Alterations in the Manufacturing Procedures

M30 Apoptosense® ELISA

The M30 Apoptosense® ELISA is intended for the quantitative determination of caspase-cleaved keratin 18 (ccK18) in blood samples or cell cultures.

Peviva AB was recently acquired by VLVbio AB and the production of M30 Apoptosense® ELISA has been transferred to a new facility. Production methods have been updated during this process. The change in the product number from 10010 to 10011 indicates this update.

The same monoclonal antibodies (M30 and M5) will be used for production. Some minor changes will be introduced with regard to the manufacturing process of the ELISA kits.

The M30 Apoptosense® ELISA products 10010 and the new version 10011 show similar characteristics:

- Plasma/serum from normal blood donors show somewhat lower signals in the updated M30 Apoptosense® ELISA (product 10011); medians: 94 U/L versus 132 U/L.
- The updated assay version generates very similar results as the previous version. In the chart to the right, 83 plasma samples from human subjects with diseases leading to epithelial apoptosis were analysed by the two assay versions. The correlation coefficient is 0.978.

Technical Modification

The wash buffer concentrate previously provided will now be exchanged to a Wash Tablet.

Reference


Contact Information

For further information and technical support please contact your distributor or VLVbio (support@vlvbio.com).

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Version 10010</th>
<th>Version 10011</th>
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</thead>
<tbody>
<tr>
<td>Median</td>
<td>132 U/L</td>
<td>94 U/L</td>
</tr>
<tr>
<td>Inter-quartile range</td>
<td>109 – 164 U/L</td>
<td>71 – 127 U/L</td>
</tr>
<tr>
<td>80th percentile</td>
<td>176 U/L</td>
<td>137 U/L</td>
</tr>
<tr>
<td>90th percentile</td>
<td>221 U/L</td>
<td>182 U/L</td>
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</tbody>
</table>

Statistics over 200 blood donor samples indicate the same characteristics, but with increased differentiation in the new version, which indicates better clinical discrimination.