

Date:28/09/22

Certificate of inspection

Customer Name: Excellas Clinics Mulund Mumbai

Model: Automated Hematology analyzer Sysmex kx21

Serial no: B8406

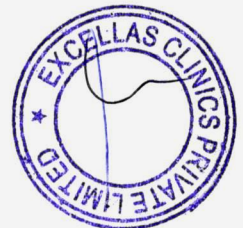
Calibration Date: 28/09/22

Material used : KX21 CAL (lot no NK0922 Exp Date 05/10/22)

By comparing data to the results of standards counter in Sysmex Corporation the calibration for kx21 analyzer parameters using the measurements standard material kx21 cal was completed. The calibration results of 03 run are summarized in the following table. Please refer to the attached sheets for details.

Technical service department

M.M.R



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Cell No.: 9967289643

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diagnova@yahoo.co.in

Certificate of inspection

Customer Name: Excellas Clinics Mulund Mumbai

Model: Automated Hematology analyzer Sysmex kx21

Serial no: B8406

Calibration Date: 28/09/22 **Next Calibration Date on or before** 27/09/23

Lab in charge: Mis Sonam pandit.

This is to certify that the above mentioned product has been verified of calibration according to the standards procedures provided by Sysmex Corporation Japan.

The reference instruments used for value assignment are managed by traceability system in sysmex corporation and these are traceable to the international standards such as ICSH.

Calibration at site performed by

Manoj Rane.

M.M.R.



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SYSMEX KA21
(3 part)

28/09/22

Calibrator's run.

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Ist Run

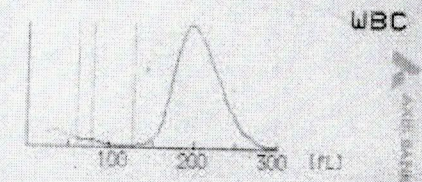
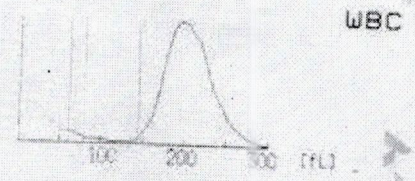
IInd Run

No. 17
Date 28/09/22 15:41
Mode WB

No. 18
Date 28/09/22 15:43
Mode WB

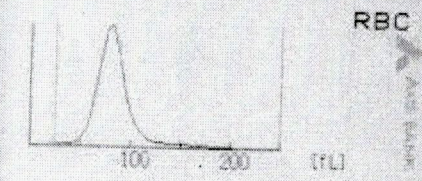
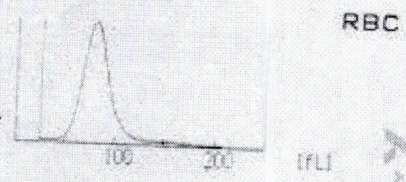
WBC $8.8 \times 10^9 / \mu L$
RBC $4.43 \times 10^6 / \mu L$
HGB 13.3g/dL
HCT 35.5%
MCV ---- -fL
MCH ---- -pg
MCHC ---- -g/dL
PLT $267 \times 10^3 / \mu L$

WBC $8.9 \times 10^9 / \mu L$
RBC $4.46 \times 10^6 / \mu L$
HGB 13.3g/dL
HCT 35.7%
MCV ---- -fL
MCH ---- -pg
MCHC ---- -g/dL
PLT $247 \times 10^3 / \mu L$



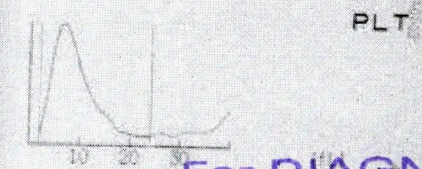
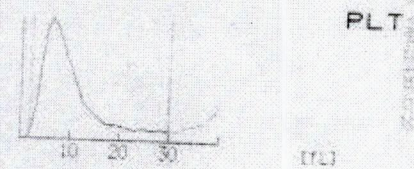
LYM% ---- -%
MXD% ---- -%
NEUT% ---- -%
LYM# ---- -x10⁹ / μL
MXD# ---- -x10⁹ / μL
NEUT# ---- -x10⁹ / μL

LYM% ---- -%
MXD% ---- -%
NEUT% ---- -%
LYM# ---- -x10⁹ / μL
MXD# ---- -x10⁹ / μL
NEUT# ---- -x10⁹ / μL



