# Hematology Survey Calibration Verification /Linearity Kit


PS by Panudda Sothanapaisan
CL Rihes

20 Nov 2024

# Materials For LN9

1. RBC/HGB Set
   - LN9-08R — LN9-13R (RBC/HGB Set)
   - 6 Samples
2. WBC Sets
   - LN9-08W — LN9-14W (WBC Set)
   - 7 Samples
3. PLT Sets
   - LN9-08P — LN9-14P (PLT Set)
   - 7 Samples

| MATERIALS FOR THIS MAILING | |
|---|---|
| LN9 | LN9-08R — LN9-13R (RBC/HGB Set) |
| | LN9-08W — LN9-14W (WBC Set) |
| | LN9-08P — LN9-14P (PLT Set) |

# Storage and Stability

## Unopened Storage

Store at 2-8°C, do not freeze.

## Open Storage

Use immediately, then discard.


## Appearance

Normal appearance indicates product integrity.

Visible hemolysis of the supernatant may indicate product deterioration. **Do not use product if deterioration is suspected.**

# Appearance

Red blood cell/hemoglobin (RBC/HGB)

Fresh whole blood , A light pink-tinted supernatant

White blood cell (WBC)

clear to pale yellow supernatant

Platelet (PLT)

Clear to brownish supernatant

# LN9-B 2024

## Hematology Survey
Calibration Verification/Linearity
Kit Instructions 

| Hematology Calibration Verification/Linearity | |
|---|---|
| **Analyte** | **Program Code** |
| | **LN9** |
| Hemoglobin | ▮ |
| Platelet count | ▮ |
| RBC count | ▮ |
| WBC count | ▮ |

**Program Information**

- Twenty 3.0-mL liquid specimens
- Conventional and International System of Units (SI) reporting offered

**Shipping Schedule**

- Shipment A: April 4
- Shipment B: September 26

# Detailed Testing Instructions

## RBC/HGB Set

1

**RBC/HGB Set**

a. Allow vials to warm at room temperature for at least 15 minutes before mixing.
b. To mix, hold vial horizontally between the palms of the hands.
c. Roll the vial back and forth **rapidly for 30 seconds.** Gently invert the vial 10 times.
d. Continue to mix the vial in this manner until the cells are completely suspended and there are no visible aggregates. **Do not shake the vial or mix on a mechanical (vortex) blood mixer.**

## WBC/PLT Sets

**WBC/PLT Sets**

a. Allow vials to warm at room temperature for at least 15 minutes before mixing.
b. Mix by vigorously agitating on a vortex mixer for 2 minutes to ensure complete dispersion of microaggregates.
c. Let vials sit undisturbed for 10 minutes to allow micro bubbles to dissipate before sampling.
d. **For WBC and PLT testing on instruments with a blood detector:** Turn off the blood detector between each sample analysis. These instruments may not be able to test the specimens that do not contain any red blood cells.

2

Gently invert the vial 10 times immediately before each sampling.

3

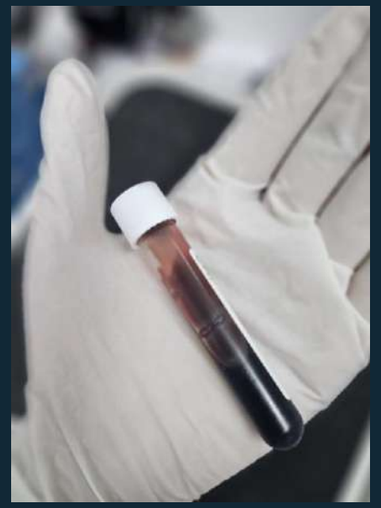
Perform **2** assays from each vial within the same run. Two data points **must** be received for each solution.

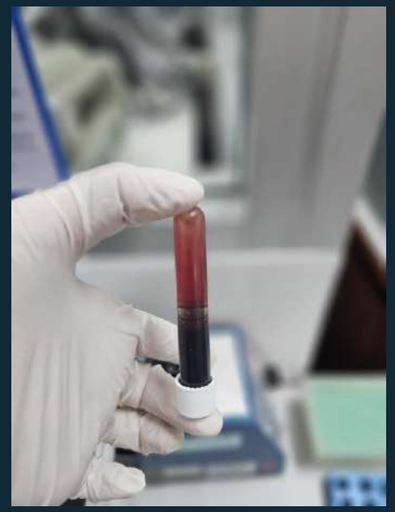
4

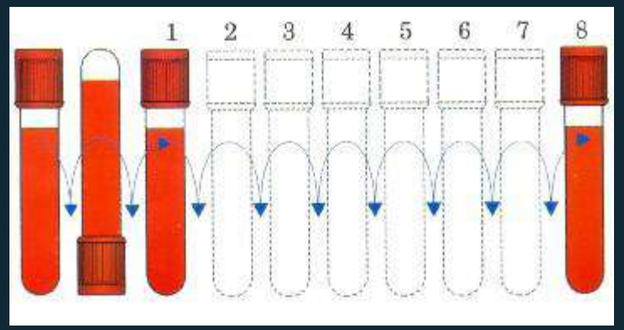
At least **4** consecutive data sets **must** be submitted to receive an evaluation for both calibration verification and linearity.

# How to Mix the Samples

## RBC/HGB Set





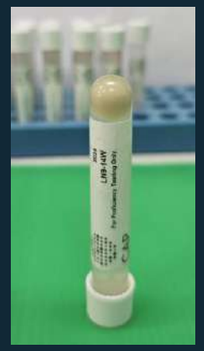



- Allow vials to warm at room temperature for at least 15 minutes before mixing.
- Roll the vial back and forth **rapidly for 30 seconds.** Gently invert the vial 10 times.
- Continue to mix the vial in this manner until the cells are completely suspended and there are no visible aggregates.

*****Do not shake the vial or mix on a mechanical (vortex) blood mixer*****

# How to Mix the Samples

WBC/PLT Sets





- Allow vials to warm at room temperature for at least 15 minutes before mixing

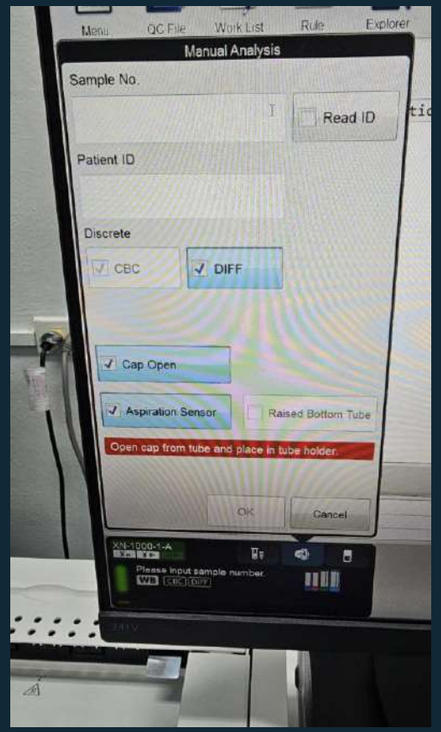
- Mix by vigorously agitating on a vortex mixer for 2 minutes to ensure complete dispersion of microaggregates.

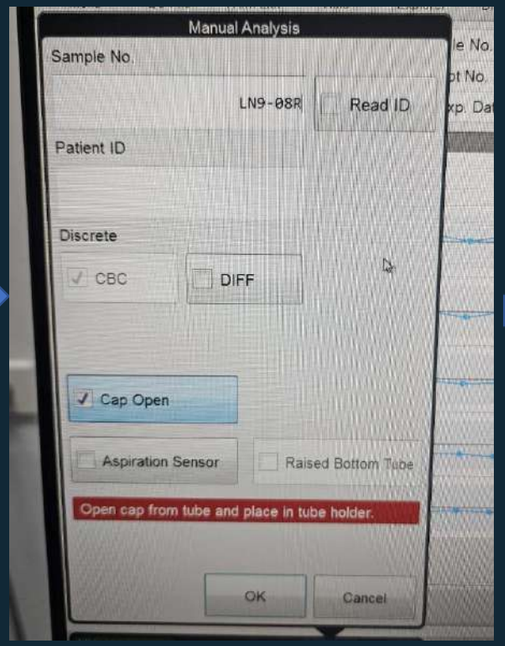
Let vials sit undisturbed for 10 minutes to allow micro bubbles to dissipate before sampling.

