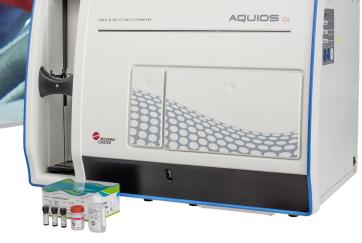
# YOU CAN HELP SAVE LIVES.WE'LL HELP YOU FIND LIVE STEM CELLS.







### 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. 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

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.



### **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



\* 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 control<sup>1</sup>, or as a single test. All panel combinations are part of the IVD solution without the need to create user-defined tests.



#### 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
Apheresis Product	15 min. after thawing	processed within 15
Bone Marrow	15 min. after thawing	minutes after thawing and kept on ice.

### **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 system<sup>2</sup>. 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.

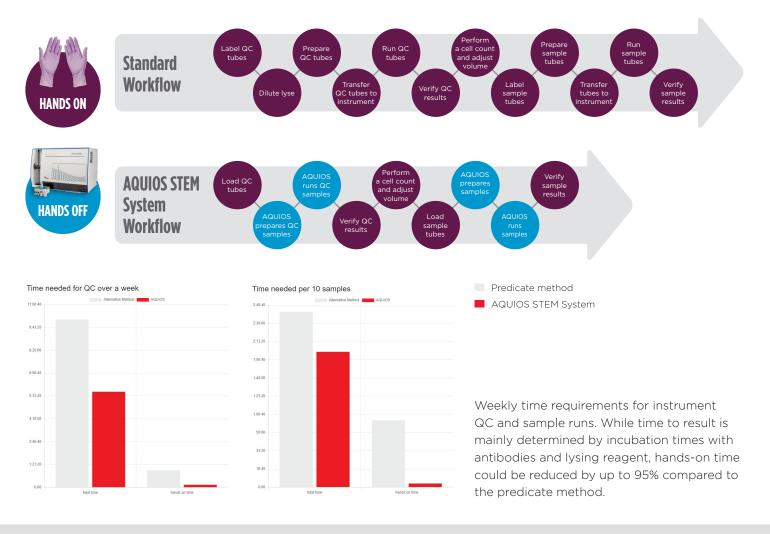


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### HOW THE AQUIOS STEM SYSTEM HELPS TO REDUCE MANUAL PROCESSING

#### 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.



#### Antibodies and reagents

AQUIOS STEM Kit contains enough reagents to analyze 50 samples in duplicate plus negative control<sup>\*\*</sup> 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/µL (Level 1)
- Approx. 30 CD34+ cells/µL (Level 2)

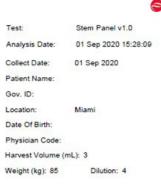
Assay values are entered into the system by scanning the barcode of the Control Cell Assay Sheet.

\*\* 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	800 SW 147th Ave., Miami, FL 33198				
Sample ID:	89351136189				
Run Date:	01 Sep 2020 15:11:15				
User:	Admin				
Specimen Type:	Whole Blood				
Patient ID:	89351136189				
Status:	Blast				
Gender:	M				
Physician:					
Instrument Serial #:	BC43072				
Report:	Summary				
Run Flags:					
Run Notifications:					
Comments:					

