Date 29 July 2013

URGENT: FIELD SAFETY NOTICE

LifeCycle – impact of Ethnic Factor to Risk Calculation

Product codes	Product name	Product version
5002-0020	LifeCycle for Prenatal Screening	v2.1, v2.2, v3.0, v3.1, v3.2 (including all revisions)

Dear Customer,

Our Quality organization has become aware of an unexpected behavior how LifeCycle risk calculation engine (Elipse) accepts and utilizes the *Ethnic Factor* given by the user. The case risk will not be calculated by applying the latest validated median equation as intended by the user, if the *Ethnic Factor* has been changed from a valid numeric value back to "0" (zero). The problem is a configurability issue rather than a software bug.

Description of the problem:

To optimize screening performance, the default median equations supplied at installation should be replaced by laboratory-specific ones as applicable, and regularly maintained on *Marker Medians* –form of the Elipse Configurator. Among other variables, the form enables establishing and maintaining marker specific *Ethnic Factors* - coefficients to be taken into account by the median equation - for the ethnic groups concerned.

For the problem to occur there must have been a validated *Ethnic Factor* for the marker in the past (by default or user defined), the value is later changed to "0" (zero) with the intention that no ethnic correction is applied. From risk calculation point of view this causes an unexpected situation, since the factor in the median equation can't be zero (instead, it should be 1 to omit the correction). Provided that the scenario above exists, and a new case is entered with that particular marker and ethnicity, Elipse automatically prioritizes a former median equation (with factor $\neq 0$) over the current one (with factor = 0), but doesn't warn or alert the user. If there are several median equations in the past, the most recent equation (with factor $\neq 0$) will be used. Consequently, this will lead to situations where risk is calculated by another equation than expected by the user. If the prerequisites conditions exists for the problem to occur, but no ethnicity is recorded when entering a case, the risk is calculated as intended.

The magnitude and direction between the calculated and expected correct risk value is dependent on the differences of the two equations involved. Therefore the impact on patient results cannot be consistently defined, but in the worst case a true low risk case could be reported as high risk. A false positive screening result can cause indirect harm due to the possibility for unnecessary medical intervention.

Advise on action to be taken by the user:

If you are using an affected software version, you should confirm on the *Marker Medians* –form that there are no *Ethnic Factors* in use where the value has been changed from a valid factor (value > 0) to "0" (zero). If situations are identified where the *Ethnic Factor* value was changed to "0", the value must be corrected to a value of "1" (one) to prevent further incorrect results. Having this change validated, the new effective date will be the day when the change was made. We strongly recommend that you check/implement this correction described above (if appropriate).

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Updating your LifeCycle installation to the latest software version (v4.0 Rev2) is also recommended. Beginning with LifeCycle version v4.0, the Elipse risk calculation engine has been replaced with a new MFH engine where this problem cannot occur.

Decisions regarding the need to review and reassess previously reported risk results should be made on a case by case basis. For assistance how to find out whether your LifeCycle is affected, how to implement the correction and how to assess the reported results, contact your local PerkinElmer representative or Software Services team (SpecimenGateSupportFI@perkinelmer.com).

Transmission of this Field Safety Notice:

Please distribute this information immediately to all individuals who need to be aware of this *LifeCycle for Prenatal Screening* issue within your organization, and to other organizations on which this action has an impact.

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 August 15, 2013.

We regret the inconvenience this is causing and we appreciate all your assistance.
For further information, please contact your local PerkinElmer representative or Software Services team (SpecimenGateSupportFI@perkinelmer.com).

Ann-Christine Fagerström
Quality Director
Wallac Oy

Enclosure(s):   Response Form

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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
5002-0020	LifeCycle for Prenatal Screening	v2.1, v2.2, v3.0, v3.1, v3.2 (including all revisions)

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. 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

   ☐ v2.1   ☐ v2.2   ☐ 3.0   ☐ 3.1   ☐ 3.1 Rev2   ☐ 3.2   ☐ 4.0   ☐ 4.0 Rev2

Signature / Date   _____ / _____

Clarification of signature _____

Laboratory / Clinic   _____

State / Country   _____

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