

Cellognost Echinococcosis

Controls and samples partly not readable in the quantitative test method

Our records indicate that your facility may have received the following product:

Table 1. Cellognost Echinococcosis - Affected Product(s)

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number	Manufacturing Date (YYYY-MM-DD)	Expiration Date (YYYY-MM-DD)
Cellognost Echinococcosis	OTSO13	10446402	48160	2017-10-27	2019-10-26

Reason for Customer Notification

Siemens Healthcare Diagnostics has confirmed that Cellognost® Echinococcosis lot 48160 may produce a higher variation of positive result interpretation which may impact the quantitative test method. Additionally it has been observed that the plates cannot be read and interpreted as expected.

The qualitative test method works without performance issues.

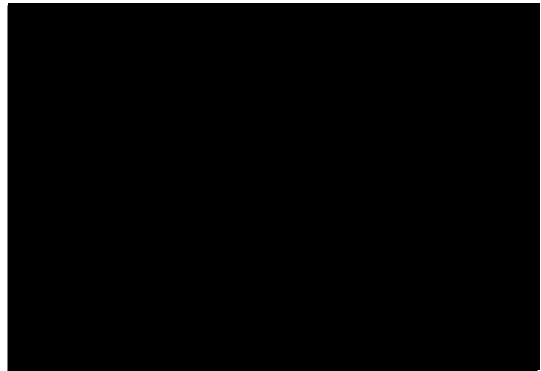
Risk to Health

To our current understanding the issue is assessed as being of negligible health risk. We have no indications for false negative results. The appearance of agglutination is stable for read-out between 2 to 24 hours.

In case of a positive result and/or indeterminate result, confirmatory and resolution testing will be triggered.

Actions to be Taken by the Customer

If you experience this issue, please contact your local Siemens representative.



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