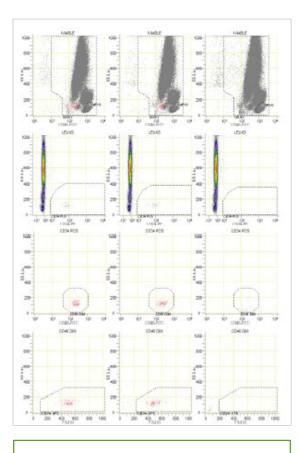


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#### Measured

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

Beckman Coulter



#### Calculated

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

Sample ID:	89351136189	Test:		Stem Pan	el v1	0
Run Date:	01 Sep 2020 15:11:15	Analysis	Date:	01 Sep 20	20 1	5:28:09
Result		Value	Flag	Normal F	nge	Action Range
Viable CD34+ H	PC Count Well 1 (cells/uL)	8.77				
	IPC Count Well 2 (cells/uL)	8.42				
	34+ HPC Count (cells/uL)	8.59				
	IPC % Diff (Well 1 vs Well 2)	2.01%				
	tes Count Well 1 (cells/uL)	17,867.97				
	tes Count Well 2 (cells/uL)	17,952.29				
	kocytes Count (cells/uL)	17,910.13 0.05%				
Leukocytes)	IPC Well 1 % (of Viable	0.05%	2			
Viable CD34+ H	PC Well 2 % (of Viable	0.05%				
Leukocytes)		0.05%				
	34+ HPC % (of Viable Leukocytes)	4.00				
DF: Dilution Fac	34+ HPC Count (cells/uL) (x DF)	34.38				
	kocyte Count (cells/uL) (x DF)	71,640.51				
HV: Harvest Vo		3.00				
	34+ HPC Count (x DF x HV)	103,137.59				
BW: Body Weig		85.00				
AVG Viable CD	34+ HPC Count per kg (x DF x HV	1,213.38				
( BW)						
CAL		1,053				
Viable CD34+ H	IPC Count Negative Ctrl (cells/uL)	0.18	3			
10800 SW 147th	Ave., Miami, FL 33196					8
Beckman Coulter 10800 SW 147th Sample ID:		Test		Stem Pan	el v1	0
10800 SW 147th	Ave., Miami, FL 33196	Test: Analysis	Date:	Stem Pan 01 Sep 20		Contract of the local sector of the local sect
10800 SW 147th Sample ID: Run Date: Statistic	Ave., Miami, FL 33198 89351136189 01 Sep 2020 15:11:15	Analysis	Flag		20 1	Contract of the local sector of the local sect
10800 SW 147th Sample ID: Run Date: Statistic **CD34+ Viabili	Ave., Miami, FL 33196 89351130189 01 Sep 2020 15:11:15 ty Well 1 % (of total CD34+)	Analysis Value 93.40%	Flag	01 Sep 20	20 1	5:28:09
10800 SW 147th Sample ID: Run Date: Statistic **CD34+ Viabili **CD34+ Viabili	Ave., Miami, FL 33198 89351130189 01 Sep 2020 15:11:15 ty Well 1 % (of total CD34+) ty Well 2 % (of total CD34+)	Analysis Value 93.40% 96.15%	Flag	01 Sep 20	20 1	5:28:09
10800 SW 147th Sample ID: Run Date: Statistic **CD34+ Viabili **CD34+ Viabili **AVG CD34+ V	Ave., Miami, FL 33198 89351130189 01 Sep 2020 15:11:15 ty Well 1 % (of total CD34+) ty Well 2 % (of total CD34+) //ability % (of total CD34+)	Analysis Value 93.40% 96.15% 94.78%	Flag	01 Sep 20	20 1	5:28:09
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10800 SW 147th Sample ID: Run Date: Statistic **CD34+ Viabili **AVG CD34+ **Total CD34+ **Total CD34+	Ave., Miami, FL 33198 89351130189 01 Sep 2020 15:11:15 ty Well 1 % (of total CD34+) Viability % (of total CD34+) HPC Count Well 1 (cells/uL) HPC Count Well 2 (cells/uL)	Analysis Value 93.40% 96.15% 94.78% 9.35 8.76	Flag	01 Sep 20	20 1	5:28:09