RDW ---- -%

RDW ---- -%



PDW ---- -fL
MPV ---- -fL
P-LCR ---- -%

PDW ---- -fL
MPV ---- -fL
P-LCR ---- -%

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LAB DIRECTOR

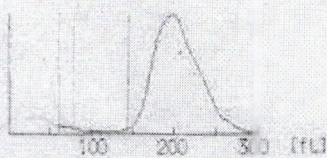


IIIrd Run

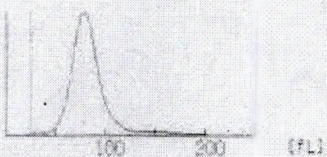
IV Run

No. 19
 Date 28/09/22 15:44
 Mode WB

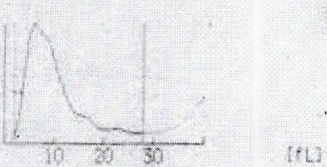
WBC $8.8 \times 10^3 / \mu\text{L}$
 RBC $4.58 \times 10^6 / \mu\text{L}$
 HGB 13.3g/dL
 HCT 36.6%
 MCV ---. -fL
 MCH ---. -pg
 MCHC ---. -g/dL
 PLT $261 \times 10^3 / \mu\text{L}$



LVM% ---. -%
 MXD% ---. -%
 NEUT% ---. -%
 LYM# ---. - $\times 10^3 / \mu\text{L}$
 MXD# ---. - $\times 10^3 / \mu\text{L}$
 NEUT# ---. - $\times 10^3 / \mu\text{L}$



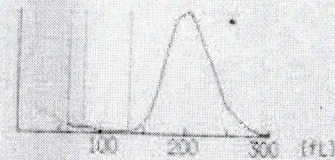
RDW ---. -%



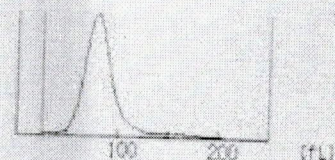
PDW ---. -fL
 MPU ---. -fL
 P-LCR ---. -%

No. 20
 Date 28/09/22 15:45
 Mode WB

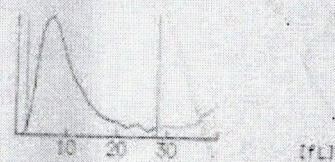
JBC $8.8 \times 10^3 / \mu\text{L}$
 RBC $4.47 \times 10^6 / \mu\text{L}$
 HGB 13.4g/dL
 HCT 35.9%
 MCV ---. -fL
 MCH ---. -pg
 MCHC ---. -g/dL
 PLT $263 \times 10^3 / \mu\text{L}$



LYM% ---. -%
 MXD% ---. -%
 NEUT% ---. -%
 LYM# ---. - $\times 10^3 / \mu\text{L}$
 MXD# ---. - $\times 10^3 / \mu\text{L}$
 NEUT# ---. - $\times 10^3 / \mu\text{L}$



RDW ---. -%



PDW ---. -fL
 MPU ---. -fL
 P-LCR ---. -%

For DIAGNOVA

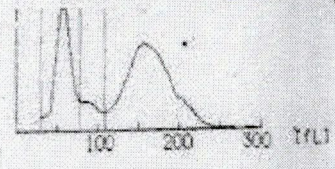
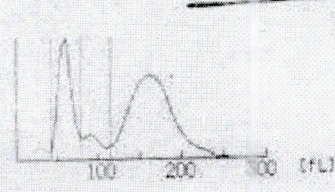


1st Balram Panigrahi
No. 5
Date 28/09/22 10:52
Mode WB

2nd Balram Panigrahi
No. 1
Date 28/09/22 15:49
Mode WB

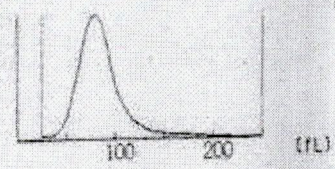
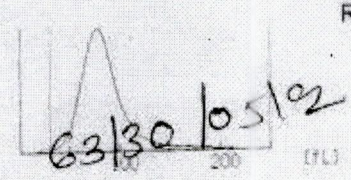
JBC $5.1 \times 10^3 / \mu\text{L}$
RBC $4.96 \times 10^6 / \mu\text{L}$
HGB 14.0g/dL
HCT 39.9%
MCV - 80.4fL
MCH 28.2Pg
MCHC 35.1g/dL
PLT $234 \times 10^3 / \mu\text{L}$

