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spinit® BC test | Product Ref. No 140101 (Blood Count)

INSTRUCTIONS FOR USE

INTENDED USE

The spinit® BC test cartridge is an *in vitro* diagnostic test used with the spinit® instrument to perform a quantitative determination of total white blood cells, 5-part differential counts and haematocrit in whole venous blood (EDTA) and capillary blood samples of human origin.

PRINCIPLES OF THE METHOD/PROCEDURE

The spinit® BC test cartridge is used to determine the total and 5-part differential leucocyte counts as well as haematocrit quantification from a small blood sample (15 µL) in a 7-minute time period without haematocrit. With haematocrit, the total assay time is 13 minutes. The microfluidic disc allows for automated sample processing: erythrocyte lysis, white blood cell specific staining and sample centrifugation. The determination of the leucocyte profile is based on a series of images acquired through an optical microscopy module that captures the specific morphology and the cellular components of each cell type and feeds them into the spinit® system software.

CALIBRATION

The spinit® instrument comes pre-loaded with standard calibration data. All spinit® BC test cartridge lots have a unique identification number which is coded together with lot specific calibration data in the product label barcode. A plug-and-play code reader is provided to this effect.

COMPOSITION

Each package contains spinit® BC test cartridges, instructions for use and 15 µL capillary tubes. Each disc contains the following reagents: saponin, methylene blue, anticoagulant reagent (EDTA), trehalose and a hydrophobic reagent. Necessary materials required but not supplied: sterile lancets approved for capillary sample collection.

WARNING AND PRECAUTIONS

Using capillary blood, the sample should be immediately introduced into the test cartridge after collection.
After introducing the sample into the disc, place it in the instrument immediately.
Do not use the teste cartridge if the pouch or the disc have been damaged.
Do not use the test cartridge after the expiry date or if the test cartridges have not been stored in accordance to recommendations.
Do not re-use the test cartridge.
Not following the above recommendations may result in test failure and an information code is displayed to the user.
All test cartridges should be disposed of immediately after use. Proper handling and disposal methods should be followed in accordance with the applicable country laws.

STORAGE AND HANDLING

The spinit® BC test cartridge shelf-life is indicated on the pouch printed label, requiring the discs to be stored in closed pouches at room temperature. Once the pouch has been opened the disc must be used within 15 minutes. DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

The spinit® BC test may be used with venous whole-blood (EDTA) and capillary whole-blood of human origin. It is ready-to-use and does not require any reagent preparation step.

PROCEDURE

Please read spinit® user manual for proper use of the system.

Please read spinit® BC quick guide for detailed information on how to perform a test.

1. Scan barcode from pouch label and follow on-screen instructions **2.** Remove disc from pouch and place it on a flat surface with label facing up **3**. Lift the adhesive flap **4.** Collect the blood sample with a 15 µL capillary tube and insert it into sample well by gently squeezing the pressing area of the capillary tube available from the holder. In replacement of the capillary tube, a micropipette can be used **5**. Remove adhesive flap protection and firmly seal the sample well **6.** Once you have the disc ready, click Next on-screen and place the disc on the tray **7**. Follow on-screen instructions.

LIMITATIONS OF THE METHOD

Blood samples with immature leucocytes and erythrocytes may influence the performance of total and differential WBC (please refer to section "INTERFERENCE").
Samples with total WBC and/or haematocrit values outside the test measurement range may impact an increased test failure rate.

PERFORMANCE CHARACTERISTICS

TEST MEASUREMENT RANGE

The spinit® BC test measurement range for total WBC is 3-30 x 10^9 cells/L when operated as per recommended procedure. The range for the 5-part differential is presented as a percentage of the total counts.

Total WBC (x10^9 cells/L)	**3-30**
Neutrophils (%)	10.0 -86.0
Lymphocytes (%)	9.0 – 78.0
Monocytes (%)	3.0 – 18.0
Eosinophils (%)	0.0 – 15.0
Basophils (%)	0.0 – 5.0
Haematrocrit (%)	20.0 – 65.0

Table 1 – Quantitative measurement range for spinit® BC test

Results below the Lower Limit of Quantitation will appear as lower than (≤) the measurement range defined for the total and 5-part differential leucocyte counts as well as haematocrit, and similarly results above the Upper Limit of Quantitation will appear as higher than (≥) the quantitative range.

PRECISION AND ACCURACY

A range of clinical samples were tested in duplicate on different days with different lots of test cartridges and spinit® instruments. A summary of the results is presented in table 2.

	N		**CV (%)**	**Bias (%)**
Haematocrit	564		1.5	-0.3
WBC Classification	**N**	**SD (x10^9 / L)**	**CV (%)**	**Bias (%)**
Leucocytes	678		6.6	0.4
Neutrophils	640		7.4	-0.2
Lymphocytes	640		9.8	-0.1
Monocytes	640		13.3	2.6
Eosinophils	640	0.05		-4.5

Table 2 – Imprecision of spinit® BC test cartridge

METHOD COMPARISON

Results from the method comparison study performed according to CLSI Document EP9-A3 on the spinit® BC system and the Siemens ADVIA 2120 (standard laboratory reference method) for the total and 5-part differential WBC counts and haematocrit values.

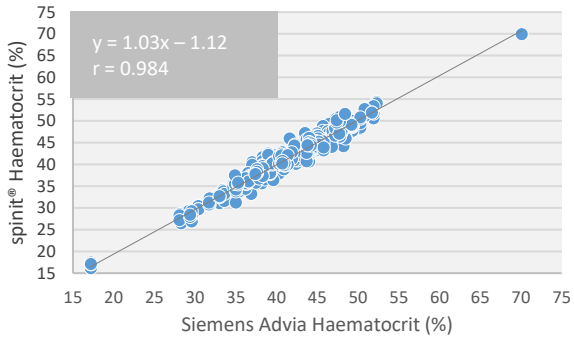


Fig 1. Equivalency of the spinit® BC test cartridge with the reference method: Siemens ADVIA 2120 for haematocrit quantification.

