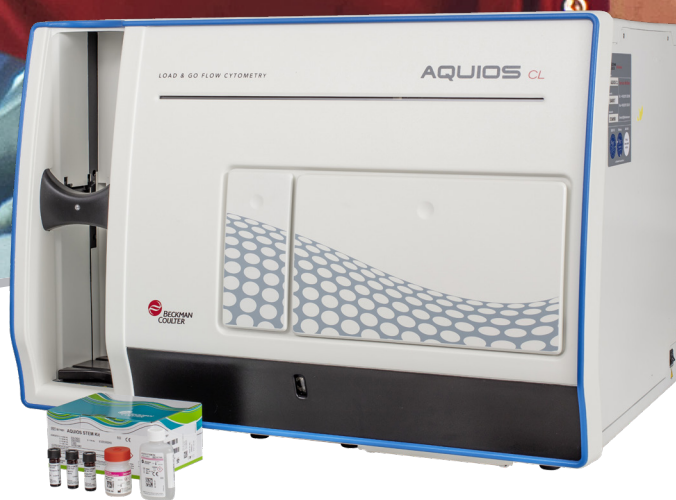




YOU CAN HELP SAVE LIVES.
WE'LL HELP YOU FIND LIVE STEM CELLS.



EMPOWER
life changing decisions.

 **BECKMAN
COULTER**
Life Sciences

AQUIOS STEM SYSTEM

The AQUIOS STEM System was designed together with leading experts in the field of clinical CD34+ enumeration with the goal to bring the Gold Standard to the next level. It is a modular approach to the automated analysis of CD34+ hematopoietic stem and progenitor cells.

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 enumeration of CD34+ and CD45+ cells in the most commonly used specimen types.

Our new AQUIOS STEM System is an evolution of the Gold Standard. Stem cells can save lives. But only if enough viable ones get transplanted. Now, our new AQUIOS STEM System makes identifying those viable cells easier—all day, every day. Used with the fully automated, Load & Go AQUIOS CL Flow Cytometer, our system maintains accuracy, reduces delays, and simplifies compliance and data tracking: supporting you as you support physicians.

beckman.com

AQUIOS CL
Load & Go
Flow
Cytometer

**AQUIOS
STEM
Kit**

**AQUIOS
STEM
Software**

**AQUIOS
STEM
CD34
Control**

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).

Leveraging full process automation on the AQUIOS CL Flow Cytometer, in combination with the innovative reagent concept of the AQUIOS STEM system, can help you to optimize your laboratory's efficiency.

The AQUIOS STEM System



Minimizes hands-on
time by up to 95%*



Reduces error-prone
steps by up to 87.5%*



Increases
turnaround time*



Is an adaptable
IVD Solution

* compared to an alternative method

FLEXIBLE & COMPLIANT ASSAY SETUP

In addition to a fully automated Load & Go workflow, the AQUIOS STEM System provides a completely new degree of adaptability with three different acquisition panels for clinical CD34+ enumeration.

All protocols follow the sequential gating strategy of the ISHAGE Guidelines. The panels provide the option to 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 control¹, or as a single test. All panel combinations are part of the IVD solution without the need to create user-defined tests.

AQUIOS STEM IVD Panel Options adapted to your needs



Duplicate PLUS negative control

- 1 CD45-FITC / CD34-PE / 7-AAD
- 2 CD45-FITC / CD34-PE / 7-AAD
- 3 CD45-FITC / CD34-CTRL / 7-AAD

Duplicate W/O negative control

- 1 CD45-FITC / CD34-PE / 7-AAD
- 2 CD45-FITC / CD34-PE / 7-AAD

Single test

- 1 CD45-FITC / CD34-PE / 7-AAD

Supported 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	Frozen samples should be processed within 15 minutes after thawing and kept on ice.
Apheresis Product	15 min. after thawing	
Bone Marrow	15 min. after thawing	

EVOLUTION OF THE GOLD STANDARD

The ideal CD34+ quantification kit for flow cytometry combines the benefits of established standards and protocols with enough flexibility to adapt reagent and software tools to today's needs of a clinical laboratory. This includes acquisition and analysis panels for different sample types without having to set up user-defined tests in parallel to IVD solutions, quality control mechanisms that meet the requirements of a highly regulated work environment, and a high degree of automation.