JBC $5.5 \times 10^3 / \mu\text{L}$
RBC $4.96 \times 10^6 / \mu\text{L}$
HGB 13.9g/dL
HCT 40.1%
MCV - 80.8fL
MCH 28.0Pg
MCHC 34.7g/dL
PLT $233 \times 10^3 / \mu\text{L}$



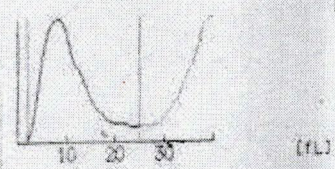
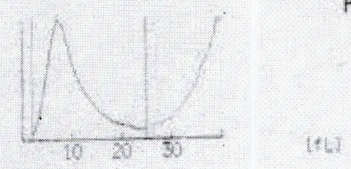
-YM% 29.1%
MXD% 8.2%
NEUT% 62.7%
-YM# $1.5 \times 10^3 / \mu\text{L}$
MXD# $0.4 \times 10^3 / \mu\text{L}$
NEUT# $3.2 \times 10^3 / \mu\text{L}$

-YM% 31.1%
MXD% 7.8%
NEUT% 61.1%
-YM# $1.7 \times 10^3 / \mu\text{L}$
MXD# $0.4 \times 10^3 / \mu\text{L}$
NEUT# $3.4 \times 10^3 / \mu\text{L}$



RDW + 17.7%

RDW + 17.5%



PDW 13.7fL
MPV 10.2fL
P-LCR 28.3%

PDW 15.1fL
MPV 10.7fL
P-LCR 32.8%

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SYSTEM RX 21
(3 part)

28/09/22

Sample IQC



level 1

No. QC01
Date 28/09/22 10:44
Mode QC

WBC	2.9x10 ³ /μL
RBC	2.48x10 ⁶ /μL
HGB	6.3g/dL
HCT	17.4%
MCV	70.2fL
MCH	25.4pg
MCHC	36.2g/dL
PLT	62x10 ³ /μL
LYM%	15.9%
MXD%	18.3%
NEUT%	65.8%
LYM#	0.5x10 ³ /μL
MXD#	0.5x10 ³ /μL
NEUT#	1.9x10 ³ /μL
W-SMV	55.3fL
W-LMV	202.4fL
RDW-CV	11.4%
RDW-SD	33.6fL
PDW	13.0fL
MPV	9.4fL
P-LCR	23.8%

Done by Sonam

QC Level - 2

No. QC01
Date 29/09/22 13:28
Mode QC

WBC	2.6x10 ³ /μL
RBC	2.43x10 ⁶ /μL
HGB	6.3g/dL
HCT	17.1%
MCV	70.4fL
MCH	25.9pg
MCHC	36.8g/dL
PLT	75x10 ³ /μL
LYM%	14.2%
MXD%	19.2%
NEUT%	66.6%
LYM#	0.4x10 ³ /μL
MXD#	0.5x10 ³ /μL
NEUT#	1.7x10 ³ /μL
W-SMV	52.8fL
W-LMV	199.0fL
RDW-CV	11.3%
RDW-SD	33.3fL
PDW	14.3fL
MPV	10.7fL
P-LCR	32.4%

Done by Sonam

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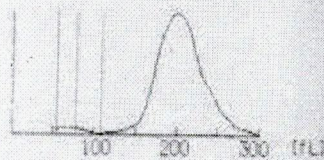
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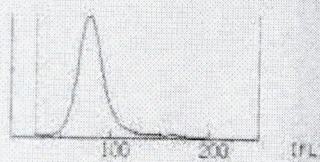
Vth Run.

