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Zybio Inc.

Calibration Certificate

Instrument : 3-Part Diffrential Heamatology Analyser-Z3

Laboratory : Dr Dasgupta's Eye Clinic & Laboratory, Rohini

Supported by : Zybio Inc.

Floor 1 to Floor 4, Building 30, No.6 of Taikang Road,
Block C of Jianqiao Industrial Park, Dadukou District, Chongqing, China 400082
Tel: +86 (0)23 6865 5509 Fax: +86 (0)23 6869 9779 Email: info@zybio.com Website: www.zybio.com

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Zybio Inc.

Calibration Certificate Protocol

This Calibration Certificate protocol is performed in the lab:Dr Dasgupta's Eye Clinic & Laboratory,Department:-Hematology Laboratory,

Installation located at: F-26/10, Sector -7, Rohini,New Delhi -110085.

- Zybio Inc. is responsible for Calibration of all following attached protocol.
- An authorized Zybio Inc. representative will physically check the system and
- proceed for the Calibration.
- This Calibration protocol will be followed as specified by the manufacturer.
- Calibration checks will also be performed to verify that the instrument has been calibrated with proper connections and utilities.
- On completion of the Calibration all the necessary documents of the System checks will be used to evaluate the instrument Calibration in accordance with the manufacturer's protocol and intended use.
- An authorized Zybio Inc. representative will verify the documents of the system checks and approve the same.
- Successful completion of this protocol will verify that this instrument has been Calibrated in accordance with the intended usage.
- Any exceptional conditions encountered during the certification studies will be identified for review and documented in deviation report. Exceptional conditions will be investigated and appropriate course of action will be determined.

Prepared by:	Zybio Inc.	
Name:	ASHOK DAKSH	
Title: ZONAL SERVICE MANAGER	Sign: Ashok	Date:21/09/2022
Approved by:		
Name:	SHIVAM GUPTA	
Title :	Sign: Shivam	Date: 21-09-22

Next Calibration Due On :-20th September,2023.

For and on behalf of
Zybio Inc.
Cui Yang

Floor 1 to Floor 4, Building 30, No.6 of Taikang Road,
Block C of Jianqiao Industrial Park, Dadukou District, Chongqing, China 400082
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Calibration Requirement:

Sr. No.	Description	Compliance Yes/No
1.	Environmental conditions as per required.	YES
2.	Physical Space Requirement as per required.	YES
3.	Electrical Requirements.	YES
4.	UPS connection available.	YES

1. The instrument has been checked for the following:

Sr. No.	Verification	Checked Yes/No
1.	Instrument is identified Serial Number: Z3220307769	YES
2.	Accessories / consumables are listed	YES
3.	System checked for any External / physical damage	YES
4.	Instruction for Use Manual provided by the Manufacturer	YES

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Calibration Certificate Procedure

General Requirements

1. Running in an indoor environment. This instrument is designed for indoor use only.
2. Ambient Temperature: 20 to 30 degree C
3. Running Humidity: 30 to 80%
4. Space between machine left door and wall, Space between machine right door and wall should both ≥ 10cm， The reserved space between the back panel and the wall ≥ 25 cm， The installation table (or floor) can bear at least 40 kg weight.
5. Running in a well – ventilated place
6. If ambient temperature and relative humidity are not in range, please use Air Conditioning
7. Instrument should not be Ran at a place which is exposed to extremely high or low temperature
8. Instrument should not be Ran at a place which is exposed directly to sunlight
9. Avoid running in place where instrument may be exposed to radio interference such as personal computer, centrifuge separator, wireless radio and communication facility
10. This instrument must be protected against splashing water.
11. Avoid shock and vibrations.
12. Avoid installation near devices causing potential interference, such as wireless communication equipment or similar devices, and centrifuges.
13. Running of this instrument in places where chemicals are stored or hazardous gas may be present is not permitted.

