



**Traditional 510(k) Summary**  
(in accordance with 21 CFR §807.92)  
BK180283

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**C. Date Prepared: July 23, 2019**

**D. Trade name: ADAMII™ CD34 System**

**Classification name:** Automated Differential Cell Counter

**Classification:** 21 CFR §862.5220, Product code GKZ, Class II

**E. Predicate device:** BD Stem Cell Enumeration Kit (BK110037; for use on the BD flow cytometer FACSCantoII or FACSCalibur)

**F. Indications for Use:**

The ADAMII™ CD34 System includes the ADAMII™-CD34 Kit which is designed for use with the ADAMII™ Instrument, a benchtop image-based fluorescence cell counter. The ADAMII™ CD34 System provides enumeration of viable CD34 cells/μL, viable CD45+ cells/μL, and calculates viable % CD34+ of viable CD45+ for the following fresh samples: mobilized peripheral blood (MPB) collected in Na-Heparin or EDTA and haematopoietic progenitor cell – apheresis (HPC-A) collected in ACD or ACD+Heparin.

The ADAMII™ CD34 System is intended for use in clinical laboratories and for in vitro diagnostic use only. It is not intended for use in point-of-care settings.

**Device Description**

ADAMII-CD34 Kit utilizes mixing sample with fluorescence-labeled antibodies and nucleic acid staining dye. The fluorescence-labeled antibodies bind specifically to the CD34+ and CD45+ cell

surface and dead cells are stained by nucleic acid staining dye. Lysis solution is added and the lysed sample is loaded into the precision stage of ADAM II instrument.

The ADAMII-CD34 Kit includes the following components:

- ADAMII-CD34 Reagent solution
- ADAMII Calibration bead
- RBC Lysis Buffer
- ADAMII Assay slide

The ADAMII Instrument 4-channel bench top assay platform using an Image-Based Fluorescence cell counter supplied with an all-in-one PC containing the software of graphical user interface. CCD detection is based on quantitative fluorometric assay technology capable of quantifying single or multiple fluorophore(s) by measuring LED-induced fluorescence from stained cells in a single-use disposable slide. Software controls the graphical user interface, communication with hardware, database management and data analysis. The software also controls the functions of the mechanical components including the motor, laser and printer control and acquisition of data from the sensor. The following parameters are generated and the results displayed (1) Viable CD34 cells/ $\mu\text{L}$ , (2) Viable CD45+ cells/ $\mu\text{L}$ , (3) Total CD34+ cells/ $\mu\text{L}$ , (4) CD34 Viability (%), and (5) Viable CD34+ of Viable CD45+ (%).

## G. Substantial Equivalence Discussion

An overview of the similarities and differences between the ADAMII™-CD34 Kit and the predicate is provided in the Tables 1 – 3 below.

**Table 1 General**

	ADAMII™ CD34 System	BD Stem Enumeration Kit BK110037
Indications for Use	<p>The ADAMII™ CD34 System includes the ADAMII™-CD34 Kit which is designed for use with the ADAMII™ Instrument, a benchtop image-based fluorescence cell counter. The ADAMII™ CD34 System provides enumeration of viable CD34 cells/<math>\mu\text{L}</math>, viable CD45+ cells/<math>\mu\text{L}</math>, and calculates viable % CD34+ of viable CD45+ for the following fresh samples: mobilized peripheral blood (MPB) collected in Na-Heparin or EDTA and haematopoietic progenitor cell – apheresis (HPC-A) collected in ACD or ACD+Heparin.</p> <p>The ADAMII™ CD34 System is intended for use in clinical laboratories and for in vitro diagnostic use only. It is not intended for use in point-of-care settings.</p>	<p>The BD™ Stem Cell Enumeration (SCE) kit provides simultaneous enumeration of viable dual-positive CD45+/CD34+ hematopoietic stem cell populations in CD34+ absolute counts (cells/<math>\mu\text{L}</math>) as well as the percentage of the total leucocyte count that is CD34+ (%CD34). The following specimens can be analyzed with this kit: normal and mobilized peripheral blood, fresh and thawed leucopheresis products, fresh and thawed bone marrow, and fresh and thawed cord blood. The kit is intended for in vitro diagnostic (IVD) use on either a BD FACSCalibur™ flow cytometer using BD CellQuest™ or BD CellQuest™ Pro software or a BD FACSCanto™ II flow cytometer using BD FACSCanto™ software.</p>
Principle Method/Technology	This assay is performed by staining the	This assay is performed by staining the sample with the reagent in