No. 21
Date 28/09/22 15:47
Mode WB

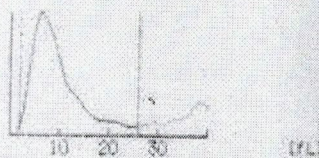
WBC $8.1 \times 10^3 / \mu\text{L}$
RBC $4.45 \times 10^6 / \mu\text{L}$
HGB 13.3g/dL
HCT 35.5%
MCV ---, -fL
MCH ---, -pg
MCHC ---, -g/dL
PLT $247 \times 10^3 / \mu\text{L}$



LYM% ---, -%
MXD% ---, -%
NEUT% ---, -%
LYM# ---, -x10³/μL
MXD# ---, -x10³/μL
NEUT# ---, -x10³/μL



RDW ---, -%



PDW ---, -fL
MPV ---, -fL
P-LCR ---, -%



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Sysmex, KX 21
(3 part)

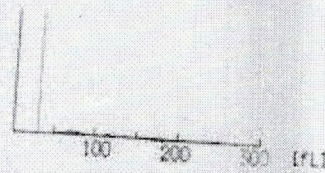
201091122

Background check

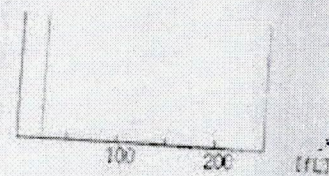


No. 5
Date 28/09/22 15:48
Mode WB

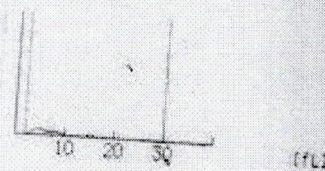
WBC 0.0 x 10³ / μ L
RBC 0.00 x 10⁶ / μ L
HGB 0.0g/dL
HCT 0.0%
MCV --- fL
MCH --- pg
MCHC --- g/dL
PLT 0 x 10³ / μ L



LYM% --- %
MYD% --- %
NEUT% --- %
LYM# --- x 10³ / μ L
MYD# --- x 10³ / μ L
NEUT# --- x 10³ / μ L



RDW --- %



PDW --- fL
MPV --- fL
P-LCR --- %



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NEK-CAL

HEMATOLOGY CALIBRATOR

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LOT NK0922



2022-10-05

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Calibration Values for Manual Mode

Parameter	Sysmex® XT-4000i	Acceptable Range	Sysmex XE-2100™ XE-2100D	Acceptable Range	Sysmex KX-21 KX-21N	Acceptable Range
WBC 10 ³ /μL	9.0	± 0.2	9.3	± 0.2	8.8	± 0.2
RBC 10 ⁶ /μL	4.47	± 0.10	4.49	± 0.10	4.42	± 0.10
HGB g/dL	13.3	± 0.2	13.5	± 0.2	13.3	± 0.2
HCT %	38.4	± 1.0	39.1	± 1.0	36.2	± 1.0
MCV fL	86.0	± 2.0	87.0	± 2.0	82.0	± 2.0
PLT 10 ³ /μL	243	± 12	235	± 12	258	± 12

Note: The instrument manufacturer states that a Sysmex Field Service Representative is solely responsible for calibration of WBC, RBC, and PLT. The operator is responsible for calibration of HGB and HCT.

INTENDED USE

NEK-CAL is designed for use in the calibration of Sysmex hematology analyzers. Please refer to the assay table for specific instrument models.

SUMMARY AND PRINCIPLE

Hematology analyzers require periodic calibration in order to generate accurate patient results. This calibrator is a stable, whole blood preparation that can be used to verify and adjust calibration of select hematology instruments.

Calibrator values for NEK-CAL are derived from replicate testing on instruments operated and maintained according to the manufacturer's instructions. Instruments are calibrated with whole blood using values determined by reference methods.

REAGENTS

NEK-CAL is an *in vitro* diagnostic reagent composed of human erythrocytes, mammalian leukocytes and mammalian platelets suspended in a plasma-like fluid with preservatives.



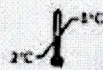
PRECAUTION

NEK-CAL 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 of this product has been tested by a FDA licensed method/test and found to be negative or non-reactive for the presence of HBsAg, Anti-HCV, NAT testing for HIV-1, HCV (RNA) and HIV-1/2. Each unit is also negative by a serological test for Syphilis (RPR or STS). Because no test method can offer complete assurance that infectious agents are absent, this 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 NEK-CAL 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 for 5 days, provided they are handled properly.

INDICATIONS OF DETERIORATION

After mixing, product should be similar in appearance to fresh 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.