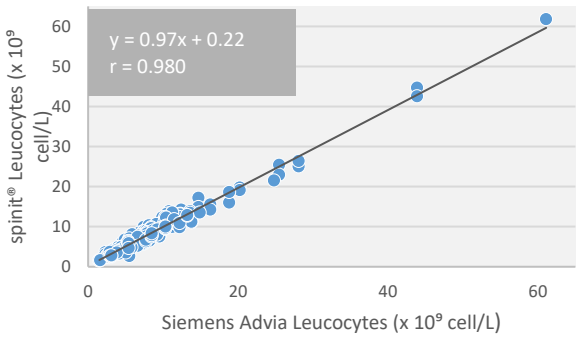


Fig 2. Equivalency of the spinit® BC test cartridge with the reference method: Siemens ADVIA 2120 for leucocyte counts

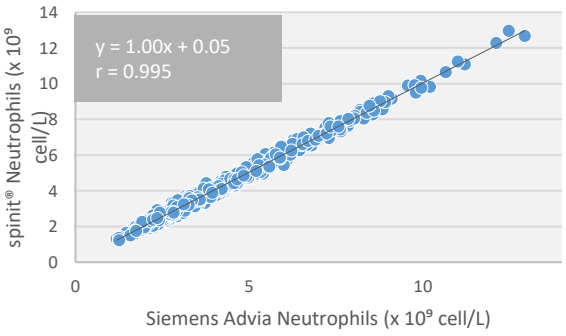


Fig 3. Equivalency of the spinit® BC test cartridge with the reference method: Siemens ADVIA 2120 for neutrophil counts

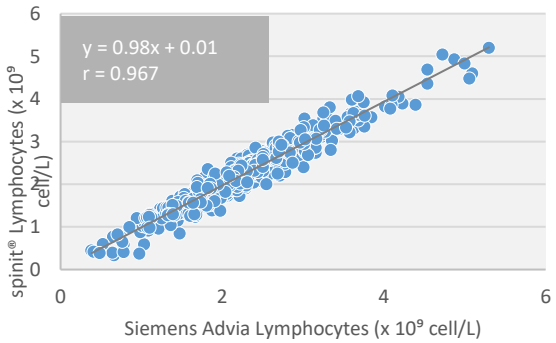


Fig 4. Equivalency of the spinit® BC test cartridge with the reference method: Siemens ADVIA 2120 for lymphocyte counts

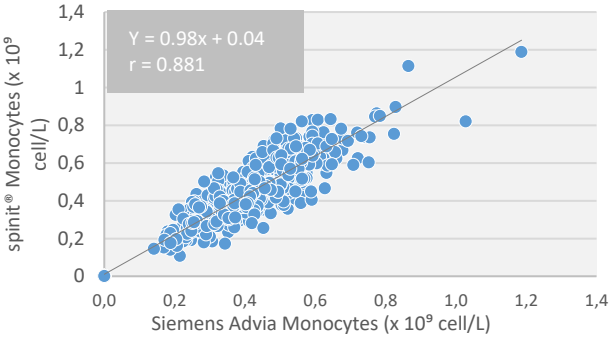


Fig 5. Equivalency of the spinit® BC test cartridge with the reference method: Siemens ADVIA 2120 for monocytes counts

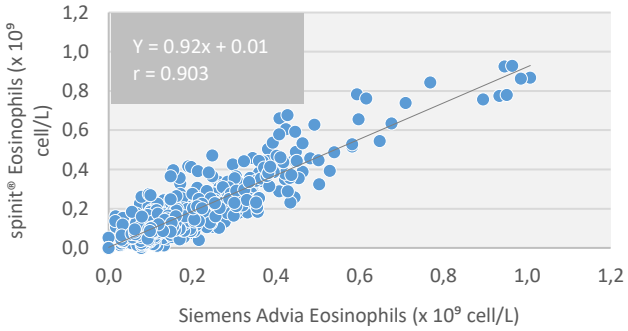


Fig 6. Equivalency of the spinit® BC test cartridge with the reference method: Siemens ADVIA 2120 for eosinophils count

INTERFERENCE

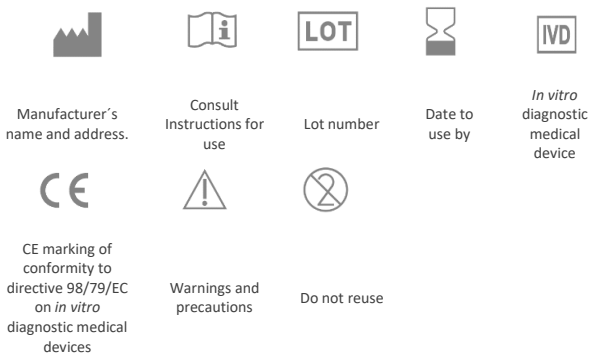
The spinit® system informs the user for the presence of immature leucocytes (IM) and nucleated red blood cells (NRC) with specific sample flags. Refer to spinit® instrument user manual for information on sample flags. For specific performance characteristics, please refer to www.biosurfit.com or contact your supplier for more information.

CONTROL MATERIAL

Each spinit® CRP test cartridge contains multiple integrated quality control verification steps to ensure reliability of the tests. If the user chooses to perform additional Quality Control checks, biosurfit recommends previously tested and commercially available quality control reagents with the respective ranges of acceptability for the spinit® system. Use Quality Control mode for control testing. See spinit® user manual for further details.

ISO13485 certified company.

SYMBOLS USED:



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