Electrical Requirements

1. Input Supply: 100- 240V with proper grounding
2. **Power Supply**: Number of Three Pin Plug Points: one

Calibration

Horizontal position checking:

Calibration Item	Yes/No
Sample probe is located In the center at aspiration position	YES
Sample probe is located in the center at WBC chamber	YES
Sample probe is located In the center at RBC Chamber	YES

Vertical position checking

Calibration Item	Yes/No
Sample Probe Is Located In Down At Aspiration Position	YES
Sample Probe Is Located In Down At WBC Chamber	YES
Sample Probe Is Located In Down At RBC Chamber	YES

Movement checking

Calibration Item	Yes/No
Vertical and Horizontal movement runs smoothly.	YES

Accuracy Check Data					
R&D 3-Part Diffrential Hematology Control,Lot-B0223					
Selected	WBC	RBC	HGB	MCV	PLT
Target	8.47	4.29	14.2	96.5	280
1	9.07	4.65	14.7	88.1	284
2	9.11	4.65	14.5	88.0	284
3	9.12	4.56	14.5	88.0	264
4	9.01	4.61	14.1	88.1	285
5	9.06	4.61	14.4	88.1	281
6	9.01	4.60	14.5	88.3	276
7	8.89	4.66	14.6	88.2	275
8	9.25	4.62	14.6	88.2	287
9	8.89	4.58	14.4	87.8	287
10	9.01	4.61	14.6	87.7	280
Mean	9.042	4.611	14.55	88.04	281.7
CV(%)	1.19	0.73	0.73	0.21	1.89
New Cal. Factor(%)	93.67	93.03	97.61	109.61	99.40
Old Cal. Factor(%)	97.00	95.00	96.00	110.00	90.00

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Report Sign Off:-

Prepared by:	Zybio Inc.	
Name:	ASHOK DAKSH	
Title: ZONAL SERVICE MANAGER	Sign: Ashok	Date:21/09/2022
Approved by:		
Name:	SHIVAM GUPTA	
Title :	Sign: Shivam	Date: 21-09-22

Next Calibration Due On:-20th September,2023.

For and on behalf of
Zybio Inc.
Cui Tang.

Floor 1 to Floor 4, Building 30, No.6 of Taikang Road,
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INSTALLATION QUALIFICATION

Instrument: 3 – Part Differential Hematology Analyzer Z3

Laboratory: Dr Dasgupta's Eye Clinic & Laboratory,Rohini

Supported by: Zybio Inc.

Floor 1 to Floor 4, Building 30, No.6 of Taikang Road,
Block C of Jianqiao Industrial Park, Dadukou District, Chongqing, China 400082
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INSTALLATION QUALIFICATION PROTOCOL

This Calibration Certificate protocol is performed in the lab: Dr Dasgupta's Eye Clinic & Laboratory,Department-Hematology Laboratory,Installation located at: :- F-26/10, Sector -7,Rohini,New Delhi -110085.

- Zybio Inc. Ltd. is responsible for installation of 3–Part Differential Hematology Analyzer Z3.
- An authorized Zybio Inc. representative will physically check the system and proceed for the installation.
- This installation protocol will be followed as specified by the manufacturer.
- Installation checks will also be performed to verify that the instrument has been installed with proper connections and utilities.
- On completion of the Installation all the necessary documents of the System checks will be used to evaluate the instrument installation in accordance with the manufacturer's protocol and intended use.
- An authorized Zybio Inc. representative will verify the documents of the system checks and approve the same.
- Successful completion of this protocol will verify that this instrument has been installed in accordance with the intended usage.
- Any exceptional conditions encountered during the qualification studies will be identified for review and documented in deviation report. Exceptional conditions will be investigated and appropriate course of action will be determined.

Prepared by:	**Zybio Inc.**	
Name:	**ASHOK DAKSH**	
Title: Zonal Service Manager	**Sign:** Ashok	**Date:21/09/2022**
Approved by:		
Name:	SHIVAM GUPTA	
Title : Application	**Sign:** Shivam	**Date:** 21-09-22

Installation Requirement:

Sr. No.	Description	Compliance Yes/No
1.	Environmental conditions as per required.	YES
2.	Physical Space Requirement as per required.	YES
3.	Electrical Requirements.	YES
4.	UPS connection available.	YES

1. The instrument has been checked for the following:

Sr. No.	Verification	Yes/No
1.	Instrument is identified Serial Number: Z3220307769	YES
2.	Accessories / consumables are listed	YES
3.	System checked for any External / physical damage	YES
4.	Instruction for Use Manual provided by the Manufacturer	YES

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INSTALLATION QUALIFICATION PROCEDURE

