

Customer: Vioma Lifesciences Pvt Ltd

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Equipment: BC 760 Auto Hematology Analyzer

Title: IQ, OQ & PQ DOCUMENT

MBQ/NKZ/031072023/BC760

## Installation Qualification for Mindray BC 760 Sr. No.:- DG7-32000377

Customer Name : Vioma Lifesciences Pvt Ltd

Contact Person : Mrs Shilpa Surpur

Instrument Model : BC 760

Serial No. : DG7-32000377

Date Of installation : 22/06/2023

The instrument was installed And was found to be working satisfactory. Preliminary Customer Training was provided And standardization of the parameters Were done. The results were found to be within the expected range and system found to be working satisfactorily.

**Customer: Vioma Lifesciences Pvt Ltd**

Service Engineer		Customer	
Name:	Nandkumar Zagade	Name:	Dr Niraj Gujar
Signature:		Signature:	

Customer: Vioma Lifesciences Pvt Ltd

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Equipment: BC 760 Auto Hematology Analyzer

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MBQ/NKZ/031072023/BC760

## Installation Certificate For BC 760 Sr. No.- DG7-32000377

This is to certify that the instrument BC 760 Sr. No:- DG7-32000377 is successfully installed and commissioned at :

**Vioma Lifesciences Pvt Ltd**

Indofill Industries Ltd , Off Swami Vivekanand Road , Azad Nagar , Sandoz Baug, P.O. Thane West , Maharashtra-400607

and the Installation Protocol/ checklist has been Successfully completed for the above Instrument.

Date of Installation : 22/06/2023

MBQ , Technical Services Department

Service Engineer		Customer	
Name:	Nandkumar Zagade	Name:	Dr Niraj Gujar
Signature:		Signature:	

Customer: Vioma Lifesciences Pvt Ltd

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Equipment: BC 760 Auto Hematology Analyzer

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MBQ/NKZ/031072023/BC760

## Installation Qualification for Mindray BC 760 Sr. No.:- DE5-230000074

Customer Name : Vioma Lifesciences Pvt Ltd

Contact Person : Mrs Shilpa Chati

Instrument Model : BC 760

Serial No. : DG7-32000377

Date Of installation : 22/06/2023

**Initial Inspection of the unit carried out and the details are as follows:**

### System Condition Report:

Found the system to have been delivered in satisfactory condition and no external physical damaged observed on the same, Package was kept in good Condition as per the directional indicators like not tilt, indicating the system has not been subjected to mechanical shocks or stored in any manner, so as to cause any damage to the same.

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**Found all the required accessories as required.**

**Installation Procedure And Checklist Attached for the records.**

**External Requirement for Installation:**

1. Input voltage of 220V-240V/50Hz or 60 Hz.
2. Recommended operating Temperature is 15-30 degree Celsius, with in Relative Humidity 30-85% and Atmospheric pressure 70-106kPa.

**Installation Qualification for BC 760 Sr. No.:- DG7-32000377**

**Carried out all the installation procedures as per the installation procedure and checklists.**

**Carried out all the necessary checks and alignments.**

**Carried out all the necessary system checks and tests.**

**Handover the Instrument for operators Training And Qualifications**

**Technical Services Department**

Service Engineer		Customer	
Name:	Nandkumar Zagade	Name:	Dr Niraj Gujar
Signature:		Signature:	

**Customer:** Vioma Lifesciences Pvt Ltd

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**Equipment:** BC 760 Auto Hematology Analyzer

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## **Performance Qualification for Mindray BC 760 Sr. No.: -DG7-32000377**

### **Calibration Parameters**

Checked and found all the control [parameters to be within the acceptable CV limits and in range.

Checked and found all controls to be within the acceptable SD.

### **System Certification:**

Study data has determined that the system described in this document either meets the necessary criteria outlined in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included.

**The system is ready for Specific Usage.**

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## Operational Qualification:

### System Certification:

Study data has determined that the system described in this document either meets all criteria outlined in this Operational Protocol, or exceptional conditions have been identified and documentation included.

Exceptional Conditions, If any Have been Addressed.

