



Date:  
Effective Date:

## Certificate of Calibration

**Customer Name: Redcliffe Lifetech Pvt. Ltd. Meerut**

**Model : Automated Hematology Analyzer Elite 580**

**Serial No. K11052133022**

**Calibration Done Date: 7.9.22**

**Next Calibration Due Date On or Before: 07-09-2023**

**Lab In-charge: . Dr. Renu Kamboj**

*This is to certify that the above-mentioned product has been verified of calibration for CBC 5 parameters (WBC, RBC, HGB, MCV and PLT) according to the standard procedures provided by Erba Lachema s.r.o, Karasek.*

Calibration at site performed by  
Engineer Name: Sharad Srivastava  
Designation: Area Service Manager  
Transasia Bio-Medicals Ltd  
Location: Meerut

Encl:

1. Certificate of Inspection
2. Assay Sheet of Hematology Calibrator (H Cal)
3. Printouts
4. Traceability Document

Date: 07-09-2022  
Effective Date: 07-09-2022

## Certificate of Inspection

1. Model: Automated Hematology Analyzer Elite 580
2. Serial No.: K11052133022
3. Calibration Date: 07-09-2022
4. Material used: H Cal (Lot No. PLUS0822, Expiry date: 10-Sep-2022)

By comparing your data to the results of the standard counters in Erba Lachema, the calibration for CBC 5 parameters using the measurement standard material (H Cal) was completed. The calibration result of 5 runs is summarized in the following table. Please refer to the attached sheets for the details.

  
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Transasia Bio-Medicals Ltd

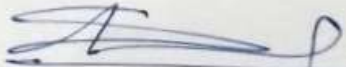
## 5. BACKGROUND CHECK

| PARAMETER | RESULT | Range                          |
|-----------|--------|--------------------------------|
| WBC       | 0.0    | $0.3 \times 10^3$ /UI or Less  |
| RBC       | 0.00   | $0.02 \times 10^6$ /uL or Less |
| HGB       | 0.0    | 0.1 g/dL or Less               |
| PLT       | 0      | $10 \times 10^3$ /uL or Less   |

  
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## 6. PRECISION STUDY PERFORMED ON THE ANALYSER USING A BLOOD SAMPLE (ORIGINAL ATTACHED)

| SMP NO         | WBC         | RBC         | HGB         | MCV         | PLT         |
|----------------|-------------|-------------|-------------|-------------|-------------|
| 1              | 8.46        | 4.21        | 12.3        | 92.4        | 163         |
| 2              | 8.65        | 4.27        | 12.3        | 92.5        | 161         |
| 3              | 8.77        | 4.16        | 12.3        | 92.3        | 167         |
| 4              | 8.49        | 4.2         | 12.3        | 92.5        | 166         |
| 5              | 8.59        | 4.27        | 12.3        | 92.6        | 157         |
| 6              | 8.4         | 4.28        | 12.3        | 92.6        | 162         |
| 7              | 8.4         | 4.34        | 12.4        | 92.6        | 160         |
| 8              | 8.45        | 4.34        | 12.4        | 92.7        | 165         |
| 9              | 8.32        | 4.29        | 12.4        | 92.7        | 161         |
| 10             | 8.49        | 4.32        | 12.4        | 92.7        | 163         |
| Mean           | 8.50        | 4.27        | 12.34       | 92.56       | 162.50      |
| SD             | 0.13        | 0.06        | 0.05        | 0.13        | 2.99        |
| CV%            | 1.57        | 1.43        | 0.42        | 0.15        | 1.84        |
| Acceptable CV% | Within 3.5% | Within 2.0% | Within 1.5% | Within 2.0% | Within 6.0% |
| Result         | PASS        | PASS        | PASS        | PASS        | PASS        |

