

Product Notification

Jun-2023

Leaking vials on haematology Quality Controls and Calibrators

Dear valued Customer,

It was brought to our attention that after piercing the vial caps septa blood residuals are observed on some. Few customers also reported stronger leakage during handling. Leakage can occur in rare cases, either caused by a piercer wear off, a slightly decentralized piercer adjustment, or rare outliers during production of the septa.

The root cause analysis of a higher number of leakages recognized since May is under evaluation. Counter measures will be implemented as soon as possible. All haematology **Quality Controls and Calibrators** may be affected. Since production of the material starts months before usage time, future lots unfortunately might show similar behaviour.

Safety and risk of infection

All materials are tested as stated in the package insert and thus the risk of infection is low.

Warnings and precautions

Do not inject or ingest.

All human source material used to manufacture XN CHECK was non-reactive for antigens to Hepatitis B (HBsAg), negative by tests for antibodies to HIV (HIV-1/HIV-2) and Hepatitis C (HCV), non-reactive for HIV-1 RNA and HCV RNA by licensed NAT, and non-reactive to Serological Test for Syphilis (STS) using techniques specified by the U.S. Food and Drug Administration. Because no known test method can assure complete absence of human pathogens, XN CHECK should be handled with appropriate precautions.

Precaution

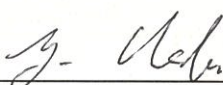
Please inform your lab staff and remind them of taking appropriate precaution for personal safety.

Additionally, we recommend storing all pierced vials in an upright position.

To prevent contamination of the inside of the analyser during automatic analyser mixing, please wipe off blood remnants from the top of the vial before placing into the analyser. If a particular vial already shows leakage during manual mixing or shows obvious strong leakage, do not measure it in closed cap mode. Closed cap measurements include mixing by the analyser.

We apologize for any inconvenience this may have caused and would like to thank you for your kind understanding.

Sincerely yours
Sysmex Corporation



Yoshiro Ueda
Vice President at Sysmex Corporation
Quality Assurance