

July 1, 2014

**URGENT: FIELD SAFETY NOTICE**  
**Risk of incorrect results from samples prepared  
with Panthera-Puncher 9**

Product Code	Product Name	Serial Numbers
2081-0010	Panthera-Puncher 9™	20810001 - 20810148

Dear Customer,

The purpose of this letter is to advise you that PerkinElmer is voluntarily recalling the PerkinElmer Panthera-Puncher 9™.

**Reason of the Voluntary Recall:**

We have become aware that extended exposure to the ionizer pins of the Panthera-Puncher 9™ can decrease the reaction signal level of assays using antibody coated microtiter plates (such as immunoassays). Our investigation has shown that uncoated plates are not affected by the phenomenon (such as enzymatic assays). The phenomenon has been determined to be localized to those wells that are located beneath or adjacent to the ionizer pins when the Panthera-Puncher 9 is idle or in sleep mode. The software allows the ionizer to remain active when the puncher is idle or has gone into sleep mode.

**Risk to Health:**

The impact on health is dependent on the assay and the associated disorder the assay screens for in the dried blood spot sample. We assessed the impact of the phenomenon using PerkinElmer Neonatal Screening assays that incorporate antibody coated plates; T4, TSH, IRT and 17-OHP. However, if a laboratory runs non-PerkinElmer assays that incorporate antibody coated plates the phenomenon may occur and therefore similar precautions should be taken when preparing dried blood spot samples for those assays.

Falsely low signal levels increase the risk of false negative newborn screening results for patients with either congenital hypothyroidism (T4 and TSH analytes) or cystic fibrosis (IRT). There is also a risk of false positive results for patients with congenital adrenal hyperplasia (17-OHP). Based on the low incidence of these diseases, the probability of an injury occurring due to the decreased signal has been assessed to be remote.

**Actions to be taken by the Customer:**

As an interim corrective measure we request users minimize the exposure time of coated plates to the ionizer by either:

- Removing the plates from the Panthera-Puncher 9 when not actively punching and processing samples in the instrument.
- Opening the plate track hatch if plates must reside in the Panthera-Puncher 9 while the instrument is idle or in sleep mode. This will interrupt power to the ionizer and eliminate any ionizer impact on the plate wells.

These interim corrective measures should continue until a final corrective action can be implemented by PerkinElmer.

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**Actions to be taken by PerkinElmer:**

- Your local PerkinElmer Representative will be contacting you to arrange a visit to inspect your instrument's ionizer voltage to support our root cause investigations.
- PerkinElmer is developing a software update that will automatically switch off the ionizer when the Panthera-Puncher 9 remains idle for a defined period of time.
- PerkinElmer is assessing the need for hardware modification that would further mitigate the contributing factors.
- Once the final corrective measures are available, your local PerkinElmer Representative will contact you to schedule installation. The service call and any updates to the software or hardware will be free of charge.

**Other Information:**

Please distribute this information immediately to any staff that may be impacted by this Panthera-Puncher 9™ issue.

To comply with regulatory requirements we request that you complete the enclosed response form and return it by fax to number +358 2 2678 357 or scan and e-mail to [TurkuQMresponse@perkinelmer.com](mailto:TurkuQMresponse@perkinelmer.com) as soon as possible, but not later than July 18, 2014.

We regret any inconvenience this product issue may cause and we appreciate your assistance. For further information, please contact your local PerkinElmer representative or [GSCustomerSupport@PerkinElmer.com](mailto:GSCustomerSupport@PerkinElmer.com).

Sincerely,



Ann-Christine Fagerström  
Quality Director  
Wallac Oy

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# RESPONSE FORM

Please complete this response form and send it by fax to +358 2 2678 357 or scan and e-mail to [TurkuQMresponse@perkinelmer.com](mailto:TurkuQMresponse@perkinelmer.com).

Product / versions affected:

Product Code	Product Name	Serial Numbers
2081-0010	Panthera-Puncher 9™	20810001-20810148

1. Have you read the letter accompanying this form? The letter provides information of the recall by PerkinElmer of the above listed devices.

Yes       No

2. Please record the serial numbers and software versions of the Panthera-Puncher 9 instruments in your possession in the table below.

Serial Number	Software Version

Serial Number	Software Version

To be signed by individual completing information above.

Printed Name \_\_\_\_\_

Signature / Date \_\_\_\_\_ / \_\_\_\_\_

Laboratory / Clinic \_\_\_\_\_

State / Country \_\_\_\_\_