  
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## Calibrator

Lot No.: PLUS0822  
Calibration Mode: Whole Blood

Exp. Date: 2022/09/10  
Print Time: 2022/09/07 17:06:53

| PARA.                                | WBC    | RBC    | HGB    | MCV    | PLT    |
|--------------------------------------|--------|--------|--------|--------|--------|
| Target                               | 9.27   | 4.49   | 13.3   | 84.6   | 258    |
| √ 1                                  | 9.23   | 4.43   | 13.2   | 83.5   | 248    |
| √ 2                                  | 9.15   | 4.45   | 13.2   | 83.2   | 256    |
| √ 3                                  | 9.16   | 4.50   | 13.4   | 83.4   | 250    |
| √ 4                                  | 9.09   | 4.49   | 13.3   | 83.5   | 242    |
| √ 5                                  | 9.04   | 4.47   | 13.3   | 83.5   | 255    |
| √ 6                                  | 9.35   | 4.51   | 13.4   | 83.4   | 241    |
| √ 7                                  | 8.96   | 4.48   | 13.3   | 83.4   | 249    |
| √ 8                                  | 9.11   | 4.46   | 13.3   | 83.7   | 257    |
| √ 9                                  | 9.21   | 4.48   | 13.3   | 83.5   | 243    |
| √ 10                                 | 9.07   | 4.52   | 13.4   | 83.4   | 243    |
| Mean                                 | 9.137  | 4.479  | 13.31  | 83.45  | 248.4  |
| CV(%)                                | 1.2    | 0.6    | 0.6    | 0.2    | 2.4    |
| New Calibration Coefficient (%)      | 101.46 | 100.25 | 99.92  | 101.38 | 103.86 |
| Original Calibration Coefficient (%) | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 |

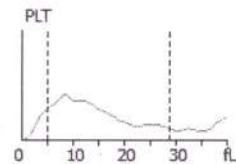
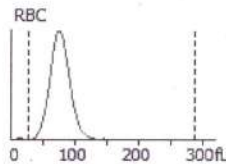
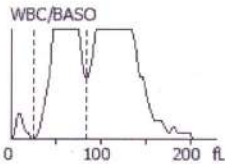


## L-J QC Analysis

|                              |                               |                            |
|------------------------------|-------------------------------|----------------------------|
| File No.: 7                  | Lot No.: EH2209L              | Level: Low                 |
| Operator: admin              | Exp. Date: 2022/11/10         | Run Time: 2022/09/07 17:39 |
| Print Time: 2022/09/13 15:26 | QC Mode: Whole Blood-CBC+DIFF | QC Sample ID:              |

| Parameter     | Result      | Ref. Range       | Unit                     |
|---------------|-------------|------------------|--------------------------|
| <b>1 WBC</b>  | <b>3.79</b> | <b>2.88-3.88</b> | <b>10<sup>3</sup>/uL</b> |
| 2 Neu%        | 49.6        | 38.3-56.3        | %                        |
| 3 Lym%        | 40.5        | 32.1-50.1        | %                        |
| 4 Mon%        | 6.3         | 2.6-10.6         | %                        |
| 5 Eos%        | 3.6         | 0.0-10.0         | %                        |
| 6 Bas%        | 56.9        | 50.6-66.6        | %                        |
| 7 Neu#        | 1.88        | 1.20-2.00        | 10 <sup>3</sup> /uL      |
| 8 Lym#        | 1.54        | 0.99-1.79        | 10 <sup>3</sup> /uL      |
| 9 Mon#        | 0.24        | 0.08-0.36        | 10 <sup>3</sup> /uL      |
| 10 Eos#       | 0.13        | 0.02-0.32        | 10 <sup>3</sup> /uL      |
| 11 Bas#       | 2.16        | 1.68-2.28        | 10 <sup>3</sup> /uL      |
| <b>12 RBC</b> | <b>2.39</b> | <b>2.15-2.51</b> | <b>10<sup>6</sup>/uL</b> |
| 13 HGB        | 6.0         | 5.4-6.2          | g/dL                     |
| 14 HCT        | 18.3        | 15.7-19.7        | %                        |
| 15 MCV        | 76.6        | 70.8-80.8        | fL                       |
| 16 MCH        | 25.3        | 22.1-27.1        | pg                       |
| 17 MCHC       | 33.1        | 29.1-35.1        | g/dL                     |
| 18 RDW-CV     | 19.7        | 16.5-22.5        | %                        |
| 19 RDW-SD     | 55.4        | 44.2-64.2        | fL                       |
| <b>20 PLT</b> | <b>50</b>   | <b>26-66</b>     | <b>10<sup>3</sup>/uL</b> |
| 21 MPV        | 11.0        | 7.4-13.4         | fL                       |
| 22 PDW-SD     | 12.6        | 9.3-15.3         | fL                       |
| 23 PDW-CV     | 14.2        | 11.0-17.0        | %                        |
| 24 PCT        | 0.054       | 0.000-0.096      | %                        |
| 25 P-LCR      | 31.6        | 20.4-36.4        | %                        |
| 26 P-LCC      | 16          | 0-30             | 10 <sup>9</sup> /L       |

