

AQUIOS STEM System

The AQUIOS STEM System is an IVD solution for the automated analysis of CD34+ hematopoietic stem and progenitor cells. It combines the automation features of the AQUIOS Load & Go Flow Cytometer with the benefits of a hematopoietic stem cell enumeration solution that was brought to the next level to meet today's automation and data traceability needs.

The AQUIOS STEM System, comprised of AQUIOS STEM Software for the AQUIOS CL Flow Cytometry System, AQUIOS STEM Kit Reagents, AQUIOS STEM CD34 Control Cells and Flow-Check Fluorospheres, is an in vitro diagnostic medical device intended to be used by laboratory professionals for the detection of the parameters CD34 and CD45 in the most commonly used specimen types.

AQUIOS STEM Kit

AQUIOS STEM Kit reagents consist of a CD45-FITC/CD34-PE murine monoclonal antibody reagent, a corresponding negative control (CD45-FITC/CD34-CTRL), an absolute count reagent (AQUIOS STEM-Count Fluorospheres), a cell viability reagent (7-AAD), and a ready-to-use lysing reagent (AQUIOS STEM Lysing Solution).

The supporting AQUIOS STEM Software provides a total of three different acquisition panels for clinical CD34+ enumeration. All protocols follow the sequential gating strategy of the ISHAGE Guidelines, and the panels provide the option to either run the "full" panel of three tests (duplicate plus negative control) as suggested by ISHAGE and mandated by the Ph. Eur., the optional ISHAGE panel without the use of a negative control, or a single test that can be used for QC purposes for rare specimen types. All panel combinations are part of the IVD solution without the need to create user defined tests.

Duplicate PLUS negative control	Duplicate W/O negative control	Single tube
CD45 / CD34-PE / 7-AAD	CD45 / CD34-PE / 7-AAD	CD45-FITC / CD34-PE / 7-AAD
CD45-FITC / CD34-PE / 7-AAD	CD45-FITC / CD34-PE / 7-AAD	
CD45-FITC / CD34-CTRL / 7-AAD		

The AQUIOS STEM concept is optimized for high performance on the AQUIOS CL Flow Cytometry system:

- No experimenting, mixing or other pre-analysis work is necessary
- Automated sample loading through cassettes
- Priority treatment of emergency (STAT) samples via single tube loading
- Full traceability empowered by barcoded vials
- Complete workflow automation by using a red cell lysing solution that is stored and handled at room temperature
- Simplified 2-level process controls that encompass clinical decision levels with barcoded assay sheets
- Connectivity to LIS and to eIQAP
- Signal when consumables are low
- Signal when quality control failed
- Signal when CD34 or CD45 cells are low



INSTRUMENT

Dimensions (W x D X H)

AQUIOS CL	Supply Cart	Workstation
82 x 56 x 56 cm	53 x 46 x 41 cm	65 x 16 x 42 cm
32 x 22 x 22 in.	21 x 18 x 16 in.	25.7 x 6.4 x 16.6 in.

Weight

AQUIOS CL	Supply cart	Workstation
59 kg (130 lbs)	11 kg (25 lbs)	12 kg (27 lbs)

Acoustic Noise Level

≤65 dBa

Heat Dissipation

Approx. 250 W (853 btu/hour)

Uninterruptible Power Manager Specifications

	North America	International
Load Current (Amps)	7.9	3.9
Load Power (VA)	800	800
Input Voltage (VAC)	96-151	181-290
Output Voltage (VAC)	120	230
Frequency (Hz)	50/60	50/60

ENVIRONMENT

Antibody Storage Temperature

2°C ≤ x ≤ 8°C

Lysing Storage Temperature

18°C ≤ x ≤ 25°C

Control Cells Storage Temperature

2°C ≤ x ≤ 8°C

SAMPLE PREPARATION

AQUIOS STEM Lysing Solution

The AQUIOS STEM Lysing Solution is a highly specific, ready to use and gentle lysing agent. The AQUIOS STEM Lysing Solution lyses red blood cells in samples sufficiently to perform monoclonal antibody panel analysis without interference from red blood cells and allows analysis without damage to white blood cells. The AQUIOS STEM Lysing Solution does not contain fixatives.

