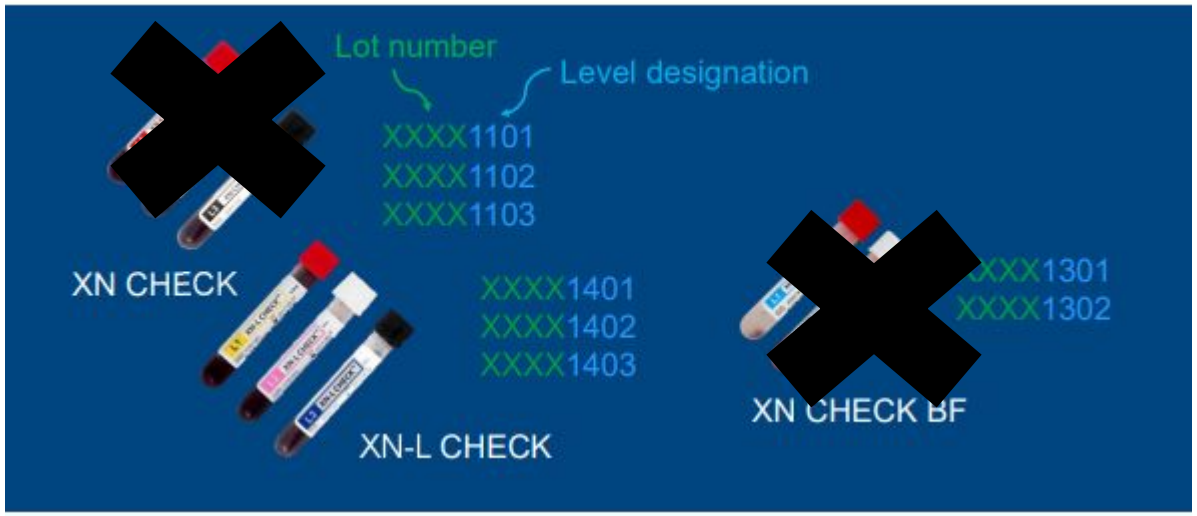
MLAB 1415: Hematology

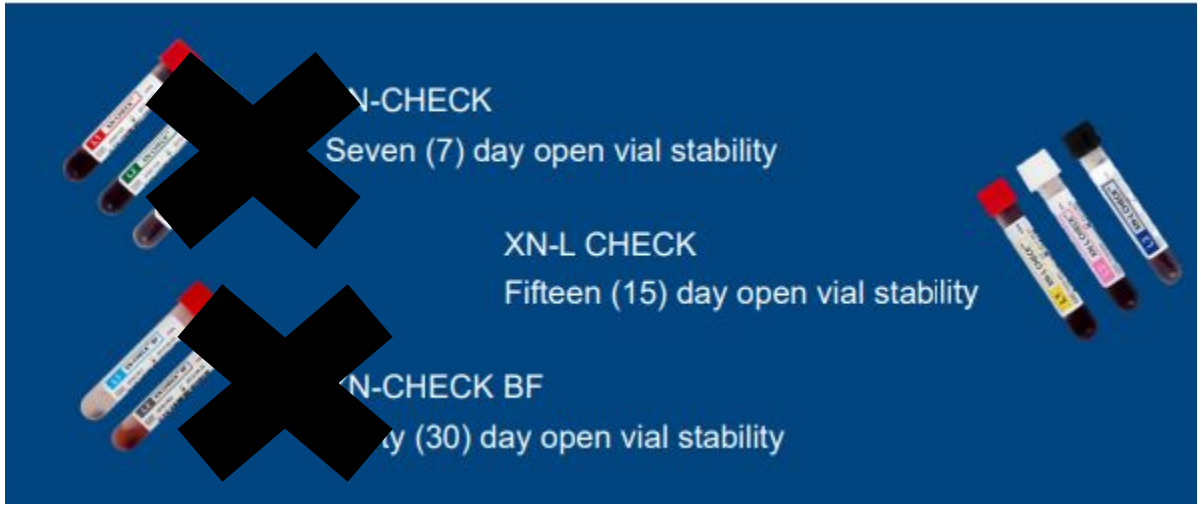
Quality Control
&
Sysmex- 430 XN

Quality Control (QC)