Peri

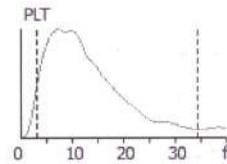
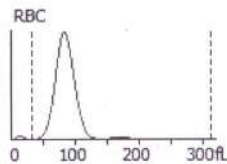
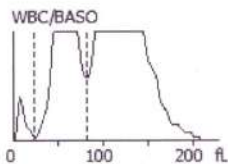


## L-J QC Analysis

|             |                  |            |                      |               |                  |
|-------------|------------------|------------|----------------------|---------------|------------------|
| File No.:   | 8                | Lot No.:   | EH2209N              | Level:        | Normal           |
| Operator:   | admin            | Exp. Date: | 2022/11/10           | Run Time:     | 2022/09/07 17:37 |
| Print Time: | 2022/09/13 15:26 | QC Mode:   | Whole Blood-CBC+DIFF | QC Sample ID: |                  |

| Parameter     | Result      | Ref. Range       | Unit                     |
|---------------|-------------|------------------|--------------------------|
| <b>1 WBC</b>  | <b>8.45</b> | <b>6.74-8.74</b> | <b>10<sup>3</sup>/uL</b> |
| 2 Neu%        | 56.9        | 48.7-64.7        | %                        |
| 3 Lym%        | 30.6        | 22.0-38.0        | %                        |
| 4 Mon%        | 7.7         | 2.2-12.2         | %                        |
| 5 Eos%        | 4.8         | 0.1-12.1         | %                        |
| 6 Bas%        | 70.0        | 62.3-78.3        | %                        |
| 7 Neu#        | 4.81        | 3.69-5.09        | 10 <sup>3</sup> /uL      |
| 8 Lym#        | 2.59        | 1.62-3.02        | 10 <sup>3</sup> /uL      |
| 9 Mon#        | 0.65        | 0.06-1.06        | 10 <sup>3</sup> /uL      |
| 10 Eos#       | 0.40        | 0.00-0.94        | 10 <sup>3</sup> /uL      |
| 11 Bas#       | 5.92        | 4.74-6.14        | 10 <sup>3</sup> /uL      |
| <b>12 RBC</b> | <b>4.64</b> | <b>4.37-4.85</b> | <b>10<sup>6</sup>/uL</b> |
| 13 HGB        | 13.5        | 12.5-13.7        | g/dL                     |
| 14 HCT        | 39.2        | 36.0-42.0        | %                        |
| 15 MCV        | 84.5        | 79.5-89.5        | fL                       |
| 16 MCH        | 29.1        | 25.8-30.8        | pg                       |
| 17 MCHC       | 34.5        | 30.8-36.8        | g/dL                     |
| 18 RDW-CV     | 16.9        | 14.7-20.7        | %                        |
| 19 RDW-SD     | 52.5        | 44.1-64.1        | fL                       |
| <b>20 PLT</b> | <b>274</b>  | <b>216-296</b>   | <b>10<sup>3</sup>/uL</b> |
| 21 MPV        | 10.1        | 6.9-12.9         | fL                       |
| 22 PDW-SD     | 12.9        | 8.9-14.9         | fL                       |
| 23 PDW-CV     | 16.7        | 13.0-19.0        | %                        |
| 24 PCT        | 0.275       | 0.152-0.352      | %                        |
| 25 P-LCR      | 27.9        | 18.2-34.2        | %                        |
| 26 P-LCC      | 76          | 42-92            | 10 <sup>9</sup> /L       |

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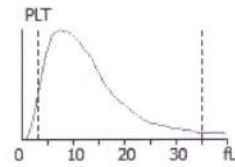
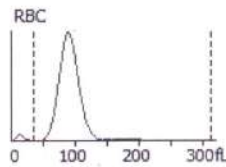
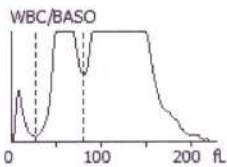