	<p>sample with the reagent and loaded into an individual ADAMII™ assay slide for absolute counts. When a sample is mixed with reagent, the fluorochrome labeled antibodies and nucleic acid dyes bind specifically to the cell surface and dead cell nucleic acids. Lysis buffer is added to lyse erythrocytes before the sample is loaded into an assay slide. The slide is placed on the precision stage of ADAMII™ Instrument, an image-based fluorescence cell counter. Focusing with a manual knob and starting image captures of the stained cells trigger automatic processes, calculating concentration of viable CD34+ cells and viable CD45+ cells, and the percentage of viable CD34+ cells in the CD45+ cell population is calculated.</p>	<p>individual BD Trucount tubes for absolute counts. When a sample is added to the reagent, the fluorochrome labeled antibodies in the reagent bind specifically to the cell surface. Additionally, the lyophilized pellet in the BD Trucount tubes dissolves, releasing a known number of fluorescent beads. Ammonium chloride is added to lyse erythrocytes before the sample is acquired on a flow cytometer. The dye 7-AAD is added to assess viability of the cells. Cells that are 7-AAD+ are not viable. During analysis of the sample, the concentration of viable CD34+ cells and viable CD45+ cells, and the percentage of viable CD34+ cells in the viable CD45+ cell population, are calculated.</p>
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**Table 2 Reagent Kits and Sample**

	ADAMII™-CD34 Kit	BD Stem Cell Enumeration Kit
Sample type/anticoagulants	MPB: EDTA; Na-Heparin HPC-A: ACD, ACD+Heparin	Anticoagulants include ACD-A and heparin; also EDTA  For leucopheresis, a mixture of ACD-A, heparin, and EDTA can also be used with this assay
Parameters in: ADAMII™ Indications for Use/ BD Principle/Methods	Viable CD34 cells/μL Viable %CD34 of viable CD45 Viable CD45 cells/μL	Viable CD34 cells/μL Viable %CD34 in viable CD45  Viable CD45
Other parameters measured and outputted <sup>1</sup>	Total CD34 CD34 viability % Total CD45 CD45 viability %	Total CD34 CD34 viability % Total CD45 CD45 viability %
Kit components	Ab reagent solution: CD34-PE/CD45-PerCP/Sytox Blue Calibration bead 10x Lysis Buffer ADAMII™ assay slide	CD45FITC/CD34PE reagent; 7-AAD reagent  Ammonium chloride lysing solution BD Trucount tubes
Measuring range	MPB: >1 – 100 viable CD34 cells/μL HPC-A: >1 – 1000 viable CD34 cells/μL  MPB: >2,500 – 50,000 viable CD45 cells/μL HPC-A: >4,800 – 355,000 viable CD45 cells/μL	CD34+ cells: 0 – 1,000 cells/μL  No measuring claim for CD45 cells

Measuring time	10 – 15 min/test	
Testing sample volume	20 µL	100 µL
Measuring volume	~8 µL	Not reported
Sample stability	24 hours	24 hours
Stain sample stability	1 hour on wet ice	1 hour on ice
Interfering conditions	<p>No interference was observed in samples with up to 5% gamma globulin.</p> <p>No interference was observed in samples with up to 20 mg/dL of bilirubin.</p> <p>No interference was observed in HPC-A samples with up to 500 mg hemoglobin.</p> <p>No interference was observed in MPB samples with up to 150 mg hemoglobin.</p> <p>It is recommended that hemolyzed samples not be tested.</p>	<p>Do not use previously fixed and stored specimens. Reject hemolyzed, clotted, or clumped specimens.</p>

**Table 3 Instruments**

	ADAMII™ Instrument	BD FACSCanto II	BD FACSCalibur
Voltage	100~240V, 1.5A, 50~60 Hz	100/115/230 VAC (50–60 Hz) 5A at 115 VAC; 2.5A at 230 VAC	120 VAC ±10%, 50/60 Hz ±2 Hz
Objective Lens	10x	NA	NA
Method of detection	High sensitivity monochrome CCD LED: Bright, Green (FITC) Yellow (PE) Red (PerCP)	Three lasers:  488 nm; 20 mW 633 nm; 17 mW 405 nm; 30 mW	488 nm; 15 mW Optional 635 nm
Configurable for output	No	Yes	Yes
Filter	FITC Ex 466/460, Em 550/50 PE Ex 525/50, Em 572/28-25 PerCP BLP01-635R (650 long pass)	FITC <100 MESF PE <50 MESF  PE-Cy™7 (525, 575, 678 or 695, 785 nm)	530 nm (FITC) 585 nm (PE/PI) >670 nm (PerCP) with base Unit
Weight	19.3 kg	≤146 kg	109 kg
Size	300W x 420L x 370H mm	64H x 91W x 61D cm	91.4H x 61.5W x 67.3D cm

## H. Summary of Performance Data:

### 1. Method Comparison – Accuracy

Samples were collected from 4 sites – two in the U.S. and 2 in Korea.

Three sites conducted testing using the FACSCantoII; one site conducted testing using the FACSCalibur.

Viable CD45 cells (1000 cells/ $\mu$ L) were assessed as part of the analysis of viable CD34 cells/ $\mu$ L and %CD34 of CD45 (Group 1) and viable CD45 (1000 cells/ $\mu$ L) were assessed alone (Group 2).