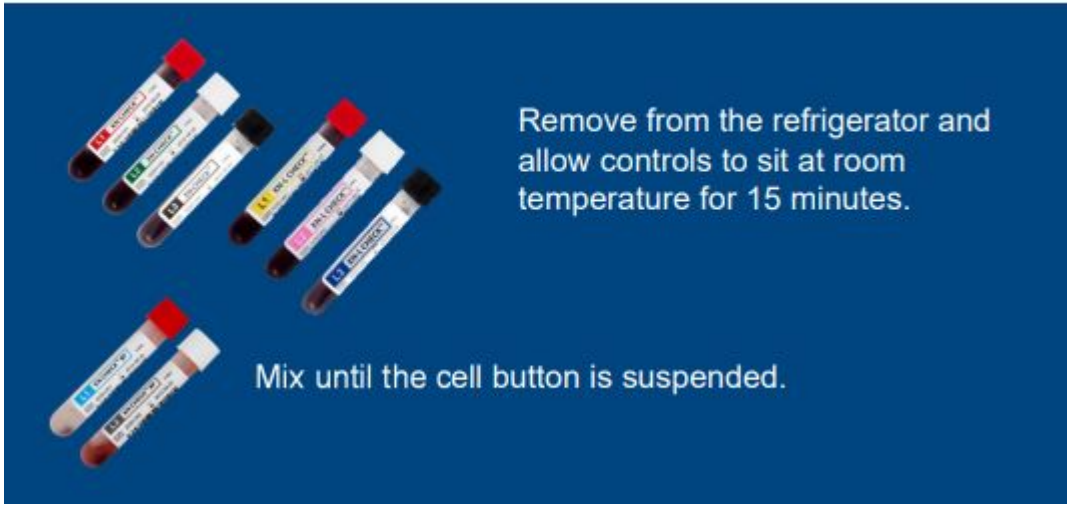
- What is QC?
  - Analyzer performance against a known standard (expected range)
    - Is it in-range?
      - Patient results will be valid
    - Is it out-of-range?
      - Patient results may be compromised
  - Commercial Controls:
    - 3 levels (low, normal, high), each vial has 3 mL of control material
    - Stored at 2-8 ^{0}C
    - Values stored in instrument computer
    - Levey-Jennings graph generated and stored for each parameter

Quality Control





QC Preparation



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 10^3 /µL	0.02-400 X 10^3 /µL

XN- 430 Reportable Ranges/Linearity

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

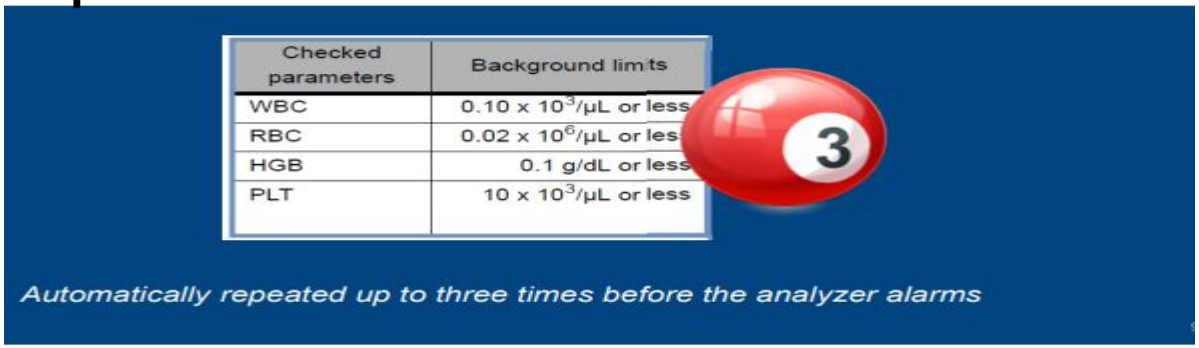
Start- Up

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.



Sample Processing-

Full tube

Microtainers

Note- Raised bottom tubes have a 250 µL 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