**The System is ready for specific usage.**

Customer Authorization: **Vioma Lifesciences Pvt Ltd**

**Indofill Industries Ltd , Off Swami Vivekanand Road , Azad Nagar ,  
Sandoz Baug,P.O.Thane West , Maharashtra-400607**

Service Engineer		Customer	
Name:	Nandkumar Zagade	Name:	Dr Niraj Gujar
Signature:		Signature:	

Customer: Vioma Lifesciences Pvt Ltd

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## Operations Qualifications for BC 760 Sr. No.- DG7-32000377

1. Verified all the Mechanical Movements : Done
2. Verified Hydraulics : Done
3. Verified Electrical Systems : Done
4. Verified the all reagents Systems : Done

### Technical Services Department

Service Engineer		Customer	
Name:	Nandkumar Zagade	Name:	Dr Niraj Gujar
Signature:		Signature:	

Customer: Vioma Lifesciences Pvt Ltd

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## Instrument Setup

1. Assembled the instrument accessories.
2. Removed the shipping Clamps.
3. Connected the LD LYSE REAGENT .
4. Connected the LH LYSE REAGENT
5. Connected the FD DYE REAGENT
6. Connected the DILUENT REAGENT.
7. Connected the Waste Tubing
8. Connected the Power cord and connection cord.
9. Initialise the machine and follow the installation procedure.

## Operational Instection

1. Checked and found Mechanical Movements OK.
2. Checked and found Hydraulics OK.
3. Checked and found Electricals OK.
4. Checked with Controls And Samples, Results Are found OK.

Service Engineer		Customer	
Name:	Nandkumar Zagade	Name:	Dr Niraj Gujar
Signature:		Signature:	



整机 FQC 检验和出厂检定记录表  
FQC Inspection & Verification Record



序列号 SN	DG7-32009377	工单号/订单号 W#/Ordering No.	96506448/5300316862.80
产品编号 Product No.	3128B-PA00001	产品型号 Product Model	BC-760 [B]
产品名称 Product Name	全自动血液细胞分析仪 Auto Hematology Analyzer	工艺代码 Engineering Code	3128
文件编号 File No	Q-3128-CTO	文件版本 Version	7.0
文件名称 File Name	整机 FQC 检测规范 FQC Inspection	/	/

检验设备 Instruments Used	序号	名称 Name	型号/编号 Model/No	有效日期 Expiry Date
	1	移液器 Pipette	13000001819	2023-05-18
2	温湿度计 Hygrothermograph	13000023300	2023-12-18	

试剂和检验物 质 Reagent & Sample Type	序号 NO.	名称 Name	批号 M.F. / Lot No	有效日期 Exp Date
	1.	DS Diluent	2022091402	2024-09-13
2.	LD	2022091201	2024-09-11	
3.	LH	2022090701	2024-09-06	
4.	7um 标粒 7um Particle	260 829	2024-05-31	
5.	ESR 清洁液 ESR solution reagent	2022081201	2024-08-11	
6.	FD	2022071001	2023-07-09	
7.	中值质控液 BC-6D/BR60	MB0123AV	2023-03-10	
8.	校准物 Calibrator	PLUS0223	2023-03-05	
9.	DR	/	/	
10.	FR	/	/	
11.	中值质控液 BC-RET	/	/	
12.	LC 溶血剂 LC Lyse	/	/	
13.	CRP 质控品 I CRP Control	/	/	
14.	CRP 乳胶试剂 CRP Latex	/	/	
15.	SAA 质控品 I CRP Control	/	/	
16.	SAA 乳胶试剂 SAA Latex	/	/	