Sample sizes tested:

The sample numbers tested were as follows:

	Group 1	Group 2
• MPB EDTA:	viable CD34 cells/ $\mu$ L N=141	viable CD45 (1000 cells/ $\mu$ L) N=139
• MPB Na-Heparin	viable CD34 cells/ $\mu$ L N=107 N=248	viable CD45 (1000 cells/ $\mu$ L) N=107 N=246
• HPC-A ACD:	viable CD34 cells/ $\mu$ L N=213	viable CD45 (1000 cells/ $\mu$ L) N=209
• HPC-A ACD+Heparin	viable CD34 cells/ $\mu$ L N=169 N=382	viable CD45 (1000 cells/ $\mu$ L) N=167 N=376
• Total	N=630	N=622

### *Bias Compared with Predicate Method*

**Table 4 Mean Bias – MPB**

Parameters	N	Absolute Difference		Relative Difference to Predicate (%)	
		Mean Absolute Bias	95% CI	Mean Relative Bias	95% CI
<b>Pooled</b>					
Viable CD34 cells/ $\mu$ L	248	0.283	-0.08 to 0.65	1.82%	0.35% to 3.29%
%CD34 in CD45	248	0	0 to 0	-0.67%	-2.31% to 0.98%
Viable CD45 (1000 cells/ $\mu$ L)	248	0.49	0.30 to 0.67	2.24%	1.49% to 2.99%
Viable CD45 (1000 cells/ $\mu$ L) only	246	0.48	0.30 to 0.67	2.24%	1.49% to 3.00%
<b>Low</b>					
Viable CD34 cells/ $\mu$ L	99	0.59	0.216 to 0.973	4.40%	1.140% to 7.653%
%CD34 in CD45	99	0.004	-0.0002 to 0.007	1.85%	-1.717% to 5.421%
Viable CD45 (1000 cells/ $\mu$ L)	99	0.31	0.062 to 0.567	1.82%	0.393% to 3.243%
Viable CD45 (1000 cells/ $\mu$ L) only	65	0.28	0.134 to 0.429	3.73%	2.028% to 5.432%
<b>Mid</b>					
Viable CD34 cells/ $\mu$ L	84	0.20	-0.391 to 0.794	0.29%	-1.419% to 2.004%
%CD34 in CD45	84	-0.002	-0.008 to 0.003	-2.03%	-3.994% to -0.075%
Viable CD45 (1000 cells/ $\mu$ L)	84	0.41	0.098 to 0.730	2.52%	1.330% to 3.703%
Viable CD45 (1000 cells/ $\mu$ L) only	91	0.24	0.005 to 0.469	1.26%	-0.032% to 2.549%
<b>High</b>					
Viable CD34 cells/ $\mu$ L	65	-0.09	-1.125 to 0.949	-0.13%	-1.392% to 1.125%
%CD34 in CD45	65	-0.01	-0.021 to -0.003	-2.74%	-4.561% to -0.909%
Viable CD45 (1000 cells/ $\mu$ L)	65	0.84	0.407 to 1.274	2.51%	1.358% to 3.669%
Viable CD45 (1000 cells/ $\mu$ L) only	90	0.88	0.441 to 1.311	2.17%	1.130% to 3.210%

**Table 5 Mean Bias – HPC-A**

Parameters	N	Absolute Difference		Relative Difference to Predicate (%)	
		Mean Absolute Bias	95% CI	Mean Relative Bias	95% CI
<b>Pooled</b>					
Viable CD34 cells/μL	382	1.67	-2.24 to 5.57	0.84%	0.11% to 1.57%
%CD34 in CD45	382	0.01	0 to 0.01	2.25%	1.29% to 3.21%
Viable CD45 (1000 cells/μL)	382	-2.35	-3.35 to -1.36	-1.32%	-2.04% to -0.60%
Viable CD45 (1000 cells/μL) only	376	-2.17	-3.12 to -1.22	-1.29%	-2.02% to -0.56%
<b>Low</b>					
Viable CD34 cells/μL	94	2.34	0.073 to 4.617	2.21%	0.434% to 3.987%
%CD34 in CD45	94	0.004	-0.006 to 0.014	3.36%	0.860% to 5.869%
Viable CD45 (1000 cells/μL)	94	-1.42	-2.584 to -0.265	-0.69%	-2.236% to 0.860%
Viable CD45 (1000 cells/μL) only	89	0.36	-0.331 to 1.061	1.39%	-0.264% to 3.047%
<b>Mid</b>					
Viable CD34 cells/μL	150	5.08	-0.961 to 11.119	1.04%	-0.183% to 2.265%
%CD34 in CD45	150	0.005	-0.003 to 0.013	2.43%	0.946% to 3.908%
Viable CD45 (1000 cells/μL)	150	-2.17	-3.862 to -0.486	-1.39%	-2.683% to -0.090%
Viable CD45 (1000 cells/μL) only	177	-2.94	-4.187 to -1.689	-2.65%	-3.761% to -1.541%
<b>High</b>					
Viable CD34 cells/μL	138	-2.51	-11.026 to 6.001	-0.31%	-1.215% to 0.602%
%CD34 in CD45	138	0.006	-0.004 to 0.015	1.30%	0.028% to 2.574%
Viable CD45 (1000 cells/μL)	138	-3.18	-5.113 to -1.255	-1.67%	-2.633% to -0.702%
Viable CD45 (1000 cells/μL) only	110	-2.99	-5.470 to -0.504	-1.27%	-2.273% to -0.274%