Z 3 Installation Site Requirements

General Requirements

1. Install in an indoor environment. This instrument is designed for indoor use only.
2. Ambient Temperature: 20 to 30 degree C
3. Installation Humidity: 30 to 80%
4. Space between machine left door and wall, Space between machine right door and wall should both ≥ 10 cm， The reserved space between the back panel and the wall ≥ 25 cm， The installation table (or floor) can bear at least 40 kg weight.
5. Install in a well – ventilated place
6. If ambient temperature and relative humidity are not in range, please use Air Conditioning
7. Instrument should not be Ran at a place which is exposed to extremely high or low temperature
8. Instrument should not be Ran at a place which is exposed directly to sunlight
9. Avoid Install in place where instrument may be exposed to radio interference such as personal computer, centrifuge separator, wireless radio and communication facility
10. This instrument must be protected against splashing water.
11. Avoid shock and vibrations.
12. Avoid installation near devices causing potential interference, such as wireless communication equipment or similar devices, and centrifuges.
13. Installation of this instrument in places where chemicals are stored or hazardous gas may be present is not permitted.

Electrical Requirements

1. Input Supply: 100- 240V with proper grounding
2. **Power Supply**: Number of Three Pin Plug Points: one

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Installation

Verify the Pre-installation Checks

If any deficiencies were noted during the pre-installation check, verify they are resolved before installation.

Check the Supplies

Make sure an adequate supply of reagents, control and calibrator are available at the site.

Inspect Packing Box

Inspect all boxes for damage. Notify shipper of damages if any.

Unpack the Analyzer

- Remove the packing material of the Analyzer.
- Place the Instrument on the table.
- Remove fixing tapes and transportation tapes.
- Connect the AC Adaptor to Power Supply Point

Report Sign Off:

Prepared by:	Zybio Inc.	
Name:	ASHOK DAKSH	
Title: Zonal Service Manager	Sign: Ashok	Date:21/09/2022
Approved by:		
Name:	SHIVAM GUPTA	
Title :	Sign:	Date: 21-09-22

OPERATION QUALIFICATION

Instrument: 3-Part Differential Hematology Analyzer Z3

Laboratory:Dr Dasgupta's Eye Clinic & Laboratory,Rohini

Supported by: Zybio Inc.

Floor 1 to Floor 4, Building 30, No.6 of Taikang Road,
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OPERATION QUALIFICATION PROTOCOL

This Calibration Certificate protocol is performed in the lab: Dr Dasgupta's Eye Clinic & Laboratory,Department-Hematology Laboratory ,

Installation located at: F-26/10, Sector -7, Rohini, New Delhi -110085.

This protocol defines the documentation that will be used to evaluate the instrument and documented in accordance with manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrumentation identified has been operational in accordance with manufacturer's specifications and intended use.

Operational checks will be performed to verify that the instrument operates according to specifications and to record the information/data to demonstrate its functions as expected.

Trained knowledgeable personnel from Zybio Inc. along with the department personnel will perform qualification studies as mentioned by the manufacturer. Department personnel will record the information. The technical person from Zybio Inc. will verify the records and write the report. This protocol is to be reviewed and approved by the head of the department and QA.

Any exceptional conditions encountered during the qualification studies will be identified for review and documented in deviation report. Exceptional conditions will be investigated and appropriate course of action will be determined.

Prepared by:	**Zybio Inc.**	
Name:	**ASHOK DAKSH**	
Title: Zonal Service Manager	**Sign:**	**Date:21/09/2022**
Approved by:		
Name:	SHIVAM GUPTA	
Title :	**Sign:**	**Date:** 21-09-22

OPERATIONAL QUALIFICATION PROTOCOL

The operational qualification protocol specifies the methodology for the installation of the specified system and calibration after successful installation qualification. Successful completion of the procedure identifies that the system has been installed according to the specified protocols and is ready for operation and subsequent performance analysis.