QUALITY CONTROL MECHANISMS

Laboratories performing CD34+ hematopoietic progenitor cell (HPC) enumeration are highly regulated in terms of data traceability, and need to establish an extensive QC system². Some key aspects of these control mechanisms are

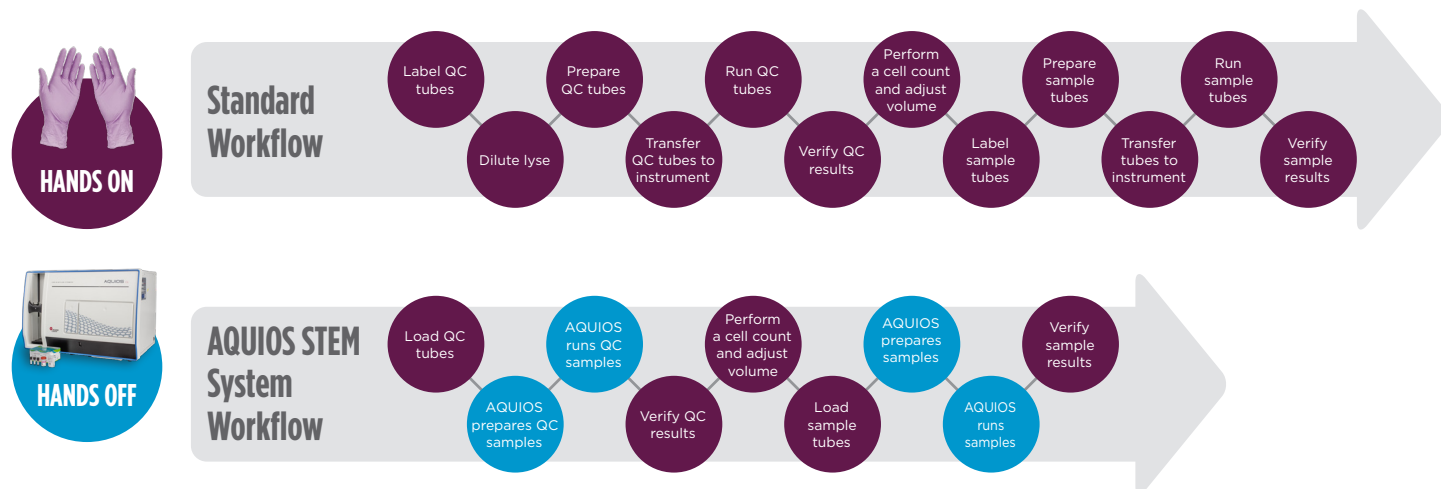
- The avoidance of sample misidentification throughout the process by adequate identification of all samples.
- Adequate provisions for monitoring the reliability, accuracy, precision, and performance of test procedures and instruments.
- Functional checks for instruments and reagents.
- The use of appropriate reference material and the documentation of ongoing proficiency testing.
- A process to prevent the use of expired reagents and supplies.
- A mechanism that allows linking the lot number, expiration date, and manufacturer of supplies and reagents to each specimen.



