

Sysmex Reagents

XN Controls Feb 2022

5.15 Control blood (XN CHECK/XN CHECK BF)

Intended use

Used to controlling the quality of hematology analyzers.

Warnings and precautions (for in vitro diagnostic use only)



Risk of infection

Always wear protective garments and gloves when using control blood. Also, wash your hands after completing the process.

The basic blood used in the control blood has tested negative for HBs antigen, HCV/HIV-1/HIV-2 antibodies, and serologic tests for syphilis. However, there are no tests that can completely rule out any infections. In addition, it has not been tested for other viruses. Therefore, handle it with the same level of care you would use when handling other blood samples that may be infectious.

Storage and shelf life after first opening

Store the control blood in a dark refrigerated place at 2 - 8°C.

If it has not been opened, you can keep it until the expiration date printed on the vial label and outer box.

For shelf life after opening, refer to the expiration date printed on the package insert or reagents specifications. (►P.5-17 "5.18 Table of reagent specifications")

5.16 Calibrator (XN CAL/XN CAL PF)

Intended use

Use the XN CAL for the calibration of the instrument for WBC, RBC, HGB, HCT, PLT, and RET.

Use the XN CAL PF for the calibration of the instrument for PLT-F (platelet count obtained from the PLT-F channel).

Warnings and precautions (for in vitro diagnostic use only)



Risk of infection

Always wear protective garments and gloves when using control blood. Also, wash your hands after completing the process.

The basic blood used in the calibrator has tested negative for HBs antigen, HCV/HIV-1/HIV-2 antibodies, and serologic tests for syphilis. However, there are no tests that can completely rule out any infections. In addition, it has not been tested for other viruses. Therefore, handle it with the same level of care you would use when handling other blood samples that may be infectious.

Storage and shelf life after first opening

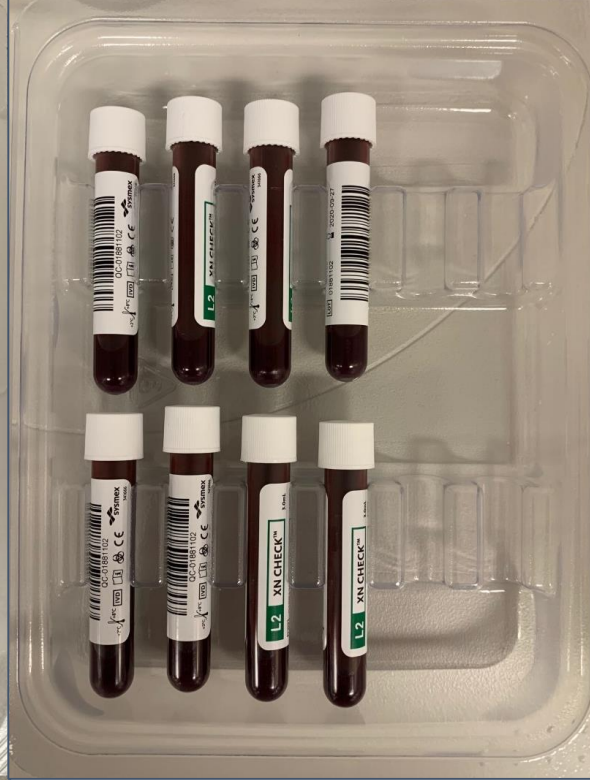
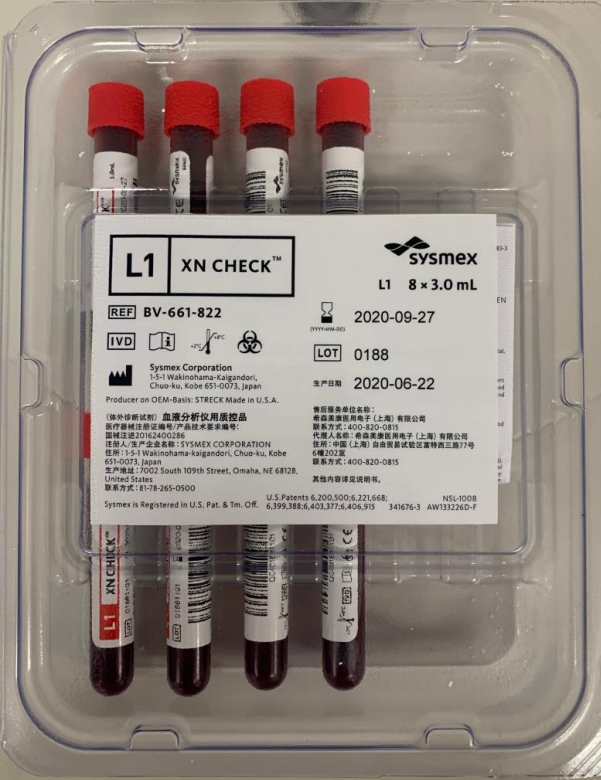
Store the calibrator in a dark refrigerated place at 2 - 8°C.

If it has not been opened, you can keep it until the expiration date printed on the vial label and outer box.

For shelf life after opening, refer to the expiration date printed on the package insert or reagents specifications. (►P.5-17 "5.18 Table of reagent specifications")

5.18.2 Table of control blood/calibrator specifications

Brand name	Volume	Storage temp.	Usage temp.	Shelf life after opening
XN CHECK	3.0 mL	2 - 8°C	15 - 30°C	7 days
XN CHECK BF	3.0 mL			30 days
XN CAL	3.0 mL			4 hours
XN CAL PF	3.0 mL			



Alfred Regime

Open vials as required
 09:00 - all three levels
 15:00 - all three levels
 19:00 - all three levels
 03:00 - all three levels

Sandringham Regime

Open new vials on Monday
 09:00 - all three levels
 12:00 – Level 1
 15:00 – Level 2
 18:00 – Level 3

*Send remainder QC to Alfred
 Friday evening*

*Running QC more frequently
 replaces need for separate drift
 control.*

Each batch always expires on
 Sunday evening.

3 levels of QC covering all parameters
 L1 – low with fluorescent platelets (light sensitive)
 L2 – Normal
 L3 – High

8 x 3ml in each pack
 7 days open vial stability
 Typically 8 weeks stability from “arrival/go live”

Targets from Assay CD.