序号 NO	检验项目 Inspection Item	检验条件/说明 Description	检验标准要求 Requirement	标准下 限 Lower Limit	标准上 限 Upper Limit	检验结果 Result	检验结论 Conclusion	
1、	外观检查 /Appearance	温度平衡和环境确认 /Temperature Balance&Enviro nment confirm	分析仪、配套试剂稀释液等在检定室内 温度平衡时间不小于2小时,温度 15℃ ~32℃,湿度 30%~85%/Time of temperature balance for the analyzer and associated reagents shall be no less than 2 hour, Temperature 15℃~32℃, Humidity 30%~85%	不涉及	不涉及	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
2、		标贴及丝印 /Label	正确/完整,符合定义.仪器上有型号、出厂 日期、序列号及厂名,符合 Z-0030-130 和 Z1-3128-CTO-01/Refer to relative requirements in process document	不涉及	不涉及	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
3、		档案检验/File	追溯表正确、完整/Refer to relative requirements in process document	不涉及	不涉及	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
4、		外观 /Appearance	分析仪无影响工作性能的机械损伤,开 关定位准确,功能良好,清洁、无杂物 /Refer to relative requirements in process document	不涉及	不涉及	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
5、		板卡、线材、管 路/PCBA, Tube,Cable	胶管无脱落折叠、压死等;线接插坚固, 无松脱;螺钉安装牢靠/Refer to relative requirements in process document	不涉及	不涉及	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
6、	开机检测 /Startup check	开机本底 /Background of Startup	WBC ≤ 0.10 × 10 <sup>9</sup> / L	0.00	0.10	0.01 × 10 <sup>9</sup> / L	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
7、			RBC ≤ 0.02 × 10 <sup>12</sup> / L	0.00	0.02	0 × 10 <sup>12</sup> / L	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
8、			HGB ≤ 1 g / L	0	1	0 g / L	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
9、			PLT ≤ 3 × 10 <sup>9</sup> / L	0	3	0 × 10 <sup>9</sup> / L	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
10、	整机配置检测/ Analyzer Configuration Test	机型配置满足订单要求 Consistent with order requirements	不涉及	不涉及	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL		
11、			试剂与机型匹配/Label consistent with model	不涉及	不涉及	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
12、	系统参数和 状态检查 System parameter & status check	版本信息/ Version information	与“Z-110-008296-00-01 软件发布说明” 或临时 ECR 中的最新版本一致/agreed with the document Z-110-008296-00-01 or Temporary ECR	不涉及	不涉及	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
13、		电压电流、温度 与压力 /Voltage,Temp &Pressure	各项数值是否在范围之内/Meet the requirement of interface	不涉及	不涉及	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
14、		机械调节状态 Adjust <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	扶正和旋转压紧组件位置正常 /Refer to relative requirements in process document	不涉及	不涉及	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
15、	光学状态检 查/Optical status check	7um 标粒 7um Particle	*DIFF FS 重心位置	不涉及	不涉及	788.42	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
16、			*DIFF FS CV	0	3.9%	3.31 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
17、			*DIFF SS 重心位置	不涉及	不涉及	1003.31	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
18、			*DIFF SS CV	0	20.0%	16.11 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
19、		校准物重心位 置均值偏差 Calibrator CG Positon	DIFF FS ≤ ±5.0%	-5.0%	5.0%	1.0 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
20、			DIFF SS ≤ ±5.0%	-5.0%	5.0%	2.5 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
21、			DIFF FL ≤ ±5.0%	-5.0%	5.0%	-3.5 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
22、			<input type="checkbox"/> YES	RET FS ≤ ±5.0%	-5.0%	5.0%	%	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL
23、			<input checked="" type="checkbox"/> NO	RET SS ≤ ±5.0%	-5.0%	5.0%	%	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL
24、		RET FL ≤ ±10.0%	-10.0%	10.0%	%	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL		
25、	本底测试 /OV blank count test	全血本底 /OV-WB	WBC ≤ 0.10 × 10 <sup>9</sup> / L	0.00	0.10	0 × 10 <sup>9</sup> / L	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
26、			RBC ≤ 0.02 × 10 <sup>12</sup> / L	0.00	0.02	0 × 10 <sup>12</sup> / L	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
27、			HGB ≤ 1 g / L	0	1	0 g / L	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
28、			PLT ≤ 3 × 10 <sup>9</sup> / L	0	3	0 × 10 <sup>9</sup> / L	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
29、			FR-CRP ≤ 0.20mg / L <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	0	0.20	mg / L	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL	
30、			SAA ≤ 2.0mg / L	0	2.0	mg / L	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL	