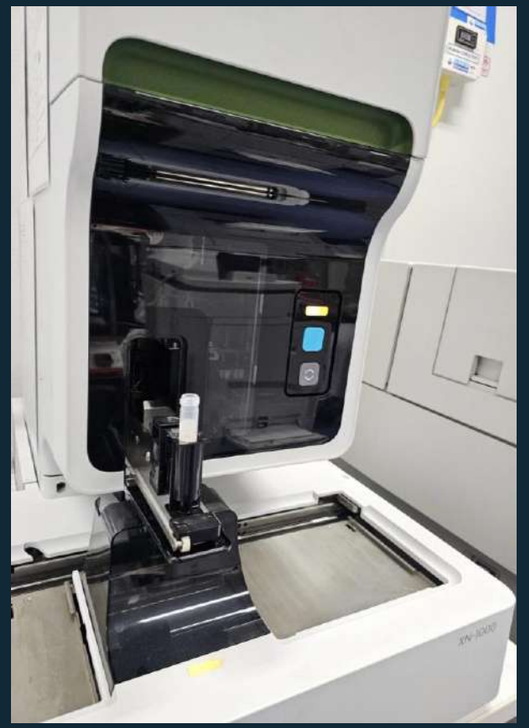
***For WBC and PLT testing on instruments with a blood detector:** Turn off the blood detector between each sample analysis. These instruments may not be able to test the specimens that do not contain any red blood cells.

# How to perform the Samples

- Gently invert the vial 10 times immediately before each sampling.
- Perform 2 assays from each vial within the same run. Two data points must be received for each solution



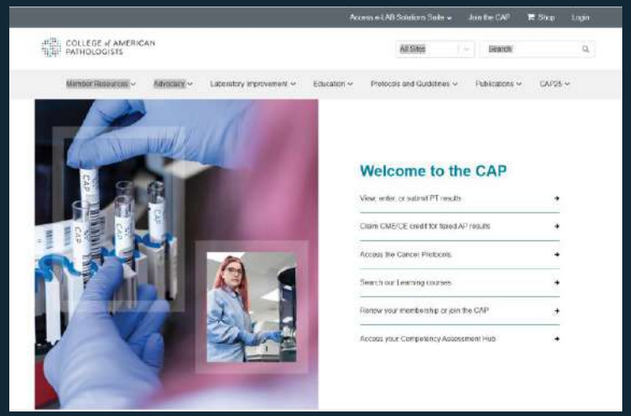
Open Cap

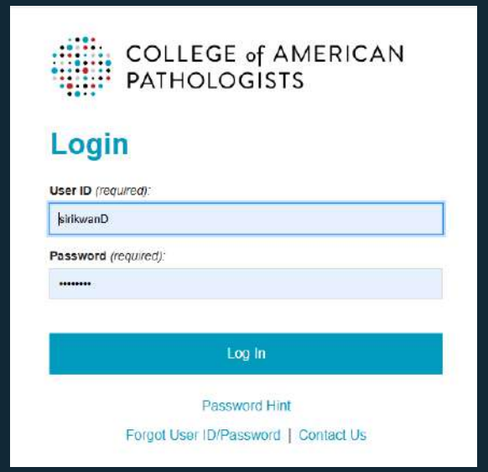
Press start
(Blue botton)

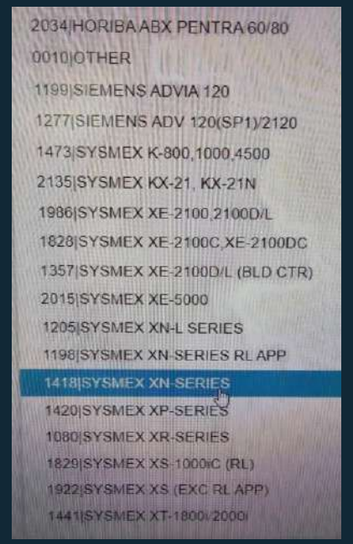
****For WBC and PLT testing on instruments with a blood detector:**
Turn off the blood detector between each sample analysis.**

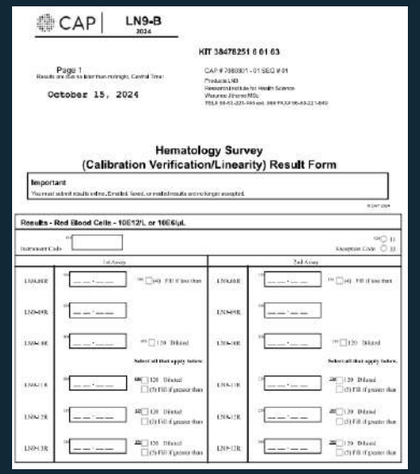
# How to Submit the Results

www.cap.org




Website

Login

Select

Data Entry

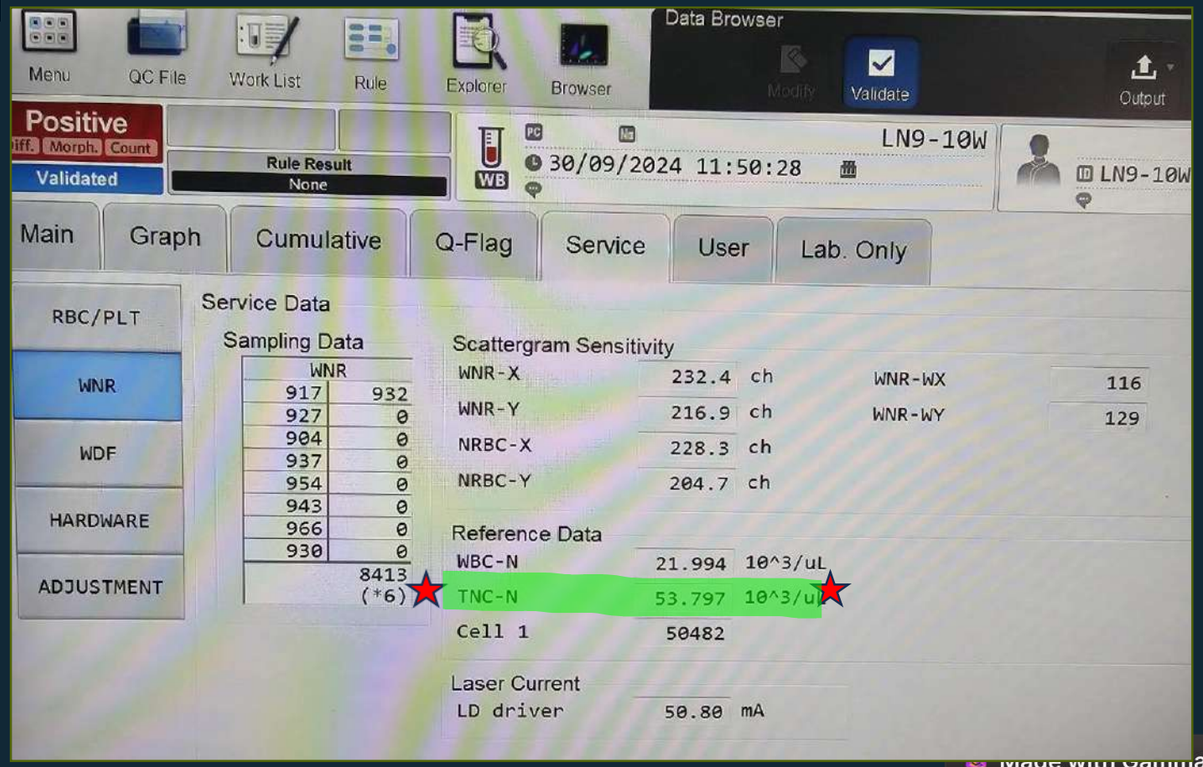
# Instrument-Specific Information

**INSTRUMENT-SPECIFIC INFORMATION**

**Instrument/method-specific notes** are provided by individual manufacturer(s). If your manufacturer did not provide the CAP with any special instructions, process specimens as you would a patient specimen or contact your manufacturer directly with any questions.