## L-J QC Analysis

File No.: 9                      Lot No.: EH2209H                      Level: High  
 Operator: admin                      Exp. Date: 2022/11/10                      Run Time: 2022/09/07 17:40  
 Print Time: 2022/09/13 15:27                      QC Mode: Whole Blood-CBC+DIFF                      QC Sample ID:

| Parameter     | Result       | Ref. Range         | Unit                     |
|---------------|--------------|--------------------|--------------------------|
| <b>1 WBC</b>  | <b>18.48</b> | <b>15.33-20.33</b> | <b>10<sup>3</sup>/uL</b> |
| 2 Neu%        | 66.2         | 56.8-70.8          | %                        |
| 3 Lym%        | 20.3         | 14.6-26.6          | %                        |
| 4 Mon%        | 7.1          | 1.2-13.2           | %                        |
| 5 Eos%        | 6.4          | 1.4-15.4           | %                        |
| 6 Bas%        | 80.3         | 72.0-88.0          | %                        |
| 7 Neu#        | 12.24        | 9.98-12.78         | 10 <sup>3</sup> /uL      |
| 8 Lym#        | 3.75         | 2.57-4.77          | 10 <sup>3</sup> /uL      |
| 9 Mon#        | 1.31         | 0.18-2.38          | 10 <sup>3</sup> /uL      |
| 10 Eos#       | 1.18         | 0.20-2.80          | 10 <sup>3</sup> /uL      |
| 11 Bas#       | 14.84        | 12.77-15.77        | 10 <sup>3</sup> /uL      |
| <b>12 RBC</b> | <b>5.46</b>  | <b>4.99-5.99</b>   | <b>10<sup>6</sup>/uL</b> |
| 13 HGB        | 17.4         | 16.3-17.9          | g/dL                     |
| 14 HCT        | 49.7         | 45.9-53.9          | %                        |
| 15 MCV        | 91.0         | 84.7-96.7          | fL                       |
| 16 MCH        | 31.9         | 28.5-33.5          | pg                       |
| 17 MCHC       | 35.0         | 31.3-37.3          | g/dL                     |
| 18 RDW-CV     | 16.3         | 13.4-19.4          | %                        |
| 19 RDW-SD     | 54.4         | 43.0-67.0          | fL                       |
| <b>20 PLT</b> | <b>509</b>   | <b>415-535</b>     | <b>10<sup>3</sup>/uL</b> |
| 21 MPV        | 9.9          | 6.7-12.7           | fL                       |
| 22 PDW-SD     | 11.8         | 8.7-14.7           | fL                       |
| 23 PDW-CV     | 15.9         | 12.9-18.9          | %                        |
| 24 PCT        | 0.506        | 0.271-0.671        | %                        |
| 25 P-LCR      | 26.0         | 17.0-33.0          | %                        |
| 26 P-LCC      | 133          | 79-149             | 10 <sup>9</sup> /L       |

*Reilly*





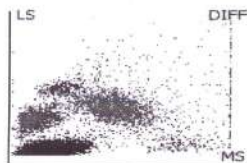
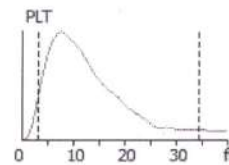
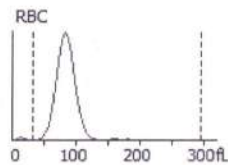
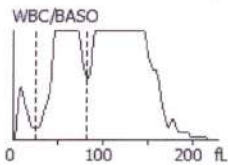


## L-J QC Analysis

|             |                  |            |                      |               |                  |
|-------------|------------------|------------|----------------------|---------------|------------------|
| File No.:   | 8                | Lot No.:   | EH2209N              | Level:        | Normal           |
| Operator:   | admin            | Exp. Date: | 2022/11/10           | Run Time:     | 2022/09/13 09:58 |
| Print Time: | 2022/09/13 15:03 | QC Mode:   | Whole Blood-CBC+DIFF | QC Sample ID: |                  |