**Regression Analysis**

**Table 6 Sample types pooled**

	R <sup>2</sup>	Slope/95% CI	Intercept/95% CI
<b>MPB (pooled)</b>			
Viable CD34 cells/μL	0.99	0.997 (0.985 - 1.009)	0.317 (-0.017 - 0.641)
%CD34 of CD45	0.99	1.000 (0.968 - 1.000)	0 (0 - 0.003)
Viable CD45 (1000 cells/μL)	0.99	1.018 (1.008 - 1.030)	0.111 (-0.072 - 0.249)
Viable CD45 (1000 cells/μL) only	0.99	1.019 (1.007 - 1.031)	0.099 (-0.073 - 0.252)
<b>HPC-A (pooled)</b>			
Viable CD34 cells/μL	0.99	0.998 (0.989 - 1.007)	2.237 (-2.033 - 6.029)
%CD34 of CD45	0.98	1.000 (0.983 - 1.007)	0.010 (0.006 - 0.013)
Viable CD45 (1000 cells/μL)	0.99	0.982 (0.972 - 0.992)	0.760 (0 - 1.495)
Viable CD45 (1000 cells/μL) only	0.99	0.982 (0.972 - 0.992)	0.768 (-0.002 - 1.506)

**Table 7 Sample type/anticoagulant pooled**

	R <sup>2</sup>	Slope/95% CI	Intercept/95% CI
<b>MPB EDTA pooled</b>			
Viable CD34 cells/μL	0.99	1.000 (0.983 - 1.018)	0.324 (-0.013 - 0.874)
%CD34 of CD45	0.99	1.000 (0.952- 1.000)	0 (0 - 0.005)
Viable CD45 (1000 cells/μL)	0.99	1.011 (0.995 - 1.027)	0.203 (0.012 - 0.529)
Viable CD45 (1000 cells/μL) only	0.99	1.011 (0.993 - 1.030)	0.201 (-0.030 - 0.544)
<b>MPB Na- Heparin pooled</b>			
Viable CD34 cells/μL	0.99	0.991 (0.974 - 1.008)	0.308 (-0.098 - 0.793)
%CD34 of CD45	0.97	1.000 (0.960 - 1.000)	0 (0 - 0.003)
Viable CD45 (1000 cells/μL)	0.99	1.027 (1.011 - 1.041)	-0.073 (-0.332 - 0.120)
Viable CD45 (1000 cells/μL) only	0.99	1.027 (1.011 - 1.041)	-0.073 (-0.332 - 0.200)
<b>HPC-A ACD pooled</b>			
Viable CD34 cells/μL	0.99	0.997 (0.985 - 1.009)	3.541 (-2.208 - 7.543)
%CD34 of CD45	0.97	0.985 (0.964-1.000)	0.014 (0.010- 0.024)
Viable CD45 (1000 cells/μL)	0.99	0.982 (0.967 -0.998)	0.627 (-0.197- 1.338)
Viable CD45 (1000 cells/μL) only	0.99	0.984 (0.969 - 1.000)	0.529 (-0.286 - 1.290)
<b>HPC ACD+Heparin pooled</b>			
Viable CD34 cells/μL	0.99	0.998 (0.985 - 1.013)	1.395 (-4.606 - 5.792)
%CD34 of CD45	0.98	1.002 (0.992 - 1.028)	0.008 (-0.002 - 0.011)
Viable CD45 (1000 cells/μL)	0.99	0.978 (0.964 - 0.992)	1.487 (-0.218 - 3.046)
Viable CD45 (1000 cells/μL) only	0.99	0.975 (0.960 - 0.990)	1.729 (-0.038 - 3.213)



