TBNK-16 (L) AUTOCLASSIFICATION

ASSAY COMPATIBILITY

CATALOG NUMBER: A1003-1L

ASSAY NAME: TBNK-16 RTF Assay (L)

ASSAY DESCRIPTION: Expanded lymphocyte subset panel with CD16 antibody and lysis buffer for leukapheresis and Streck CD-Chex Plus®, Normal control material (Item Numbers 213323, 213365, and 213367) or samples requiring RBC lysis.

PANEL DESCRIPTION

MARKER	FLUOROPHORE	CLONE
CD45	PE/Cy7	HI30
CD3	PE/Cy5	UCHT1
CD14	PE/Dazzle 594	M5E2
CD19	PE	HIB19
CD56	AF488	HCD56
CD16	AF488	3G8
Viability	DiYO-3	N/A
Count beads	N/A	N/A

The Accellix Platform automates your entire GMP cell phenotyping process from sample preparation to data acquisition and analysis, in order to generate rapid results directly in the manufacturing suite. Central to our enabling technology are standard and custom assays. These assays allow for sample preparation in a stable, single-use microfluidic cartridge using unitized and dried reagents that are stable at ambient temperatures. The dried reagent also has control beads, enabling cell counting and in-run QC for every assay. Each assay incorporates an Accellix cartridge with a unique QR code, simplifying the workflow and reducing the chances for human error. The autoclassification software (algorithm-based analysis) automatically analyzes the compensated flow cytometry data using multi-parametric analysis and provides realtime results on the Accellix instrument screen at the conclusion of each run.

DESCRIPTION AND INTENDED USE

The Accellix TBNK-16 (L) autoclassification data analysis software complements the TBNK-16 RTF Assay (L) to automatically classify and enumerate lymphocyte populations using multi-parametric analysis, dynamically setting gates for each cell subset in each run. The assay and software are intended for both fresh and frozen leukapheresis samples. Additionally, the operator can select an option on the screen to run autoclassification specific to Streck CD-Chex Plus®, Normal control material. Control material parameter specifications for the Accellix Automated Flow Cytometer are available from Streck RUO assay specification sheets for each control material lot. The Accellix instrument tabulates the autoclassification results on-screen immediately after completion of the assay run and reports the results in a digital PDF file along with traceability information such as operator, Accellix assay lot, and software version. In addition, graphical results are generated for rapid and clear visual review of the data as well as providing an indication of how the software performed. To allow flexibility for oversight by subject matter experts, Flow Cytometry Standard (FCS) files are generated and exported along with the automated results.

KEY BENEFITS

+ **Autoclassification improves reproducibility by removing subjectivity from manual gate placement.**

+ **Automating analysis greatly shortens time to results in comparison to manual gating by applying objective logic for gate placement and classification of cells over manual analysis, reducing potential errors in data interpretation.**

+ **Automated results are generated immediately after each run, enabling users to quickly make informed decisions.**

+ **Assay reportables are configurable and include warning flags for flow disturbances and low event counts.**