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10800 SW 147th Sample ID: Run Date: Statistic **CD34+ Viabili **CD34+ Viabili **Total CD34+ **Total CD34+ **Total CD34+ **Total CD34+ **Total CD34+	Ave., Miami, FL 33198 89351130189 01 Sep 2020 15:11:15 ty Well 1 % (of total CD34+) ty Well 2 % (of total CD34+) HPC Count Vell 1 (cells/uL) HPC Count Vell 1 (cells/uL) 034+ HPC Count Vell 2 (cells/uL) 034+ HPC Count Vell 2 (cells/uL)	Analysis Value 93.40% 96.15% 94.78% 9.33 8.76 9.37 9.37	Flag	01 Sep 20	20 1	5:28:09
10800 SW 147th Sample ID: Run Date: Statistic **CD34+ Viabili **CD34+ Viabili **AVG CD34+ **Total CD34+ **Total CD34+ **AVG Total CD **WBC Count V **WBC Count V **WBC Count V **WBC Count V	Ave., Miami, FL 33198 89351130189 01 Sep 2020 15:11:15 ty Well 1 % (of total CD34+) ty Well 2 % (of total CD34+) HPC Count Well 2 (cels/uL) HPC Count Well 2 (cels/uL) Vell 1 (cels/uL) Vell 1 (cels/uL) Vell 2 (cels/uL) Vell 2 (cels/uL)	Analysis Value 93.40% 96.15% 94.78% 9.36 8.76 9.37 9.30 18,016.48	Flag	01 Sep 20	20 1	5:28:09
10900 SW 147th Sample ID: Run Date: <b>Statistic</b> **CD34+ Viabili **CD34+ Viabili **CD34+ Viabili **AVG CD34+ **Total CD34+ **Total CD34+ **Total CD34+ **Total CD34+ **Total CD34+ **AVG Count V **WBC Count V **WBC Count V **WBC COUNT V **WBC COUNT V	Ave., Miami, FL 33198 89351130189 01 Sep 2020 15:11:15 ty Weil 1 % (of total CD34+) Yability % (of total CD34+) HPC Count Weil 2 (cells/uL) HPC Count (veil 2 (cells/uL)) HPC Count (cells/uL) Veil 2 (cells/uL) Veil 2 (cells/uL) Veil 2 (cells/uL) Veil 2 (cells/uL)	Analysis Value 93.40% 96.15% 94.78% 9.478% 9.07 18,016.44 18,096.05 18,056.65 99.18%	Flag	01 Sep 20	20 1	5:28:09
10800 SW 147th Sample ID: Run Date: <b>Statistic</b> **CD34+ Vlabili **CD34+ Vlabili **CD34+ Vlabili **Total CD34+ **Total CD34+ **Total CD34+ **AVG Total CD **WBC Count V **WBC Count V **Sample Vlabili **Sample Vlabili **Sample Vlabili	Ave., Miami, FL 33198 89351139189 01 Sep 2020 15:11:15 ty Well 1% (of total CD34+) y Well 2% (of total CD34+) HPC Count Well 1 (cells/uL) HPC Count Well 2 (cells/uL) 344 HPC Count (cells/uL) 344 HPC Count (cells/uL) 344 HPC Count (cells/uL) 144 HPC (cell	Analysis Value 93.40% 96.15% 94.78% 9.78% 9.75% 18,016.44 18,096.90 18,056.66 99.18% 99.20%	Flag	01 Sep 20	20 1	5:28:09
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10800 SW 147th Sample ID: Run Date: <b>Statistic</b> **CD34+ Vlabili **CD34+ Vlabili **CD34+ Vlabili **Total CD34+ **Total CD34+ **WBC Count V **WBC Count V **WBC Count V **WBC Count V **AVG Sample **Total CD34+ **Total CD34+	Ave., Miami, FL 33198 89351130189 01 Sep 2020 15:11:15 ty Weil 1 % (of total CD34+) Viability % (of total CD34+) HPC Count Weil 1 (cells/uL) HPC Count Veil 2 (cells/uL) 144+ HPC Count (cells/uL) 147+ HPC Count (cells/uL) 147+ HPC Count (cells/uL) 147+ HPC Count Negative Ctrl (cells/uL)	Analysis Value 93.40% 96.15% 94.78% 9.78% 9.93 8.77 9.00 18,016.44 18,096.90 18,056.65 99.18% 99.20% 99.19% 0.22	Flag	01 Sep 20	20 1	5:28:09
