510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K160606

B. Purpose for Submission:

New quality control device to support the performance of the BC-5390 Auto Hematology Analyzer (K160429)

C. Measurand:

Complete blood count: WBC (10^3/µL), RBC (10^6/µL), HGB (g/dL), HCT (%), MCV (fL), MCH (pg), MCHC (g/dL), RDW-CV (%), RDW-SD, PLT (10^3/µL), MPV (fL). Leukocyte 5-part differential: Neu#, Lym#, Mon#, Eos#, Bas#, Neu%, Lym%, Mon%, Eos%, Bas%.

D. Type of Test:

Quantitative

E. Applicant:

R&D Systems, Inc.

F. Proprietary and Established Names:

BC-5D Hematology Controls

G. Regulatory Information:

1. Regulation section:

   21 CFR § 864.8625 Hematology quality control mixture

2. Classification:

   Class II

3. Product code:

   JPK

4. Panel:

Hematology (81)

H. Intended Use:

1. Intended use(s):

   BC-5D is an assayed whole blood control designed for Mindray BC-5390 (Mindray 5000 series) Auto Hematology Analyzer for the following parameters: WBC, Neu#, Lym#, Mon#, Eos#, Bas#, Neu%, Lym%, Mon%, Eos%, Bas%, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, and MPV.

2. Indication(s) for use:

   Same as intended use

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   Mindray BC-5390 Auto Hematology Analyzer

I. Device Description:

The BC-5D Hematology Control (also referred to as BC-5D) consists of three levels of controls (Low, Normal, and High). BC-5D is a stabilized *in vitro* diagnostic product composed of the following: human erythrocytes, mammalian leukocytes, and platelets suspended in a plasma-like fluid with preservatives.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   CBC-XE Hematology Control

2. Predicate 510(k) number(s):

   K042094

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Storage Conditions	Open-vial: 14 days Closed-vial: 75 days	Same

Differences		
Item	Device	Predicate
Intended use	BC-5D is an assayed whole blood control designed for Mindray BC-5390 (Mindray 5000 series) Auto Hematology Analyzer for the following parameters: WBC, Neu#, Lym#, Mon#, Eos#, Bas#, Neu%, Lym%, Mon%, Eos%, Bas%, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, and MPV.	R&D CBC-XE Hematology Control is a tri-level control designed for use in monitoring the accuracy and precision of Sysmex™ hematology instruments. Refer to assay sheet for specific instrument models.
Parameters	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, Bas#, Bas%, Neu#, Neu%, Eos#, Eos%, Lym#, Lym%, Mon#, Mon%, RDW-CV, RDW-SD, and MPV	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, PDW, MPV, P-LCR, IRF, Bas#, Bas%, Neu#, Neu%, Eos#, Eos%, Lym#, Lym%, Mon#, Mon%, RDW-CV, RDW-SD, NRBC%, and Ret%

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP05-A3: Evaluation of Precision Performance of Quantitative Measurement Procedures; Approved Guideline – Third Edition.

CLSI EP25-A: Evaluation of Stability of *In Vitro* Diagnostic Reagents; Approved Guideline.

L. Test Principle:

The BC-5D Hematology Control is a quality control material designed to monitor the performance of the BC-5390 Auto Hematology Analyzer.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   Estimates of precision were obtained from a multisite study where each site analyzed all levels of one lot of BC-5D Hematology Controls. At each site, each control level was analyzed over 20 days, two runs per day and two replicates per run. The final

dataset resulted in a total of 80 measurements per lot and control level (low, normal and high). The precision profile included the following variance components: repeatability (within-run), between-run, between-day, and total variability. The results of the precision studies met the performance specifications for each BC-5D Hematology Control level.