1. **Abbott Cell-Dyn 4000** and **Sapphire users:** Instruments may report WBCs as nucleated red blood cells (nRBC). Users should report the sum of WBC and nRBC on the result form.
2. **Abbott Cell-Dyn 3500/3700 users:** The WBC set and the platelet set do not contain RBCs. The RBCs are used to trigger sampling volume in the instrument. The operator must allow the full instrument sample time by not removing the sample until the instrument sampling needle wash block moves down.
3. **Siemens ADVIA** and **Sysmex XE-series users:** Analyzers have the capability of enumerating nRBC and correcting the WBC count, report the **uncorrected** WBC results.
4. **Sysmex XN-series users:** Report the Total Nucleated Count (TNC-N) as the WBC count. To obtain the TNC-N:
   a. Select the result from the Explorer browser screen, select the “Service Tab.”
   b. Select ”WNR” from the menu to the left. Find the “TNC-N” count.
   c. Report the “TNC-N” count for the WBC.

***Report the TNC-N count for the WBC***



# Evaluation Report

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 - cap.org
Laboratory Quality Solutions



**CAP Number:** 7080301-01 **Kit #:** 01
**Institution:** Rsch Inst for Hlth Sci Chiang Mai U
**Attention:** Warunee Jit-aree MSc
**City/State:** Chiang Mai, 50202

**Kit ID:** 38478251
**Kit Mailed:** 09/23/2024
**Original Evaluation:** 10/18/2024
**Next Mailing Date:** 03/31/2025

**EVALUATION**
**ORIGINAL**

## LN9-B 2024 Hematology Calibration Verification/Linearity

### Executive Summary

| Analyte | Calibration Verification | Linearity Evaluation | Page # |
|---|---|---|---|
| Red Blood Cells 10E12/L (10E6/µL) | ***Different*** | Linear from 0.305 to 7.500 | 2 - 3 |
| Hemoglobin g/dL | Verified from 0.90 to 23.40 | Linear from 0.90 to 23.40 | 4 - 5 |
| White Blood Cells 10E9/L (10E3/µL) | Verified from 0.60 to 375.95 | Linear from 0.60 to 375.95 | 6 - 7 |
| Platelets 10E9/L (10E3/µL) | Verified from 8.0 to 3823.0 | Linear from 8.0 to 3823.0 | 8 - 9 |

**Troubleshooting resources:**

- Calibration Verification Troubleshooting Guide and Investigation Checklist - available in the Participant Summary and ELSS

# Evaluation Report



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EVALUATION
ORIGINAL

## LN9-B 2024 Hematology Calibration Verification/Linearity
## Red Blood Cells 10E12/L (10E6/µL) Calibration Verification Evaluation

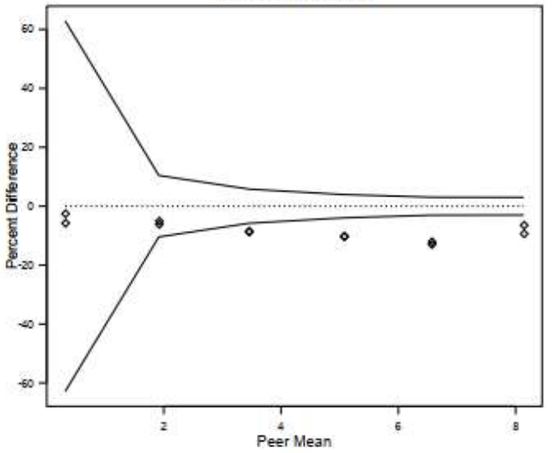
**Evaluation Result: Different**
Peer Instrument: SYSMEX XN-SERIES

Allowable Error: 3% or 0.2 10E12/L (10E6/µL), whichever is greater

| Specimen | Assay 1 | Assay 2 | Your Mean | Peer Mean | Peer N | Difference | Allowable Error |
|---|---|---|---|---|---|---|---|
| LN9-08R | 0.31 | 0.30 | 0.305 | 0.318 | 571 | -0.013x10E12/L | ± 0.200x10E12/L |
| LN9-09R | 1.82 | 1.80 | 1.810 | 1.916 | 574 | -0.106x10E12/L | ± 0.200x10E12/L |
| LN9-10R | 3.16 | 3.15 | 3.155 | 3.450 | 574 | -0.295x10E12/L | ± 0.200x10E12/L |
| LN9-11R | 4.56 | 4.55 | 4.555 | 5.073 | 574 | -0.518x10E12/L | ± 0.200x10E12/L |
| LN9-12R | 5.72 | 5.78 | 5.750 | 6.566 | 574 | -0.816x10E12/L | ± 0.200x10E12/L |
| LN9-13R | 7.38 | 7.62 | 7.500 | 8.138 | 574 | -7.8% | ± 3.0% |

*Note: 10E12/L is equivalent to 10E6/µL.*

Calibration Verification Plot: Percent Differences with Allowable Error Limits




RBC

**Peer Results Summary Table:**
**Evaluation of Instrument Performance**

Peer Group Size: 574

| Range | Calibration Verification | | Linearity Evaluation | | |
|---|---|---|---|---|---|
| | % Verified | % Different | % Linear | % Nonlinear | % Imprecise |
| LN9-08R - 13R | 95.1 | 1.7 | 97.2 | 0.2 | 1.2 |
| LN9-08R - 12R | 1.0 | 0.0 | 0.3 | 0.0 | 0.0 |
| LN9-09R - 13R | 0.7 | 0.2 | 0.3 | 0.0 | 0.2 |
| LN9-08R - 11R | 1.2 | 0.0 | 0.5 | 0.0 | 0.0 |



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EVALUATION
ORIGINAL

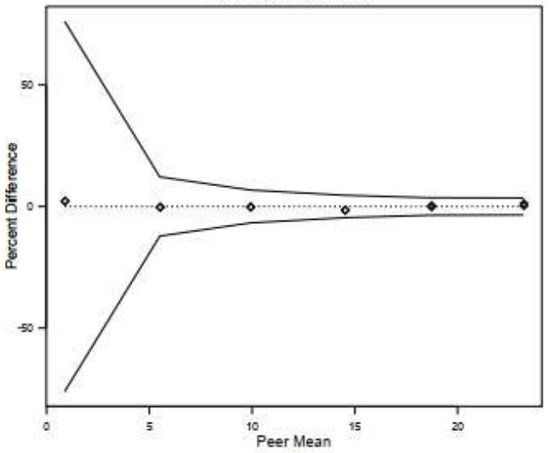
## LN9-B 2024 Hematology Calibration Verification/Linearity
## Hemoglobin g/dL Calibration Verification Evaluation

**Evaluation Result: Verified from 0.90 to 23.40**
Peer Instrument: SYSMEX XN-SERIES

Allowable Error: 3.5% or 0.67 g/dL, whichever is greater

| Specimen | Assay 1 | Assay 2 | Your Mean | Peer Mean | Peer N | Difference | Allowable Error |
|---|---|---|---|---|---|---|---|
| LN9-08R | 0.9 | 0.9 | 0.90 | 0.88 | 567 | 0.02 g/dL | ± 0.67 g/dL |
| LN9-09R | 5.5 | 5.5 | 5.50 | 5.51 | 573 | -0.01 g/dL | ± 0.67 g/dL |
| LN9-10R | 9.9 | 9.9 | 9.90 | 9.91 | 573 | -0.01 g/dL | ± 0.67 g/dL |
| LN9-11R | 14.3 | 14.3 | 14.30 | 14.51 | 573 | -0.21 g/dL | ± 0.67 g/dL |
| LN9-12R | 18.7 | 18.8 | 18.75 | 18.71 | 573 | 0.04 g/dL | ± 0.67 g/dL |
| LN9-13R | 23.5 | 23.3 | 23.40 | 23.20 | 572 | 0.9% | ± 3.5% |

