

## Urgent - Field Safety Notice

### Samsung LABGEO<sup>PT</sup> Renal Test 6

#### High value of Sodium (Na)

Dear Customer,

As part of Samsung Electronics' continuous focus on reliability and safety, we continuously monitor the performance of our products. Samsung had been informed of an issue from a customer in Israel about a data result for Sodium in the Samsung LABGEO Renal Test 6 as giving a high value. After internal evaluation, we have identified that the test Samsung LABGEO<sup>PT</sup> Renal Test 6 may possibly give a high value of Sodium.

This letter is intended to provide you with information regarding:

- what the issue is, and under what circumstances it may occur
- the actions you can take to avoid or minimize the occurrence of the issue
- the actions planned by Samsung Electronics to correct the issue

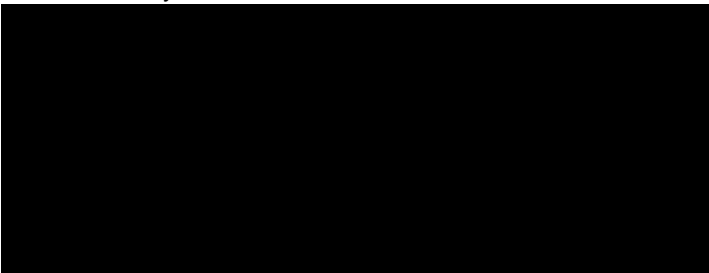
**This document contains important information for the safe and proper use of Samsung Electronics HME Products**

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

If you need any further information or support concerning this, please contact your local Samsung Electronics representative.

We apologize for any inconvenience that this may cause and trust that this information is adequately addressing any concerns you may have.


Sincerely,



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Affected Products	Device Name(s)	LOT Number
	Samsung LABGEO <sup>PT</sup> Renal Test 6	Please see Appendix
<b>Description of Problem</b>	A customer in Israel had seen that the data result for Sodium (Na) in the Samsung LABGEO Renal Test 6 was giving a high value. After evaluation, it was identified that the Samsung LABGEO Renal Test 6 may potentially give a high value for sodium. No adverse event reports have been received from the field in association with this problem.	
<b>Root Cause(s)</b>	Samsung are in the process of identifying the root cause of this issue.  The Samsung R&D teams are currently studying the possibility that the chemical component in the Renal Test may be leaching out onto the spacer sheet and investigating the stability of the product	
<b>Potential Hazards</b>	The potential hazards associated with the Sodium (Na) value being higher than the reference range may cause customer inconvenience due to undergoing additional testing or may potentially lead to an event such as misdiagnosis.  To mitigate these hazards, the Samsung LABGEO Renal Test 6 comes with an insert, advising the user that the result obtained cannot be used for a medical decision without further information.  “When used in diagnosis, the result value must always be evaluated along with the patient’s medical history, clinical experiments, and other inquiries.”	
<b>How to Identify Affected Products</b>	A label is attached in the outer box and each pouch.	

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<p><b>Remedial Actions to be Taken by Users</b></p>	<p>For all affected End Users to stop using the affected cartridges listed in the Appendix</p>
<p><b>Corrective Actions Planned by Samsung</b></p>	<p>Samsung plan on recalling all affected lots of the LABGEO Renal Test 6 panel as identified in the appendix.</p> <p>A communication has been sent to all affected distributors/ end users to stop using the affected cartridges.</p> <p>Samsung will compensate users that had received the listed affected lots.</p>
<p><b>Support Contacts</b></p>	<p>If you need any further information or support concerning this problem, please contact local representative.</p>

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#### INSTRUCTIONS FOR DISTRIBUTORS:

- 1) Please read the Field Safety Notice documentation in detail.
- 2) If you have any affected devices in stock/warehousing, please quarantine them immediately.
- 3) Please review and complete the “acknowledgement form” provided in this FSN and return to the Authorised Representative at [s.sur@samsung.com](mailto:s.sur@samsung.com) and copy [eu.vigilance@samsung.com](mailto:eu.vigilance@samsung.com) as soon as possible.
- 4) Please pass this entire package of FSN documentation onto your customers and ask them to return the completed “acknowledgement form”.
  - a) Once “acknowledgement forms” have been received, please forward copies on to Samsung.
- 5) Complete “consignee information form” detailing the location of all devices for which you are responsible and return to Samsung as soon as possible – in order to effectively carry out this FSCA we need to identify the location of all affected devices.
- 6) If required and instructed by this FSN documentation, please undertake all relevant service actions as soon as is practicably possible.
  - a) If service actions are required to be undertaken by you as a distributor, please complete the attached “service record form” and return to Samsung as soon as is possible. You may use the service form provided in this FSN or your own service log forms.

#### INSTRUCTIONS FOR USERS:

- 1) Please read the Field Safety Notice documentation in detail.
- 2) Follow the instructions provided in this FSN in relation to any actions which are required of you.
- 3) Please complete the provided “acknowledgement form” and return to your supplier as soon as possible.
- 4) If required and instructed by this FSN documentation, please undertake all relevant service actions as soon as is practicably possible.
  - a) If service actions are required to be undertaken by you as an end-user, please complete the attached “service record form” and return to your supplier as soon as is possible. You may use the service form provided in this FSN or your own service log forms.

#### Appendix

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Lot number	Lot number
Q00MAG69	Q00MAG8P
Q00MAG6G	Q00MAG8Q
Q00MAG77	Q00MAG91
Q00MAG7A	Q00MAG92
Q00MAG7E	Q00MAG98
Q00MAG7F	Q00MAG99
Q00MAG7G	Q00MAG9F
Q00MAG7H	Q00MAG9G
Q00MAG7M	Q00MAG9M
Q00MAG7S	Q00MAGA1
Q00MAG7T	Q00MAGA6
Q00MAG84	Q00MAGAD
Q00MAG85	Q00MAGAE
Q00MAG8C	Q00MAGAJ
Q00MAG8I	Q00MAGAK
Q00MAG8J	Q00MAGAS

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**FSN Acknowledgement**

Dear Distributor,

Please complete the form below.

<p><b>Affected End users &amp; Lot Information</b></p>	<p>Please provide details of all end users – include the date of distribution, lot numbers and the number of test affected. Please refer to the FSN.</p> <p><b>Supplied to:</b></p> <p><b>Date of distribution:</b></p> <p><b>Lot Number:</b></p> <p><b>Number of tests:</b></p>
<p><b>End user communication</b></p>	<ul style="list-style-type: none"> <li>• Please verify the dates of when all the end users were informed of the FSN?  <b>(Please attach a confirmation of receipt of the FSN from <u>each end user</u>)</b></li>   <li>• Please verify if each end user has actioned the FSN as provided by Samsung  <b>(Please attach a confirmation of receipt of completed actions)</b></li>   <li>• Was the FSN translated into your local language? ( <input type="checkbox"/> Yes <input type="checkbox"/> No )                      If yes, please also send us the translated FSN.</li> </ul>
<p><b>Distributor's Information &amp; confirmation of</b></p>	<p><b>Date FSN was received from Samsung:</b></p>

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<b>receipt of FSN</b>	<b>Distributor's Name:</b>  <b>Address:</b>  <b>Country:</b>  <b>Contact person (Print Name):</b>  <b>Signature:</b>  <b>Date:</b>
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Please print & sign the acknowledgement and send a scanned copy to [s.sur@samsung.com](mailto:s.sur@samsung.com) & [eu.vigilance@samsung.com](mailto:eu.vigilance@samsung.com) by January 29, 2016

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