REFERENCES

1. User Manual Z 3

OPERATIONAL QUALIFICATION SCHEDULE

The following activities mentioned below have to be performed to complete the operational qualification

Fluidic Initialization

[√] Yes [ ] No

Successful blank run after fluidic initialization

[√] Yes [ ] No

System time setting

a) Enter into "setup" => "System time" to set date & time

System time setting

[√] Yes [ ] No

Print setting

a) Enter into "setup" => "Print "to set printer setting(internal / external) /laboratory name

Printer Seting

[√] Yes [ ] No

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Parameter range & unit setting

[v] Yes [ ]

Sample run

[v] Yes [ ] No

Shutdown of Analyzer

[v] Yes [ ] No

Report Sign Off:

Prepared by:	Zybio Inc.	
Name:	Ashok Daksh	
Title: Zonal Service Manager	Sign: Ashok	Date: 21/09/2022
Approved by:		
Name:	SHIVAM GUPTA	
Title :	Sign: Shivam	Date: 21-09-22

Deviation: None

Conclusion: This report certifies that the instrument operation is as per the specification recommended by the manufacturer.

PERFORMANCE QUALIFICATION

Instrument: 3-Part Differential Hematology Analyzer Z3

Laboratory: Dr Dasgupta's Eye Clinic & Laboratory, Rohini

Supported by: Zybio Inc.

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PERFORMANCE QUALIFICATION PROTOCOL

This Calibration Certificate protocol is performed in the lab: Dr Dasgupta's Eye Clinic & Laboratory,Department-Hematology Laboratory,

Installation located at : F-26/10, Sector-7, Rohini,New Delhi-110085.

This protocol will define the documentation that will be used to evaluate the instrument and documented in accordance with the user specification requirements. Successful completion of this protocol will verify that the instrument performance consistently meets pre-determined specifications under normal conditions.

Performance checks will be carried out by repeatedly running the system on its intended schedule and record the information/data to demonstrate that it consistently meets the required performance, as expected.

Department personnel along with the trained personnel from Zybio Inc. will perform qualification studies as mentioned in this protocol. Department personnel will record the information and write the report. The technical person from Zybio Inc. will verify the records. The reports will be reviewed by head of the department and approved by QA person. This protocol is to be reviewed and approved by the head of the department and QA.

Any exceptional conditions encountered during the qualification studies will be identified for review and documented in deviation report. Exceptional conditions will be investigated and appropriate course of action will be determined.

Prepared by:	**Zybio Inc.**		
Name:	**ASHOK DAKSH**		
Title: ZONAL SERVICE MANAGER	**Sign:** Ashok		**Date:21/09/2022**
Approved by:			
Name:	ASHOK SHIVAM GUPTA		
Title :	**Sign:** Ashok Shivam		**Date: 21-09-2022**

PC-1002

PERFORMANCE QUALIFICATION PROCEDURE

1. Test runs successfully.

Performance	Yes/No
Blank run completed successfully within setting time	Yes
Results of blank run are within acceptable range	Yes
Sample run completed successfully within setting time	Yes
Results of sample run are within acceptable range	Yes
Accuracy Check	Yes
Reproducibility Check	Yes

Reproducibility check

Performed the reproducibility check by running the Control for 10 times.

Table E: Reproducibility Check Data

R&D 3 PART Differential HEAMATOLOGY CONTROL LEVEL 1 LOT NO B0223L					
Replicates	WBC	RBC	HGB	MCV	PLT
1	2.11	2.12	6.1	82.7	80
2	2.09	2.12	6	82.9	77
3	2.16	2.11	6	82.6	77
4	2.08	2.09	5.9	82.7	79
5	2.13	2.13	6.1	82.3	79
6	2.11	2.15	6.1	82.6	83
7	2.17	2.14	6.1	82.7	75
8	2.17	2.1	6	82.5	82
9	2.09	2.1	6.1	82.9	85
10	2.13	2.15	6.1	82.9	81
Mean	2.124	2.121	6.05	82.68	79.8
SD	0.034	0.021	0.071	0.193	3.048
CV%	1.6%	1.0%	1.2%	0.2%	3.8%

R&D 3 PART Differential HEAMATOLOGY CONTROL LEVEL 2 LOT NO B0223N					
Replicates	WBC	RBC	HGB	MCV	PLT
1	8.57	4.35	14.3	96.4	278
2	8.81	4.31	14.3	96.2	287
3	8.49	4.29	14.1	96.2	273
4	8.53	4.29	14	96	282
5	8.48	4.22	14.1	14.1	270
6	8.6	4.3	14.3	96.4	299
7	8.43	4.23	14.1	96.4	287
8	8.49	4.33	14.3	96.5	285
9	8.64	4.3	14.3	96.5	284
10	8.41	4.38	14.4	96.4	288
Mean	8.545	4.3	14.22	88.11	283.3
SD	0.118	0.049	0.132	26.005	8.247
CV%	1.4%	1.1%	0.9%	29.5%	2.9%