Calibration Verification Plot: Percent Differences with Allowable Error Limits




HGB

**Peer Results Summary Table:**
**Evaluation of Instrument Performance**

Peer Group Size: 573

| Range | Calibration Verification | | Linearity Evaluation | | |
|---|---|---|---|---|---|
| | % Verified | % Different | % Linear | % Nonlinear | % Imprecise |
| LN9-08R - 13R | 96.9 | 1.0 | 97.9 | 0.0 | 0.7 |
| LN9-08R - 12R | 0.9 | 0.0 | 0.3 | 0.0 | 0.0 |
| LN9-09R - 13R | 1.0 | 0.0 | 0.9 | 0.0 | 0.0 |
| LN9-09R - 12R | 0.2 | 0.0 | 0.2 | 0.0 | 0.0 |

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EVALUATION
ORIGINAL

## LN9-B 2024 Hematology Calibration Verification/Linearity
## White Blood Cells 10E9/L (10E3/µL) Calibration Verification Evaluation

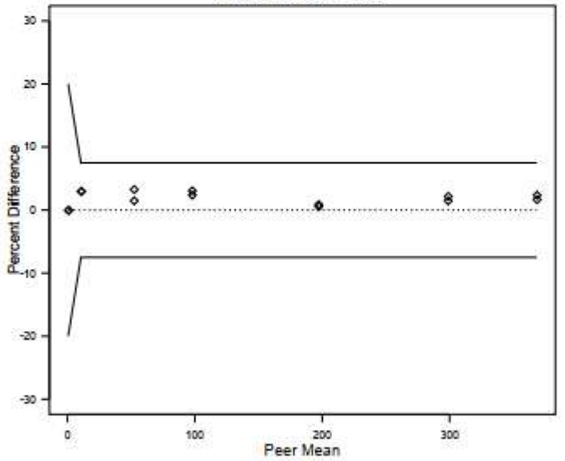
**Evaluation Result: Verified from 0.60 to 375.95**
Peer Instrument: SYSMEX XN-SERIES

Allowable Error: 7.5% or 0.12 10E9/L (10E3/µL), whichever is greater

| Specimen | Assay 1 | Assay 2 | Your Mean | Peer Mean | Peer N | Difference | Allowable Error |
|---|---|---|---|---|---|---|---|
| LN9-08W | 0.6 | 0.6 | 0.60 | 0.60 | 568 | 0.00x10E9/L | ± 0.12x10E9/L |
| LN9-09W | 10.9 | 10.9 | 10.90 | 10.58 | 569 | 3.0% | ± 7.5% |
| LN9-10W | 53.8 | 52.9 | 53.35 | 52.10 | 569 | 2.4% | ± 7.5% |
| LN9-11W | 100.0 | 100.7 | 100.35 | 97.70 | 570 | 2.7% | ± 7.5% |
| LN9-12W | 198.8 | 198.1 | 198.45 | 196.95 | 569 | 0.8% | ± 7.5% |
| LN9-13W | 305.3 | 303.1 | 304.20 | 298.65 | 569 | 1.9% | ± 7.5% |
| LN9-14W | 374.8 | 377.1 | 375.95 | 368.36 | 569 | 2.1% | ± 7.5% |

*Note: 10E9/L is equivalent to 10E3/µL.*

Calibration Verification Plot: Percent Differences with Allowable Error Limits




WBC

**Peer Results Summary Table:**
**Evaluation of Instrument Performance**

Peer Group Size: 570

| Range | Calibration Verification | | Linearity Evaluation | | |
|---|---|---|---|---|---|
| | % Verified | % Different | % Linear | % Nonlinear | % Imprecise |
| LN9-08W - 14W | 80.9 | 14.7 | 87.9 | 0.4 | 2.1 |
| LN9-08W - 13W | 0.5 | 0.0 | 1.1 | 0.0 | 0.0 |
| LN9-09W - 14W | 0.9 | 0.0 | 0.2 | 0.0 | 0.0 |
| LN9-08W - 12W | 0.4 | 0.0 | 2.3 | 0.0 | 0.0 |
| LN9-08W - 11W | 2.3 | 0.2 | 6.0 | 0.0 | 0.0 |
| LN9-11W - 14W | 0.2 | 0.0 | 0.2 | 0.0 | 0.0 |



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EVALUATION
ORIGINAL

## LN9-B 2024 Hematology Calibration Verification/Linearity
## Platelets 10E9/L (10E3/µL) Calibration Verification Evaluation

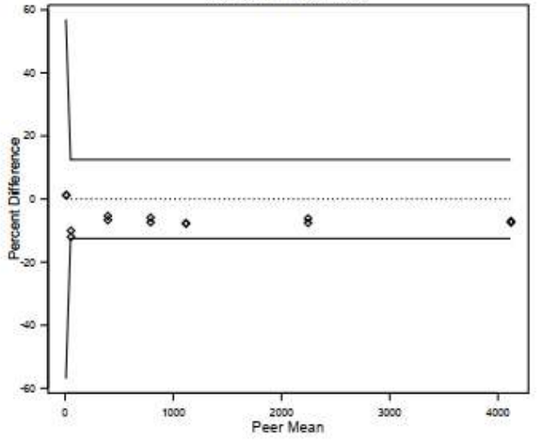
**Evaluation Result: Verified from 8.0 to 3823.0**
Peer Instrument: SYSMEX XN-SERIES

Allowable Error: 12.5% or 4.5 10E9/L (10E3/µL), whichever is greater

| Specimen | Assay 1 | Assay 2 | Your Mean | Peer Mean | Peer N | Difference | Allowable Error |
|---|---|---|---|---|---|---|---|
| LN9-08P | 8 | 8 | 8.0 | 7.9 | 572 | 0.1x10E9/L | ± 4.5x10E9/L |
| LN9-09P | 46 | 45 | 45.5 | 51.1 | 573 | -11.0% | ± 12.5% |
| LN9-10P | 371 | 366 | 368.5 | 391.7 | 573 | -5.9% | ± 12.5% |
| LN9-11P | 741 | 729 | 735.0 | 786.7 | 573 | -6.6% | ± 12.5% |
| LN9-12P | 1029 | 1028 | 1028.5 | 1113.4 | 570 | -7.6% | ± 12.5% |
| LN9-13P | 2073 | 2105 | 2089.0 | 2241.2 | 570 | -6.8% | ± 12.5% |
| LN9-14P | 3833 | 3813 | 3823.0 | 4116.5 | 569 | -7.1% | ± 12.5% |

*Note: 10E9/L is equivalent to 10E3/µL.*

Calibration Verification Plot: Percent Differences with Allowable Error Limits




PLT

**Peer Results Summary Table:**
**Evaluation of Instrument Performance**

Peer Group Size: 573

| Range | Calibration Verification | | Linearity Evaluation | | |
|---|---|---|---|---|---|
| | % Verified | % Different | % Linear | % Nonlinear | % Imprecise |
| LN9-08P - 14P | 91.6 | 5.6 | 97.9 | 0.2 | 0.0 |
| LN9-08P - 13P | 1.0 | 0.2 | 1.0 | 0.0 | 0.0 |
| LN9-09P - 14P | 0.7 | 0.0 | 0.2 | 0.0 | 0.0 |
| LN9-08P - 12P | 0.2 | 0.0 | 0.2 | 0.0 | 0.0 |
| LN9-08P - 11P | 0.7 | 0.0 | 0.5 | 0.0 | 0.0 |

h Gamma

# Evaluation Report



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Laboratory Quality Solutions

CAP Number: 7080301-01 Kit #: 01
Institution: Rsch Inst for Hlth Sci Chiang Mai U
Attention: Warunee Jit-aree MSc
City/State: Chiang Mai, 50202

Kit ID: 38478251
Kit Mailed: 09/23/2024
Original Evaluation: 10/18/2024
Next Mailing Date: 03/31/2025

