



A facsimile from

NDC, INC.

Djana Milliken Compliance Specialist

Phone: 615-366-3225

Fax 615-229-6801

To: Purchasing or Regulations
Department

*****URGENT*****

Date: 05/13/2016

4 pages + Cover

*****This is being faxed to the "bill to" account for your company. Please distribute to any/all branches.**

**Regarding: Beckman Coulter – Gastrocult Important Notice
Item # 66040**

Comments:

Dear Distributor, attached is a letter we received from Beckman Coulter regarding the product notice on their item 66040 (please see attached for Lot Numbers). Our records indicate that you purchased this product from us. Please read attached letter and check your inventory for any affected product with listed lot number. If you have any of this product in stock please fill out attached "Request for return" form, so that we can issue you a RGA for return. Also **Please make note that no credit will be issued without an RGA.** If you have any questions please feel free to contact me.

It is very important that we receive a response, a record of receipt is very important in documentation of these types of notices.

Additionally, if you have distributed these products to your customers, please advise them of the recall, and have them return any affected product to you.

Thanks,

Djana Milliken
Compliance Specialist
NDC, Inc.



May 3, 2016

IMPORTANT PRODUCT NOTICE
Gastrocuccult - Test for Gastric Occult Blood and pH

REF	Description	LOT	
66040	Gastrocuccult 40T, 10 Kits/Case	See Table 1	See Table 1

Dear Beckman Coulter Distributor,

As a valued partner, we wanted to make you aware of an Important Product Notice that we are initiating. This information is focused on the Gastrocuccult Test for Gastric Occult Blood and pH.

Attached you will find an Important Product Notice for the Gastrocuccult Test Device. As a Beckman Coulter distributor, please forward the letter to all customers who have purchased or have been shipped the Gastrocuccult Test Lots listed below in Table 1.

If you or your customers have any questions, please feel free to call the Beckman Coulter Technical Support at 800-877-6242.

We apologize for any inconvenience this announcement has caused you or your customers. As always, we appreciate your continued support and cooperation.

Sincerely,

Marwan Fathallah
Vice President Quality Assurance and Regulatory Affairs
Encl: Important Product Notice
Response Form

Table 1

REF	Description	LOT	
66040	Gastrocuccult 40T, 10 Kits/Case	20241A, 20241B, 20241C, 20241D	2016-Apr-30
		20441, 20441A	2016-Sep-30
		20151, 20251, 20351	2017-Mar-26
		20451, 20651, 20751, 20751A, 20751B, 20751C, 20751D	2017-May-31
		20851, 20851A	2017-Dec-31
		20161, 20161A, 20161B, 20261, 20261A, 20261B	2018-Jan-31

IPN-27783

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Beckman Coulter, Inc.
11800 S.W. 147th Avenue
Miami, FL 33196-2500

Mailing Address:
11800 S.W. 147th Avenue
P.O. Box 169015
Miami, FL 33116-9015

Customer Service: (800) 526-7694
Product Information: (800) 526-6932
(800) 327-6531 (305) 380-3800
Internet : www.beckmancoulter.com

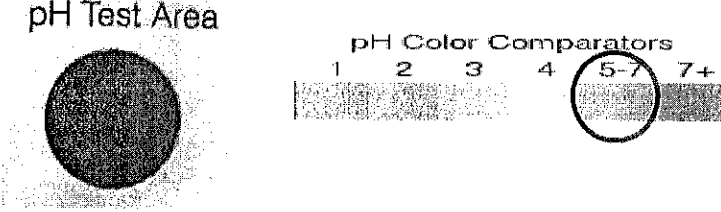
May 3, 2016

IMPORTANT PRODUCT NOTICE
Gastrocult - Test for Gastric Occult Blood and pH

REF	Description	LOT	
66040	Gastrocult 40T, 10 Kits/Case	See Table 1	See Table 1

Dear Beckman Coulter Customer,

Beckman Coulter is sending this letter regarding an issue with the pH test area on the Gastrocult Test kit.

ISSUE:	The pH test area for the Gastrocult lot numbers listed in Table 1 may display an unexpected color for a sample at a pH 7 reading when compared to the associated section of the Color Comparator bar.
IMPACT:	<p>When a sample with a pH 7 is applied, the results in the pH Test Area may exhibit a brownish-yellow color reading (see the figure below) instead of the expected olive green color as shown on the pH Color Comparator bar.</p> <div style="text-align: center;">  <p>The diagram shows a circular 'pH Test Area' on the left. To its right is a horizontal 'pH Color Comparator' bar divided into six segments labeled 1, 2, 3, 4, 5-7, and 7+. The 5-7 segment is circled in black.</p> </div> <ul style="list-style-type: none"> • This color difference may lead to incorrect pH readings on patient samples and the buffer at a pH 7 level. • The gastric occult blood test portion of the Gastrocult slide is NOT affected.
ACTION:	At this time, based on testing, Beckman Coulter recommends the use of both the olive green and the brown-yellow colors as acceptable and accurate indications of a 5-7 pH reading.
RESOLUTION:	An investigation is underway to determine the root cause of this issue.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter. Complete and return the enclosed response form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact our Customer Support Center or your Beckman Coulter distributor.

- Via our website, <http://www.beckmancoulter.com/customersupport/support>
- Via phone, call 800-877-6242 in the United States and Canada.

IPN-27783



We apologize for any inconvenience that this caused your laboratory.

Sincerely,

Marwan Fathallah
Vice President Quality Assurance and Regulatory Affairs
Encl: Response Form

Table 1

REF	Description	LOT	
66040	Gastrocult 40T, 10 Kits/Case	20241A, 20241B, 20241C, 20241D	2016-Apr-30
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		20151, 20251, 20351	2017-Mar-26
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Product Information: (800) 526-6932
(800) 327-6531 (305) 380-3800
Internet : www.beckmancoulter.com



May 13, 2016

**Please respond by
May 27, 2016**

BCK

REQUEST FOR RETURN FORM

Customer Information

Account No. _____

Account Name _____

Address _____

City/State/Zip _____

Contact Name _____

Phone No. _____

Fax No. _____

Email _____

Inventory Information

Item number	Lot number	Expiration Date	Quantity to return
BCK 66040			

- I have read and understood the information within the accompanying notification. All relevant customers/personnel have been informed of its contents, any necessary actions taken.
- We have inspected our inventory and have no product related to this recall to return

Returned Completed form to: Djana Milliken
 Fax #: 615.229.6801
 Email: compliance@ndc-inc.com