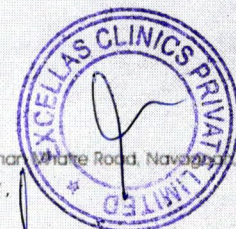
For DIAGNOVA

Proprietor

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Instruments • Reagents • Maintenance

LAB

NEK-CAL

HEMATOLOGY CALIBRATOR

Diagnostica

Complete solutions



INSTRUCTIONS FOR USE

A. Mixing and handling directions:

1. Remove tubes from the refrigerator and allow to warm at room temperature (15 - 30°C or 59 - 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 running each sample.
3. After sampling:
 - a) Automatic Sample Handling: Remove the tube from the sample handler immediately after sampling.
 - b) Manual Sample Handling: Carefully wipe the tube rim and cap with a lint-free tissue and replace the cap.
4. Return tubes to refrigerator within 30 minutes of use.

B. Analyze Calibrator:

1. Prime the instrument once by aspirating calibrator sample. Discard the result.
2. Analyze calibrator according to the calibration procedure in the Operator's Manual for your instrument.
3. Compare the mean value for each parameter to the assigned value.
 - a) If the difference is within the Range, calibration is optional.
 - b) If the difference is not within the Range, calibration may be needed.
4. Ranges given on the assay sheet are intended as guidelines for evaluating instrument calibration. Acceptable ranges should be established by each laboratory. If the calibrator recovered data is outside the range found on the assay sheet with stable control results, interlaboratory QC and/or Proficiency Testing reports that have excellent peer group agreement, this may indicate possible product damage. Do not use the product if deterioration is suspected.

C. Adjust instrument calibration and verify results:

1. Calibrate the instrument by using the calibration adjustment procedures described in the Operator's Manual for your instrument.
2. Verify calibration by analyzing calibrator and repeat step 3 under "Analyze Calibrator".
3. Confirm calibration by running quality control material.

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.

REFERENCE METHODS

1. **WBC:** A series of 1:500 dilutions are made with calibrated glassware. Counting is performed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.
2. **RBC:** A series of 1:50,000 dilutions are made with calibrated glassware. Counting is performed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.
3. **HGB:** Hemoglobin value is determined by spectrophotometric procedure according to CLSI Standard H15-A3 and is traceable to ICSH/WHO International Haemoglobinocyanide Standard.
4. **HCT:** Packed cell volume (PCV) is measured by the microhematocrit procedure according to CLSI Standard H7-A3. No correction is made for trapped plasma.
5. **PLT:** A series of 1:126 dilutions are made using calibrated glassware in 1% ammonium oxalate. Platelets are counted using a hemocytometer and phase contrast microscopy.

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.

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

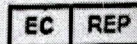
For assistance in resolving calibrator problems, please call Technical Service at (800) 523-3395. For additional information on R&D Systems, Inc. hematology controls and calibrators, or to place an order, call Customer Service at (800) 428-4246.

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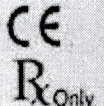


R & D Systems, Inc.
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AIS042-004 Rev. 06/13



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For DIAGNOVA

Proprietor

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Instruments • Reagents • Maintenance

NEK-CAL
Hematology Calibrator
CALIBRATOR

Intended Use:

NEK-CAL is designed for use in the calibration of Sysmex hematology analyzers. Please refer to the assay table for specific instrument models.

Summary and Principle:

Hematology analyzers require periodic calibration in order to generate accurate patient results. This calibrator is a stable, whole blood preparation that can be used to verify and adjust calibration of select hematology instruments.

Calibrator values for NEK-CAL are derived from replicate testing on instruments operated and maintained according to the manufacturer's instructions. Instruments are calibrated with whole blood using values determined by reference methods.

Reagents:

NEK-CAL is an *in vitro* diagnostic reagent composed of human erythrocytes, mammalian leukocytes and mammalian platelets suspended in a plasma-like fluid with preservatives.



Precaution:

NEK-CAL 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 of this product has been tested by a FDA licensed method/test and found to be negative or non-reactive for the presence of HBsAg, Anti-HCV, NAT testing for HIV-1, HCV (RNA) and HIV-1/2. Each unit is also negative by a serological test for Syphilis (RPR or STS). Because no test method can offer complete assurance that infectious agents are absent, this material should be handled as potentially infectious. When handling or disposing of vials follow precautions for patient specimens as specified in the OSHA Blood borne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

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Stability and Storage:

Store NEK-CAL 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 for 5 days, provided they are handled properly.