		<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO						
31、		WBC≤2.5%	0.0%	2.5%	1.1	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
32、		RBC≤1.5%	0.0%	1.5%	0.9	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
33、		HGB≤1.0%极差 (R) ≤3	0.0%	1.0%	0.9	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
34、			0	3	3			
35、		MCV≤1.0%	0.0%	1.0%	0.2	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
36、		PLT-I≤4.0%	0.0%	4.0%	2.2	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
37、		Neu#≤6.0%	0.0%	6.0%	1.6	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
38、		Lym#≤6.0%	0.0%	6.0%	2.5	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
39、		Mon#≤16.0%	0.0%	16.0%	2.8	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
40、		Eos#≤20.0% or ±0.12×10 <sup>9</sup> /L(d)	0.0%	20.0%	5.9	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
41、			-0.12	0.12	0.05	×10 <sup>9</sup> /L		
42、		Bas#≤30.0% or ±0.06×10 <sup>9</sup> /L(d)	0.0%	30.0%	9.6	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
43、			-0.06	0.06	0.01	×10 <sup>9</sup> /L		
44、		IMG#≤25.0% or ±0.12×10 <sup>9</sup> /L(d)	0.0%	25.0%	13.7	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
45、			-0.12	0.12	0.02	×10 <sup>9</sup> /L		
46、		Neu%≤6.0%	0.0%	6.0%	1.5	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
47、		Lym%≤6.0%	0.0%	6.0%	1.9	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
48、		Mon%≤16.0%	0.0%	16.0%	4.7	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
49、		Eos%≤20.0% or ±1.5% (d)	0.0%	20.0%	5.3	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
50、			-1.5%	1.5%	0.6	% (d)		
51、		Bas%≤30.0% or ±1.0% (d)	0.0%	30.0%	9.4	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
52、			-1.0%	1.0%	0.2	% (d)		
53、		IMG%≤25.0% or ±1.5%(d)	0.0%	25.0%	14.2	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
54、			-1.5%	1.5%	0.3	% (d)		
55、	自动/开放-全血重复性测试	HCT≤ 1.5%	0.0%	1.5%	0.9	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
56、		MCH≤ 1.5%	0.0%	1.5%	0.5	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
57、	Auto/open WB	MCHC≤ 1.5%	0.0%	1.5%	0.6	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
58、	repeatability	RDW-CV≤ 2.0%	0.0%	2.0%	0.6	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
59、		RDW-SD≤ 2.0%	0.0%	2.0%	0.6	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
60、		MPV≤ 3.0%	0.0%	3.0%	1.0	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
61、		PDW≤ 10.0%	0.0%	10.0%	0.7	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
62、		PCT≤ 5.0%	0.0%	5.0%	2.9	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
63、		P-LCC≤ 15.0%	0.0%	15.0%	4.3	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
64、		P-LCR≤ 15.0%	0.0%	15.0%	2.1	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
65、		NRBC%≤25.0%或±1.5%(d)	0.0%	25.0%	20.5	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
66、			-1.5%	1.5%	0.79	%(d)		
67、		NRBC#≤25.0%或±0.12×10 <sup>9</sup> /L(d)	0.0%	25.0%	20.7	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
68、			-0.12	0.12	0.061	×10 <sup>9</sup> /L		
69、		ESR≤5%	0.0%	5.0%	0.4	%		<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
70、		IPF≤ 25.0%	0.0%	25.0%		%		<input type="checkbox"/> PASS <input type="checkbox"/> FAIL
71、		RET#≤15.0%	0.0%	15.0%		%		<input type="checkbox"/> PASS <input type="checkbox"/> FAIL
72、		RET%≤15.0%	0.0%	15.0%		%		<input type="checkbox"/> PASS <input type="checkbox"/> FAIL
73、		IRF≤ 30.0%	0.0%	30.0%		%		<input type="checkbox"/> PASS <input type="checkbox"/> FAIL
74、	BC-RET/BR60	LFR≤30.0%	0.0%	30.0%		%		<input type="checkbox"/> PASS <input type="checkbox"/> FAIL
75、	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	MFR≤ 50%	0.0%	50.0%		%		<input type="checkbox"/> PASS <input type="checkbox"/> FAIL
76、		HFR≤100%或±2.0%(d)	0.0%	100.0%		%		<input type="checkbox"/> PASS <input type="checkbox"/> FAIL
77、			-2.0%	2.0%		%(d)		
78、		RHE≤5.0%	0.0%	5.0%		%		<input type="checkbox"/> PASS <input type="checkbox"/> FAIL
79、		PLT-O≤4.0%	0.0%	4.0%		%		<input type="checkbox"/> PASS <input type="checkbox"/> FAIL
80、	CRP I	FR-CRP≤4.0%	0.0%	4.0%		%		<input type="checkbox"/> PASS <input type="checkbox"/> FAIL
		<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO						