Monoclonal Antibodies

The AQUIOS STEM Kit comprises two separate murine monoclonal antibody panel reagents as well as a viability dye. Each murine monoclonal antibody is conjugated to a specific fluorochrome and specific for a different cell surface antigen:

- CD45-FITC/CD34-PE reagent
- CD45-FITC Isoclonic Control-PE reagent
- 7-AAD Viability Dye

AQUIOS STEM-Count Fluorospheres

AQUIOS STEM-Count Fluorospheres is a fluorescent microsphere reagent for direct determination of the absolute counts of white blood cell subsets in biological specimens.

QUALITY CONTROL

AQUIOS STEM CD34 Control Cells

AQUIOS STEM CD34 Control Cells are liquid preparations of stabilized human leukocytes (lymphocytes, monocytes and granulocytes) and erythrocytes that have lysing, light scatter, antigen expression and antibody staining properties representative of those found in human whole blood specimens. Target values for the Control Cells will be scanned via assay sheets.

Flow-Check Fluorospheres

Flow-Check Fluorospheres are an assayed suspension of fluorospheres (fluorescent microspheres) used for daily verification of a flow cytometer's optical alignment and fluidics system.

ANALYSIS ALGORITHM

AQUIOS STEM Software

The AQUIOS STEM algorithm is the software analysis component that works in conjunction with AQUIOS STEM Kit reagents to automatically identify and enumerate viable Leukocytes (CD45+ populations) and viable CD34+ HPC cells according to ISHAGE guidelines. The algorithm combines information from AQUIOS parameters (FS, SS and Fluorescence FL1-FL4) to automatically generate gates and regions to accurately identify populations of interests.

The software has electronic audit trail of test date, operator and patient ID, sample and consumable ID, reagents used, and reactions recorded. Additional there is the option to insert the collection date, the weight of the patient as well as the date of birth.

The AQUIOS STEM Software can calculate the values for:

- Viable CD34+ cells per kg
- Viable Leukocytes per kg
- Viable CD34+ % (of total CD34+)
- Sample Viability % (of WBC)

SPECIMEN TYPES

Fresh

Sample Type	Stability	Storage
Peripheral Whole Blood	20 hours	18°C ≤ x ≤ 25°C
Mobilized Whole Blood	20 hours	18°C ≤ x ≤ 25°C
Cord Blood	24 hours	18°C ≤ x ≤ 25°C
Apheresis	24 hours	2°C ≤ x ≤ 8°C
Bone Marrow	24 hours	2°C ≤ x ≤ 8°C

Frozen

Sample Type	Stability	Storage
Cord Blood	15 min. after thawing	Keep on ice
Apheresis Product	15 min. after thawing	Keep on ice
Bone Marrow	15 min. after thawing	Keep on ice

PERFORMANCE CHARACTERISTICS

	CD34c	CD45c
Limit of Blank	0.49	31.33
Limit of Detection	1.49	35.33
Limit of Quantitation	2.00	36.00
Upper 95% Confidence Limit of Limit of Quantitation	4.00	36.00

REFERENCE INTERVAL

Parameter	Units	N	Mean	Lower Limit (90% confidence bounds)	Upper Limit (90% confidence bounds)
CD34+	Absolute viable count (cells/μL)	120	2.75	0.88 (0.54-1.02)	6.16 (5.33-10.80)
% CD34+	% viable CD34+ of viable CD45+	120	0.05	0.01 (0.01-0.02)	0.09 (0.08-0.14)
CD45+	Absolute viable count (cells/μL)	120	6203.35	3746.91 (2660.36-4363.74)	8901.82 (8262.02-9883.23)

ORDERING INFORMATION

Part Number	CD45c
B39101	AQUIOS CL Flow Cytometry System (100-120v)
B39102	AQUIOS CL Flow Cytometry System (220-240v)
C89793	AQUIOS STEM Upgrade Kit
B77691	AQUIOS STEM Kit, 50 tests
C43667	AQUIOS STEM CD34 Control Cells, 2 levels, 15 tests each
6605359	Flow-Check Beads, 3x10 mL



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