Date: November XX, 2019

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.

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 TurkuQMresponse@perkinelmer.com 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.

Rina Wahlroos
Quality Director
PerkinElmer Turku Site

R2019003

Date: November XX, 2019

ATTACHMENT 1. LIST OF AFFECTED 3306-0010 GSP NEONATAL IRT KIT LOTS

Kit Lot Number	Pack Lot Number	UDI
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

ATTACHMENT 2. RESPONSE FORM Date: November XX, 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 _____

R2019003