| Parameter     | Result      | Ref. Range       | Unit                     |
|---------------|-------------|------------------|--------------------------|
| <b>1 WBC</b>  | <b>7.95</b> | <b>6.74-8.74</b> | <b>10<sup>3</sup>/uL</b> |
| 2 Neu%        | 58.3        | 48.7-64.7        | %                        |
| 3 Lym%        | 30.3        | 22.0-38.0        | %                        |
| 4 Mon%        | 6.8         | 2.2-12.2         | %                        |
| 5 Eos%        | 4.6         | 0.1-12.1         | %                        |
| 6 Bas%        | 71.0        | 62.3-78.3        | %                        |
| 7 Neu#        | 4.64        | 3.69-5.09        | 10 <sup>3</sup> /uL      |
| 8 Lym#        | 2.41        | 1.62-3.02        | 10 <sup>3</sup> /uL      |
| 9 Mon#        | 0.54        | 0.06-1.06        | 10 <sup>3</sup> /uL      |
| 10 Eos#       | 0.36        | 0.00-0.94        | 10 <sup>3</sup> /uL      |
| 11 Bas#       | 5.65        | 4.74-6.14        | 10 <sup>3</sup> /uL      |
| <b>12 RBC</b> | <b>4.64</b> | <b>4.37-4.85</b> | <b>10<sup>6</sup>/uL</b> |
| 13 HGB        | 13.4        | 12.5-13.7        | g/dL                     |
| 14 HCT        | 39.0        | 36.0-42.0        | %                        |
| 15 MCV        | 84.1        | 79.5-89.5        | fL                       |
| 16 MCH        | 29.0        | 25.8-30.8        | pg                       |
| 17 MCHC       | 34.5        | 30.8-36.8        | g/dL                     |
| 18 RDW-CV     | 16.9        | 14.7-20.7        | %                        |
| 19 RDW-SD     | 52.1        | 44.1-64.1        | fL                       |
| <b>20 PLT</b> | <b>266</b>  | <b>216-296</b>   | <b>10<sup>3</sup>/uL</b> |
| 21 MPV        | 10.0        | 6.9-12.9         | fL                       |
| 22 PDW-SD     | 12.9        | 8.9-14.9         | fL                       |
| 23 PDW-CV     | 16.7        | 13.0-19.0        | %                        |
| 24 PCT        | 0.266       | 0.152-0.352      | %                        |
| 25 P-LCR      | 27.6        | 18.2-34.2        | %                        |
| 26 P-LCC      | 73          | 42-92            | 10 <sup>9</sup> /L       |

Pass



# L-J QC Analysis

File No.: 9

Lot No.: EH2209H

Level: High

Operator: admin

Exp. Date: 2022/11/10

Run Time: 2022/09/13 10:00

Print Time: 2022/09/13 15:03

QC Mode: Whole Blood-CBC+DIFF

QC Sample ID:

| Parameter     | Result       | Ref. Range         | Unit                     |
|---------------|--------------|--------------------|--------------------------|
| <b>1 WBC</b>  | <b>18.43</b> | <b>15.33-20.33</b> | <b>10<sup>3</sup>/uL</b> |
| 2 Neu%        | 67.4         | 56.8-70.8          | %                        |
| 3 Lym%        | 19.5         | 14.6-26.6          | %                        |
| 4 Mon%        | 7.0          | 1.2-13.2           | %                        |
| 5 Eos%        | 6.1          | 1.4-15.4           | %                        |
| 6 Bas%        | 80.8         | 72.0-88.0          | %                        |
| 7 Neu#        | 12.43        | 9.98-12.78         | 10 <sup>3</sup> /uL      |
| 8 Lym#        | 3.59         | 2.57-4.77          | 10 <sup>3</sup> /uL      |
| 9 Mon#        | 1.29         | 0.18-2.38          | 10 <sup>3</sup> /uL      |
| 10 Eos#       | 1.12         | 0.20-2.80          | 10 <sup>3</sup> /uL      |
| 11 Bas#       | 14.90        | 12.77-15.77        | 10 <sup>3</sup> /uL      |
| <b>12 RBC</b> | <b>5.54</b>  | <b>4.99-5.99</b>   | <b>10<sup>6</sup>/uL</b> |
| 13 HGB        | 17.5         | 16.3-17.9          | g/dL                     |
| 14 HCT        | 50.1         | 45.9-53.9          | %                        |
| 15 MCV        | 90.5         | 84.7-96.7          | fL                       |
| 16 MCH        | 31.6         | 28.5-33.5          | pg                       |
| 17 MCHC       | 34.9         | 31.3-37.3          | g/dL                     |
| 18 RDW-CV     | 16.6         | 13.4-19.4          | %                        |
| 19 RDW-SD     | 54.7         | 43.0-67.0          | fL                       |
| <b>20 PLT</b> | <b>482</b>   | <b>415-535</b>     | <b>10<sup>3</sup>/uL</b> |
| 21 MPV        | 9.9          | 6.7-12.7           | fL                       |
| 22 PDW-SD     | 11.9         | 8.7-14.7           | fL                       |
| 23 PDW-CV     | 16.0         | 12.9-18.9          | %                        |
| 24 PCT        | 0.475        | 0.271-0.671        | %                        |
| 25 P-LCR      | 26.0         | 17.0-33.0          | %                        |
| 26 P-LCC      | 126          | 79-149             | 10 <sup>9</sup> /L       |

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