WHAT IS YOUR CURRENT PRACTICE?
IS THERE A NEED TO CALIBRATE SYSMEX HEMATOLOGY ANALYZER?

YES
Definition
Calibration involves any adjustments made to an instrument to correct the results recovered so that they match “truth”, which is defined by standards or reference procedures.

➡️ This procedure ensures that results for blood specimens analysed on all instruments of a given model will show worldwide homology.
1. **A Reference material** whose value is used for the independent variable in a calibration function.

2. **SCS-1000 hematology calibrator** is used for WBC, RBC, PLT, HGB and HCT calibration.

3. The calibration value assignment of the SCS-1000 is traceable to International conventional reference measurement procedures.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC/RBC count calibration</td>
<td>ICSH reference method for enumeration of erythrocytes and leucocytes</td>
</tr>
<tr>
<td>Platelet count calibration</td>
<td>ICSH reference method for platelet method</td>
</tr>
<tr>
<td>HGB calibration</td>
<td>ICSH reference method on hemoglobinometry</td>
</tr>
<tr>
<td>HCT calibration</td>
<td>ICSH reference method for the packed cell method</td>
</tr>
</tbody>
</table>

ICSH : International Council for Standardization in Haematology

QC vs Calibration

QC is Not Calibration!

• **QC** is checking to see if the analyzer is producing correct results
  – checking the instrument’s calibration and other analytical processes

• **Calibration** is “setting” the analyzer to give correct results
  – Use calibration material/calibrator, not QC material
What is Frequency of Calibration?

Comply with

1. Manufacturer’s recommendations
2. Laboratory quality policy
3. Regulatory body regulations
4. Accreditation bodies requirements.
Calibration Requirement Recommended by Sysmex

The manufacturer recommendations (in the operator manual) are as following:

1. During installation of analyzer at customer site.
2. After a major Preventive maintenance or change of major components.
3. When QC data begin to reflect an unusual trend or are outside of the acceptable limits and cannot be corrected by maintenance troubleshooting the instrument.
4. The laboratory's established schedule requires more frequent calibration or calibration verification.
5. The Sysmex service representative advised to do so.
6. Regulatory standards require periodic calibration verification.
Record of Calibration

Calibration must be documented and the following record must be maintained:

1. Calibration Report with calibrator data and QC data and printouts
2. Certificate of calibration (optional)

• Remarks:
  1. QC must be performed after calibration to verify that the calibration is successful
  2. Calibration report and certificate of calibration (optional) must be issued by service organisation.
  3. Standard template for commissioning report (include calibration) and calibration report can be download from NPP.
Commisioning Report

***YOUR COMPANY LETTER HEAD***

XT-2000i Commissioning Report

Customer: __________________________ Date: __________________________
Serial No: __________________________

1 BACKGROUND VERIFICATION
1.1 Background check was done by executing the Auto Rinsing. The results are as below:

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Results</th>
<th>Acceptable Range</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC</td>
<td>≤ 0.1 x 10^3/μL</td>
<td>PASS</td>
<td></td>
</tr>
<tr>
<td>DIFF-WBC</td>
<td>≤ 0.2 x 10^3/μL</td>
<td>PASS</td>
<td></td>
</tr>
<tr>
<td>RBC</td>
<td>≤ 0.02 x 10^6/μL</td>
<td>PASS</td>
<td></td>
</tr>
<tr>
<td>MCH</td>
<td>≤ 0.1g/dL</td>
<td>PASS</td>
<td></td>
</tr>
<tr>
<td>PLT</td>
<td>≤ 5 x 10^9/μL</td>
<td>PASS</td>
<td></td>
</tr>
<tr>
<td>RBC-D</td>
<td>≤ 30 x 10^9/μL</td>
<td>PASS</td>
<td></td>
</tr>
<tr>
<td>PLT-Q</td>
<td>≤ 10 x 10^9/μL</td>
<td>PASS</td>
<td></td>
</tr>
</tbody>
</table>

2 OPTICAL ALIGNMENT FOR FORWARD SCATTERING (FSC)
2.1 The Dynospheres SS-072-P latex was prepared with 1 drop of SS-072-P to 10 mL cellpack. The diluted latex was analyzed to determine the Optical Axis of the FSC. The results are as below:

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Results</th>
<th>Acceptable Range</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSC (X)</td>
<td>130 ± 50</td>
<td>FAIL</td>
<td></td>
</tr>
<tr>
<td>FSC (W)</td>
<td>Less than 0.5%</td>
<td>PASS</td>
<td></td>
</tr>
</tbody>
</table>

3 OPTICAL ALIGNMENT FOR SIDE FLUORESCENCE (SFL) & SIDE SCATTERING (SSC)
3.1 The Fluorochrome Latex A-7312 was prepared with 1 drop of A-7312 to 10mL cellpack. The diluted latex was analyzed to determine the Optical Axis alignment of the SFL & SSC. The results are as below:

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Results</th>
<th>Acceptable Range</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>SFL (X)</td>
<td>130 ± 50</td>
<td>FAIL</td>
<td></td>
</tr>
<tr>
<td>SFL (W)</td>
<td>Less than 0.450</td>
<td>PASS</td>
<td></td>
</tr>
<tr>
<td>SSC (X)</td>
<td>≥ 30</td>
<td>FAIL</td>
<td></td>
</tr>
<tr>
<td>SSC (W)</td>
<td>Less than 0.450</td>
<td>PASS</td>
<td></td>
</tr>
</tbody>
</table>

4 RBC CLOG LEVEL ADJUSTMENT
4.1 The RBC clog adjustment is monitored after the background check. The result is as below:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Result</th>
<th>Acceptable Range</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBC Clog</td>
<td>100 ± 2</td>
<td>FAIL</td>
<td></td>
</tr>
</tbody>
</table>
Calibration Report

***YOUR COMPANY LETTER HEAD***

XT-1800i Calibration Report

Customer: __________________________  Date: __________________________
Serial No: __________________________

1 BACKGROUND VERIFICATION
1.1 Background check was done by executing the Auto Rinsing. The results are as below:

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Results</th>
<th>Acceptable Range</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC</td>
<td>≤ 0.1 x 10^3/μL</td>
<td>PASS</td>
<td></td>
</tr>
<tr>
<td>DIF-WBC</td>
<td>≤ 2 x 10^3/μL</td>
<td>PASS</td>
<td></td>
</tr>
<tr>
<td>RBC</td>
<td>≤ 0.02 x 10^6/μL</td>
<td>PASS</td>
<td></td>
</tr>
<tr>
<td>HGB</td>
<td>≤ 6 g/dL</td>
<td>PASS</td>
<td></td>
</tr>
<tr>
<td>PLT</td>
<td>≤ 8 x 10^3/μL</td>
<td>PASS</td>
<td></td>
</tr>
</tbody>
</table>

2 OPTICAL ALIGNMENT FOR FORWARD SCATTERING (FSC)
2.1 The Dynospheres SS-072-P latex was prepared with 1 drop of SS-072-P to 10mL cellpack. The diluted latex was analyzed to determine the Optical Axis of the FSC. The results are as below:

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Results</th>
<th>Acceptable Range</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSC (X)</td>
<td>130 ± 50</td>
<td>FAIL</td>
<td></td>
</tr>
<tr>
<td>FSC (W)</td>
<td>Less than 0.279</td>
<td>PASS</td>
<td></td>
</tr>
</tbody>
</table>

3 OPTICAL ALIGNMENT FOR SIDE FLUORESCENCE (SFL & SIDE SCATTING (SSC)
3.1 The Fluorescence Latex A-7312 was prepared with 1 drop of A-7312 to 10mL cellpack. The diluted latex was analyzed to determine the Optical Axis alignment of the SFL & SSC. The results are as below:

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Results</th>
<th>Acceptable Range</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>SFL (X)</td>
<td>130 ± 50</td>
<td>FAIL</td>
<td></td>
</tr>
<tr>
<td>SFL (W)</td>
<td>Less than 0.469</td>
<td>PASS</td>
<td></td>
</tr>
<tr>
<td>SSC (X)</td>
<td>≤ 30</td>
<td>FAIL</td>
<td></td>
</tr>
<tr>
<td>SSC (W)</td>
<td>Less than 0.469</td>
<td>PASS</td>
<td></td>
</tr>
</tbody>
</table>