Indications of Deterioration:

After mixing, product should be similar in appearance to fresh 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.**



Instructions for Use:

A. Mixing and handling directions:

1. Remove tubes from the refrigerator and allow to warm at room temperature (15-30°C or 59-86°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 running each sample.
3. After sampling:
 - a) Automatic Sample Handling: Remove the tube from the sample handler immediately after sampling.
 - b) Manual Sample Handling: Carefully wipe the tube rim and cap with a lint-free tissue and replace the cap.
4. Return tubes to refrigerator within 30 minutes of use.

B. Analyze Calibrator:

1. Prime the instrument once by aspirating calibrator sample. Discard the result.
2. Analyze calibrator according to the calibration procedure in the Operator's Manual for your instrument.
3. Compare the mean value for each parameter to the assigned value.
 - a) If the difference is within the Range, calibration is optional.
 - b) If the difference is not within the Range, calibration may be needed.
4. Acceptable Ranges given on the assay sheet are intended as guidelines, but not absolute limits, for evaluating instrument calibration. Acceptable calibration should be established by each laboratory.



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C. Adjust instrument calibration and verify results:

1. Calibrate the instrument by using the calibration adjustment procedures described in the Operator's Manual for your instrument
2. Verify calibration by analyzing calibrator and repeat step 3 under "Analyze Calibrator".

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.

Reference Method

1. **WBC:** A series of 1:500 dilutions are made with calibrated glassware. Counting is performed on a Coulter Counter Z series instrument. All counts are corrected for coincidence
2. **RBC:** A series of 1:50,000 dilutions are made with calibrated glassware. Counting is performed on a Coulter Counter Z series instrument. All counts are corrected for coincidence
3. **HGB:** Hemoglobin value is determined by spectrophotometric procedure according to CLSI Standard H15-A3 and is traceable to ICSH/WHO International Haemoglobinocyanide Standard.
4. **HCT:** Packed cell volume (PCV) is measured by the microhematocrit procedure according to CLSI Standard H7-A3. No correction is made for trapped plasma.
5. **PLT:** A series of 1:126 dilutions are made using calibrated glassware in 1% ammonium oxalate. Platelets are counted using a hemocytometer and phase contrast microscopy.

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.

All brands and products are trademarks or registered trademarks of their respective companies.

Symbol Legends:

Symbol	Explanation of Symbol	Symbol	Explanation of Symbol	Symbol	Explanation of Symbol
	Consult instructions for use		Warning		Use by (date or month of expiry)
	In vitro diagnostic device		Manufacturer		Calibrator
	Store at 2 - 8 °C		Catalogue number		Control
	Precautions		Batch code No.		Authorized Representative

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CE EC REP

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CALIBRATION RUN

	WBC	RBC	HB	HCT	PLT
1 ST	8.8	4.43	13.3	35.5	267
2 ND	8.9	4.46	13.3	35.7	247
3RD	8.8	4.58	13.3	36.6	261
4TH	8.8	4.47	13.4	35.9	263
5TH	8.1	4.45	13.3	35.5	247

CALIBRATOR VALUE	WBC	RBC	HB	HCT	PLT
	8.8	4.42	13.3	36	258
RANGE+/-	0.2	0.1	0.2	1	12
LOW	8.6	4.32	35	80	246
HIGH	8.9	4.525	37	84	270

1 ST RUN	9.1	4.42	13.4	36.3	271
2 ND RUN	9.1	4.55	13.4	36.4	271

OLD FACTOR	101	101	101.5	103	100
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NEW FACTOR	98	99	100		95
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PRECISION STUDY PERFORMED ON THE ANALYSER USING BLOOD SAMPLES

	WBC	RBC	HGB	HCT	PLT
1	5.3	4.97	13.9	40.5	235
2	5.2	4.96	14	39.9	244
3	5.3	4.94	14	40.1	236
4	5.5	4.96	13.9	40.1	233
5	5.5	4.9	14	39.7	237
6	5.4	4.95	14	40.1	242
7	5.5	4.95	14.1	40.2	243
8	5.4	4.97	14.2	40.1	249
9	5.4	4.98	14.1	40	240
10	5.4	4.97	14.1	40	237

MEAN	5.3	4.95	14	40	239
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SD	0.099442893	0.02273	0.094868	0.205751	4.903513
cv	1.876280992	0.459198	0.677631	0.514377	2.051679



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