EVALUATION
ORIGINAL

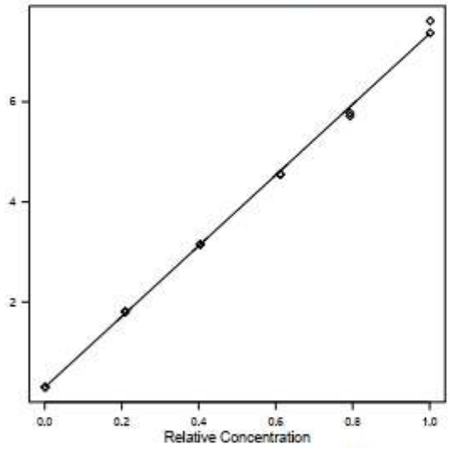
## LN9-B 2024 Hematology Calibration Verification/Linearity
## Red Blood Cells 10E12/L (10E6/µL) Linearity Evaluation

**Evaluation Result: Linear from 0.305 to 7.500**
Instrument: SYSMEX XN-SERIES

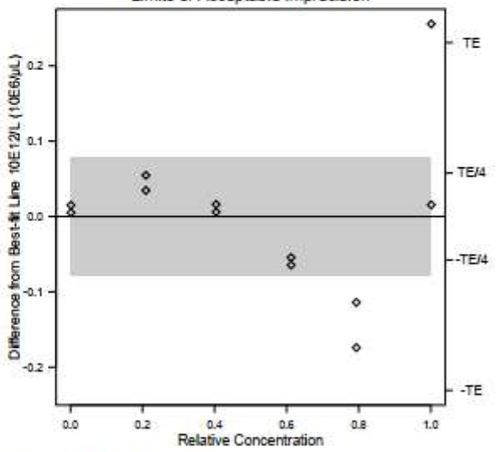
Evaluation Type: Standard
Goal for Total Error (TE): 6%

| Specimen | Assay 1 | Assay 2 | Your Mean | Best-fit Target | Relative Concentration |
|---|---|---|---|---|---|
| LN9-08R | 0.31 | 0.30 | 0.305 | 0.295 | 0.000 |
| LN9-09R | 1.82 | 1.80 | 1.810 | 1.765 | 0.208 |
| LN9-10R | 3.16 | 3.15 | 3.155 | 3.144 | 0.403 |
| LN9-11R | 4.56 | 4.55 | 4.555 | 4.614 | 0.611 |
| LN9-12R | 5.72 | 5.78 | 5.750 | 5.894 | 0.792 |
| LN9-13R | 7.38 | 7.62 | 7.500 | 7.364 | 1.000 |

Linearity Plot 1: Reported Results with Best-fit Line




Linearity Plot 2: Differences with Limits of Acceptable Imprecision




RBC

Mean of Included Results: 3.846 10E12/L (10E6/µL)

◇ Included in best-fit line
○ Excluded from best-fit line

Your plot has one or more points within your linear range that fall outside of the shaded area. Since your evaluation is Linear, no remedial action is necessary.

Points can fall outside of the shaded area for two reasons:
1) an average is used to estimate imprecision, so many small differences can offset a few large differences, and
2) clinically insignificant nonlinearity (curved fit) can contribute to differences between your results and the best-fit straight line.

Larger differences may be an early warning sign of nonlinearity, poor repeatability, or poor fit.



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Laboratory Quality Solutions

CAP Number: 7080301-01 Kit #: 01
Institution: Rsch Inst for Hlth Sci Chiang Mai U
Attention: Warunee Jit-aree MSc
City/State: Chiang Mai, 50202

Kit ID: 38478251
Kit Mailed: 09/23/2024
Original Evaluation: 10/18/2024
Next Mailing Date: 03/31/2025

EVALUATION
ORIGINAL

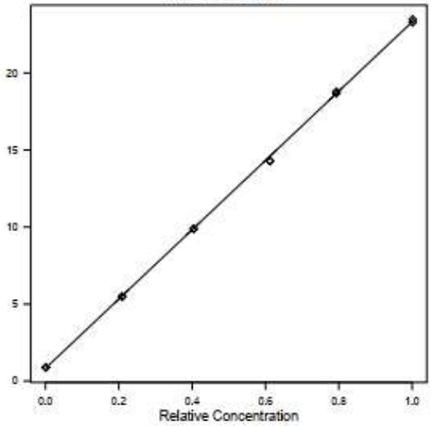
## LN9-B 2024 Hematology Calibration Verification/Linearity
## Hemoglobin g/dL Linearity Evaluation

**Evaluation Result: Linear from 0.90 to 23.40**
Instrument: SYSMEX XN-SERIES

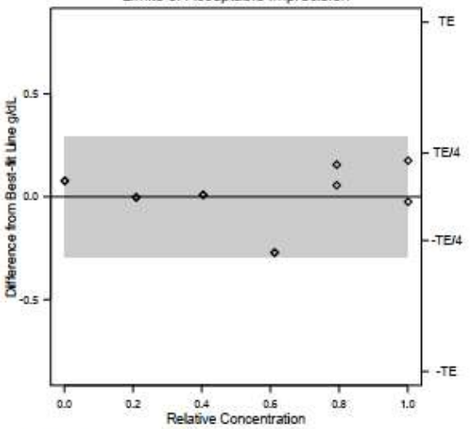
Evaluation Type: Standard
Goal for Total Error (TE): 7%

| Specimen | Assay 1 | Assay 2 | Your Mean | Best-fit Target | Relative Concentration |
|---|---|---|---|---|---|
| LN9-08R | 0.9 | 0.9 | 0.90 | 0.82 | 0.000 |
| LN9-09R | 5.5 | 5.5 | 5.50 | 5.50 | 0.208 |
| LN9-10R | 9.9 | 9.9 | 9.90 | 9.89 | 0.403 |
| LN9-11R | 14.3 | 14.3 | 14.30 | 14.57 | 0.611 |
| LN9-12R | 18.7 | 18.8 | 18.75 | 18.64 | 0.792 |
| LN9-13R | 23.5 | 23.3 | 23.40 | 23.32 | 1.000 |

Linearity Plot 1: Reported Results with Best-fit Line




Linearity Plot 2: Differences with Limits of Acceptable Imprecision




HGB

Mean of Included Results: 12.12 g/dL

◇ Included in best-fit line
○ Excluded from best-fit line

# Evaluation Report



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EVALUATION
ORIGINAL

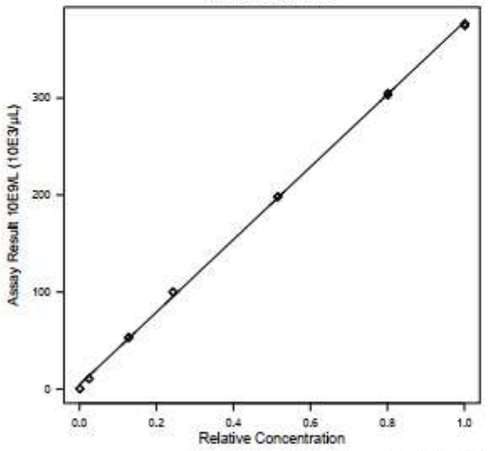
## LN9-B 2024 Hematology Calibration Verification/Linearity
## White Blood Cells 10E9/L (10E3/µL) Linearity Evaluation