**Table 8 MPB by anticoagulant Low, Mid, High**

	R <sup>2</sup>	Slope/95% CI	Intercept/95% CI
<b>MPB EDTA</b>			
Low			
Viable CD34 cells/μL	0.91	1.065 (0.993- 1.181)	-0.293 (-1.623 -0.759)
%CD34 of CD45	0.99	1.000 (0.984 - 1.071)	0 (-0.004 - 0.002)
Viable CD45 (1000 cells/μL)	0.97	1.036 (0.970 - 1.096)	-0.074 (-0.636 – 0.656)
Viable CD45 (1000 cells/μL) only	0.93	1.059 (0.9754 – 1.140)	-0.009 (-0.721 - 0.667)
Mid			
Viable CD34 cells/μL	0.90	1.021 (0.939-1.123)	-0.551 (-3.938- 2.314)
%CD34 of CD45	1.00	1.000 (0.948 - 1.052)	0 (-0.013 - 0.006)
Viable CD45 (1000 cells/μL)	0.99	1.009 (0.983 - 1.038)	0.310 (-0.067 - 0.836)
Viable CD45 (1000 cells/μL) only	0.92	1.047 (0.978 - 1.121)	-0.322 (-1.616 - 0.780)
High			
Viable CD34 cells/μL	0.97	1.038 (0.983 - 1.121)	-2.733 (-9.199 - 2.104)
%CD34 of CD45	1.00	0.945 (0.913 - 1.000)	0.008 (-0 .005 - 0.017)
Viable CD45 (1000 cells/μL)	1.00	1.003 (0.982 -1.025)	0.282 (-0.385 - 0.879)
Viable CD45 (1000 cells/μL) only	0.95	1.017 (0.964 - 1.099)	-0.153 (-2.806 - 1.649)
<b>MPB Na- Heparin</b>			
Low			
Viable CD34 cells/μL	0.92	0.975 (0.905 - 1.068)	0.506 (-0.363 - 1.305)
%CD34 of CD45	0.94	1.001 (0.995 - 1.153)	0.0 (-0.013 - 0.001)
Viable CD45 (1000 cells/μL)	1.00	1.032 (1.000 - 1.064)	-0.003 (-0.427 - 0.329)
Viable CD45 (1000 cells/μL) only	0.96	0.988 (0.917 - 1.075)	0.317 (-0.375 - 0.749)
Mid			
Viable CD34 cells/μL	0.91	1.004 (0.877- 1.157)	-0.119 (-5.281 - 3.831)
%CD34 of CD45	0.97	0.998 (0.903 - 1.000)	-0.010 (-0.026 - 0.010)
Viable CD45 (1000 cells/μL)	0.99	0.983 (0.937- 1.036)	0.361 (-0.505- 1.231)
Viable CD45 (1000 cells/μL) only	0.97	1.061 (1.001 - 1.143)	-0.857 (-2.614 - 0.366)
High			
Viable CD34 cells/μL	0.97	0.978 (0.919 - 1.040)	1.463 (-3.604 - 6.048)
%CD34 of CD45	0.96	0.998 (0.903 - 1.000)	0 (0 – 0.018)
Viable CD45 (1000 cells/μL)	0.98	1.034 (0.991 - 1.084)	-0.275 (-2.073- 1.092)
Viable CD45 (1000 cells/μL) only	0.96	1.050 (0.991 - 1.126)	-1.1 (-4.3 - 1.2)

**Table 9 HPC-A by anticoagulant Low, Mid, High**

	R <sup>2</sup>	Slope/95% CI	Intercept/95% CI
<b>HPC-A ACD</b>			
Low			
Viable CD34 cells/μL	0.98	1.027 (0.987 - 1.071)	0.994 (-5.650 - 4.904)
%CD34 of CD45	0.98	0.974 (0.935 - 1.019)	0.010 (0.000 - 0.022)
Viable CD45 (1000 cells/μL)	0.98	0.973 (0.935 - 1.010)	0.970 (0.074 - 2.474)
Viable CD45 (1000 cells/μL) only	0.96	1.028 (0.999 - 1.059)	-0.084 (-0.977 - 0.581)
Mid			
Viable CD34 cells/μL	0.90	1.014 (0.977 - 1.070)	-3.762 (-25.41 - 13.56)
%CD34 of CD45	0.96	0.977 (0.946 - 1.003)	0.019 (0.009 - to 0.030)
Viable CD45 (1000 cells/μL)	0.99	0.985 (0.958 - 1.011)	0.518 (-0.787- 2.459)
Viable CD45 (1000 cells/μL) only	0.94	0.969 (0.916 - 1.022)	-0.312 (-5.790 - 5.351)
High			
Viable CD34 cells/μL	0.95	1.004 (0.942 to 1.075)	-4.607 (-73.94 - 53.09)
%CD34 of CD45	0.97	0.986 (0.933-1.028)	0.017 (-0.002- 0.043)
Viable CD45 (1000 cells/μL)	0.98	1.010 (0.9725 - 1.055)	-4.655 (-11.90 - 0.756)
Viable CD45 (1000 cells/μL) only	0.96	1.002 (0.940 - 1.081)	-1.354 (-19.11 - 11.40)
<b>HPC-A ACD+Heparin</b>			
Low			
Viable CD34 cells/μL	0.97	1.060 (0.944 - 1.043)	1.060 (-3.522 - 5.460)
%CD34 of CD45	0.96	0.992 (0.947 - 1.066)	0.002 (-0.003 - 0.010)
Viable CD45 (1000 cells/μL)	0.99	0.965 (0.938- 1.000)	0.619 (-0.590- 2.911)
Viable CD45 (1000 cells/μL) only	0.98	0.996 (0.9479 - 1.043)	0.305 (-0.997 - 2.900)
Mid			
Viable CD34 cells/μL	0.93	0.999 (0.944 - 1.066)	0.803 (-28.14 - 24.79)
%CD34 of CD45	0.97	0.995 (0.937 - 1.027)	0.011 (0 - 0.027)
Viable CD45 (1000 cells/μL)	0.97	0.967 (0.927 - 1.003)	3.098 (-1.012 - 7.561)
Viable CD45 (1000 cells/μL) only	0.90	1.018 (0.907 - 1.139)	-1.851 (-15.68 - 10.27)
High			
Viable CD34 cells/μL	0.93	1.003 (0.945- 1.071)	-1.740 (-58.09 - 49.72)
%CD34 of CD45	0.98	1.029 (1.000 - 1.072)	-0.008 (-0.025 - 0.010)
Viable CD45 (1000 cells/μL)	0.99	0.978 (0.951 - 1.000)	1.770 (-2.198 - 7.225)
Viable CD45 (1000 cells/μL) only	0.96	0.999 (0.958 - 1.055)	-4.671 (-16.326- 4.996)

