Wash Reagents

Current Revision and Date[a]	11203547 Rev. 03, 2022-03		
Product Name	ADVIA 2120 and ADVIA 2120i RBC Flow Cell Wash	20 x 3.7mL	REF 10734561
	ADVIA 2120 and ADVIA 2120i Perox Flow Cell Wash	20 x 3.7mL	REF 11306489
	ADVIA 2120 and ADVIA 2120i Aspiration Pathway Wash	20 x 3.7mL	REF 11306490
	ADVIA 2120 and ADVIA 2120i Vent Line Wash	4 x 100mL	REF 11306492
Systems	ADVIA 2120 and ADVIA 2120i		

[a] A vertical bar in the page margin indicates technical content that differs from the previous version.

CE

Intended Use

For in vitro diagnostic use as a cleaning agent for automatic or semi-automatic cleaning of hydraulic pathways on ADVIA 2120 and ADVIA 2120i Hematology systems

Material Description	Storage	Stability[a]
ADVIA 2120/2120i RBC Flow Cell Wash Volume: 3.7 mL Sodium hypochlorite 0.28M	2–8°C	Until expiration date on product
ADVIA 2120/2120i Perox Flow Cell Wash Volume: 3.7 mL Sodium hydroxide, 50 mmol/L; 2-(2-Ethoxyethoxy)ethanol, 894 mmol/L; Surfactant	15–30°C	Until expiration date on product
ADVIA 2120/2120i Aspiration Pathway Wash Volume: 3.7 mL Sodium hypochlorite 0.28M	2–8°C	Until expiration date on product
ADVIA 2120/2120i Vent Line Wash Volume: 100 mL Sodium hypochlorite 0.28M	2–8°C	Until expiration date on product

[a] Refer to *Storage and Stability*.

Warnings and Precautions

For *in vitro* diagnostic use.

For Professional Use.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

Safety data sheets (SDS) available on siemens-healthineers.com.

H290 **H315** **H319** **H412** **P234, P264, P280, P273, P337 + P313, P390, P501**	**Warning!** May be corrosive to metals. Causes skin irritation. Causes serious eye irritation. Harmful to aquatic life with long lasting effects. Keep only in original container. Wash hands thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. Avoid release to the environment. If eye irritation persists: Get medical advice/attention. Absorb spillage to prevent material damage. Dispose of contents and container in accordance with all local, regional, and national regulations. **Contains**: Sodium hypochlorite (ADVIA 2120 and ADVIA 2120i RBC Flow Cell Wash; ADVIA 2120 and ADVIA 2120i Aspiration Pathway Wash and ADVIA 2120 and ADVIA 2120i Vent Line Wash)

H290 **H319** **P234, P280, P337+P313 P390, P501**	**Warning!** May be corrosive to metals. Causes serious eye irritation. Keep only in original container. Wear protective gloves/protective clothing/eye protection/face protection. If eye irritation persists: Get medical advice/attention. Absorb spillage to prevent material damage. Dispose of contents and container in accordance with all local, regional, and national regulations. **Contains**: sodium hydroxide, dodecyldimethylamine oxide (ADVIA 2120 and ADVIA 2120i Perox Flow Cell Wash)

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

Storage and Stability

Store ADVIA 2120/2120i RBC Flow Cell Wash, ADVIA 2120/2120i Aspiration Pathway Wash and ADVIA 2120/2120i Vent Line Wash in an upright position. Unopened reagents are stable until the expiration date on the product when stored at 2–8°C.

Store ADVIA 2120/2120i Perox Flow Cell Wash in an upright position. Unopened reagents are stable until the expiration date on the product when stored at 15–30°C.

Do not use products beyond the expiration date printed on the product labeling.

Preparing the Reagents

All reagents are liquid and ready to use. Products are designed to be totally consumed at time of use, therefore no open bottle stability is claimed. For information about the loading and use of the cleaning products, please refer to *Instructions for Use*.

Instructions for Use

Automatic Hydraulic Pathway Wash

Recommended frequency to conduct RBC Flow Cell, Perox Flow Cell and Aspiration Pathway Washes is weekly. If this maintenance is performed on Automation, disable before running the wash reagent tubes. Enable after completion of procedure.