**Evaluation Result: Linear from 0.60 to 375.95**
Instrument: SYSMEX XN-SERIES

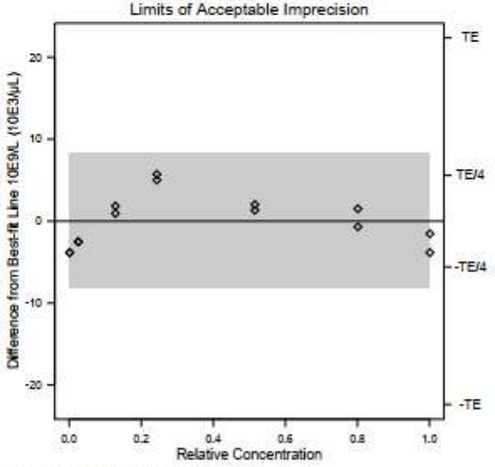
Evaluation Type: Standard
Goal for Total Error (TE): 15%

| Specimen | Assay 1 | Assay 2 | Your Mean | Best-fit Target | Relative Concentration |
|---|---|---|---|---|---|
| LN9-08W | 0.6 | 0.6 | 0.60 | 4.41 | 0.000 |
| LN9-09W | 10.9 | 10.9 | 10.90 | 13.39 | 0.024 |
| LN9-10W | 53.8 | 52.9 | 53.35 | 51.93 | 0.127 |
| LN9-11W | 100.0 | 100.7 | 100.35 | 94.96 | 0.242 |
| LN9-12W | 198.8 | 198.1 | 198.45 | 196.74 | 0.514 |
| LN9-13W | 305.3 | 303.1 | 304.20 | 303.76 | 0.800 |
| LN9-14W | 374.8 | 377.1 | 375.95 | 378.60 | 1.000 |

Linearity Plot 1: Reported Results with Best-fit Line




Linearity Plot 2: Differences with Limits of Acceptable Imprecision




Mean of Included Results: 149.11 10E9/L (10E3/µL)

◇ Included in best-fit line
○ Excluded from best-fit line

WBC



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Kit ID: 38478251
Kit Mailed: 09/23/2024
Original Evaluation: 10/18/2024
Next Mailing Date: 03/31/2025

EVALUATION
ORIGINAL

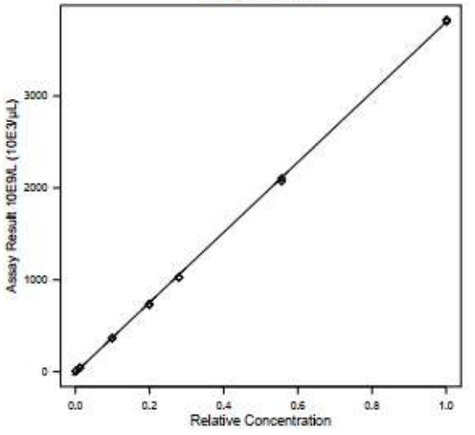
## LN9-B 2024 Hematology Calibration Verification/Linearity
## Platelets 10E9/L (10E3/µL) Linearity Evaluation

**Evaluation Result: Linear from 8.0 to 3823.0**
Instrument: SYSMEX XN-SERIES

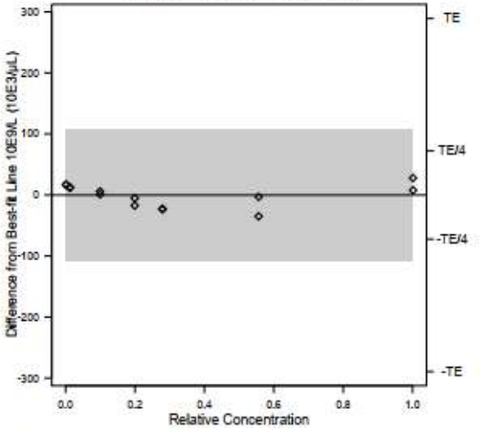
Evaluation Type: Standard
Goal for Total Error (TE): 25%

| Specimen | Assay 1 | Assay 2 | Your Mean | Best-fit Target | Relative Concentration |
|---|---|---|---|---|---|
| LN9-08P | 8 | 8 | 8.0 | < 0 | 0.000 |
| LN9-09P | 46 | 45 | 45.5 | 32.8 | 0.011 |
| LN9-10P | 371 | 366 | 368.5 | 364.6 | 0.098 |
| LN9-11P | 741 | 729 | 735.0 | 746.0 | 0.198 |
| LN9-12P | 1029 | 1028 | 1028.5 | 1051.1 | 0.278 |
| LN9-13P | 2073 | 2105 | 2089.0 | 2107.6 | 0.555 |
| LN9-14P | 3833 | 3813 | 3823.0 | 3804.8 | 1.000 |

Linearity Plot 1: Reported Results with Best-fit Line




Linearity Plot 2: Differences with Limits of Acceptable Imprecision




Mean of Included Results: 1156.8 10E9/L (10E3/µL)

◇ Included in best-fit line
○ Excluded from best-fit line

PLT

# Troubleshooting



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**Kit ID:** 38478251
**Kit Mailed:** 09/23/2024
**Original Evaluation:** 10/18/2024
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**EVALUATION**
**ORIGINAL**

**LN9-B 2024 Hematology Calibration Verification/Linearity**
**Red Blood Cells 10E12/L (10E6/µL) Calibration Verification Evaluation**

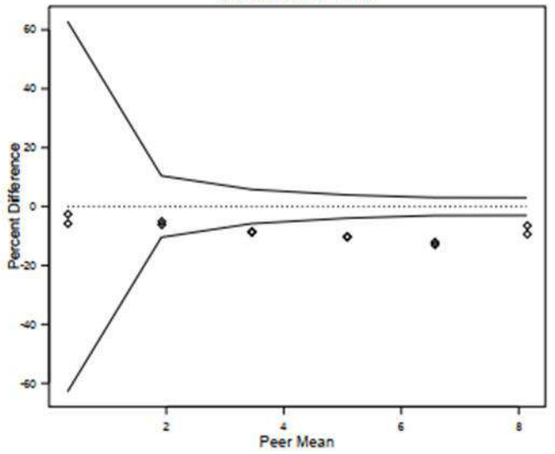
**Evaluation Result: Different**
Peer Instrument: SYSMEX XN-SERIES

Allowable Error: 3% or 0.2 10E12/L (10E6/µL), whichever is greater

| Specimen | Assay 1 | Assay 2 | Your Mean | Peer Mean | Peer N | Difference | Allowable Error |
|---|---|---|---|---|---|---|---|
| LN9-08R | 0.31 | 0.30 | 0.305 | 0.318 | 571 | -0.013x10E12/L | ± 0.200x10E12/L |
| LN9-09R | 1.82 | 1.80 | 1.810 | 1.916 | 574 | -0.106x10E12/L | ± 0.200x10E12/L |
| LN9-10R | 3.16 | 3.15 | 3.155 | 3.450 | 574 | -0.295x10E12/L | ± 0.200x10E12/L |
| LN9-11R | 4.56 | 4.55 | 4.555 | 5.073 | 574 | -0.518x10E12/L | ± 0.200x10E12/L |
| LN9-12R | 5.72 | 5.78 | 5.750 | 6.566 | 574 | -0.816x10E12/L | ± 0.200x10E12/L |
| LN9-13R | 7.38 | 7.62 | 7.500 | 8.138 | 574 | -7.8% | ± 3.0% |

*Note: 10E12/L is equivalent to 10E6/µL.*

Calibration Verification Plot: Percent Differences with Allowable Error Limits




**Peer Results Summary Table:**
**Evaluation of Instrument Performance**

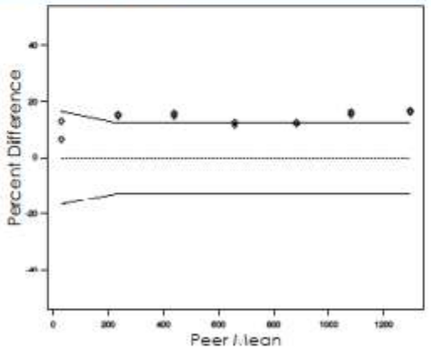
Peer Group Size: 574

| Range | Calibration Verification | | Linearity Evaluation | | |
|---|---|---|---|---|---|
| | % Verified | % Different | % Linear | % Nonlinear | % Imprecise |
| LN9-08R - 13R | 95.1 | 1.7 | 97.2 | 0.2 | 1.2 |
| LN9-08R - 12R | 1.0 | 0.0 | 0.3 | 0.0 | 0.0 |
| LN9-09R - 13R | 0.7 | 0.2 | 0.3 | 0.0 | 0.2 |
| LN9-08R - 11R | 1.2 | 0.0 | 0.5 | 0.0 | 0.0 |

## Calibration Verification Troubleshooting Guide

This troubleshooting guide provides suggested actions if you receive a calibration verification evaluation result of Different, or if your evaluation result is Verified over a range that does not include all of your reported results. To use this guide, determine which of the following examples is most similar to your calibration verification plot. Refer to the corresponding suggested actions, in conjunction with the CVL Investigation Checklist for Problematic Results, to investigate possible causes and corrective actions.