## 2. Precision

### Study 1

Estimates of assay precision were assessed at the NanoEnTek Research laboratory using two levels of control material with ranges of:

- >22.3 to ≤ 36.3 CD34 cells/μL
- >86.8 to ≤ 126.8 CD34 cells/μL)

Two replicates on two separate runs for 20 days were assessed for Repeatability (within-run), between-run, between-day, and within-laboratory precision.

**Table 10 Study 1 results**

CD34 Count Mean (cells/μL)	Repeatability		Between Run		Between Day		Within Laboratory	
	SD	CV	SD	CV	SD	CV	SD	CV
31.614	2.987	9.4%	0.000	0.0%	2.187	6.9%	3.702	11.7%
106.220	5.557	5.2%	0.000	0.0%	6.537	6.2%	8.580	8.1%

### Study 2

An additional single site study was conducted at the NanoEnTek Research laboratory using a lower control (range 9.7 – 17.7 CD34 cells/μL). Two replicates on two separate runs per day for 21 days were assessed.

**Table 11 Study 2 results**

CD34 Count Mean (cells/uL)	Repeatability		Between Run		Between Day		Within Laboratory	
	SD	CV	SD	CV	SD	CV	SD	CV
12.615	1.620	12.8%	1.006	8.0%	0.005	2.9%	1.942	15.4%
%CD34 of CD45 Mean	Repeatability		Between Run		Between Day		Within Laboratory	
	SD	CV	SD	CV	SD	CV	SD	CV
0.181	0.025	13.6%	0.016	8.6%	0.005	2.9%	0.030	16.4%
CD45 Count Mean (cells/uL)	Repeatability		Between Run		Between Day		Within Laboratory	
	SD	CV	SD	CV	SD	CV	SD	CV
6985.959	224.878	3.2%	140.769	2.0%	140.306	2.0%	300.120	4.3%

*Study 3*

An additional single site study was conducted at the NanoEnTek Research laboratory using 3 lots of reagents, 3 operator/instruments, using 3 levels of control:

**Table 12 Control ranges**

	CD34 cells/ $\mu$ L	CD34 %	CD45 cells/ $\mu$ L
Low	9.2-17.2	0.13-0.27	5600-7600
Med	25.6-39.6	0.39-0.59	5700-7700
High	92.2-132.2	1.32-1.92	5900-7900

Three replicates on two separate runs per day for 21 days were assessed for lot-to-lot, operator-to-operator, and instrument-to-instrument precision.

**Table 13 Instrument to Instrument**

Instrument-to-Instrument												
Sample	Mean Value	N	Repeatability		Between- Days		Between-Run		Between-Lot		Reproducibility	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low CD34 cells/uL	12.15	252	2.15	17.68	0.00	0.00	0.15	1.26	0.00	0.00	2.15	17.73
Low CD34%	0.18	252	0.03	18.08	0.00	0.00	0.00	0.00	0.00	0.00	0.03	18.08
Low CD45 cells	6910.66	249	65.03	0.94	12.52	0.18	0.00	0.00	0.00	0.00	75.43	1.09
Med CD34 cells/uL	32.20	252	3.33	10.34	0.71	2.21	0.44	1.37	0.46	1.43	3.46	10.76
Med CD34%	0.47	251	0.05	10.43	0.01	2.22	0.01	1.33	0.01	1.33	0.05	11.24
Med CD45 cells	6922.56	252	56.08	0.81	29.45	0.43	16.77	0.24	7.80	0.11	65.99	0.95
High CD34 cells/uL	110.99	252	7.17	6.46	0.00	0.00	0.00	0.00	0.24	0.21	7.18	6.47
High CD34%	1.61	252	0.10	6.41	0.01	0.41	0.00	0.00	0.01	0.47	0.10	6.44
High CD45 cells	6907.84	252	63.51	0.92	8.18	0.12	7.45	0.11	2.43	0.04	64.52	0.93

