PerkinElmer®

HUMAN HEALTH | ENVIRONMENTAL HEALTH

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URGENT: FIELD SAFETY NOTICE

LifeCycle risk calculation error possible if chorionicity is entered for twins

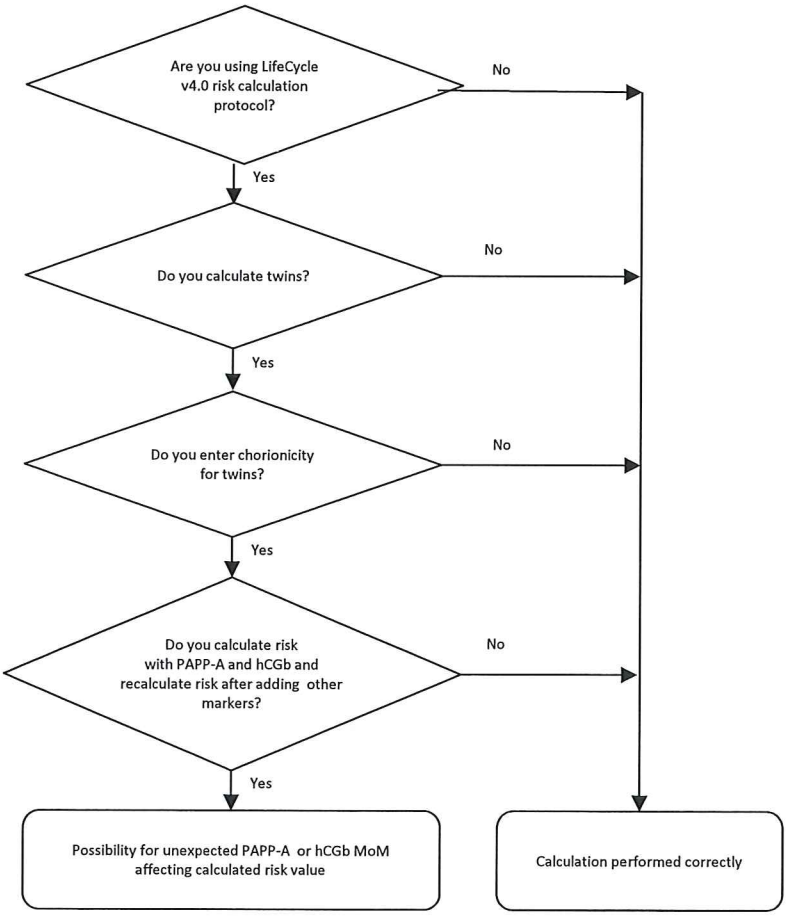
Product codes	Product name	Product version
5014-0020	LifeCycle for Prenatal Screening	v4.0, v4.0 Rev 2 and v4.0 Rev 3

Dear Customer,

We have become aware that ***LifeCycle for Prenatal Screening*** (5014-0020) may generate an incorrect risk calculation result for twins if LifeCycle v4.0 risk calculation protocol is used and a particular sequence of actions occur.

Reason for the Voluntary FSCA:
The issue is related to chorionicity correction of twins, which can be applied only with biomarker results for hCGb, PAPP-A and PlGF in 1st trimester. If a second sample (e.g. 2nd trimester or DVPI examination) is attached to the same case, the MoMs should be cleared in order to recalculate the MoMs without chorionicity correction. If there are no gestational age calculation changes made, the 1st trimester sample MoMs will remain. Since 1st trimester MoMs are chorionicity corrected when chorionicity is given, the MoM values are too low resulting in unexpected risk values. If close to cut-off, a true risk value might end up on the opposite side of the cut-off and be reported as opposite risk result

The following flow-chart describes step-to-step what needs to occur to trigger the incorrect calculation. If your answer to **any** of the questions is "No", your risk calculation will be performed (or has been performed) correctly. If **all** the answers are "Yes", your risk calculation can be affected.



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Risk to Health:
It is not possible to predict to which direction and how much the change will be when the error is encountered. Most critical are the cases where the risk value is close to the cut-off, and a true low risk value is reported incorrectly as a high risk value. A false positive screening result can cause indirect harm due to possibility for unnecessary confirmatory testing and/or medical intervention.

Actions to be taken by the Customer:
If you are using the affected software version and you would like to follow the screening model described above, you should ensure that the MoM's for hCGb, PAPP-A and PlGF biomarkers are always cleared before recalculating the risk when a second sample is added to the same case. This can be achieved by clearing the chorionicity information and saving the case data.

The LifeCycle issue will be corrected by upgrading your installation to v4.0 Rev 4 that PerkinElmer is currently developing. We strongly recommend that you update your LifeCycle to v4.0 Rev 4 to remove all risk to patients of a false screening result and potential liability for yourself stemming from reporting an erroneous patient result. The new software revision will be free of charge to the existing customers, and you will be contacted soon by your local PerkinElmer (Wallac Oy) representative to make the necessary arrangements.

Actions to be taken by PerkinElmer:

1) PerkinElmer has developed a Database Investigation Script that can be used to determine if any affected calculations exists in your LifeCycle database. For assistance on how to review your LifeCycle database by utilizing this tool contact your local PerkinElmer representative or Software Services team (SpecimenGateSupportFI@perkinelmer.com). Any decisions regarding the need to reassess/recalculate previously reported risk value results should be made on a case by case basis.
2) When available, the final corrective measure is a new LifeCycle v4.0 Rev 4 from PerkinElmer to resolve the reported issue. Installation of the new software v4.0 Rev 4 is strongly recommended to all affected LifeCycle installations. You will be notified when the software update is available and it will be provided to you free of charge.

Transmission of this Field Safety Notice:
Please distribute this information immediately to any staff that may be impacted by this LifeCycle 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 as scanned by e-mail to TurkuQMresponse@perkinelmer.com as soon as possible, but not later than June 12, 2015.

We regret any inconvenience this product issue may cause and we appreciate your assistance. For further information, please contact your local PerkinElmer representative or SpecimenGateSupportFI@perkinelmer.com.

Sincerely,

Ann-Christine Fagerström
Quality Director
Wallac Oy

Wallac Oy Business Identity Code: 0937168-4 Registered office: Turku

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RESPONSE FORM

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

Product(s) affected:

PRODUCT CODES	PRODUCT NAME	VERSION NUMBER
5014-0020	LifeCycle for Prenatal Screening	v4.0, v4.0 Rev 2 and v4.0 Rev 3

1. Have you read the letter accompanying this form? The letter provides information of the recall/field safety corrective action by Wallac Oy of the above listed product versions.

   ☐ Yes ☐ No

2. Regarding the recommended correction I prefer to (choose only one alternative):

   have v4.0 Rev 4 installed ☐

   continue without v4.0 Rev 4 installed ☐

3. Which software version do you currently have in use? If you are uncertain about which software version you are using, you can easily find it out from LifeCycle™ by selecting "Help → About LifeCycle

   ☐ 4.0 ☐ 4.0 Rev 2 ☐ 4.0 Rev 3

Signature / Date _____ / _____

Clarification of signature _____

Laboratory / Clinic _____

State / Country _____

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