Perform the automatic hydraulic pathway wash using the following steps:

1. Let two vials of ADVIA 2120/2120i RBC Flow Cell Wash and five vials of ADVIA 2120/2120i Aspiration Pathway Wash stand for 15–20 minutes to come to room temperature.
2. Load Five vials of ADVIA 2120/2120i Aspiration Pathway Wash onto the sampler rack.
3. Load two vials of ADVIA 2120/2120i RBC Flow Cell Wash onto the sampler rack.
4. Load two vials of ADVIA 2120/2120i Perox Flow Cell Wash onto the sampler rack.
5. Ensure the barcode labels on each tube are facing out and are accessible to the autosampler barcode reader.
6. Push the Start button on the system.
7. The system will automatically advance the sample rack and begin the automated pathway washes.
8. Sample rack will be ejected out of the system.
9. Verify the system performance by running QC material. Confirm QC results are within assigned range.
10. The analyzer is ready to resume normal analysis after the completion of the cleaning event.

Semi-automatic Hydraulic Pathway Wash

Recommended frequency to conduct the Vent Line Wash is monthly.

Perform the semi-automatic hydraulic pathway wash using the following steps:

1. Let one bottle of ADVIA 2120/2120i Vent Line Wash stand for 15–20 minutes to come to room temperature.
2. Prepare a container with 100 ml of DI water.
3. Open the bottle of ADVIA 2120/2120i Vent Line Wash and remove the vent overflow tubing from overflow bottle.
4. Insert tubing into the RBC and Perox shuttle chamber vent line fittings. If no overflow tube installed, attach a 12-inch (300.5-mm), 0.081-ID piece of tubing to the vent ports (SMN 10310236).
5. Fully immerse each vent line tubing into the ADVIA 2120/2120i Vent Line Wash bottle.
6. At the Utilities menu, select Hydraulic Functions. Then select Clean UFC Vent Lines and Chambers.
7. Read all instructions on screen. Select All then Start.
8. When the cleaning event is completed, place the tubing into a container with 100mL di-Water and repeat the above steps.
9. Remove the tubing from the DI water container and repeat the above steps to aspirate air.
10. Reinstall all tubing back into the overflow bottle and remove the tubing from the RBC and Perox shuttle chamber vent line fittings.
11. Run a Refresh (background Count) from the Startup Screen.

12. Verify the system performance by running QC material. Confirm QC results are within assigned range.
13. The analyzer is ready to resume normal analysis after the completion of the cleaning event.

Technical Assistance

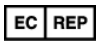
According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.

For customer support, contact your local technical support provider or distributor.

siemens-healthineers.com

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
	Manufacturer	5.1.1[a]		Authorized representative in the European Community	5.1.2[a]
	Use-by date	5.1.4[a]		Authorized representative in Switzerland	Proprietary
	Catalog number	5.1.6[a]		Batch code	5.1.5[a]
	Consult Instructions for Use	5.4.3[a]		Contains sufficient for <n> tests	5.5.5[a]
	Internet URL address to access the electronic instructions for use	Proprietary		Version of Instructions for Use	Proprietary
	*In vitro* diagnostic medical device	5.5.1[a]		Revision	Proprietary
	Prescription device (US only)	FDA[c]		Unique Device Identifier	5.7.10[b]
	CE Marking with Notified Body	EU IVDR[d]		CE Marking	EU IVDR[d]
	Temperature limit	5.3.7[a]		Keep away from sunlight	5.3.2[a]
	Upper limit of temperature	5.3.6[a]		Lower limit of temperature	5.3.5[a]
	Do not re-use	5.4.2[a]		Do not freeze	Proprietary
	Recycle	1135[e]		This way up	0623[e]
	Biological risks	5.4.1[a]		Caution	5.4.4[a]

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
YYYY-MM-DD	Date format (year-month-day)	N/A	**YYYY-MM**	Date format (year-month)	N/A
	Target	Proprietary		Interval	Proprietary

[a] International Standard Organization (ISO). ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied.

[b] ISO 15223-1:2020-04

[c] Federal Register. Vol. 81, No 115. Wednesday, June 15, 2016. Rules and Regulations: 38911.

[d] IVDR REGULATION (EU) 2017/746

[e] International Standard Organization (ISO). ISO 7000 Graphical symbols for use on equipment.

Legal Information


Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591 USA

Siemens Healthineers Headquarters
Siemens Healthcare GmbH
Henkestraße 127
91052 Erlangen
Germany
Phone: +49 9131 84-0
siemens-healthineers.com