DIAGON®

D-check 3P

Baross str.52.Budapest
Hungary-1047

HEMATOLOGY CONTROLS
CONTROL

INTENDED USE
D-check 3P is a control designed to monitor values on Abbott Cell-Dyn® 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 3P is an *in vitro* diagnostic reagent composed of human erythrocytes, mammalian leukocytes, and mammalian platelets suspended in a plasma-like fluid with preservatives.

PRECAUTION

D-check 3P is intended for *in vitro* diagnostic use only by trained personnel.

WARNING:
POTENTIAL BIOHAZARDOUS MATERIAL.
This product contains human-sourced and/or potentially infectious components. For specifics please refer to the REAGENT section of this package insert. Components from human donors used in preparation of this product were tested by FDA approved methods for the presence of the antibodies to Human Immunodeficiency Virus (HIV-1 and HIV-2) and Hepatitis C Virus (HCV), as well as for Hepatitis B Virus surface antigen and found to be negative. No know method can offer complete assurance that products derived from human sources or containing inactivated microorganisms will not transmit infection. When handling or disposing of product, follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (OSHA 29 CFR art 1910.1030) or other equivalent biosafety procedures.

STABILITY AND STORAGE
Store D-check 3P upright at 2 - 8º C (35- 46º F) when not in use. **Protect tubes from overheating and freezing.** Unopened tubes are stable through the expiration date. Opened tubes are stable for 8 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 supematant may appear cloudy and reddish: this is normal and does not indicate deterioration. Other discoloration, very dark red supematant 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 to warm to room temperature (15 to 30ºC or 59 to 86ºF) 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 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 Operator's 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 using the instrument manufacturer's recommended reagents. 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 and expected biological variability of the control material.

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 reevaluate 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

Digitally signed by Stoianova Elena
Date: 2025.07.10 11:30:00 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

EC REP IVD CE