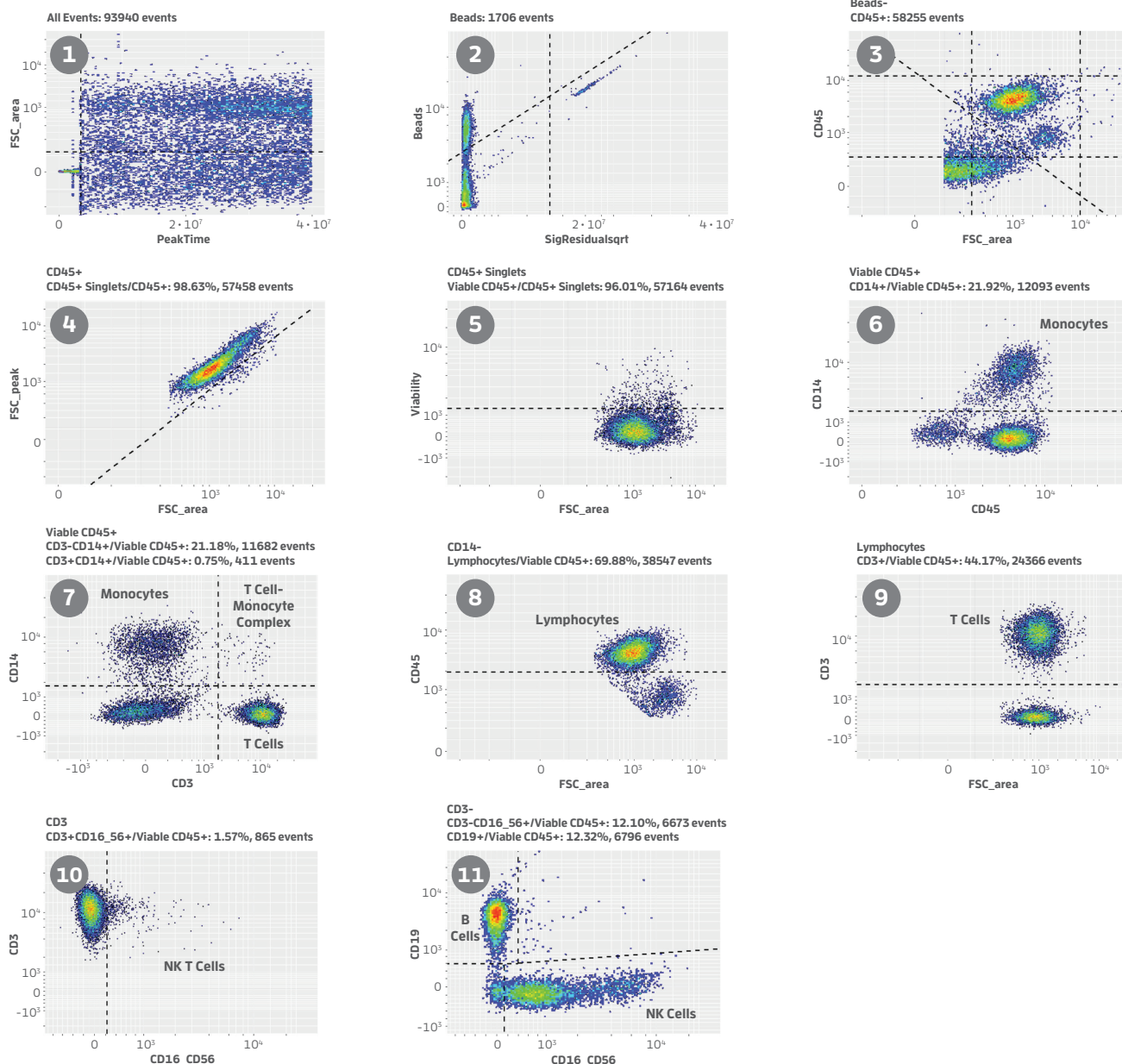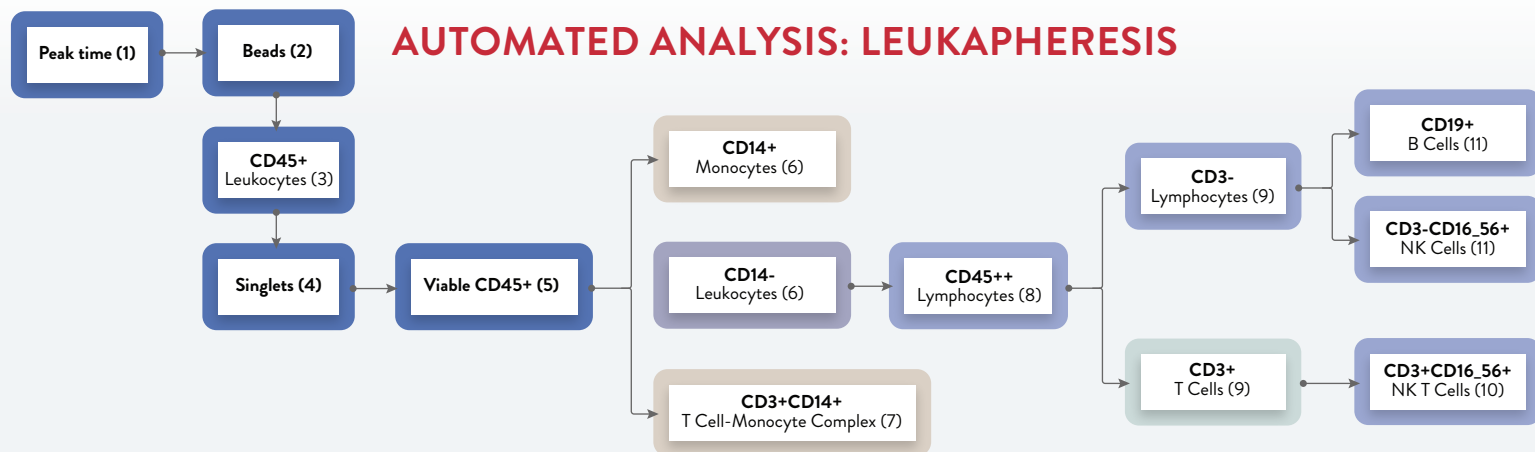# AUTOMATED ANALYSIS: LEUKAPHERESIS

