

Hematek® Slide Stainer
ADVIA® Autoslide System

Follow-Up Communication for:

Hematek and ADVIA Autoslide Wright-Giemsa Stain and Modified Wright's Stain Precipitation

Siemens Healthcare Diagnostics is communicating follow-up information to the Customer Notification HC18-04.A.OUS, regarding the Hematek Wright-Giemsa Stain and Modified Wright's Stain Precipitation.

The initial communication (HC18-04.A.OUS) identified the Hematek Wright-Giemsa Stain Paks and Hematek Modified Wright's Stain Paks that may have been leaving precipitation on the slides after staining.

This follow-up communication contains information regarding an additional Hematek Wright-Giemsa Stain Pak lot number, three (3) lots of ADVIA Autoslide Wright-Giemsa Stain and four (4) lots of ADVIA Autoslide Modified Wright's Stain that are also impacted by this issue.

Please follow the instruction in the "Actions to be Taken" section of this communication.

Note: Changes in the description of the issue and actions to be taken by the customer that are different from the first Urgent Field Safety Notice (HC18-04.A.OUS) are indicated in '**BOLD**'.

Our records indicate that your facility may have received the following product(s):

Table 1. Hematek System and ADVIA Autoslide System Affected Product(s)

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number	Expiration Date (YYYY-MM-DD)	Manufacturing (YYYY-MM-DD)
Hematek Wright-Giemsa Stain Pak	01178588	10314755	439684	2019-02-09	2018-02-14
			442399	2019-02-28	2018-03-08
			447880	2019-04-10	2018-04-19
			447881	2019-05-07	2018-05-16
			454062	2019-06-21	2018-06-25
Hematek Modified Wright Stain Pak	06689653	10310965	433521	2018-12-26	2018-01-05
			439679	2019-01-26	2018-01-31
			442400	2019-03-28	2018-04-03
			447882	2019-04-26	2018-05-08

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number	Expiration Date (YYYY-MM-DD)	Manufacturing (YYYY-MM-DD)
ADVIA Autoslide Wright-Giemsa Stain	08096536	10327568	436599	2019-07-08	2018-01-10
			444992	2019-10-09	2018-04-13
			450784	2019-11-03	2018-05-07
			453816	2019-11-24	2018-05-31
ADVIA Autoslide Modified Wright's Stain	08100142	10327576	434422	2019-07-02	2018-01-05
			440006	2019-07-31	2018-02-02
			452513	2019-11-01	2018-05-14

Reason for Recall

The purpose of this communication is to inform you of an issue with the products indicated in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics has confirmed that Hematek Wright-Giemsa Stain Paks, Hematek Modified Wright Stain Paks, **ADVIA Autoslide Wright-Giemsa Stain and ADVIA Autoslide Modified Wright's Stain** may leave precipitate on slides **or cause poor coloration** after staining.

Customer complaints indicate that the lots of stain included in Table 1 may form precipitate on a slide **or cause poor coloration** during the staining process. This precipitation **or poor coloration** may make it more difficult to successfully perform peripheral blood microscopy procedures. This problem has been linked to a single lot of raw material used in manufacturing.

Risk to Health

The potential exists for an apparent delay to testing when this issue occurs, with negligible risk to health. Siemens is not recommending a laboratory look back of previously generated results as slides affected by this issue are not readable and therefore are not being reported.

Actions to be Taken by the Customer

- **If you experience precipitation deposits or poor coloration that makes it more difficult to successfully perform peripheral blood microscopy procedure**, discontinue use of and discard the kit/stain lots listed in Table 1.
- Review your inventory of these products to determine your laboratory's replacement needs.
- Complete and return the Product Replacement Form attached to this letter to request your no-charge replacement product(s).
- Perform a cleaning of your Hematek Slide Stainer **or ADVIA Autoslide** as outlined in the Hematek System Instruction Manual **or ADVIA Autoslide Operator Guide**.

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

ADVIA and Hematek are trademarks of Siemens Healthcare Diagnostics Inc.

Hematek and ADVIA Autoslide Wright-Giemsa Stain and Modified Wright's Stain Precipitation

PRODUCT REPLACEMENT FORM

Hematek® Slide Stainer and ADVIA® Autoslide – Hematek and ADVIA Autoslide Wright-Giemsa Stain and Modified Wright's Stain Precipitation

This form is to be used to request no-charge replacement product for the enclosed Siemens Healthcare Diagnostics Customer Notification HC18-04.B.OUS dated **October 2018** regarding Hematek® Slide Stainer and ADVIA® Autoslide – Hematek and ADVIA Autoslide Wright-Giemsa Stain and Modified Wright's Stain Precipitation.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

Do you now have any of the noted product(s) on hand? Please check
inventories before answering.

Yes ☐

No ☐

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Hematek Stain Paks Product Description/Product Catalog #/SMN #/Lot #	Quantity Discarded/ Replacement Quantity Required
Hematek Wright-Giemsa Stain Pak/Product Catalog 01178588/SMN 10314755/Lot Number 439684	
Hematek Wright-Giemsa Stain Pak/Product Catalog 01178588/SMN 10314755/Lot Number 442399	
Hematek Wright-Giemsa Stain Pak/Product Catalog 01178588/SMN 10314755/Lot Number 447880	
Hematek Wright-Giemsa Stain Pak/Product Catalog 01178588/SMN 10314755/Lot Number 447881	
Hematek Wright-Giemsa Stain Pak/Product Catalog 01178588/SMN 10314755/Lot Number 454062	
Hematek Modified Wright's Stain Pak/Product Catalog 06689653/SMN 10310965/Lot Number 433521	
Hematek Modified Wright's Stain Pak/Product Catalog 06689653/SMN 10310965/Lot Number 439679	
Hematek Modified Wright's Stain Pak/Product Catalog 06689653/SMN 10310965/Lot Number 442400	
Hematek Modified Wright's Stain Pak/Product Catalog 06689653/SMN 10310965/Lot Number 447882	
ADVIA Autoslide Stain Product Description/Product Catalog #/SMN #/Lot #	Quantity Discarded/ Replacement Quantity Required
ADVIA Autoslide Wright-Giemsa Stain/Product Catalog 08096536/SMN 10327568/Lot Number 436599	
ADVIA Autoslide Wright-Giemsa Stain/Product Catalog 08096536/SMN 10327568/Lot Number 444992	
ADVIA Autoslide Wright-Giemsa Stain/Product Catalog 08096536/SMN 10327568/Lot Number 450784	
ADVIA Autoslide Wright-Giemsa Stain/Product Catalog 08096536/SMN 10327568/Lot Number 453816	

Hematek and ADVIA Autoslide Wright-Giemsa Stain and Modified Wright's Stain Precipitation

ADVIA Autoslide Stain Product Description/Product Catalog #/SMN #/Lot #	Quantity Discarded/ Replacement Quantity Required
ADVIA Autoslide Modified Wright's Stain/Product Catalog 08100142/SMN 10327576/Lot Number 434422	
ADVIA Autoslide Modified Wright's Stain/Product Catalog 08100142/SMN 10327576/Lot Number 440006	
ADVIA Autoslide Modified Wright's Stain/Product Catalog 08100142/SMN 10327576/Lot Number 452513	

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Customer Sold To #: _____

Customer Ship To #: _____

Please send a scanned copy of the completed form via email to XXXX@XXXX.

Or to fax this completed form to the Customer Care Center at XXXXXX.

If you have any questions, contact your local Siemens technical support representative.