### Constant Bias




Review the **ANALYTICAL** section of the investigation checklist. Analytical problems that produce a constant bias may be due to a calibration error. Recalibration may be needed.

Review the **CLERICAL** section of the investigation checklist. Clerical errors that result in a constant bias are likely due to units of measure or decimal place errors, or incorrect peer group assignment. Clerical errors may indicate a need for additional staff training.

# CVL Survey Investigation Checklist for Problematic Results

| Analytical | YES | NO | NA |
|---|---|---|---|
| Was the written procedure followed? | ☒ | ☐ | ☐ |
| Was instrument maintenance performed on schedule? | ☒ | ☐ | ☐ |
| Were quality control results acceptable? | ☒ | ☐ | ☐ |
| Was the most recent calibration acceptable and within established stability limits at the time testing was performed? | ☒ | ☐ | ☐ |
| Does a review of recent proficiency testing results or past CVL results indicate evenly distributed data without bias? | ☐ | ☐ | ☒ |
| Were the reagents prepared according to procedure? | ☒ | ☐ | ☐ |
| Were the reagents within their open stability acceptable range? | ☒ | ☐ | ☐ |
| Was the intended result within the measuring range for the instrument? | ☒ | ☐ | ☐ |
| Was the dilution protocol followed when diluting samples that are out of range? | ☐ | ☐ | ☒ |
| Does a review of records indicate that there were no related instrument/test problems noted prior to or after the testing was performed? | ☒ | ☐ | ☐ |

**A response of "No" to any of these questions may indicate an analytical error. These types of errors could indicate a failure to follow recommended instrument maintenance and calibration. You may need to review the instructions provided with the testing material and/or laboratory procedures. If recalibration has not already occurred, recalibrate the instrument.**

# CVL Survey Investigation Checklist for Problematic Results

| Clerical | YES | NO | NA |
|---|---|---|---|
| Were the results correctly transcribed from the instrument read-out or report? | ☒ | ☐ | ☐ |
| Was the correct instrument/method/reagent code reported on the result form? | ☒ | ☐ | ☐ |
| Do the units of measure match between the result form and the instrument results? | ☒ | ☐ | ☐ |
| Is the decimal place correct? | ☒ | ☐ | ☐ |
| Does the submitted result match the result found on the calibration verification evaluation report? | ☒ | ☐ | ☐ |
| If the result was out of range and a dilution was performed, was the correct dilution factor used in the calculation of the final result? | ☐ | ☒ | ☐ |

**A response of "No" to any of these questions may indicate a clerical error. Although reporting of testing results is unlike those for patient results, clerical errors may indicate a need for additional staff training, review of kit instructions, or investigation of the reporting format provided by the testing device. If results reported on the result form do not match the results found on the evaluation report, please contact the CAP Customer Contact Center at 800-323-4040.**

# EQA Evaluation for Quantitative Testing

| | | | |
|---|---|---|---|
| Date: | 28 Aug 2024 | EQA Provider: | OWA: TH1021AI |
| Laboratory: | HID0131_RIHES<br>Research Institute for Health Sciences at Chiang Mai University, Chiang Mai,Thailand | Panel: | Hematology HEFG435-2 2024 |

**Summary:** This EQA event was successful for all protocol analytes.

**Investigation Reports** are required for all **protocol analytes** scoring less than 100%. The analytes requiring investigation are:
None

**Internal investigations** are recommended for non-protocol analytes scoring less than 100% , and for any bias, shifts and/or trends identified below:

Bias noted:
**Positive:** Platelet Count
**Negative:** None

Shifts noted:
**Positive:** None
**Negative:** None

Trends noted:
**Positive:** None
**Negative:** None

Non-Protocol Analytes scoring less than 100%:
None

**Comments:**
Congratulations on your successful EQA results.

**Reviewer:**
**Amy Rada, BS MLS(ASCP)CM**
**Senior International QA/QC Coordinator**

# EQA Evaluation Report 2/2024

## Performance Report

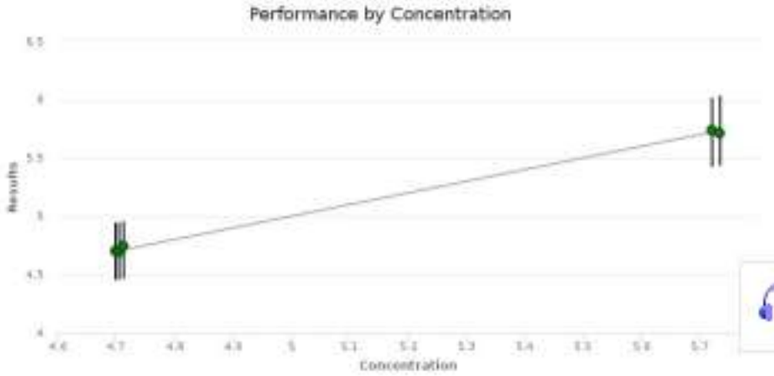

Print Date 2024/Aug/17
Status Final

| | | |
|---|---|---|
| **Participant** | TH1021AI | Research Institute for Health Sciences |
| **Subscription ID** | 275066 | HEFG435 Hematology 5-Part Differential |
| **Results Deadline** | 2024/Jul/17 | |
| **Accreditation** | ACCREDITED | This program is provided by Oneworld Accuracy Inc. within the scope of its ISO/IEC 17043:2010 accreditation by A2LA under certificate 4839.01. |

Instrument Model: Sysmex XN-1000

| | PARTICIPANT DATA | | | COMPARATIVE GROUP DATA | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Analyte / Sample | Result | PAD Score(%) | Grade | Statistical Count | Mean | SD | CV(%) | PG:Description | Acceptable Range | Evaluation Criteria | |
| **Red Blood Cell Count 10^6/ L** | | | | | | | | | | | |
| A | 4.74 | 11.86 | ACC | 41 | 4.712 | 0.046 | 1.0 | ID:Sysmex XN-1000 | 4.47 - 4.95 | Peer Group Mean | 5.0% |
| B | 5.71 | -8.71 | ACC | 41 | 5.735 | 0.055 | 1.0 | ID:Sysmex XN-1000 | 5.44 - 6.03 | Peer Group Mean | 5.0% |
| C | 4.69 | -5.96 | ACC | 39 | 4.704 | 0.042 | 0.9 | ID:Sysmex XN-1000 | 4.46 - 4.94 | Peer Group Mean | 5.0% |
| D | 5.74 | 6.64 | ACC | 39 | 5.721 | 0.057 | 1.0 | ID:Sysmex XN-1000 | 5.43 - 6.01 | Peer Group Mean | 5.0% |
| E | 4.70 | 0.85 | ACC | 39 | 4.698 | 0.049 | 1.0 | ID:Sysmex XN-1000 | 4.46 - 4.94 | Peer Group Mean | 5.0% |