81、		SAA I <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	SAA ≤ 8.0%	0.0%	8.0%	%	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL	
82、	封闭/开放 预稀释重复 性测试 Close/open Prediluent repeatability	(BC-6D)	WBC ≤ 3.5%	0.0%	3.5%	1.8 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
83、			RBC ≤ 2.0%	0.0%	2.0%	1.0 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
84、			HGB ≤ 2.0%	0.0%	2.0%	1.1 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
85、			MCV ≤ 3.0%	0.0%	3.0%	0.2 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
86、			PLT-I ≤ 8.0%	0.0%	8.0%	2.8 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
87、			Neu# ≤ 12.0%	0.0%	12.0%	3.2 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
88、			Lym# ≤ 12.0%	0.0%	12.0%	2.3 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
89、			Mon# ≤ 32.0%	0.0%	32.0%	6.7 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
90、			Eos# ≤ 40.0% or ±0.24 × 10 <sup>9</sup> /L(d)	0.0%	40.0%	5.9 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
91、				-0.24	0.24	0.06 × 10 <sup>9</sup> /L(d)	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL	
92、					0.0%	60.0%	19.9 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
93、					-0.12	0.12	0.03 × 10 <sup>9</sup> /L(d)	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
94、						12.0%	2.7 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
95、						12.0%	2.6 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
96、						32.0%	5.3 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
97、						40.0%	5.7 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
98、					-3.0%	3.0%	0.6 % (d)	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
99、						60.0%	20.9 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
100、					-2.0%	2.0%	0.6 % (d)	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
101、						3.0%	1.1 %	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL
102、		BC-RET/BR60	RET# ≤ 30.0%	0.0%	30.0%	%	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL	
103、		<input type="checkbox"/> YES	RET% ≤ 30.0%	0.0%	30.0%	%	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL	
104、		<input checked="" type="checkbox"/> NO	PLT-O ≤ 8.0%	0.0%	8.0%	%	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL	
105、	体液测试/ Body fluid test	体液本底 /blank	WBC-BF: ≤ 0.001 × 10 <sup>9</sup> / L	0.000	0.001	0 × 10 <sup>9</sup> / L	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL	
106、			RBC-BF: ≤ 0.003 × 10 <sup>12</sup> / L	0.000	0.003	0 × 10 <sup>12</sup> / L	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL	
107、		体液携带污染 /carryover	WBC-BF: ≤ 0.3%	-0.3%	0.3%	0 %	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL	
108、			RBC-BF: ≤ 0.3%	-0.3%	0.3%	0 %	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL	
109、		体液重复性测 试/Body fluid repeatability	WBC-BF: ≤ 30%	0.0%	30.0%	6.0 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
110、			RBC-BF: ≤ 40% or 极差 (Range) ≤ 0.007 × 10 <sup>12</sup> / L	0.0%	40.0%	4.6 %	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
111、			0.000	0.007	0.072 × 10 <sup>12</sup> / L	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL		
112、	订单符合项 检查 /Purchase order compliance	机器配置检验 /Machine version	机器版本与配置相符/The machine version shall match its configuration	不涉及	不涉及	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL	
113、		语言检测 /Language check	语言正确/language is correct.	不涉及	不涉及	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
114、	数据导出/ Data export	数据导出和保 存/Data export and save	已按工艺要求导出和保存数据/All date exported and saved as proces documentation requirement	不涉及	不涉及	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
115、	打包检验 /Pack-up	执行打包程序 /Carryout pack-up	按工艺要求执行打包程序, 打包过程正 常/Pack-up as process documentation requirement and performed properly	不涉及	不涉及	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
116、	仪器清洁和 固定/Clean and Fixation	仪器清洁/Clean	按工艺要求清洁/Clean as process documentation requirement	不涉及	不涉及	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	
117、		活动部件固定 /Moving Part Fixation	按工艺要求固定/Fixed as process documentation requirement	不涉及	不涉及	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL	

118、	最终检验 /Final Test	完成交接 /Delivery receipt	按规定完成交接/Delivery receipt and tractability table inspection as requirement	不涉及	不涉及	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
119、		外观装配检查 /Appearance inspection	按工艺要求检查/inspect as process documentation requirement	不涉及	不涉及	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL
120、	整体评价/ Overall Evaluation	整体评价/ Overall Evaluation	合格 / 不合格 PASS/FAIL	不涉及	不涉及	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	<input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL

测试人/Test by 刘红研测试日期/Test date 2023-02-15

## 说明：

- (1) 操作人员参考填写模板将检测结果填写到相应记录表中。
- (2) 检验结果中有数字的项目填写测试数据或 NA, 无数字的项目填写 OK 或 NA, 在检验结论中填写 PASS 或 FAIL。
- (3) 由于配置不同不涉及的项目检验结果填写不涉及, 检验结论中为空白。
- (4) 表格中带\*号项, 不参与最终结果的判定, 只作记录留在。

## Directions

- (1) The operators fill the results in the appropriate tables refer to the template.
- (2) In the result row, fill the form with test data in digital or OK/NG, fill the conclusion row in PASS or FAIL.
- (3) For inspection items not applicable to certain configurations, mark checkbox with "No", and leave the "Conclusion" cell blank.
- (4) the item which carry "\*" are just for reference, not the criterion for the final result.