BC-5D Hematology Control Lot BC3V4

Parameter	Control Level	Mean	Within-run		Between-run		Between-day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
WBC ($10^3/\mu L$)	Low	3.393	0.061	1.80	0.038	1.10	0.017	0.50	0.074	2.20
	Normal	7.511	0.137	1.80	0.075	1.00	0.093	1.20	0.182	2.40
	High	16.011	0.217	1.40	0.082	0.50	0.16	1.00	0.282	1.80
Neu# ($10^3/\mu L$)	Low	1.726	0.043	2.50	0.017	1.00	0	0.00	0.047	2.70
	Normal	4.389	0.092	2.10	0.022	0.50	0.06	1.40	0.112	2.60
	High	10.327	0.17	1.60	0	0.00	0.1	1.00	0.197	1.90
Lym# ($10^3/\mu L$)	Low	1.324	0.039	3.00	0	0.00	0.015	1.10	0.042	3.20
	Normal	2.16	0.049	2.30	0.039	1.80	0	0.00	0.062	2.90
	High	3.071	0.068	2.20	0.052	1.70	0.013	0.40	0.087	2.80
Mon# ($10^3/\mu L$)	Low	0.185	0.016	8.70	0	0.00	0.005	2.50	0.017	9.10
	Normal	0.402	0.022	5.60	0.012	3.00	0	0.00	0.025	6.30
	High	0.965	0.039	4.00	0	0.00	0.016	1.60	0.042	4.30
Eos# ($10^3/\mu L$)	Low	0.158	0.012	7.90	0.008	5.00	0	0.00	0.015	9.30
	Normal	0.561	0.027	4.80	0.014	2.50	0.017	3.10	0.035	6.20
	High	1.647	0.065	3.90	0.042	2.60	0.01	0.60	0.078	4.70
Bas# ($10^3/\mu L$)	Low	0.787	0.017	2.20	0.016	2.10	0	0.00	0.023	3.00
	Normal	2.021	0.041	2.00	0.019	0.90	0.021	1.00	0.05	2.50
	High	4.916	0.069	1.40	0.012	0.20	0.05	1.00	0.086	1.80
Neu%	Low	50.77	0.93	1.80	0	0.00	0.23	0.50	0.96	1.90
	Normal	58.42	0.52	0.90	0.3	0.50	0	0.00	0.6	1.00
	High	64.52	0.45	0.70	0.3	0.50	0	0.00	0.55	0.80
Lym%	Low	38.97	0.96	2.50	0	0.00	0	0.00	0.96	2.50
	Normal	28.74	0.5	1.80	0.14	0.50	0.11	0.40	0.54	1.90
	High	19.19	0.38	2.00	0.18	0.90	0	0.00	0.41	2.20
Mon%	Low	5.51	0.43	7.90	0	0.00	0.09	1.50	0.44	8.00
	Normal	5.37	0.26	4.90	0.13	2.40	0	0.00	0.29	5.40
	High	6.02	0.25	4.10	0	0.00	0.06	1.00	0.26	4.30
Eos%	Low	4.75	0.33	6.90	0.21	4.40	0	0.00	0.39	8.20
	Normal	7.48	0.32	4.20	0.14	1.90	0.13	1.80	0.37	5.00
	High	10.27	0.37	3.60	0.23	2.20	0	0.00	0.43	4.20
Bas%	Low	23.19	0.39	1.70	0.17	0.70	0.1	0.40	0.43	1.90
	Normal	26.91	0.28	1.00	0.09	0.30	0	0.00	0.29	1.10
	High	30.7	0.14	0.50	0.03	0.10	0.08	0.30	0.17	0.50
RBC ($10^6/\mu L$)	Low	2.555	0.024	0.90	0	0.00	0.028	1.10	0.037	1.50
	Normal	4.7	0.046	1.00	0.37	0.80	0.074	1.60	0.094	2.00
	High	5.293	0.062	1.20	0	0.00	0.071	1.30	0.094	1.80
HGB (g/dL)	Low	6.05	0.06	0.90	0.04	0.60	0.07	1.20	0.1	1.70
	Normal	13.44	0.09	0.70	0.13	1.00	0.22	1.60	0.27	2.00
	High	16.89	0.15	0.90	0.1	0.60	0.25	1.50	0.31	1.90
HCT (%)	Low	19.19	0.18	1.00	0.16	0.80	0.18	1.00	0.3	1.60
	Normal	40.88	0.39	1.00	0.48	1.20	0.71	1.70	0.95	2.30
	High	50.91	0.56	1.10	0.26	0.50	0.89	1.80	1.09	2.10
MCV (fL)	Low	75.13	0.18	0.20	0.53	0.70	0	0.00	0.56	0.70