10800 SW 147th Sample ID: Run Date: <b>Statistic</b> **CD34+ Viabili **CD34+ Viabili **TOtal CD34+ **Total CD34+ **Total CD34+ **AVG Total CD34+ **AVG MBC Count V *WBC Count V *WBC Count V **WBC Count V **WBC Count V **WG BC Count V **AVG WBC Count V **AVG WBC Count V **AVG MBC Count V	Ave., Miami, FL 33198 89351130189 01 Sep 2020 15:11:15 ty Well 1 % (of total CD34+) ty Well 2 % (of total CD34+) HPC Count Well 1 (cels/uL) HPC Count Well 2 (cels/uL) 34+ HPC Count Kells/UL) Vell 1 (cels/uL) Vell 1 (cels/uL) vell 1 (cels/uL) ty Well 1 % (of WBC) try Well 2 % (of WBC) Viability % (of WBC) HPC Count Negative Ctrl (cels/uL) actor	Analysis Value 93.40% 94.78% 94.78% 9.33 8.76 9.07 18,016.44 18,096.95 18,056.65 99.18% 99.20% 99.20% 99.19% 0.22 4.00	Flag	01 Sep 20	20 1	5:28:09
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10800 SW 147th Sample ID: Run Date: Statistic **CD34+ Viabili **CD34+ Viabili **CO34+ Viabili **TOtal CD34+ **Total CD34+ **Total CD34+ **Total CD34+ **AVG WBC Count V *WBC Count V *WBC Count V *WBC Count V **WBC Count V **AVG WBC CC **Cample Viabili **Sample Viabili **Sample Viabili **Sample Viabili **Sample Viabili **Sample Viabili **Total CD34+ **Total CD34+ **Total CD34+ **Total CD34+ **Total CD34+ **Total CD34+ **AVG WBC CC **Viable Events	Ave., Miami, FL 33198 89351136189 01 Sep 2020 15:11:15 ty Well 1 % (of total CD34+) ty Well 2 % (of total CD34+) HPC Court Well 1 (cells/uL) HPC Court Well 1 (cells/uL) HPC Court (cells/uL) Vell 1 (cells/uL) vell 1 (cells/uL) vell 1 % (of WBC) ty Well 1 % (of WBC) ty Well 1 % (of WBC) HPC Court Negative Ctrl (cells/uL) ador 134+ HPC Court (cells/uL) (x DF) urt (cells/uL) (x DF)	Analysis Value 93.40% 94.78% 94.78% 9.33 8.76 9.07 18.016.44 18.096.99 18.056.66 9.9.18% 9.9.20% 9.9.20% 9.0.22 4.00 3.6.22 7.2,226.76 202,077	Flag	01 Sep 20	20 1	5:28:09
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10800 SW 147th Sample ID: Run Date: Statistic **CD34+ Vlabili **CD34+ Vlabili **CD34+ Vlabili **CD34 CD34+ **Total CD34+ **Total CD34+ **WBC Count V **WBC Count V **WBC Count V **WBC Count V **WBC Count V **WBC Count V **AVG Total CD **AVG Sample **Total CD34+ **Dratal Events **AVG WBC CC **Viable Events *Viable Leukoo *Viable Leukoo	Ave., Miami, FL 33198 89351130189 01 Sep 2020 15:11:15 ty Weil 1 % (of total CD34+) ty Weil 2 % (of total CD34+) HPC Count Weil 1 (cells/uL) HPC Count Weil 2 (cells/uL) 34+ HPC Count (cells/uL) Weil 1 (cells/uL) Weil 2 % (of WBC) ty Weil 4 % (of WBC) ty Weil 4 % (of WBC) HPC Count Negative Ctrl (cells/uL) actor At+ HPC Count (cells/uL) (x DF) unt (cells/uL) (x DF) Weil 1 Weil 2 Sytes Events Weil 1 Sytes Events Weil 2	Analysis Value 93.40% 94.78% 94.78% 94.78% 9.07 18.016.44 18.056.66 99.18% 99.20% 99.19% 99.20% 72.226.77 202.077 213.38 201.757 213.161	Flag 6 6 7 7 7 7 7 7 7 7 7 7 7 7 7	01 Sep 20	20 1	5:28:09
