

FIELD SAFETY NOTICE
**Potential for decreased measured IRT analyte concentrations with
GSP Neonatal IRT kit 3306-0010**

Dear Customer,

The purpose of this letter is to advise you that PerkinElmer is voluntarily initiating a field safety corrective action of GSP Neonatal IRT kit lots identified in Attachment 1.

Reason for the Correction:

We have become aware that measured IRT analyte concentrations in neonatal dried blood spot specimens may be decreased up to 65% if the sample has been collected using citrate or EDTA tubes or capillaries before applying onto the filter paper.

External quality assurance e.g. proficiency test samples may contain citrate or EDTA and therefore the measured IRT analyte concentrations may be decreased with these samples in a similar manner.

Risk to Health:

If the sample has been collected using citrate or EDTA tubes or capillaries, the decrease in measured IRT analyte concentration may lead to false negative screening result. The probability of injury has been assessed to be low based on preferred sample collection method for newborn screening i.e. blood being collected from a heel prick with direct application onto the filter paper and based on the low incidence of the Cystic Fibrosis.

The decrease in IRT measurements for external quality assurance samples does not cause direct risk to health. The risk is only possible, if the issue results in remedial actions by the clinical laboratory due to unacceptable external quality assurance scheme result and therefore reporting of a true positive cystic fibrosis case is delayed.

Actions to be taken:

- Do not use citrate or EDTA in blood collection. Use the preferred method for sample collection i.e. blood collected from a heel prick with direct application onto the filter paper.
- Please note that the external quality assurance results may be affected by the issue if the samples contain anticoagulants such as citrate or EDTA
- Complete the Response Form and return the Response Form to PerkinElmer.

Other Information:

Please distribute this information immediately to any staff that may be impacted by this issue. Please distribute this field safety notice to the Chairman Medical Board and relevant Head-of-Department of the affected healthcare facilities.

To comply with regulatory requirements we require that you complete the enclosed Response Form and return it to fax number +358 2 2678 357 or as scanned document by e-mail to [REDACTED] as soon as possible, but not later than 31st January, 2020.

We regret the inconvenience this issue may cause to you and we appreciate your understanding. For further information, please contact your local PerkinElmer representative.

[REDACTED]
Anita Kuvaja
Quality Director
PerkinElmer Turku Site

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ATTACHMENT 1. LIST OF AFFECTED KIT LOTS

Product Code	Product Name	Kit Lot Number	Pack Lot Number	UDI
3306-0010	GSP Neonatal IRT	669839	1066983901	(01)06438147320516(17)201031(10)669839
		670070	1067007001	(01)06438147320516(17)201031(10)670070
		670617	1067061701	(01)06438147320516(17)201031(10)670617
		670745	1067074501	(01)06438147320516(17)201231(10)670745
		671039	1067103901	(01)06438147320516(17)201231(10)671039
		671642	1067164201	(01)06438147320516(17)210131(10)671642
		671642	1067164202	(01)06438147320516(17)210131(10)671642
		672298	1067229801	(01)06438147320516(17)201231(10)672298
		672298	1067229802	(01)06438147320516(17)201231(10)672298
		672425	1067242501	(01)06438147320516(17)210228(10)672425
		672425	1067242502	(01)06438147320516(17)210228(10)672425
		672425	1067242503	(01)06438147320516(17)210228(10)672425
		672734	1067273401	(01)06438147320516(17)210131(10)672734
		672970	1067297001	(01)06438147320516(17)210228(10)672970
		673112	1067311201	(01)06438147320516(17)210331(10)673112
		673300	1067330001	(01)06438147320516(17)210331(10)673300
		673395	1067339501	(01)06438147320516(17)210331(10)673395
		673531	1067353101	(01)06438147320516(17)210331(10)673531
		673531	1067353102	(01)06438147320516(17)210331(10)673531
		674169	1067416901	(01)06438147320516(17)210331(10)674169
		674506	1067450601	(01)06438147320516(17)210228(10)674506
		674507	1067450701	(01)06438147320516(17)210630(10)674507
		674917	1067491701	(01)06438147320516(17)210630(10)674917
		675208	1067520801	(01)06438147320516(17)210630(10)675208
		675209	1067520901	(01)06438147320516(17)210630(10)675209
		676006	1067600601	(01)06438147320516(17)210630(10)676006
		676460	1067646001	(01)06438147320516(17)210831(10)676460

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ATTACHMENT 2. RESPONSE FORM

Date: November 28, 2019

Please complete this response form and return it by fax to number +358 2 2678 357 or as scanned document by e-mail to TurkuQMresponse@perkinelmer.com.

1. Have you read the letter accompanying this form? The letter provides information about the field safety corrective action by PerkinElmer affecting the product and lots listed in attachment 1 to this letter.

Yes No

2. Are you aware that your laboratory has received neonatal samples that contain citrate or EDTA?

Yes No

If yes, this concerns:

Occasional samples only

Citrate or EDTA tubes/capillaries are routinely used and therefore the issue affects all/ most of the samples

Laboratory/ Institute: _____

Signature _____

Date _____

Printed Name _____

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