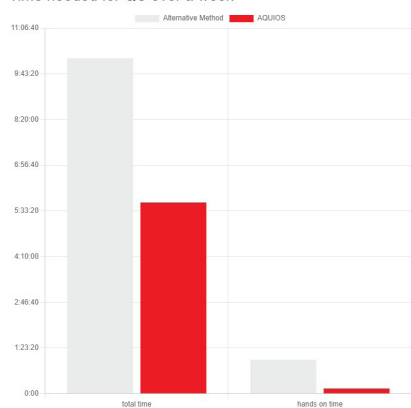
HOW THE AQUIOS STEM SYSTEM HELPS TO REDUCE MANUAL PROCESSING

WORKFLOW STEPS

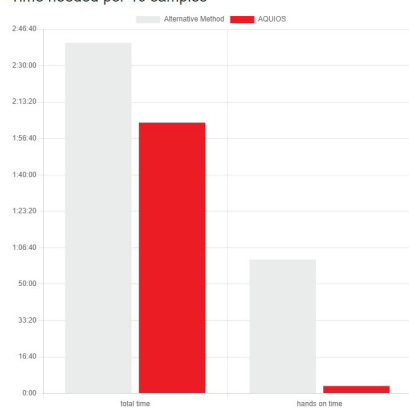
Several different steps should be performed before the analysis of stem cells. With the AQUIOS STEM System, samples are loaded either using a cassette autoloader or the Single Tube Loader for STAT samples that are prioritized over other samples in the queue. Sample preparation is performed automatically by the system.



Time needed for QC over a week



Time needed per 10 samples



■ Predicate method
■ AQUIOS STEM System

Weekly time requirements for instrument QC and sample runs. While time to result is mainly determined by incubation times with antibodies and lysing reagent, hands-on time could be reduced by up to 95% compared to the predicate method.

Antibodies and reagents

AQUIOS STEM Kit contains enough reagents to analyze 50 samples in duplicate plus negative control** and consists of:

- A CD45-FITC/CD34-PE murine monoclonal antibody reagent
- A corresponding negative control (CD45-FITC/CD34-CTRL)
- A cell viability reagent (7-AAD)
- A pH-stable lysing solution
- Counting beads with automation-ready buoyancy

Process controls

AQUIOS STEM CD34 Control Cells are liquid preparations of stabilized human leukocytes for the verification of the parameters CD34 and CD45 as part of the AQUIOS STEM System. Each kit contains two levels of CD34 with:

- Approx. 10 CD34+ cells/ μ L (Level 1)
- Approx. 30 CD34+ cells/ μ L (Level 2)

Assay values are entered into the system by scanning the barcode of the Control Cell Assay Sheet.

** Reagents for CD34 and CD45 contain the clones recommended by the ISHAGE Guideline

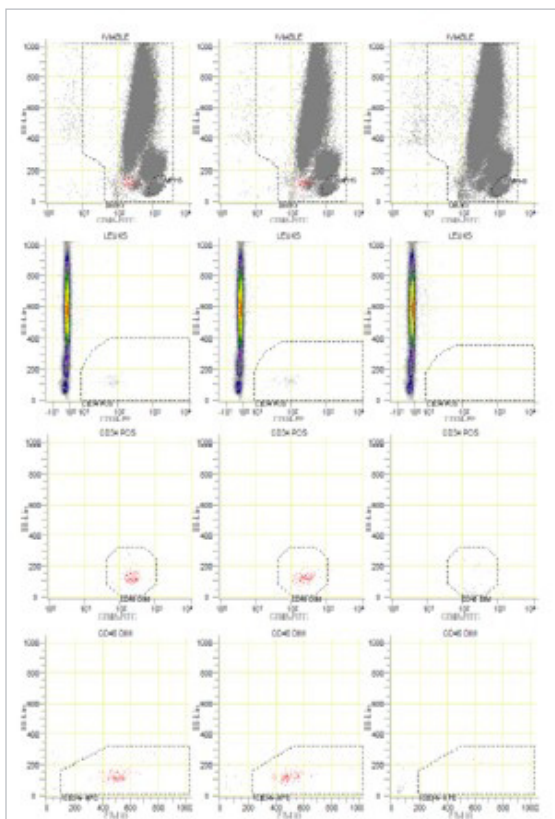
LABORATORY REPORT WITH RESULTS AND STATISTICS

