

BC-BF

HEMATOLOGY CONTROLS

CONTROL

Assay Values and Expected Ranges

QCP Data Months: September, October

LOT BFI0924A

2024-11-10

Analyzer	Parameter	LEVEL 1		LEVEL 2		LEVEL 3	
		LOT	BFI0924A-1	LOT	BFI0924A-2	LOT	BFI0924A-3
Mindray BC-6800, BC-6600	WBC-BF 10 ⁹ /L	0.069	± 0.035	0.241	± 0.193	0.914	± 0.183
	RBC-BF 10 ¹² /L	0.025	± 0.008	0.072	± 0.014	0.480	± 0.034
	TC-BF # 10 ⁹ /L	0.069	± 0.035	0.241	± 0.193	0.916	± 0.183
	PMN %	67.5	± 12.0	71.2	± 8.0	83.9	± 6.0
	PMN # 10 ⁹ /L	0.047	± 0.036	0.172	± 0.172	0.767	± 0.219
	MN %	32.5	± 12.0	28.8	± 8.0	16.1	± 6.0
	MN # 10 ⁹ /L	0.022	± 0.022	0.069	± 0.069	0.147	± 0.095
Mindray BC-6000, BC-6100, BC-6200, BC-6000Plus, BC-6100Plus	WBC-BF 10 ⁹ /L	0.072	± 0.036	0.251	± 0.201	0.942	± 0.188
	RBC-BF 10 ¹² /L	0.024	± 0.007	0.068	± 0.014	0.448	± 0.031
	TC-BF # 10 ⁹ /L	0.073	± 0.037	0.252	± 0.202	0.944	± 0.189
	PMN %	67.9	± 12.0	71.8	± 8.0	84.7	± 6.0
	PMN # 10 ⁹ /L	0.049	± 0.037	0.180	± 0.180	0.798	± 0.227
	MN %	32.1	± 12.0	28.2	± 8.0	15.3	± 6.0
	MN # 10 ⁹ /L	0.023	± 0.023	0.071	± 0.071	0.144	± 0.097
Mindray BC-6600Plus, BC-6700Plus, BC-6800Plus	WBC-BF 10 ⁹ /L	0.077	± 0.039	0.258	± 0.206	0.984	± 0.197
	RBC-BF 10 ¹² /L	0.025	± 0.008	0.073	± 0.015	0.486	± 0.034
	TC-BF # 10 ⁹ /L	0.077	± 0.039	0.261	± 0.209	0.988	± 0.198
	PMN %	69.4	± 12.0	70.5	± 8.0	84.4	± 6.0
	PMN # 10 ⁹ /L	0.053	± 0.041	0.182	± 0.182	0.830	± 0.238
	MN%	30.6	± 12.0	29.5	± 8.0	15.6	± 6.0
	MN # 10 ⁹ /L	0.024	± 0.024	0.076	± 0.076	0.154	± 0.101
Mindray BC-700[R], BC-720[R], BC-760[R], BC-780[R], BC-700 [R] CS, BC-760[R] CS, BC-700[B], BC-760[B]	WBC-BF 10 ⁹ /L	0.074	± 0.037	0.243	± 0.194	0.934	± 0.187
	RBC-BF 10 ¹² /L	0.023	± 0.007	0.067	± 0.013	0.445	± 0.031
	TC-BF # 10 ⁹ /L	0.074	± 0.037	0.244	± 0.195	0.935	± 0.187
	PMN %	68.0	± 12.0	71.3	± 8.0	84.1	± 6.0
	PMN # 10 ⁹ /L	0.050	± 0.039	0.173	± 0.173	0.785	± 0.225
	MN%	32.0	± 12.0	28.7	± 8.0	15.9	± 6.0
	MN # 10 ⁹ /L	0.024	± 0.024	0.070	± 0.070	0.149	± 0.096
Mindray BC-7500[B] CRP, BC-7500 [R] CRP, BC-7500 [N] CRP, BC-7500 [NR] CRP	WBC-BF 10 ⁹ /L	0.070	± 0.035	0.232	± 0.186	0.889	± 0.178
	RBC-BF 10 ¹² /L	0.024	± 0.007	0.072	± 0.014	0.478	± 0.033
	TC-BF # 10 ⁹ /L	0.070	± 0.035	0.233	± 0.186	0.890	± 0.178
	PMN %	68.5	± 12.0	72.0	± 8.0	84.5	± 6.0
	PMN # 10 ⁹ /L	0.048	± 0.037	0.167	± 0.167	0.751	± 0.215
	MN%	31.5	± 12.0	28.0	± 8.0	15.5	± 6.0
	MN # 10 ⁹ /L	0.022	± 0.022	0.065	± 0.065	0.138	± 0.091

BC-BF

HEMATOLOGY CONTROLS

CONTROL

INTENDED USE

The BC-BF Control is an assayed hematology control intended to monitor the reliability of hematology instruments that quantitatively measure red and white blood cell counts in cerebrospinal fluids, serous fluids, and synovial fluids.

