




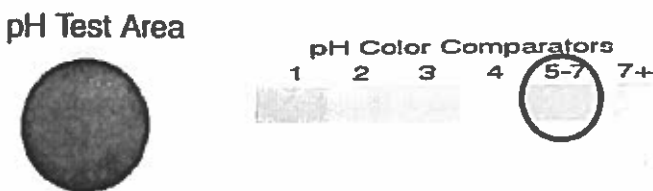
May 3, 2016

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

REF	Description	LOT	
66040	Gastrocult 40T, 10 Kits/Case	Sec 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;">  </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

Beckman Coulter, Inc.
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Miami, FL 33196-2500

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



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
		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

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