

VERSANT® kPCR Molecular System Sample Preparation Module

Heater - Shaker Incompatibility with DeepWell Plate Leads to Reduced Instrument Reliability

The VERSANT® kPCR Molecular System Sample Preparation Module uses a DeepWell plate manufactured by Nunc, and sold under the Nunc catalog number 278743. Siemens Healthcare Diagnostics supplies this plate to customers under the Siemens REF number 06691055 and SMN 10283255.

Our records indicate that you may have received 96-well DeepWell plates from one of the following lot numbers, produced after 19 September 2011.

Table 1. Affected Lots of DeepWell Plates (REF 06691055, SMN 10283255)

120571	124628
120572	125967
120573	

Plates from the affected lots in Table 1 have been associated with an increased likelihood of sample processing errors. Plates from the affected lots are compliant with the manufacturer's specifications, but do not fit well on the instrument fixtures. This incompatibility with our instrument can cause errors leading to loss of samples or premature termination of runs.

Siemens is conducting a voluntary corrective action for 96-well DeepWell plates for lot numbers 120571, 120572, 120573, 124628 and 125967. Please immediately discontinue the use of these lots of DeepWell plates with the VERSANT kPCR Molecular System.

Each DeepWell plate is packaged in an individual pouch, without a lot number. Sixty (60) pouched plates are packaged in a bag marked with the lot number. If you have plates with lot numbers that you cannot identify, and that were shipped to you after 19 September 2011, you must check the plates for proper fit before use.

To check a plate for proper fit, place it on the Heater Shaker.

- A properly fitting plate will readily drop into its normal operational position.
- An incompatible plate will wedge into place before seating fully, and may come to rest as much as 1cm above the normal operational position.

It is important to only use plates that are from lots known to be compatible (i.e., not in those lots listed above), or plates that will pass this fit test.

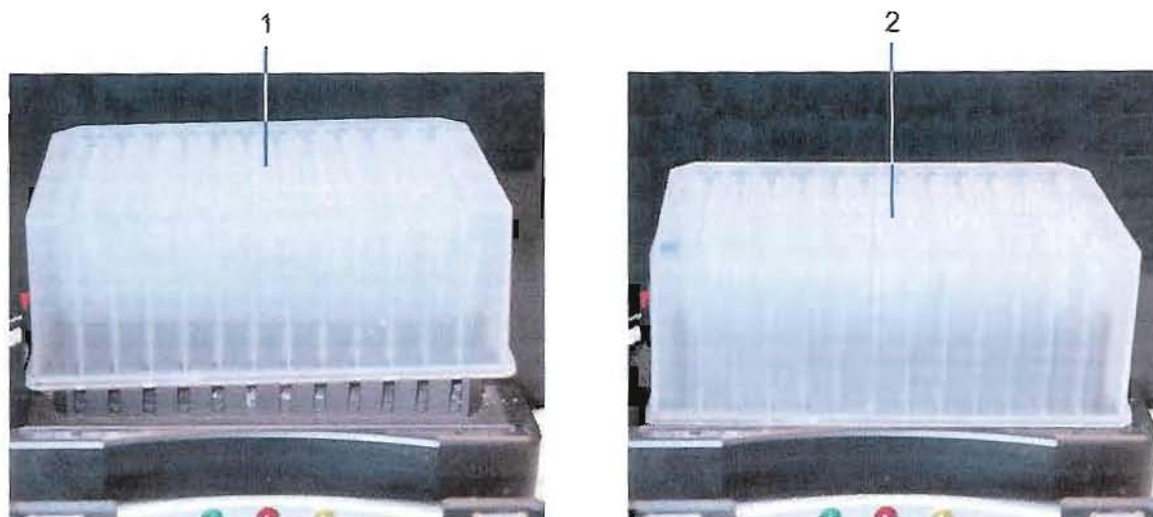
Siemens Healthcare Diagnostics

511 Benedict Avenue
Tarrytown, NY 10591

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Figure 1. Examples of Incompatible and Compatible DeepWell Plates



- 1 Example of an incompatible DeepWell plate: it does not seat fully on the heater shaker.
- 2 Example of a compatible DeepWell plate: it seats fully on the heater shaker.

You may contact your Siemens Customer Service Center at [###-###-####] to request a replacement at no charge for any DeepWell plates in the affected lots that you have purchased from Siemens.

Siemens has negotiated an exclusive agreement with the manufacturer to return to the previous manufacturing process for DeepWell plates for the VERSANT kPCR Molecular System. You can continue to use Siemens REF 06691055 and SMN 10283255 to order these compatible plates. New supplies of compatible plates will bear the Nunc catalog number 278015.

DeepWell plates compatible with the VERSANT kPCR Molecular System must only be purchased through Siemens. Plates purchased direct from the manufacturer, or through independent suppliers, cannot be guaranteed to be compatible.

We apologize for the inconvenience that this situation has caused. Thank you for your patience and continued support.

FIELD CORRECTION EFFECTIVENESS CHECK

Heater - Shaker Incompatibility with DeepWell Plate Leads to Reduced Instrument Reliability

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated February 2012 regarding the Heater - Shaker Incompatibility with DeepWell Plates. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare diagnostics at the fax number indicated at the bottom of this page.

1. Did your facility receive a field correction letter from Siemens Healthcare Diagnostics regarding the Heater - Shaker Incompatibility with DeepWell Plates? Yes ☐ No ☐
2. Did we effectively communicate all necessary information? Yes ☐ No ☐
3. Do you now have any of the noted product on hand? (Please check inventories before answering.) Yes ☐ No ☐
4. If the answer to the question above is Yes, do you intend to take the recommended action as requested? Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution:

Instrument Serial Number:

Street:

City:

State:

Phone:

PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT
(###) ###-####

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