

# Calibration Certificate

Instrument : 3 – Part Differential Hematology Analyzer Z3

Laboratory : Life Care Diagnostic

Supported by : Zybio Inc.

## Calibration Certificate Protocol

This Calibration Certificate protocol is performed in the lab: Life Care Diagnostic.

Installation located at: Shop No.16/17, Taradutt Sankul Complex ,Infront of Vidya Medical Chouk ,Taluka – Khalapur,Dist – Raigad Pin – 410206,Maharashtra.

- 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:	Rajan S.Karnik		
Title: Zonal Service Manager	Sign:	Date:20/04/2020	
Approved by:			
Name:	Mr.Sushant V.Patil		
Title : Proprietor	Sign:	Date:20/04/2020	

For and on behalf of  
**Zybio Inc.**  
*Cui Yang*  
Authorized Signature(s)

**Calibration Requirement:**

<b>Sr. No.</b>	<b>Description</b>	<b>Compliance Yes/No</b>
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:**

<b>Sr. No.</b>	<b>Verification</b>	<b>Checked Yes/No</b>
1.	Instrument is identified  Serial Number: <u>EZY2100Z3190400596</u>	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

# 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  $\geq 10$  cm, The reserved space between the back panel and the wall  $\geq 25$  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

### Report Sign Off:

Prepared by:	Zybio Inc.		
Name:	Rajan S.Karnik		
Title: Zonal Service Manager	Sign:	Date:20/04/2020	
Approved by:			
Name:	Mr.Sushant V.Patil		
Title : Proprietor	Sign:	Date:20/04/2020	

