

CC to the Chairman Medical Board
and relevant Head of Departments

Hematek® Slide Stainer

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

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

Table 1. Hematek 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/
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

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 and Hematek Modified Wright Stain Paks may leave precipitate on slides after staining.

Customer complaints indicate that the lots of stain included in Table 1 may form precipitate on a slide during the staining process. This precipitation 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

- Discontinue use of and discard the kit 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 as outlined in the Hematek System Instruction Manual.

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.

Hematek® is a trademark of Siemens Healthcare Diagnostics Inc.

FIELD CORRECTION EFFECTIVENESS CHECK

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

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice HC18-04.A.OUS dated August 2018 regarding Hematek® Slide Stainer - Hematek Wright-Giemsa Stain and Modified Wright's Stain Precipitation. Please read each question and indicate the appropriate answer.

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

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes • No •
2. 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.

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 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	

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