



63 Community Drive,
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URGENT MEDICAL DEVICE CORRECTION

Date March 5, 2010

To: Chris Brueske
MINNESOTA DEPARTMENT
Newborn Screening Program
Public Health Laboratory
601 Robert Street North
St. Paul, MN 55155-2531

Re: **903 Newborn Screening Card**
Detachment of 903 Portions from Demographic Portion of Card

Dear Customer,

Whatman, part of GE Healthcare, has recently become aware of a quality issue associated with 903 Newborn Screening Cards that may impact patient safety.

Please ensure that all pertinent persons in your organization are made aware of this safety notification and the recommended actions.

Safety Issue Whatman has received a small number of reports of a quality issue where partial or complete detachment of the '903' paper from the demographic portion of the card has occurred.

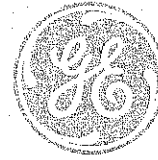
The quality issue relates to partial or complete detachment of the 903 paper from the demographic portion of the card.

This may require an infant to be subject to a screening re-test and possibly delay results. This potential defect may be detected by inspecting the product as instructed below.

Affected Product Details	Product:	903 Newborn Screening Card
		903 MSPR1 MN 183-1204
	Product REF:	10534602
	LOT No:	All LOT's produced from 2007 to present.

Safety Instruction As a precaution we recommend that users inspect cards before use as follows:

- Prior to recording patient demographic details on the card and obtaining a patient sample, inspect the card, and ensure the 903 Paper Portion is firmly and completely fixed to the Demographic portion.
- If the 903 Paper Portion of the card partially or completely detaches from the Demographic portion of the card, discard the card. Obtain a new card and inspect as above.
- If acceptable per your protocol, to prevent any opportunity for 903 paper detachment from the demographic portion, please staple or tape as you deem appropriate, the 903 paper portion to the demographic portion at two points.



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- Whatman recommends that 903 cards be handled while wearing gloves to avoid contamination of the 903 Paper Portion.

Product Correction Whatman's investigation is ongoing to identify and correct this quality issue where partial or complete detachment of the '903' paper from the demographic portion of the card has occurred.

Contact Information If Whatman customers/users have any questions in relation to this customer notification, please contact Whatman customer service or product management representative

Role	Customer Service	Product Management
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Please be assured that maintaining a high level of safety and quality is our priority. If you have any questions, please contact us immediately.

Sincerely,

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