Parameter	Control Level	Mean	Within-run		Between-run		Between-day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
	Normal	86.97	0.16	0.20	0.58	0.70	0.23	0.30	0.64	0.70
	High	96.18	0.19	0.20	0.59	0.60	0.29	0.30	0.69	0.70
MCH (pg)	Low	23.62	0.2	0.80	0.03	0.10	0.06	0.20	0.21	0.90
	Normal	28.59	0.17	0.60	0.12	0.40	0	0.00	0.2	0.70
	High	31.89	0.23	0.70	0	0.00	0.05	0.20	0.23	0.70
MCHC (g/dL)	Low	31.44	0.26	0.80	0.09	0.30	0.12	0.40	0.3	1.00
	Normal	32.87	0.18	0.60	0.19	0.60	0.1	0.30	0.28	0.90
	High	33.16	0.22	0.70	0.14	0.40	0.03	0.10	0.27	0.80
RDW-CV (%)	Low	13.72	0.11	0.80	0.09	0.70	0.11	0.80	0.19	1.40
	Normal	13.52	0.1	0.70	0.04	0.30	0.08	0.60	0.13	1.00
	High	12.9	0.09	0.70	0.09	0.70	0.08	0.60	0.15	1.10
RDW-SD (fL)	Low	39.14	0.36	0.90	0.07	0.20	0.14	0.30	0.39	1.00
	Normal	44.26	0.25	0.60	0.13	0.30	0.26	0.60	0.39	0.90
	High	46.02	0.29	0.60	0.13	0.30	0.29	0.60	0.43	0.90
PLT (10^3/µL)	Low	51.8	3.4	6.60	0	0.00	1.6	3.00	3.8	7.30
	Normal	263.9	5.8	2.20	0.5	0.20	2.5	1.00	6.3	2.40
	High	513.4	8.5	1.60	3	0.60	0.9	0.20	9	1.80
MPV (fL)	Low	10.06	0.44	4.40	0	0.00	0	0.00	0.44	4.40
	Normal	10.66	0.14	1.30	0	0.00	0.06	0.60	0.16	1.50
	High	10.55	0.08	0.80	0.02	0.20	0.02	0.20	0.09	0.80

BC-5D Hematology Control Lot BC3V1

Parameter	Control Level	Mean	Within-run		Between-run		Between-day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
WBC (10^3/µL)	Low	3.169	0.072	2.3	0.042	1.3	0.048	1.5	0.097	3.0
	Normal	7.784	0.105	1.4	0.067	0.9	0.043	0.6	0.132	1.7
	High	16.176	0.150	0.9	0.130	0.8	0.000	0.0	0.199	1.2
Neu# (10^3/µL)	Low	1.675	0.051	3.1	0.038	2.3	0.030	1.8	0.071	4.2
	Normal	4.347	0.084	1.9	0.053	1.2	0.044	1.0	0.109	2.5
	High	10.465	0.128	1.2	0.135	1.3	0.005	0.0	0.186	1.8
Lym# (10^3/µL)	Low	1.175	0.040	3.4	0.000	0.0	0.013	1.1	0.042	3.6
	Normal	2.360	0.050	2.1	0.000	0.0	0.018	0.8	0.053	2.3
	High	3.074	0.066	2.2	0.053	1.7	0.032	1.0	0.091	2.9
Mon# (10^3/µL)	Low	0.157	0.015	9.4	0.005	2.9	0.000	0.0	0.015	9.8
	Normal	0.464	0.040	8.5	0.000	0.0	0.021	4.6	0.045	9.7
	High	1.046	0.041	3.9	0.004	0.4	0.016	1.5	0.044	4.2
Eos# (10^3/µL)	Low	0.161	0.018	11.1	0.000	0.0	0.004	2.4	0.018	11.4
	Normal	0.614	0.024	3.9	0.016	2.6	0.000	0.0	0.029	4.7
	High	1.591	0.051	3.2	0.000	0.0	0.032	2.0	0.060	3.8
Bas# (10^3/µL)	Low	0.719	0.021	2.9	0.010	1.4	0.010	1.4	0.026	3.6
	Normal	2.031	0.034	1.7	0.024	1.2	0.008	0.4	0.042	2.1
	High	4.943	0.052	1.1	0.047	1.0	0.000	0.0	0.071	1.4
Neu%	Low	52.77	0.99	1.9	0.57	1.1	0.00	0.0	1.14	2.2
	Normal	55.83	0.68	1.2	0.29	0.5	0.22	0.4	0.77	1.4
	High	64.71	0.53	0.8	0.37	0.6	0.25	0.4	0.69	1.1
Lym%	Low	37.02	1.06	2.9	0.36	1.0	0.20	0.5	1.14	3.1
	Normal	30.32	0.52	1.7	0.17	0.6	0.30	1.0	0.63	2.1
	High	19.03	0.40	2.1	0.35	1.8	0.07	0.4	0.53	2.8
Mon%	Low	5.03	0.41	8.2	0.08	1.5	0.00	0.0	0.42	8.3
	Normal	5.96	0.50	8.4	0.00	0.0	0.27	4.5	0.57	9.6
	High	6.44	0.24	3.7	0.07	1.2	0.10	1.6	0.27	4.2