# Monthly IQC September 2024

Clinical Laboratory, RIHES, CMU XN series admin

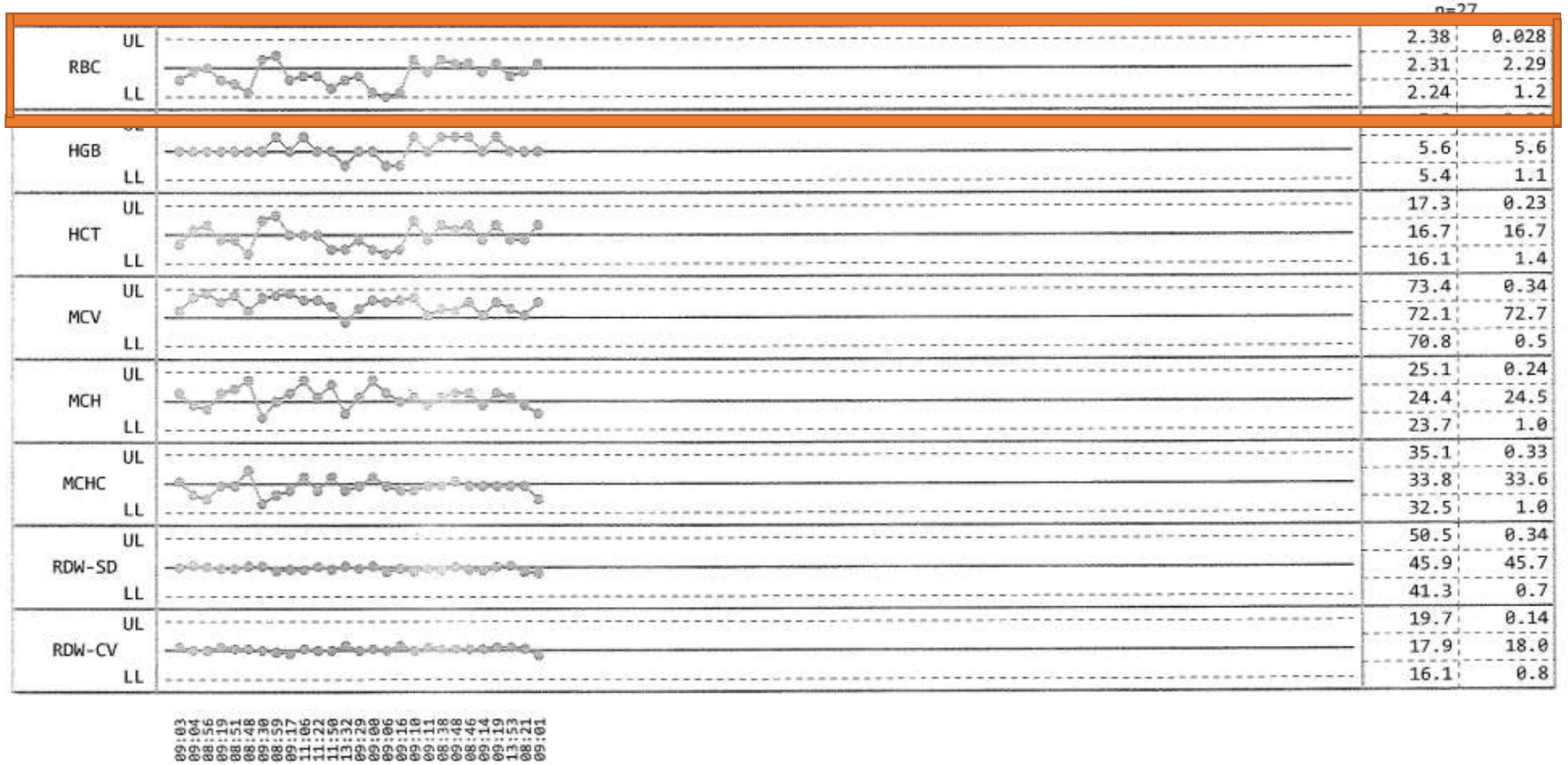
QC Chart

Shift All

| Nickname | Material | Lot No. | Exp. Date | Date From | To |
|---|---|---|---|---|---|
| XN-1000-1-A | Control Level1 | QC-42121101 | 20/10/2024 | 02/09/2024 | 30/09/2024 |

| UL | SD |
|---|---|
| Target | Mean |
| LL | CV (%) |

n=27



# Monthly IQC October 2024

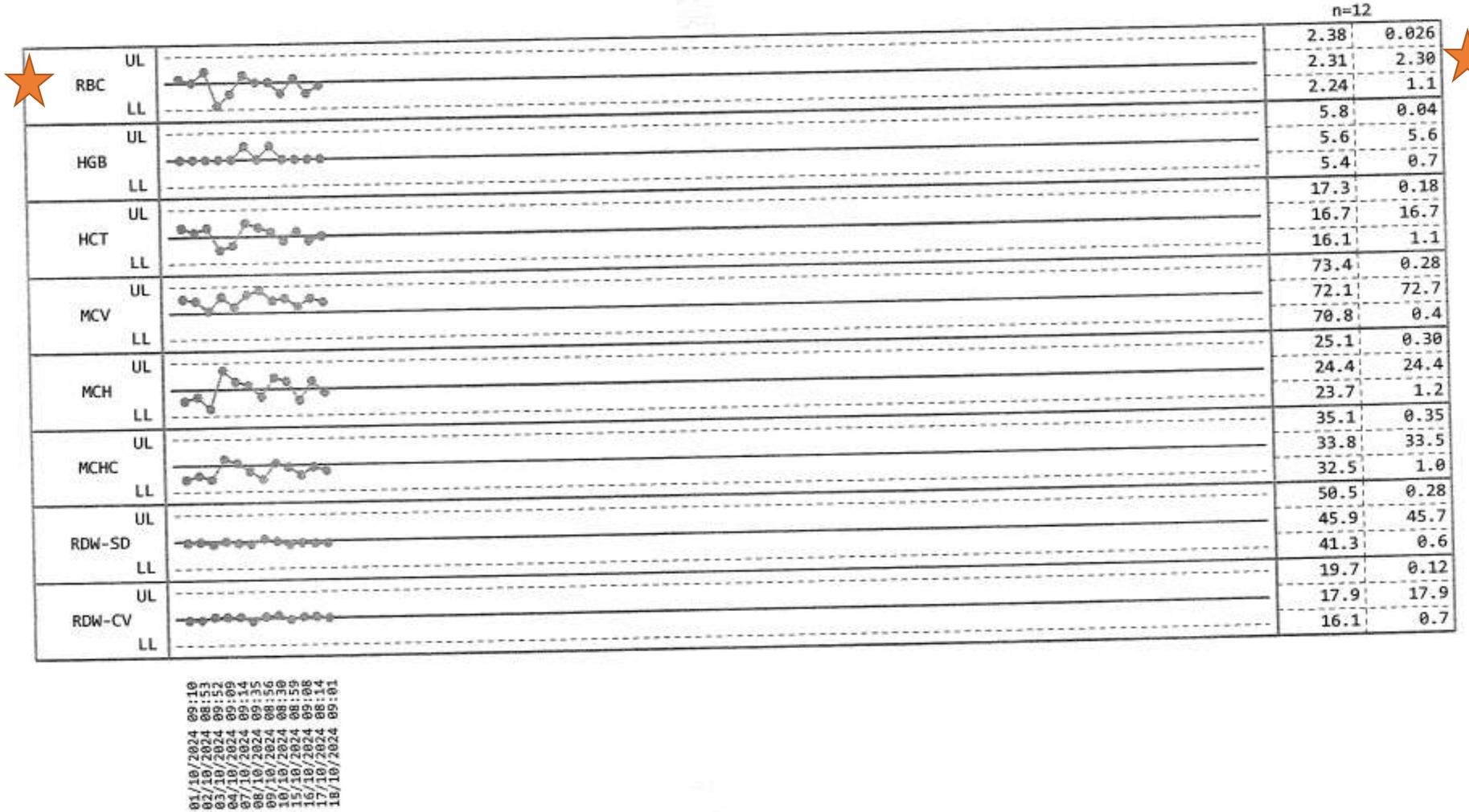
Clinical Laboratory, RIHES, CMU XN series admin

QC Chart

Shift All

| Nickname | Material | Lot No. | Exp. Date | Date From | To |
|---|---|---|---|---|---|
| XN-1000-1-A | Control Level1 | QC-42121101 | 20/10/2024 | 01/10/2024 | 18/10/2024 |

| | |
|---|---|
| UL | SD |
| Target | Mean |
| LL | CV (%) |



# THANK YOU FOR YOUR ATTENTION!