**Table 14 Lot-to-Lot**

Lot-to-Lot												
Sample	Mean Value	N	Repeatability		Between- Days		Between-Run		Between-Lot		Reproducibility	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low CD34 cells/uL	11.62	252	1.90	16.34	0.31	2.65	0.00	0.00	0.00	0.00	1.92	16.55
Low CD34%	0.17	252	0.03	16.92	0.00	2.76	0.00	0.00	0.00	0.00	0.03	17.14
Low CD45 cells	6954.45	249	87.61	1.26	8.38	0.12	0.00	0.00	0.00	0.00	98.02	1.41
Med CD34 cells/uL	34.09	252	3.45	10.12	0.00	0.00	0.00	0.00	0.00	0.00	3.45	10.12
Med CD34%	0.50	252	0.05	10.44	0.00	0.00	0.00	0.00	0.00	0.00	0.05	10.44
Med CD45 cells	6875.40	252	112.45	1.64	27.11	0.39	36.11	0.53	26.61	0.39	124.07	1.80
High CD34 cells/uL	114.66	251	6.13	5.35	1.24	1.08	1.68	1.46	1.61	1.40	6.98	6.09
High CD34%	1.66	251	0.09	5.66	0.01	0.89	0.02	1.46	0.03	1.61	0.11	6.42
High CD45 cells	6904.05	249	94.49	1.37	21.00	0.30	0.00	0.00	0.00	0.00	114.19	1.66

**Table 15 Operator-to-Operator**

Operator-to-Operator												
Sample	Mean Value	N	Repeatability		Between- Days		Between-Run		Between-Lot		Reproducibility	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low CD34 cells/uL	11.93	252	1.93	16.20	0.63	5.25	0.09	0.74	0.00	0.00	2.03	17.05
Low CD34%	0.17	252	0.03	16.28	0.01	5.61	0.00	1.97	0.00	0.00	0.03	17.33
Low CD45 cells	6932.55	250	79.01	1.14	6.41	0.09	0.00	0.00	11.64	0.17	84.24	1.21
Med CD34 cells/uL	32.11	252	3.34	10.39	0.00	0.00	0.00	0.00	0.42	1.32	3.36	10.47
Med CD34%	0.46	252	0.05	10.91	0.00	0.00	0.00	0.00	0.01	1.31	0.05	10.98
Med CD45 cells	6914.99	249	61.04	0.88	0.00	0.00	13.12	0.19	0.00	0.00	71.53	1.04
High CD34 cells/uL	109.78	251	6.58	5.99	0.00	0.00	0.00	0.00	0.00	0.00	6.75	6.15
High CD34%	1.58	251	0.09	5.93	0.00	0.00	0.00	0.00	0.00	0.00	0.10	6.08
High CD45 cells	6926.21	252	65.69	0.95	28.50	0.41	16.11	0.23	1.24	0.02	73.40	1.06

*Study 4*

A multi-site study was conducted at 3 external sites using 3 levels of control material with ranges of:

**Table 16 Control ranges**

	CD34 cells/ $\mu$ L	CD34 %	CD45 cells/ $\mu$ L
Low	9.7-17.7	0.12-0.26	5800-7800
Med	25.4-39.4	0.36-0.56	5900-7900
High	86.0-126.0	1.22-1.82	5900-7900

Three replicates on two separate runs per day for 5 days were assessed for between days, between runs, between sites and total Reproducibility %CV.

**Table 17 Study 4 results**

Sample	Mean Value	N	Repeatability		Between- Days		Between-Run		Between-Site		Reproducibility	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low CD34 cells/uL	12.2	90	1.76	14.5	0.6	4.9	0.59	4.8	1.29	10.6	2.3	19.2
Low CD34%	0.1752	90	0.025	14.4	0.008	4.3	0.009	4.9	0.018	10.1	0.033	18.9
Low CD45 cells	6942.1	90	143.52	2.1	56.78	0.8	0	0	0	0	154.3	2.2
Med CD34 cells/uL	32.11	90	3.26	10.2	1.17	3.6	0	0	1.41	4.4	3.7	11.6
Med CD34%	0.4612	90	0.046	10	0.015	3.3	0	0	0.02	4.3	0.052	11.4
Med CD45 cells	6960.3	90	122	1.8	9.5	0.1	0	0	24.2	0.3	124.7	1.8
High CD34 cells/uL	108.1	90	6.396	5.9	0	0	2.948	2.7	6.862	6.3	9.8	9.1
High CD34%	1.559	90	0.097	6.2	0.025	1.6	0.028	1.8	0.1	6.4	0.144	9.3
High CD45 cells	6937.3	90	114.308	1.6	36.779	0.5	40.102	0.6	0	0	126.6	1.8

*Study 5*

An Anticoagulant Interference Study was conducted that demonstrated that there was no statistically or clinically relevant differences between sample types/anticoagulants.

Single site testing at 3 sites was therefore conducted using 6 levels of HPC-A ACD clinical samples. One lot of reagent and one operator/instrument per site tested 3 replicates per sample over 6 runs in 24 hours (sample stability limit).