Parameter	Control Level	Mean	Within-run		Between-run		Between-day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Eos%	Low	5.18	0.53	10.2	0.00	0.0	0.00	0.0	0.53	10.2
	Normal	7.89	0.27	3.4	0.21	2.6	0.00	0.0	0.34	4.3
	High	9.82	0.31	3.1	0.00	0.0	0.24	2.4	0.39	4.0
Bas%	Low	22.69	0.41	1.8	0.22	1.0	0.00	0.0	0.46	2.0
	Normal	26.09	0.29	1.1	0.11	0.4	0.03	0.1	0.31	1.2
	High	30.56	0.20	0.6	0.00	0.0	0.04	0.1	0.20	0.7
RBC (10^6/µL)	Low	2.178	0.020	0.9	0.000	0.0	0.010	0.5	0.022	1.0
	Normal	4.229	0.034	0.8	0.034	0.8	0.034	0.8	0.059	1.4
	High	5.019	0.039	0.8	0.038	0.8	0.047	0.9	0.072	1.4
HGB (g/dL)	Low	5.84	0.05	0.8	0.03	0.5	0.03	0.4	0.06	1.0
	Normal	12.10	0.06	0.5	0.07	0.6	0.12	1.0	0.16	1.3
	High	15.76	0.08	0.5	0.11	0.7	0.13	0.8	0.19	1.2
HCT (%)	Low	18.53	0.17	0.9	0.06	0.3	0.10	0.5	0.20	1.1
	Normal	37.79	0.29	0.8	0.31	0.8	0.36	1.0	0.56	1.5
	High	49.89	0.39	0.8	0.45	0.9	0.51	1.0	0.78	1.6
MCV	Low	85.12	0.17	0.2	0.28	0.3	0.39	0.5	0.51	0.6
	Normal	89.37	0.16	0.2	0.28	0.3	0.29	0.3	0.43	0.5
	High	99.42	0.18	0.2	0.31	0.3	0.18	0.2	0.40	0.4
MCH	Low	26.86	0.23	0.8	0.00	0.0	0.12	0.4	0.26	1.0
	Normal	28.62	0.21	0.7	0.10	0.4	0.00	0.0	0.24	0.8
	High	31.41	0.21	0.7	0.00	0.0	0.09	0.3	0.22	0.7
MCHC (g/dL)	Low	31.56	0.27	0.9	0.00	0.0	0.19	0.6	0.33	1.1
	Normal	32.03	0.23	0.7	0.09	0.3	0.12	0.4	0.28	0.9
	High	31.60	0.22	0.7	0.12	0.4	0.06	0.2	0.26	0.8
RDW-CV (%)	Low	14.27	0.15	1.1	0.14	1.0	0.17	1.2	0.26	1.9
	Normal	14.03	0.09	0.7	0.10	0.7	0.15	1.0	0.20	1.4
	High	14.24	0.10	0.7	0.12	0.9	0.10	0.7	0.19	1.3
RDW-SD (fL)	Low	44.04	0.41	0.9	0.09	0.2	0.24	0.5	0.49	1.1
	Normal	45.41	0.40	0.9	0.11	0.2	0.11	0.2	0.43	0.9
	High	50.08	0.38	0.8	0.00	0.0	0.16	0.3	0.42	0.8
PLT (10^3/µL)	Low	68.7	5.3	7.7	0.0	0.0	2.9	4.2	6.0	8.8
	Normal	253.7	5.5	2.2	3.7	1.5	7.0	2.8	9.6	3.8
	High	479.3	6.9	1.4	5.7	1.2	6.7	1.4	11.2	2.3
MPV (fL)	Low	11.59	0.66	5.7	0.00	0.0	0.33	2.9	0.74	6.4
	Normal	13.01	0.12	1.0	0.00	0.0	0.10	0.7	0.16	1.2
	High	12.94	0.12	0.9	0.00	0.0	0.02	0.2	0.12	0.9

