StatusFlow^{Lo}

Flow Cytometry Control

CONTROL

FOR *IN VITRO* DIAGNOSTIC USE

ASSAY VALUES AND EXPECTED RANGES

LOT FC0717-4L

QCP DATA MONTHS: **JULY**

2017-08-05

WBC/µL	**3,632**
Lymphocytes/µL	**1,258**
Lymphocyte %	**34.6**

Phenotype	% Total Lymphocytes (Range)	Number/µL (Range)
CD3+	**54.1** (44.1 - 64.1)	**680.6** (530.9 - 830.3)
CD3+/CD4+	**12.1** (8.1 - 16.1)	**152.2** (91.3 - 213.1)
CD3+/CD8+	**37.0** (30.0 - 44.0)	**465.5** (341.2 - 589.7)
CD19+	**24.3** (18.3 - 30.3)	**305.7** (191.7 - 419.7)
CD3-/CD16+56+*	**19.4** (14.4 - 24.4)	**244.1** (180.8 - 307.3)

* These values were derived using the reagents listed below. Slight differences in cell counts may be obtained with antibodies from different sources.

Antibody (Fluorochrome)	Manufacturer
CD3 / CD8 / CD45 / CD4 (FITC / PE / PerCP / APC)	Becton Dickinson
CD3 / CD16+CD56 / CD45 / CD19 (FITC / PE / PerCP / APC)	Becton Dickinson

INTENDED USE

StatusFlow^{Lo} is intended as a complete process control for immunophenotyping by flow cytometry. It is a control for antibody staining, RBC lysis, instrument set-up, instrument performance and data analysis.

SUMMARY AND PRINCIPLE

Lymphocyte immunophenotyping by flow cytometry is a complex, multi-step process. Validity of immunophenotyping results depends on efficient RBC lysis and clear separation of leukocyte subpopulations based on light scatter characteristics and reactivity with cell-specific, fluorescent monoclonal antibodies. StatusFlow^{Lo} is a stable control, with assigned values, that can be used to monitor the immunophenotyping process.

REAGENTS

StatusFlow^{Lo} is an *in vitro* diagnostic reagent composed of human erythrocytes and leukocytes suspended in a plasma-like fluid with preservatives.

PRECAUTION

StatusFlow^{Lo} 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 by a FDA licensed method/test and found to be negative or non-reactive for the presence of HBsAg, Anti-HCV, NAT testing for HIV-1, HCV (RNA), HIV-1/2 and Anti-HTLV I/II. Each unit is also negative by a serological test 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.
When handling or disposing of vials follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

STABILITY AND STORAGE

Store StatusFlow^{Lo} 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 tubes are stable for 9 thermal cycles (uses), provided they are handled properly.

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INDICATIONS OF DETERIORATION

Product should be reddish and slightly cloudy. Discoloration of the tubes may indicate deterioration or contamination. **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 - 30° C or 59 - 86° 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 30 - 60 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 10 times immediately before sampling.
3. After sampling:
   a) Clean residual material from the cap and tube rim with lint-free tissue. Replace 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

Some staining parameters of StatusFlow^{Lo} may differ from those observed with fresh whole blood. The use of additional fixatives following lysis of the RBC component in StatusFlow^{Lo} may affect performance and is not recommended. Do not use beyond the labeled expiration date.

Expected values are listed as percent of total lymphocytes or as number of each phenotype. Number/µL is calculated by multiplying the percent of each phenotype by total lymphocyte count obtained through independent analysis using a combination of technologies. Customers with Ortho Cytoron Absolute flow cytometers should generate their own means and associated ranges for absolute numbers. StatusFlow^{Lo} is not intended as a control for hematology whole blood analyzers.

When converting percent lymphocytes to number of lymphocytes, use Lymph count reported on assay sheet.
StatusFlow^{Lo} is not designed to act as an indicator of cellular viability. Use of vital staining dyes such as propidium iodide or 7-amino-actinomycin-D with this product is not recommended.

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.

TYPICAL DATA:

FIGURE 1

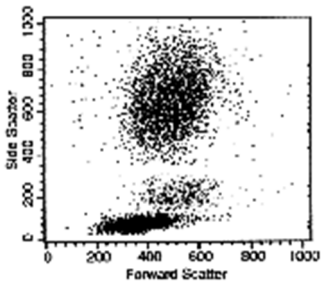

Figure 1: Typical light scatter dot plot of the StatusFlow^{Lo} stabilized whole blood control.

FIGURE 2

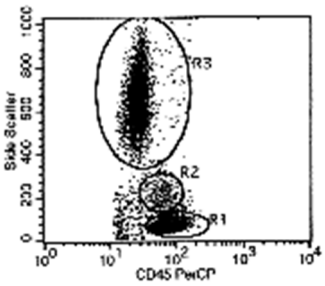

Figure 2: Dual parameter dot plot of StatusFlow^{Lo} stained with anti-CD45 vs. side scatter.

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. No quantitative data are reported nor can results be guaranteed with antibodies to markers not listed.

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

For assistance in resolving control recovery problems, please call Technical Service at (800) 523-3395. For additional information on R&D Systems, Inc. hematology controls and calibrators, or to place an order, call Customer Service at (800) 428-4246.

QUALITY CONTROL PROGRAM

For information on CBC-Monitor, our Inter-Laboratory Quality Control Program, call (800) 523-3395 ext. 4435.

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EC REP

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