

N.B. PLEASE TAKE NOTE OF ANALYSIS DATES

PARTICIPANT INSTRUCTIONS

5-PART DIFF CBC-X (SYSMEX HAEMATOLOGY ANALYSERS) – CYCLE 7

Expiry date: 2019-07

Please check your kit upon arrival and call Thistle immediately if there are any problems with your kit or samples. We will advise you on the correct protocol to follow.

Introduction:

It is important to read and understand this document. If you have any queries please contact Thistle QA immediately for assistance.

Characteristics:

Your pack contains 3 x 4.5ml primary tubes of reagent composed of human and porcine cells in a plasma-like fluid with preservatives. The vials are labelled with a cycle and sample number.

Factors that could influence the testing of the sample

Important: Vials should be stored at 2 – 8 °C in an upright position

Unopened tubes are stable through the expiration date. Opened tubes are stable for 15 days or 15 pierces, whichever comes first provided they are handled properly.

Protect tubes from overheating and freezing. Please take care to ensure that the box does not come into contact with the freezer plate at the back of the fridge, as this causes haemolysis.

Transport samples at 2 – 8 °C.

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.**

Do not shake the vial.

Please treat as a routine patient sample.

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 Incomplete mixing of a tube prior to use invalidates both the sample withdrawn and any remaining material in the tube.

INSTRUCTIONS FOR USE

PLEASE ANALYSE IN THE INSTRUMENT CONTROL MODE

1. Remove tubes from the refrigerator and allow to warm to room temperature (15° - 30° C) 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. **Analyse 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 opened for sampling, clean residual material from the cap and tube rim with a lint-free tissue and replace the cap tightly.
 - b) Return tubes to refrigerator within 30 minutes of use.

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Safety:

POTENTIALLY BIOHAZARDOUS MATERIAL. For in vitro diagnostic use. Each human donor/unit used in the preparation of this product has been tested and found to be negative or non-reactive for the presence of HBsAg, Anti-HCV, NAT testing for HIV-1, HCV (RNA) and HIV-1/2. Each unit is also negative for Syphilis (RPR or STS). Because no test method can offer complete assurance that infectious agents are absent, this material should be handled as potentially infectious. For complete protection exercise the normal precautions required for handling laboratory specimens. Dispose of used samples as you would patient samples.

Return of Results:

Each of the samples has a number printed on the label. We recommend analysis dates as shown below. Please send your results at **the latest** on the final cut-off date given below. If the recommended analysis date does not allow you to get results to us on time, please analyse earlier. If in doubt, please contact Thistle immediately for assistance. No results will be accepted after the final cut-off date.

Additional Notes:

The reports will be posted / e-mailed within 7-10 working days after the FINAL cut-off date.
Collusion and/or falsification of EQA results are not good accreditation practice.

Return Dates for Results

<u>Sample No:</u>	<u>Analysis Dates:</u>	<u>Final Cut-off Dates:</u>
1.	13 May 2019	20 May 2019
2.	03 June 2019	10 June 2019
3.	24 June 2019	01 July 2019