Figure 1 - Gating hierarchy and plots of representative TBNK-16 RTF Assay (L) (Cat. No. A1003-1L) run with leukapheresis sample on the Accellix Platform. Assay-specific autoclassification software classified and enumerated cell subsets. From left to right, top to bottom: time gate (plot 1) to exclude flow disturbances, identification and exclusion of assay beads used for ratiometric cell counting (plot 2), CD45+ leukocytes (plot 3), singlets (plot 4), viable cells (plot 5), identification and exclusion of CD14+ monocytes (plot 6), CD14+ cells are further gated to identify cells which are also CD3- (plot 7), CD14- population was gated on CD45 bright lymphocytes (plot 8), CD3+ T cells (plot 9), CD3+CD16_CD56+ NK T Cells (plot 10), CD3-CD16_CD56+ NK Cells, and CD19+ B cells (plot 11).

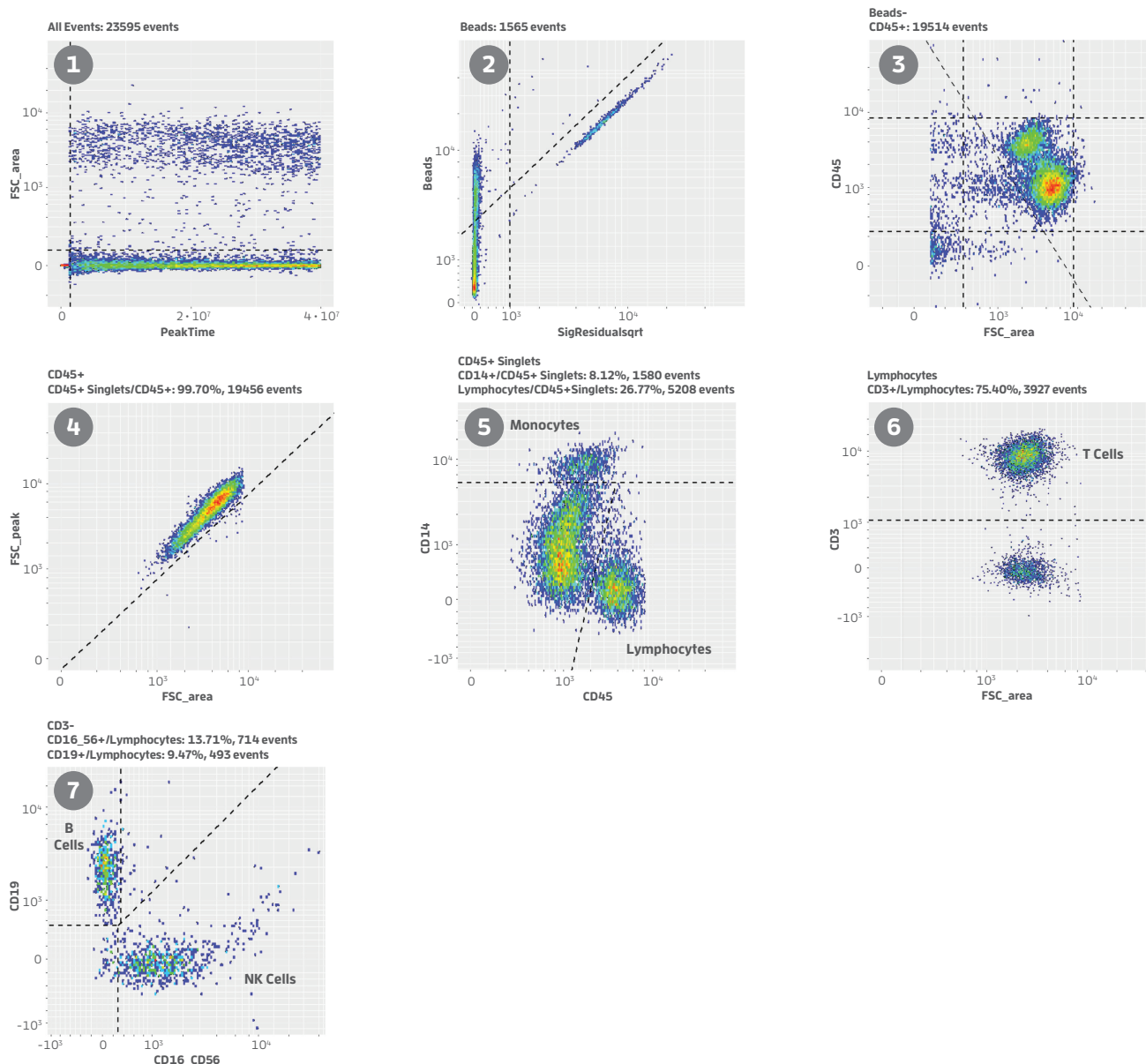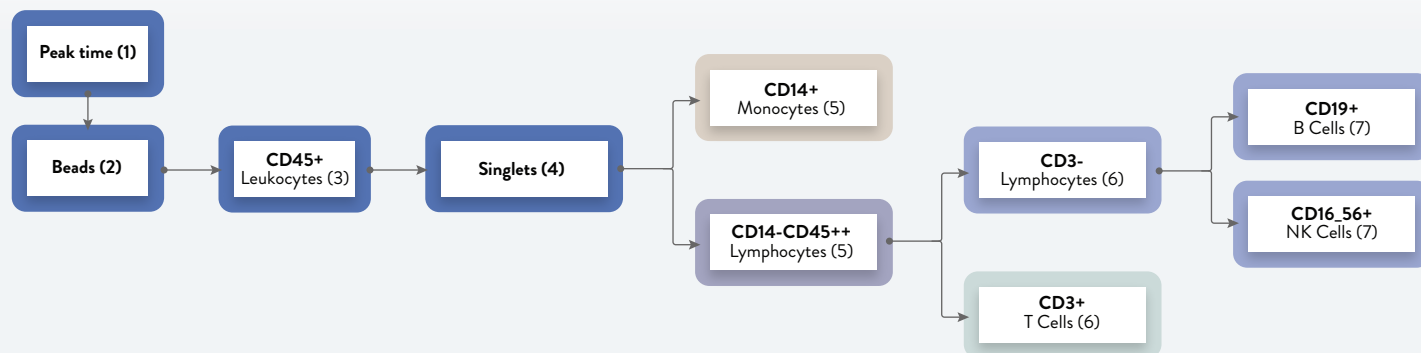# AUTOMATED ANALYSIS: STRECK CD-CHEX PLUS®, NORMAL CONTROL MATERIAL

Figure 2 - Gating hierarchy and plots of representative TBNK-16 RTF Assay (Cat. No. A1003-1L) run with control sample (Streck CD-Chex Plus®) on the Accellix Platform. Assay-specific autoclassification software classified and enumerated cell subsets. From left to right, top to bottom: time gate (plot 1) to exclude flow disturbances, identification and exclusion of assay beads used for ratiometric cell counting (plot 2), CD45+ leukocytes (plot 3), singlets (plot 4), CD14+ monocytes and CD14-CD45 bright lymphocytes (plot 5), CD3+ T cells (plot 6), CD3-CD16_CD56+ NK Cells, and CD19+ B cells (plot 7).