**Table 18 Study 5 results Site 1**

Target Concentration Viable CD34 cells/ $\mu$ L	Site 1			
	Parameters	Viable CD34 cells/ $\mu$ L	Viable CD45 cells/ $\mu$ L	Viable % CD34 of CD45
17 cells/ $\mu$ L	Mean	16.14	3270.04	0.50
	SD	2.22	230.65	0.09
	%CV	13.76%	7.05%	17.60%
35 cells/ $\mu$ L	Mean	36.78	6455.58	0.57%
	SD	3.23	443.08	0.05%
	%CV	8.78%	6.86%	9.49%
68 cells/ $\mu$ L	Mean	68.42	4648.85	1.48%
	SD	4.66	262.57	0.15%
	%CV	6.81%	5.65%	9.86%
100 cells/ $\mu$ L	Mean	92.69	5652.53	1.64%
	SD	5.39	234.42	0.12%
	%CV	5.82%	4.15%	7.25%
450 cells/ $\mu$ L	Mean	469.43	28077.02	1.67%
	SD	27.76	1762.08	0.08%
	%CV	5.91%	6.28%	4.95 %
960 cells/ $\mu$ L	Mean	893.36	75292.90	1.18%
	SD	41.29	2274.17	0.06%
	%CV	4.62%	3.02%	4.93%

**Table 19 Study 5 results Site 2**

Target Concentration Viable CD34 cells/ $\mu$ L	Site 2			
	Parameters	Viable CD34 cells/ $\mu$ L	Viable CD45 cells/ $\mu$ L	Viable %CD34 of CD45
17 cells/ $\mu$ L	Mean	16.91	3364.35	0.51%
	SD	2.05	271.88	0.06%
	%CV	12.15%	8.08%	12.14%
35 cells/ $\mu$ L	Mean	35.03	6494.72	0.54%
	SD	3.96	198.25	0.06%
	%CV	11.29%	3.05%	10.85 %
68 cells/ $\mu$ L	Mean	66.41	4036.08	1.65%
	SD	4.49	210.81	0.17%
	%CV	6.76%	5.22%	10.58 %
100 cells/ $\mu$ L	Mean	100.63	6650.66	1.52%
	SD	5.92	296.61	0.10%
	%CV	5.88%	4.46%	6.79 %
450 cells/ $\mu$ L	Mean	440.06	28360.64	1.55%
	SD	24.89	829.78	0.10%
	%CV	5.66%	2.93%	6.48 %
960 cells/ $\mu$ L	Mean	53124.13	977.56	1.84%
	SD	1566.41	43.31	0.06%
	%CV	2.95%	4.43%	3.36 %

**Table 20 Study 5 results Site 3**

Target Concentration Viable CD34 cells/ $\mu$ L	Site 3			
	Measuring parameters	Viable CD34 cells/ $\mu$ L	Viable CD45 cells/ $\mu$ L	Viable %CD34 of CD45
17 cells/ $\mu$ L	Mean	16.76	3325.93	0.50%
	SD	2.42	170.27	0.06%
	%CV	14.47%	5.12%	12.19%
35 cells/ $\mu$ L	Mean	32.05	19447.80	0.54%
	SD	3.31	1393.72	0.06%
	%CV	10.32%	7.17%	10.55 %
68 cells/ $\mu$ L	Mean	73.41	25862.38	0.28%
	SD	4.34	1400.05	0.01%
	%CV	5.91%	5.41%	5.00%
100 cells/ $\mu$ L	Mean	97.08	24993.61	0.39%
	SD	5.48	1066.57	0.02%
	%CV	5.65%	4.27%	5.74%
450 cells/ $\mu$ L	Mean	422.49	106235.80	0.40%
	SD	17.45	6060.55	0.03%
	%CV	4.13%	5.70%	7.21%
960 cells/ $\mu$ L	Mean	1002.17	44158.78	2.27%
	SD	23.76	2044.63	0.10%
	%CV	2.37%	4.63%	4.28%



### 3. Summary of Linearity

- MPB: >1 – >100 CD34 cells/μL
- HPC-A: >1 – >1000 CD34 cells/μL
- MPB: >2,500 – >50,000 viable CD45 cells/μL
- HPC-A: >4,800 – >355,000 viable CD45 cells/μL

### 4. Summary of Reagent Stability (Reagent Shelf-life)

Real-time stability testing for the CD34 reagent kit was performed. Kit component reagent stability was assessed for each kit components, and the Kit was observed to be stable up to 12 months.

### 5. Summary of Sample Stability

Age of stained sample and age of stored sample are 1 and 24 hours, respectively.

## **J. Proposed Labeling**

The labeling complies with 21 CFR §809.10. Symbols used in labeling comply with ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.

## **K. Compliance with standards and guidelines**

Testing complied with the following guidelines except where modifications were required by FDA:

- EN 61010-1:2010 (ed 3) Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements
- EN 61010-2-081:2001 (ed 1) +A1:2003 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
- EN 61010-2-101:2002 (ed 1) Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
- EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements
- EN 61326-2-6:2013 Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment
- CLSI EP05-A3, Evaluation of Precision Performance of Quantitative Measurement Methods
- CLSI EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures; A Statistical Approach; Approved Guideline
- CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline
- CLSI EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guidelines
- CLSI EP09-A3, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline (*withdrawn but current at time of testing*)

## **L. Conclusion**

The submitted information in this premarket notification is complete and supports a substantial equivalence determination when compared to the predicate device. The ADAMII™ CD34 System will perform as expected.