

# MLAB 1415: Hematology

Quality Control  
&  
Sysmex- 430 XN



# Quality Control (QC)

- What is QC?
  - Analyzer performance against a known standard (expected range)
    - Is it in-range?
      - Patient results will be valid
    - Is it out-of-range?
      - Patient results may be compromised
  - Commercial Controls:
    - 3 levels (low, normal, high), each vial has 3 mL of control material
    - Stored at 2-8 °C
    - Values stored in instrument computer
    - Levey-Jennings graph generated and stored for each parameter



# Quality Control

Lot number

Level designation

XXXX1101  
XXXX1102  
XXXX1103

XXXX1401  
XXXX1402  
XXXX1403

XXXX1301  
XXXX1302

XN CHECK

XN-L CHECK

XN CHECK BF

The diagram illustrates the lot numbering system for three different XN CHECK models. Each model has three distinct lot numbers. The 'XXXX' part of the lot number represents the level designation, which is consistent across all models within a single lot. The last four digits (1101-1103, 1401-1403, 1301-1302) represent the specific lot number. The models shown are XN CHECK, XN-L CHECK, and XN CHECK BF. Some vials are obscured by black X marks.


XN-CHECK  
Seven (7) day open vial stability

XN-L CHECK  
Fifteen (15) day open vial stability

XN-CHECK BF  
Thirty (30) day open vial stability

The diagram shows the open vial stability for each model. XN-CHECK has a 7-day stability, XN-L CHECK has a 15-day stability, and XN-CHECK BF has a 30-day stability. The vials are shown with their respective labels and are partially obscured by black X marks.

# QC Preparation



Remove from the refrigerator and allow controls to sit at room temperature for 15 minutes.

Mix until the cell button is suspended.

# Linearity (Reportable Range/ AMR)

- Instruments are calibrated for each analyte with a range that is clinically relevant.
- With concentrations above or below the reportable range or Linearity range, the result does not correspond with the calibration curve in linear fashion.
- Results outside of linearity are NOT acceptable.
- Linearity ranges vary by instrument.

– Example:

Parameter	Coulter STKS	Advia
WBC	0.0 -99.9 X 10 <sup>3</sup> /μL	0.02-400 X 10 <sup>3</sup> /μL

# XN- 430 Reportable Ranges/Linearity

Parameter	Reportable Range/ Units
WBC	0.04-440.00 x 10 <sup>3</sup> /μL
RBC	0.02-8.60 x 10 <sup>6</sup> /μL
HGB	0.1-26.0 g/dL
HCT	0.2-74.5 %
PLT	2- 5,000 10 <sup>3</sup> /μL

# Sysmex- XN-430

## Principle

- Quantitative automated hematology analyzer for the in vitro diagnostic use in determining whole blood parameters.
- Closed tube analysis
- 6-part differential
- The instrument uses **direct** measurements by
  - Impedance- RBC/ PLT
  - Flow cytometry- WBC DIFF
  - SLS (hemoglobin method)- HGB
- Hematocrit is **calculated** by the RBC pulse height detection method.

# Sysmex 430 XN Parameters

Parameters	
WBC	Neut #
RBC	Lymph#
HGB	Mono #
HCT	Eo#
MCV	Baso#
MCH	Neut %
MCHC	Lymph %
PLT	Mono %
RDW	Eo %
MPV	Baso %

# Automation Specs

Number of samples which can be analyzed per hour: 60

Number of tests performed on this analyzer: 1- CBC (see parameters slide)

Quality control: Three levels run each day of patient testing, or following instrument repair, reagent lot change, or when indicated.

Calibration: Shift in control values, replacement of instrument parts, reagent number change, or when indicated

Preventative maintenance: Daily: start up, weekly cleaning with Cellclean and shut down, general cleaning

Acceptable samples: whole blood from an EDTA tube ran within 4 hours of collection

Limitations: Lipemia, cold agglutinins, high WBC's




# Sample Requirements

- EDTA 2K/3K Whole Blood
- Analysis within 4 hours of draw
- Unacceptable specimens
  - Clotted, or those containing clots
  - Grossly hemolyzed
  - Lipemic, icteric, cold agglutinins

# Start- Up

1. If the system is turned OFF
  2. Press the green power button on the front of the instrument
  3. Check the status indicator light to see when ready
  4. If needed, enter user/password
  5. Instrument initialization=background check
1. See next slide




Status	Indication
	Ready; Analyzing, Start-up, changing modes, Shutdown (blinking)
	Error; Start-up, Shutdown (blinking)
	Error

# Background Check

- Background check verifies the rinse, temperature, and stabilization are in optimal conditions. The background check can be done up to a maximum of three times.

Checked parameters	Background limits
WBC	$0.10 \times 10^3/\mu\text{L}$ or less
RBC	$0.02 \times 10^6/\mu\text{L}$ or less
HGB	0.1 g/dL or less
PLT	$10 \times 10^3/\mu\text{L}$ or less



*Automatically repeated up to three times before the analyzer alarms*

# Sample Processing-

## Full tube

Minimum Volume Requirements:

**1 mL**

Cap Open

**300  $\mu$ L**

Cap Open



XN-430/ XN-450

## Microtainers

Minimum Volume Requirements:

**100  $\mu$ L**

Cap Open



XN-430/ XN-450



Note- Raised bottom tubes have a 250  $\mu$ L minimum

# Reagents

Reagent	Function	Open Expiration
Cellpack DCL	Diluent	60 days
Sulfolyser SLS (1.5L)	Lysing reagent that releases the hemoglobin to be measured.	60 days
Lysercell WDF	Lyses the RBCs, then with Fluorocell dyes WBCs to categorize into WBC populations.	90 days
Fluorocell WDF	Used to stain WBCs for determination of differential count	90 days



# Reagent Replacement

- Reagent Replacement screen

- Through Error message
- Reagent Level Display icon
- Maintenance > Exchange > Reagent Replace



- Reagent Replacement screen

- On-board expiration date
- Lot number
- Number of tests left/DCL volume



# Daily Maintenance/Shutdown

## Shutdown

- Performed every 24 hours
- 2 minutes
- Automatically powers off the analyzer



# Weekly Maintenance

## Routine Cleaning

- Performed every 7 days
- Use CELLCLEAN® AUTO
- 15 minutes
- Automatically powers off the analyzer