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10800 SW 147th Sample ID: Run Date: <b>Statistic</b> **CD34+ Viabili **CD34+ Viabili **CD34+ Viabili **AVG CD34+ **Total CD34+ **Total CD34+ **AVG Total CC **WBC Count V *WBC Count V *WBC Count V **WBC Count V **Vable Count V **AVG WBC CC **Viable Events *Viable Leukov *Viable CD34 **Viable CD34 **Viable CD34	Ave., Miami, FL 33198 89351130189 01 Sep 2020 15:11:15 ty Well 1 % (of total CD34+) ty Well 2 % (of total CD34+) HPC Count Vell 7 (cells/uL) HPC Count Vell 7 (cells/uL) HPC Count (cells/uL) 034+ HPC Count (cells/uL) 034+ HPC Count (cells/uL) 034+ HPC Count (cells/uL) well 7 % (of WBC) ty Well 2 % (of WBC) ty Well 2 % (of WBC) ty Well 2 % (of WBC) 14+ HPC Count (cells/uL) ador 134+ HPC Count (cells/uL) (x DF) unt (cells/uL) (x DF) Unt (cells/uL) (x DF) Well 1 Yeles Events Well 1 HPC Events Well 2 HPC Events Well 3 HPC Events Well 1 HPC Events Well 1 HPC Events Well 1	Analysis Value 93.40% 94.78% 94.78% 9.07 18.016.44 18.096.92 18.056.65 99.18% 99.20% 90.20% 202.21% 2	Flag 6 6 7 7 8 9 6 6 7 7 8 9 6 7 7 8 9 9 7 7 8 9 9 7 7 8 9 9 9 9 7 7 8 9 9 9 9 9 9 9 9 9 9 9 9 9	01 Sep 20	20 1	5:28:09
10800 SW 147th Sample ID: Run Date: Statistic **CD34+ Vlabili **CD34+ Vlabili **CD34+ Vlabili **CD34 Vlabili **Total CD34+ **Total CD34+ **Total CD34+ **Total CD34+ **WBC Count V **WBC Count V **Total CD34+ **Total CD34+ **Total CD34+ **Total CD34+ **Total CD34+ *Vlabie CD34+ *Vlabie CD34 *Vlabie CD34 **Single Beads	Ave., Miami, FL 33198 89351130189 01 Sep 2020 15:11:15 ty Well 1 % (of total CD34+) ty Well 2 % (of total CD34+) HPC Count Vell 7 (cells/uL) HPC Count Vell 7 (cells/uL) HPC Count (cells/uL) 034+ HPC Count (cells/uL) 034+ HPC Count (cells/uL) 034+ HPC Count (cells/uL) well 7 % (of WBC) ty Well 2 % (of WBC) ty Well 2 % (of WBC) ty Well 2 % (of WBC) 14+ HPC Count (cells/uL) ador 134+ HPC Count (cells/uL) (x DF) unt (cells/uL) (x DF) Unt (cells/uL) (x DF) Well 1 Yeles Events Well 1 HPC Events Well 2 HPC Events Well 3 HPC Events Well 1 HPC Events Well 1 HPC Events Well 1	Analysis Value 93.40% 94.76% 94.78% 94.78% 9.07 18,016.42 18,056.96 99.18% 99.19% 99.20% 99.19% 0.22 72,226,77 213,383 201,755 213,166 213,385 201,755 213,285 201,755 213,285 201,755 213,285 201,755 213,285 201,755 213,285 201,755 213,285 201,755 213,285 201,755 205	Flag 5 5 7 7 7 7 7 7 7 7 7 7 7 7 7	01 Sep 20	20 1	5:28:09

### **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 UPG	RADE 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/µL (level 1) and approx. 30 CD34+ cells/µL (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			

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#### References

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