D-CHECK D PLUS
HEMATOLOGY CONTROLS

CONTROL

PRODUCT NAME
D-Check D Plus 2,5L; D-Check D Plus 2,5N; D-Check D Plus 2,5H; D-Check D Plus 3L; D-Check D Plus 3N; D-Check D Plus 3H, D-Check D Plus 4L; D-Check D Plus 4N; D-Check D Plus 4H

Cat. No.: DDC18PT2,5 L; DDC18PT2,5N; DDC18PT2,5H; DDC18PT3L; DDC18PT3N; DDC18PT3H, DDC18PT4L; DDC18PT4N; DDC18PT4H

INTENDED USE
D-Check D Plus is a control designed to monitor accuracy and precision of automated and semi-automated impedance type hematology analyzers. Please refer to the assay table for specific instrument models.

SUMMARY AND PRINCIPLE
It is an established laboratory practice to use a stable control to monitor the performance of diagnostic tests. This control is composed of stable materials that provide a means of monitoring the performance of hematology blood cell counters. It is sampled in the same manner as a patient specimen.

REAGENTS
D-Check D Plus is an in vitro diagnostic reagent composed of Human and mammalian erythrocytes, simulated leukocytes, and simulated platelets suspended in a plasma-like fluid with preservatives.

PRECAUTION
D-Check D Plus is intended for in vitro diagnostic use only by trained personnel.

WARNING:
POTENTIAL BIOHAZARDOUS MATERIAL
For in vitro diagnostic use. Each human donor/unit used in the preparation of this product has been tested against HBsAg, anti-HIV 1-2, anti-HCV, anti-TP by CE-marked screening test <3/2005.(II.10.); 8/2003.(III.13.) Decree of Health Ministry> and have been found ***NON REACTIVE***.
Because no test method can offer complete assurance that infectious agents are absent, this material should be handled as potentially infectious. When handling or disposing of product, follow the EU-OSHA good practice information about prevention and protection in the healthcare sector or other equivalent biosafety procedures.

STABILITY AND STORAGE
Store D-Check D Plus upright at 2 - 8° C (35 - 46° F) when not in use. **Protect tubes from overheating and freezing**. Unopened tubes are stable through the expiration date. Opened vials are stable for 30 days, provided they are handled properly.

INDICATIONS OF DETERIORATION
After mixing, product should be similar in appearance to fresh whole blood. In unmixed tubes, the supernatant may appear cloudy and reddish; this is normal and does not indicate deterioration. Other discoloration, very dark red supernatant or unacceptable results may indicate deterioration. **Do not use the product if deterioration is suspected.**

INSTRUCTIONS FOR USE
1. Remove tubes from the refrigerator and allow them to warm to room temperature (15 to 25°C or 59 to 77°F) for 15 minutes before mixing.
2. To mix, hold a tube horizontally between the palms of the hands. **Do not pre-mix on a mechanical mixer.**
   a) Roll the tube back and forth for 20 - 30 seconds; occasionally in invert the tube. Mix vigorously, but do not shake.
   b) Continue to mix in this manner until the red cells are completely suspended. Tubes stored for a long time may require extra mixing.
   c) Gently invert the tube 8-10 times immediately before sampling.
3. Analyze the sample as instructed in the Quality Control section of the Operators Manual for your instrument.
4. After sampling:
   a) If tube has been open for sampling, clean residual material from the cap and tube rim with a lint-free tissue. Replace the cap tightly.
   b) Return tubes to refrigerator within 30 minutes of use.

EXPECTED RESULTS
Verify that the lot number on the tube matches the lot number on the table of assay values. Assay values are determined on well-maintained, properly calibrated instruments. Reagent differences, maintenance, operating technique, and calibration may contribute to inter-laboratory variation.

PERFORMANCE CHARACTERISTICS
Assigned values are presented as a Mean and Range. The Mean is derived from replicate testing on instruments operated and maintained according to the manufacturer's instructions. The Range is an estimate of variation between laboratories and also takes into account inherent imprecision of the method.
Assay values on a new lot of control should be 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 are acceptable. The laboratory's recovered mean should be within the assay range.
For greater control sensitivity each laboratory should establish its own mean and acceptable range and periodically re-evaluate the mean. The laboratory range may include values outside of the assay range. The user may establish assay values not listed on the Assay Sheet, if the control is suitable for the method.

LIMITATIONS
The performance of this product is assured only if it is properly stored and used as described in this insert. Incomplete mixing of a tube prior to use invalidates both the sample withdrawn and any remaining material in the tube.

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE
For technical assistance or additional information, please call your dealer or local distributor. If there is no, you may call DIAGON Ltd. Technical Service at +36 1-369-6500.

Symbols			
IVD	In Vitro Diagnostic Medical Device		Consult Instructions For Use
	Biological Risk		Temperature Limitation
	Manufacturer		Use By
LOT	Batch Code	CE	CE mark
REF	Catalog Number		

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IVD CE