SUMMARY AND PRINCIPLE

It is an established laboratory practice to use a stable control to monitor the performance of diagnostic tests. This control is composed of stable materials which provide a means of monitoring the performance of hematology blood cell counters. It is sampled in the same manner as a patient specimen.

REAGENTS

BC-BF Control is an in vitro diagnostic reagent composed of human erythrocytes and bovine leukocytes suspended in a fluid with preservatives.



PRECAUTION

BC-BF is intended for in vitro diagnostic use only by trained personnel.



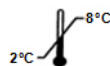
WARNING:

POTENTIAL BIOHAZARDOUS MATERIAL For in vitro diagnostic use. Each human donor/unit used in the preparation R&D Systems' products has been tested, and yielded non-reactive / negative results, according to FDA guidelines as contained in 21 CFR 610.40(a)(b).

Specifically, a sample from each donation used has been tested by FDA-licensed tests and found nonreactive / negative for:

1. Antibodies to human immunodeficiency virus (anti-HIV 1,2), hepatitis C virus (anti-HCV), and antibodies to Trypanosoma cruzi (T cruzi, the causative agent of Chagas disease), and nonreactive for hepatitis B surface antigen (HBsAg).
2. Nucleic acid tests (NAT) for HCV ribonucleic acid (RNA), HIV-1 RNA, HBV deoxyribonucleic acid (DNA) and West Nile virus (WNV) RNA
3. Serologic test for syphilis

Because no test method can offer complete assurance that infectious agents are absent, material should be handled as potentially infectious. When handling or disposing of vials follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.



STABILITY AND STORAGE

Store BC-BF upright at 2 -8°C (35 - 46°F) when not in use. Protect tubes from overheating and freezing. Unopened tubes are stable through the expiration date. Opened tubes are stable 30 days, provided they are handled properly.

INDICATIONS OF DETERIORATION

After mixing, product should be similar in appearance to diluted whole blood. In unmixed tubes, the supernatant may appear cloudy and reddish; this is normal and does not indicate deterioration. Other discoloration, very dark red supernatant or unacceptable results may indicate deterioration. Do not use the product if deterioration is suspected.



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INSTRUCTIONS FOR USE

Note: Begin with a system rinse to reduce carryover. It is critical that the background counts be low prior to running body fluid controls. Run controls from lowest to highest concentration to reduce carryover.

1. Remove tubes from the refrigerator and allow to warm to room temperature (15 to 30°C or 59 to 86°F) for 15 minutes before mixing.
2. To mix, hold a tube horizontally between the palms of the hands. **Do not pre-mix on a mechanical mixer.**
 - a) Roll the tube back and forth for 20 - 30 seconds; occasionally invert the tube. Mix vigorously, but do not shake.
 - b) Continue to mix in this manner until the red cells are completely suspended. Tubes stored for a long time may require extra mixing.
 - c) Gently invert the tube 8 - 10 times immediately before sampling.
3. Analyze the sample as instructed in the Operator's Manual for your instrument.
4. After sampling:
 - a) If tube has been open for sampling, clean residual material from the cap and tube rim with a lint-free tissue. Replace the cap tightly.
 - b) Return tubes to refrigerator within 30 minutes of use.

EXPECTED RESULTS

Verify that the lot number on the tube matches the lot number on the table of assay values. Assay values are determined on well-maintained, properly calibrated instruments using the instrument manufacturer's recommended reagents. Reagent differences, maintenance, operating technique, and calibration may contribute to inter-laboratory variation.

PERFORMANCE CHARACTERISTICS

Assigned values are presented as a Mean and Range. The Mean is derived from replicate testing on instruments operated and maintained according to the manufacturer's instructions. The Range is an estimate of variation between laboratories and also takes into account inherent imprecision of the method and expected biological variability of the control material.

Assay values on a new lot of control should be confirmed before the new lot is put into routine use. Test the new lot when the instrument is in good working order and quality control results on the old lot are acceptable. The laboratory's recovered mean should be within the assay range.

LIMITATIONS

The performance of this product is assured only if it is properly stored and used as described in this insert. Incomplete mixing of a tube prior to use invalidates both the sample withdrawn and any remaining material in the tube.

Assay values and expected ranges given are intended only as guidelines and each laboratory should perform their own test system validation and establish tolerance limits.

**MANUFACTURED FOR SHENZHEN MINDRAY
BIO-MEDICAL ELECTRONICS CO., LTD.**

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

For additional information on Mindray hematology controls and calibrators, to place an order or for assistance in resolving control recovery problems, please email your local Mindray representative at service@mindray.com.