BC-5D Hematology Control Lot BC3V3

Parameter	Control Level	Mean	Within-run		Between-run		Between-day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
WBC (10^3/µL)	Low	3.736	0.090	2.4	0.000	0.0	0.051	1.4	0.103	2.8
	Normal	8.392	0.117	1.4	0.066	0.8	0.038	0.5	0.140	1.7
	High	18.255	0.229	1.3	0.000	0.0	0.155	0.9	0.277	1.5
Neu# (10^3/µL)	Low	1.987	0.050	2.5	0.020	1.0	0.034	1.7	0.064	3.2
	Normal	4.778	0.079	1.7	0.023	0.5	0.024	0.5	0.086	1.8
	High	11.187	0.178	1.6	0.000	0.0	0.088	0.8	0.199	1.8
Lym# (10^3/µL)	Low	1.348	0.057	4.2	0.000	0.0	0.011	0.8	0.058	4.3
	Normal	2.654	0.055	2.1	0.054	2.0	0.013	0.5	0.078	2.9
	High	4.283	0.137	3.2	0.000	0.0	0.019	0.4	0.138	3.2
Mon# (10^3/µL)	Low	0.254	0.017	6.9	0.011	4.4	0.005	1.9	0.021	8.4
	Normal	0.534	0.040	7.5	0.017	3.1	0.022	4.2	0.049	9.1

Parameter	Control Level	Mean	Within-run		Between-run		Between-day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
	High	1.345	0.090	6.7	0.048	3.6	0.000	0.0	0.102	7.6
Eos# (10^3/µL)	Low	0.147	0.015	10.0	0.000	0.0	0.005	3.5	0.016	10.6
	Normal	0.425	0.023	5.3	0.012	2.8	0.011	2.6	0.028	6.5
	High	1.440	0.044	3.1	0.012	0.8	0.054	3.8	0.071	4.9
Bas# (10^3/µL)	Low	0.877	0.027	3.1	0.003	0.3	0.001	0.1	0.027	3.1
	Normal	2.172	0.032	1.5	0.028	1.3	0.016	0.7	0.045	2.1
	High	5.310	0.072	1.4	0.022	0.4	0.040	0.8	0.086	1.6
Neu%	Low	53.09	0.93	1.8	0.43	0.8	0.00	0.0	1.03	1.9
	Normal	56.93	0.53	0.9	0.32	0.6	0.00	0.0	0.62	1.1
	High	61.30	0.52	0.9	0.05	0.1	0.41	0.7	0.67	1.1
Lym%	Low	36.05	1.07	3.0	0.00	0.0	0.37	1.0	1.13	3.1
	Normal	31.61	0.48	1.5	0.34	1.1	0.23	0.7	0.63	2.0
	High	23.48	0.70	3.0	0.07	0.3	0.00	0.0	0.71	3.0
Mon%	Low	6.85	0.44	6.4	0.29	4.3	0.00	0.0	0.53	7.7
	Normal	6.38	0.45	7.1	0.21	3.4	0.28	4.3	0.57	9.0
	High	7.35	0.50	6.8	0.22	3.0	0.00	0.0	0.54	7.4
Eos%	Low	4.01	0.38	9.6	0.00	0.0	0.12	2.9	0.40	10.0
	Normal	5.08	0.27	5.3	0.12	2.4	0.13	2.5	0.32	6.3
	High	7.87	0.23	3.0	0.06	0.7	0.25	3.2	0.35	4.4
Bas%	Low	23.47	0.37	1.6	0.00	0.0	0.23	1.0	0.44	1.9
	Normal	25.88	0.26	1.0	0.15	0.6	0.11	0.4	0.32	1.2
	High	29.09	0.18	0.6	0.00	0.0	0.02	0.1	0.18	0.6
RBC (10^6/µL)	Low	2.532	0.029	1.2	0.013	0.5	0.010	0.4	0.034	1.3
	Normal	5.273	0.051	1.0	0.026	0.5	0.020	0.4	0.060	1.1
	High	5.536	0.044	0.8	0.021	0.4	0.034	0.6	0.060	1.1
HGB (g/dL)	Low	6.03	0.07	1.1	0.04	0.7	0.03	0.5	0.09	1.4
	Normal	13.75	0.08	0.6	0.04	0.3	0.07	0.5	0.12	0.9
	High	17.12	0.10	0.6	0.09	0.5	0.07	0.4	0.15	0.9
HCT (%)	Low	18.32	0.21	1.1	0.13	0.7	0.20	1.1	0.31	1.7
	Normal	41.94	0.40	0.9	0.30	0.7	0.32	0.8	0.59	1.4
	High	51.38	0.42	0.8	0.29	0.6	0.42	0.8	0.66	1.3
MCV (fL)	Low	72.38	0.14	0.2	0.28	0.4	0.58	0.8	0.66	0.9
	Normal	79.53	0.15	0.2	0.24	0.3	0.44	0.6	0.52	0.7
	High	92.81	0.17	0.2	0.19	0.2	0.53	0.6	0.58	0.6
MCH (pg)	Low	23.85	0.27	1.1	0.17	0.7	0.00	0.0	0.32	1.4
	Normal	26.07	0.21	0.8	0.10	0.4	0.04	0.1	0.23	0.9
	High	30.94	0.21	0.7	0.03	0.1	0.06	0.2	0.22	0.7
MCHC (g/dL)	Low	32.96	0.38	1.1	0.24	0.7	0.15	0.5	0.47	1.4
	Normal	32.79	0.24	0.7	0.19	0.6	0.19	0.6	0.36	1.1
	High	33.33	0.23	0.7	0.03	0.1	0.16	0.5	0.28	0.9
RDW-CV (%)	Low	14.16	0.12	0.9	0.07	0.5	0.08	0.6	0.16	1.2
	Normal	14.21	0.09	0.7	0.07	0.5	0.10	0.7	0.16	1.1
	High	11.66	0.09	0.8	0.07	0.6	0.07	0.6	0.14	1.2
RDW-SD (fL)	Low	38.44	0.33	0.9	0.00	0.0	0.19	0.5	0.38	1.0
	Normal	41.78	0.32	0.8	0.00	0.0	0.21	0.5	0.38	0.9
	High	40.85	0.29	0.7	0.12	0.3	0.03	0.1	0.32	0.8
PLT (10^3/µL)	Low	50.6	2.9	5.7	0.0	0.0	1.4	2.7	3.2	6.3
	Normal	265.1	5.5	2.1	0.0	0.0	3.1	1.2	6.4	2.4
	High	509.2	8.1	1.6	0.0	0.0	4.7	0.9	9.3	1.8
MPV (fL)	Low	9.60	0.34	3.5	0.12	1.3	0.26	2.7	0.44	4.6
	Normal	10.43	0.13	1.2	0.04	0.4	0.04	0.4	0.14	1.3
	High	10.48	0.08	0.7	0.04	0.4	0.03	0.3	0.09	0.9