4 RBC CLOG LEVEL ADJUSTMENT
4.1 The RBC clog adjustment is monitored after the background check. The result is as below:

<table>
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<th>Parameter</th>
<th>Result</th>
<th>Acceptable Range</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBC Clog</td>
<td>100 ± 2</td>
<td>PASS</td>
<td></td>
</tr>
</tbody>
</table>
Low accuracy and low precision (poor repeatability)
Stone age man missed the bull's-eye and the 3 attempts were not near each other.

Low accuracy but high precision
Robin Hood's Merry Man missed the bull's-eye but the 3 attempts were near each other.

Higher accuracy but low precision
Native American's 3 attempts were near the bull's-eye, but were not near each other.

High accuracy and high precision
Olympic archer hit the bull's-eye 3 times!
Quality Control

• Definition

A system of maintaining standards in manufactured products by testing a sample of the output against the specification

• Purpose

Ensure that reported results are accountable
Quality Control

• A quality control should be performed:
  – Before any start of operation
  – At least every 8 hours during operation
  – After replenishment of components
  – After maintenance
  – If there is any doubt about the accuracy of the analysis value
Sysmex Quality Control Material

- Eightcheck 3WP
  - Poch-100i, KX-21, XP-Series
- e-Check(XS)
  - XS-Series
- e-Check(XT/XE)
  - XT-Series, XE-Series
- XN-Check
  - XN-Series
- XN-Check BF
  - XN-Series
- XN-L Check
  - XN-L
XN CHECK **Level 1:**

- New platelet component can be stained by PLT-F stain.
  - *Required for monitoring PLT-F*

**XN CHECK L2 and L3:**

- do not include stainable thrombocyte components, the cell concentration does not allow that (technical limitation)

**Expected PLT \(10^3/\mu l\) Concentrations**

- Low (L1) : 35-65 → approx. 80*
- Normal (L2) : 190-250
- High (L3) : 400-700

*HE/ISSUE 42, 30 Sept 2016*
<table>
<thead>
<tr>
<th>QC Material</th>
<th>Packing</th>
<th>Open Stability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eightcheck 3WP</td>
<td>1.5 ml</td>
<td>7 days</td>
</tr>
<tr>
<td>e-Check (XS)</td>
<td>1.5 ml</td>
<td>14 days</td>
</tr>
<tr>
<td>e-Check (XT/XE)</td>
<td>3.0 ml</td>
<td>7 days</td>
</tr>
<tr>
<td>XN-Check</td>
<td>3.0 ml</td>
<td>7 days</td>
</tr>
<tr>
<td>XN-Check BF</td>
<td>3.0 ml</td>
<td>30 days</td>
</tr>
<tr>
<td>XN-L Check</td>
<td>3.0 ml</td>
<td>14 days</td>
</tr>
</tbody>
</table>
Commonly used QC method:

- Levey-Jennings chart
- QC Rules
- Westgard Rules
Levey-Jennings Chart: Example

Rules:
• $1_{2s}$
• $1_{3s}$
• $2_{2s}$
• $R_{4s}$
• $1_{3s}/2_{2s}/R_{4s}$

• Warning Rule
• Rejection Rule
Variables affecting Control results

Analyzer
- Mechanical
- Temperature
- Optical
- Maintenance

Reagents
- Reagents
- Standard
- Reference / Calibration

Controls
- Status
- Reconstitution
- Handling
- Freezing
What do you do when your QC run is out?

• First do not release any results
• Do NOT automatically repeat the control!
• Investigate and determine the type of error (random or systematic)
• Look at your QC/QA Records
  – Instrument function and condition
    • Any sign of instrument deterioration (frequency and length of downtime & why, unscheduled PM), temperature checks
  – Calibration and Calibration verification
    • Lot #, expiry date, date (& why) of calibration
  – Previous control runs (any bias observed)
    • Lot#, expiry date of current run
  – Reagent Storage, Reconstitution and Handling
We Believe the Possibilities.
KEEP CALM AND MATUR NUWUN