Hematocrit (Hct) and Mean Corpuscular Volume (MCV) determinations and/or calculation of MCV, Mean Corpuscular Haemoglobin (MCH) and Mean Corpuscular Haemoglobin Concentration (MCHC), Red Cell Distribution Width (RDW), Platelet Count (PLT) and Platelet Distribution Width (PDW).

INstrublood Classic is available in "normal" and "abnormal" levels. A single set of assay values is furnished with each lot for all parameters. These assay values are derived by automated procedures and are valid for most counting instruments.

COMPOSITION

Human Red Blood Cells, Human Platelets, simulated White Blood Cells, simulated plasma, stabilizers and preservatives. Quantitative ranges of the cellular components vary with each lot of normal and abnormal INstrublood Classic. (Refer to the assay sheet supplied with each lot).

PRECAUTIONS

For in vitro diagnostic use only. Source material from which this product was derived, blood from blood banks, was tested for hepatitis B surface antigen (HBsAg), anti hepatitis C virus (HCV) and anti-HIV by FDA required tests. Only donations with negative findings were used for its manufacture. Nevertheless every product obtained from human body fluids should be considered infectious.

Do not use if grossly haemolysed, contaminated or if any one of the parameters suffers a significant change which does not appear to be caused by procedural error, or if the product's appearance does not resemble whole human blood.

STORAGE AND STABILITY

INstrublood Classic should be stored under refrigeration at 2-6 °C protected from extreme temperatures when in use.

Do not freeze.

INstrublood Classic is stable for not less than 15 weeks from date of manufacture. See assay sheet for expiration date. To protect against changes in assay values due to contamination or evaporation, an INstrublood Classic vial should be discarded after two weeks of daily use.

RESULTS

Assay values are derived from properly calibrated automated instruments.



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LIMITATIONS

The analyst responsible for using INstrublood Classic must be acquainted with haematology instrumentation used in the test. Precision and accuracy in semi-automated and manual counting is a function in many cases of the technician's skill and degree of confidence.

PERFORMANCE CHARACTERISTICS

Each lot of INstrublood Classic is tested with instruments and procedures described in the results section. Accuracy in testing is achieved through careful calibration of the instruments using normal whole human blood and the precision is reflected in the reported acceptable range on the assay sheet. Ranges for indices are based on a statistical distribution about the mean value. The ranges listed on the assay sheet represents the mean acceptable range.

The obtained values and indices of INstrublood Classic are affected by reagents (Blood Cell Diluent and Lysing Haemoglobin Reagents) and by the care with which your instruments has been maintained and operated. The instruments can be considered functioning properly if at least 95% of all test results obtained with INstrublood Classic are within the acceptable range given. When three or more consecutive measurements are beyond the acceptable range given, it may mean that the instrument is not operating properly or that the INstrublood Classic is changing in one or more ways. When such a situation arises, the calibration of the instrument should not be changed until the following steps are properly completed:

1. Clean the instrument, check all glassware and fluid lines to be sure they are clean and free of bubbles.
2. Repeat the daily check on the operation and test the electronic performance of your instrument in accordance with the manufacturer's instructions.
3. Check reagents used including INstrublood Classic and fresh EDTA blood with another instrument, if possible and/or manually.

QUALITY CONTROL PROGRAM

Participation in an external quality control program is possible.

This unique Q.C. and proficiency program is designed to give a measure of accuracy and precision in haematology cell counting. It provides an inter-laboratory summary report according to the testing method. This comprehensive analysis is available at no charge with a standing order of INstrublood Classic.

NOTES

1. For in vitro diagnostic use only.
2. For professional use only.
3. Always contact InstruChemie for the complete product insert and latest edition.
4. Printed in the Netherlands, INstrublood Classic-summary-280728-1.FEN