Beckman Coulter
10800 SW 147th Ave., Miami, FL 33196

Sample ID: 89351136189 Test: Stem Panel v1.0
Run Date: 01 Sep 2020 15:11:15 Analysis Date: 01 Sep 2020 15:28:09
User: Admin Collect Date: 01 Sep 2020
Specimen Type: Whole Blood Patient Name:
Patient ID: 89351136189 Gov. ID:
Status: Blast Location: Miami
Gender: M Date Of Birth:
Physician: Physician Code:
Instrument Serial #: BC43072 Harvest Volume (mL): 3
Report: Summary Weight (kg): 85 Dilution: 4
Run Flags:
Run Notifications:
Comments:

Measured

- Viable CD34+ Cells
- Viable Leukocytes
- Viable Events
- Beads



Beckman Coulter
10800 SW 147th Ave., Miami, FL 33196

Sample ID: 89351136189 Test: Stem Panel v1.0
Run Date: 01 Sep 2020 15:11:15 Analysis Date: 01 Sep 2020 15:28:09

Result	Value	Flag	Normal Range	Action Range
Viable CD34+ HPC Count Well 1 (cells/uL)	8.77			
Viable CD34+ HPC Count Well 2 (cells/uL)	8.42			
AVG Viable CD34+ HPC Count (cells/uL)	8.59			
Viable CD34+ HPC % Diff (Well 1 vs Well 2)	2.01%			
Viable Leukocytes Count Well 1 (cells/uL)	17,867.97			
Viable Leukocytes Count Well 2 (cells/uL)	17,952.29			
AVG Viable Leukocytes Count (cells/uL)	17,910.13			
Viable CD34+ HPC Well 1 % (of Viable Leukocytes)	0.05%			
Viable CD34+ HPC Well 2 % (of Viable Leukocytes)	0.05%			
AVG Viable CD34+ HPC % (of Viable Leukocytes)	0.05%			
DF: Dilution Factor	4.00			
AVG Viable CD34+ HPC Count (cells/uL) (x DF)	34.38			
AVG Viable Leukocyte Count (cells/uL) (x DF)	71,640.51			
HV: Harvest Volume (mL)	3.00			
AVG Viable CD34+ HPC Count (x DF x HV)	103,137.59			
BW: Body Weight (kg)	85.00			
AVG Viable CD34+ HPC Count per kg (x DF x HV / BW)	1,213.38			
CAL	1,053			
Viable CD34+ HPC Count Negative Ctrl (cells/uL)	0.18			

Beckman Coulter
10800 SW 147th Ave., Miami, FL 33196

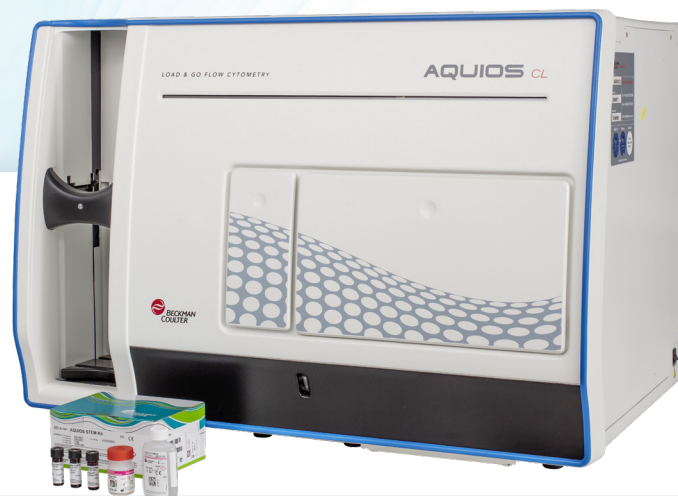
Sample ID: 89351136189 Test: Stem Panel v1.0
Run Date: 01 Sep 2020 15:11:15 Analysis Date: 01 Sep 2020 15:28:09

