GA Generic Assays GMBH
Ludwig-Erhard-Ring 3
D-15827 Dahlewitz
Tel.: +49 (0) 33708 4417 0
Fax: +49 (0) 33708 4417 25
info@mgenericassays.com

Dahlewitz, 19.09.2019

Dear customer,

Important customer information /
FSN (Field Safety Notice)

Corrective action 2019/09/19-5003

Product: Anti-Gangliosid Dot, REF 5003
Lot: 19 5003 05/1

Problem description: Mislabeling of both conjugates included in the kit

Based on customer reports we have determined that the batch19 5003 05/1 of our product Anti-Gangliosid Dot, REF 5003, contains mislabeled reagents. In some of the 5003 kits the conjugate labels are interchanged: IgM label on IgG conjugate (red coded) and IgG label on IgM conjugate (green coded). Kits with correct labeling (red coded IgG conjugate, green coded IgM conjugate) are not involved and can be normally used.

We ask you to check your stock and not to continue using products from the affected lot. Please inform us about the remaining test kits by means of the attached feedback form. GA Generic Assays will refund the costs for the unused kits and deliver a replacement as soon as possible.

Do not use kits showing the wrong labeling!

Results obtained with the lot 19 5003 05/1 have to be critically reviewed.

The Anti-Ganglioside Dot is used for the determination of autoantibodies against gangliosides in the framework of the serological diagnosis of autoimmune neuropathies. Antibody profiles to 12 gangliosides and sulfatide are determined. IgG and IgM antibodies to gangliosides can play a pathogenic role in the etiopathogenesis of autoimmune peripheral neuropathies. Interchange of IgG/IgM results may lead to misinterpretation of clinical diagnosis, as IgM antibodies are often markers of chronic form of polyneuropathy and IgG antibodies are often characterizing an active form of polyneuropathy. General detection of autoimmune polyneuropathy is given if both conjugates are used separately or in mixed form and not influenced by label mistake.

Previous results obtained with affected kits of the lot should be checked carefully with regard to the conjugate mistake:

- negative results can be confirmed if both conjugates or mixed conjugates have been used
- the result of the positive control can indicate the wrong process, as the positive control is only positive for IgG (positive IgM result of the control is showing the interchange)
- positive patient results obtained with lot 19 5003 05/1 have to be re-interpreted with regard to conjugate interchange (see above, possible chronic and active forms of disease)

GA Generic Assays GMBH
Ludwig-Erhard-Ring 3
D-15827 Dahlewitz
Tel.: +49 (0) 33708 4417 0
Fax: +49 (0) 33708 4417 25
info@mgenericassays.com

Risk for the patient:

In this context both isotypes have got the same diagnostic value. Thus, the confusion thereof does not have a therapy consequence. However, IgG antibodies against gangliosides appear to occur more prevalent in acute variants of peripheral neurological diseases, whereas IgM antibodies seem to be more characteristic for chronic variants. As a consequence, the confusion of both isotypes can give misleading information for the differential diagnosis of peripheral neuropathies.

Since autoantibodies are not yet included in the diagnostic criteria of these illnesses and clinical characteristics are used by neurologists as main criteria, the impact on the differential diagnosis may be limited. The IFU of the kit corroborates this point and states that the diagnosis of a clinical entity should not be based solely on diagnostic criteria.

What you should do

- Please use the attached fax form or email to inform us of the number of test kits still available so that we can send you a replacement.
- Please return the affected kits to us.
- If you had any problems with the products of the batches mentioned, please inform us.

Passing on this customer information:

This notification should be f orwarded to all affected parties and persons. If you have any further questions, please contact our product manager. You can reach Mr. Büttner at +49 (0) 33708-4417-43.