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XW QC CHECK™
Hematology Control for Sysmex XW-100

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Intended use
XW QC CHECK is a stabilized whole blood matrix designed for statistical process control of Sysmex XW-100 hematology analyzer. It is not intended for calibration of the analyzer. This product is for in vitro use only.

Components
XW QC CHECK control consists of stabilized human erythrocytes, mammalian and simulated leukocytes, and a platelet component in a plasma-like medium. This product is provided in three levels: low, normal, and high concentrations.

Warning and precautions
All human source material used to manufacture this product 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), West Nile Virus and for antibodies to T. cruzi using techniques specified by the U.S. Food and Drug Administration. Because no known test method can assure complete absence of human pathogens, this product should be handled with appropriate precautions.

Storage and shelf life of unopened product
1. XW QC CHECK is shipped every 28 days. Upon shipment closed vial product life is 45 days.
2. Upon arrival store XW QC CHECK vials at 15 °C to 25 °C (59 °F-77 °F). (Store at 2 °C to 25 °C (36 °F-77 °F) prior to receipt at customer site). Storage outside this temperature range risks product damage. When properly stored, unused vials are stable until the expiration date on vial. Unused material should be discarded after arrival of a new lot or upon the expiration date on the vials, whichever comes first. The expiration is tracked automatically by the XW-100. Do not add residual to a new vial.

Indications of product deterioration
Temperature extremes can alter performance without visible changes to the control. Moderate hemolysis is normal. Suspect deterioration when the analyzer rejects the control results. When a problem persists after troubleshooting, call Customer Technical Support at 1-888-879-7639.

Procedure
1. XW QC CHECK is shipped fully reconstituted and ready for use.
2. Remove vial(s) from packaging.
3. Verify caps are secure. Follow the on-screen XW QC CHECK vial mixing instructions correctly; DO NOT shake.
4. Follow instructions on the analyzer for analysis of control material.

Performance characteristics and limitations
1. XW QC CHECK is for use on the Sysmex XW-100 hematology analyzer.
2. Product is to be used as supplied. Dilution or mixing of levels invalidates stability and intended use.

Manufacturer:
Sysmex Corporation
1-5-1 Wakinohama-Kaigandori
Chuo-ku, Kobe 651-0073, Japan

"Producer" on OEM-Basis:
STRECK, Inc.
7002 S. 109th Street La Vista, NE 68128, U.S.A.

Distributed by:
Sysmex America, Inc.
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Product information
XW QC CHECK 2.0 mL / vial

Date of issue or revision
09/2017, Rev.3

Printed in U.S.A.

REF	Catalogue number
IVD	In vitro diagnostic medical device
	Manufacturer
	Consult instructions for use
	Temperature limitation
	Use by
LOT	Batch code
	Biological Risks
RxOnly	By prescription only* *In compliance with U.S. FDA requirements

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