Statistic	Value	Flag	Normal Range	Action Range
**CD34+ Viability Well 1 % (of total CD34+)	93.40%			
**CD34+ Viability Well 2 % (of total CD34+)	96.15%			
**AVG CD34+ Viability % (of total CD34+)	94.78%			
**Total CD34+ HPC Count Well 1 (cells/uL)	9.39			
**Total CD34+ HPC Count Well 2 (cells/uL)	8.76			
**AVG Total CD34+ HPC Count (cells/uL)	9.07			
**WBC Count Well 1 (cells/uL)	18,016.48			
**WBC Count Well 2 (cells/uL)	18,096.90			
**AVG WBC Count (cells/uL)	18,056.69			
**Sample Viability Well 1 % (of WBC)	99.18%			
**Sample Viability Well 2 % (of WBC)	99.20%			
**AVG Sample Viability % (of WBC)	99.19%			
**Total CD34+ HPC Count Negative Ctrl (cells/uL)	0.23			
**DF: Dilution Factor	4.00			
**AVG Total CD34+ HPC Count (cells/uL) (x DF)	36.29			
**AVG WBC Count (cells/uL) (x DF)	72,226.76			
**Viable Events Well 1	202,077			
**Viable Events Well 2	213,383			
**Viable Leukocytes Events Well 1	201,757			
**Viable Leukocytes Events Well 2	213,160			
**Viable CD34+ HPC Events Well 1	99			
**Viable CD34+ HPC Events Well 2	100			
**Viable CD34+ HPC Events Negative Ctrl	4			
**Single Beads Events Well 1	11,890			
**Single Beads Events Well 2	12,503			
**Single Beads Events Negative Ctrl	23,243			

Calculated

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

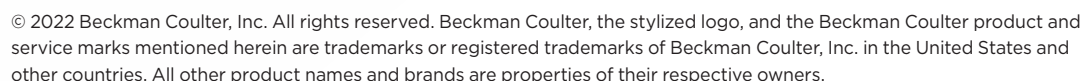
ORDER INFORMATION



INSTRUMENT	DESCRIPTION	REGULATORY STATUS	PART NUMBER
AQUIOS CL Flow Cytometry System (100-120v)	AQUIOS CL Flow Cytometry System with Uninterruptible Power Manager (100-120 V)	CE-IVD	B39101
AQUIOS CL Flow Cytometry System (220-240v)	AQUIOS CL Flow Cytometry System with Uninterruptible Power Manager (220-240 V)	CE-IVD	B39102
AQUIOS STEM UPGRADE KIT			
AQUIOS STEM Upgrade Kit	Includes AQUIOS STEM Software, Flow-Count Holder, and Adapter	CE-IVD	C89793
REAGENTS			
AQUIOS STEM Kit, 50 tests	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.	CE-IVD	B77691
AQUIOS STEM CD34 Control Cells, 2 levels, 15 tests each	AQUIOS STEM CD34 Control Cells are liquid preparations of stabilized human leukocytes for the verification of the parameters CD34 and CD45 as part of the AQUIOS STEM System. Each kit contains 2 levels of CD34 with approx. 10 CD34+ cells/ μ L (level 1) and approx. 30 CD34+ cells/ μ L (level 2).	CE-IVD	C43667
Flow-Check Beads, 3x10 mL	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.	CE-IVD	6605359

[illegible]

1. Sutherland DR, Anderson L, Keeney M, Nayar R, Chin-Yee I: **The ISHAGE guidelines for CD34+ cell determination by flow cytometry.** International Society of Hematotherapy and Graft Engineering. J Hematother. 1996 Jun;5(3):213-226.
2. Dorn-Beineke A, Sack U: **Quality control and validation in flow cytometry.** J Lab Med 2016; 40 s1:1-13.



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