R&D 3 PART Differential HEAMATOLOGY CONTROL LEVEL 3 LOT NO B0223H					
Replicates	WBC	RBC	HGB	MCV	PLT
1	21.42	5.3	18.9	104.7	557
2	21.67	5.44	19.4	104.8	557
3	22.01	5.46	19.2	104.9	563
4	21.37	5.45	19.3	104.8	540
5	21.77	5.54	19.5	104.9	560
6	21.51	5.48	19.3	105.3	559
7	21.91	5.49	19.3	104.8	560
8	22..01	5.47	19.4	104.7	548
9	21.44	5.47	19.3	104.8	548
10	22.02	5.47	19.4	104.8	557
Mean	21.68	5.46	19.30	104.85	554.90
SD	0.26	0.06	0.16	0.17	7.19
CV%	1.19%	1.13%	0.85%	0.16%	1.30%

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Accuracy Check :-

Ran Control and verify that all the results are within the specified limits.

R&D 3 PART Differential HEAMATOLOGY CONTROL LEVEL 1 LOT NO B0223L					
Replicates	WBC	RBC	HGB	MCV	PLT
1	2.11	2.12	6.1	82.7	80
2	2.09	2.12	6	82.9	77
3	2.16	2.11	6	82.6	77
4	2.08	2.09	5.9	82.7	79
5	2.13	2.13	6.1	82.3	79
6	2.11	2.15	6.1	82.6	83
7	2.17	2.14	6.1	82.7	75
8	2.17	2.1	6	82.5	82
9	2.09	2.1	6.1	82.9	85
10	2.13	2.15	6.1	82.9	81
Mean	2.124	2.121	6.05	82.68	79.8
SD	0.034	0.021	0.071	0.193	3.048
CV%	1.6%	1.0%	1.2%	0.2%	3.8%
Target	2.10	2.11	6.00	82.2	71.00

R&D 3 PART Differential HEAMATOLOGY CONTROL LEVEL 2 LOT NO B0223N					
Replicates	WBC	RBC	HGB	MCV	PLT
1	8.57	4.35	14.3	96.4	278
2	8.81	4.31	14.3	96.2	287
3	8.49	4.29	14.1	96.2	273
4	8.53	4.29	14	96	282
5	8.48	4.22	14.1	14.1	270
6	8.6	4.3	14.3	96.4	299
7	8.43	4.23	14.1	96.4	287
8	8.49	4.33	14.3	96.5	285
9	8.64	4.3	14.3	96.5	284
10	8.41	4.38	14.4	96.4	288
Mean	8.545	4.3	14.22	88.11	283.3
SD	0.118	0.049	0.132	26.005	8.247
CV%	1.4%	1.1%	0.9%	29.5%	2.9%
Target	8.47	4.29	14.2	95.5	280.00

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R&D 3 PART Differential HEAMATOLOGY CONTROL LEVEL 3 LOT NO B0222					
Replicates	WBC	RBC	HGB	MCV	PLT
1	21.42	5.3	18.9	104.7	557
2	21.67	5.44	19.4	104.8	557
3	22.01	5.46	19.2	104.9	563
4	21.37	5.45	19.3	104.8	540
5	21.77	5.54	19.5	104.9	560
6	21.51	5.48	19.3	105.3	559
7	21.91	5.49	19.3	104.8	560
8	22..01	5.47	19.4	104.7	548
9	21.44	5.47	19.3	104.8	548
10	22.02	5.47	19.4	104.8	557
Mean	21.68	5.46	19.30	104.85	554.90
SD	0.26	0.06	0.16	0.17	7.19
CV%	1.19%	1.13%	0.85%	0.16%	1.30%
Target	22.60	5.48	19.7	104.2	572

Prepared by:	Zybio Inc.		
Name:	ASHOK DAKSH		
Title: ZONAL SERVICE MANAGER	Sign:		Date:21/09/2022
Approved by:			
Name:	SHIVAM GUPTA		
Title :	Sign:		Date: 21-09-22

Deviation: None

Conclusion: This report certifies that the instrument is qualified to perform as per manufacturer's specifications.

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