b. *Linearity/assay reportable range:*

Not applicable.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Stability
To verify the 14-day open-vial stability claim, a real-time stability study was performed by testing three separate BC-5D lots on a single BC-5390 Auto Hematology Analyzer. The BC-5D lots were selected near the end of the established shelf-life. Two lots were analyzed at 14 different time points; whereas one lot was analyzed at 13 time points. The specified time points extended one day beyond the claimed stability.

To verify the BC-5D Hematology Control 75-day closed-vial stability claim, a real-time stability study was also performed to verify the 75-day closed-vial stability claim. Three separate lots were analyzed at several different time points extending well beyond the claimed stability. Stability was assessed in terms of measurand drift for each control level and lot in accordance with CLSI EP25-A.

Expected Values
Value assignment was performed for each BC-5D Hematology Control level on calibrated BC-5390 Auto Hematology Analyzers. Three replicates were performed per control level and vial over two days. The expected assay ranges were based on ± 2.0 SD.

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*

Not applicable.

f. *Assay cut-off:*

Not applicable.

2. Comparison studies:
   a. *Method comparison with predicate device:*

   Not applicable.

   b. *Matrix comparison:*

   Not applicable.

3. Clinical studies:

   a. *Clinical Sensitivity:*

      Not applicable.

   b. *Clinical specificity:*

      Not applicable.

   c. *Other clinical supportive data (when a. and b. are not applicable):*

      Not applicable.

4. Clinical cut-off:

   Not applicable.

5. Expected values/Reference range:

   Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and does support a substantial equivalence decision.