HDL / LDL / CK-MB Calibrator

For calibration of HDL-Cholesterol determination (direct method and PTA method)
For calibration of LDL-Cholesterol determination (direct method)
For calibration of CK-MB activity determination (immuno-inhibition method)

INTENDED USE
BIOLABO HDL / LDL / CK-MB calibrator is a preparation of lyophilised human serum containing different forms of lipoproteins, including high density lipoproteins (HDL), low density lipoproteins (LDL) and CK-MB. The HDL / LDL Cholesterol values are traceable to SRM® 1951b (Standard Reference Material®) which values were determined at CDC (Center for Disease Control) and are around the medical decision level. HDL activity was determined under standardized conditions, using BIOLABO reagents and masterlot calibrator, and metrologically controlled instrument. To be used with:
- BIOLABO HDL-Cholesterol (direct method)
- BIOLABO HDL-Cholesterol (PTA method)
- BIOLABO LDL-Cholesterol (direct method)
- BIOLABO CK-MB (immuno-inhibition method)

SAFETY CAUTIONS
BIOLABO reagents are designated for professional, in vitro diagnostic use.

- **Caution**: Human origin. Each component of this product has been tested with FDA-approved methods and found nonreactive for the presence of HBsAg, HCV and antibodies to HIV/1.2. Because no known test method can offer complete assurance that infectious agents are absent, this material should be handled as potentially infectious.
- Use adequate protections (overalls, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with skin or eyes, thoroughly wash affected areas with plenty of water and seek medical advice.
- Reagent contains sodium azide (concentration < 0.1%) which may react with copper and lead plumbing. Flush with plenty of water when disposing.
- Material Safety Data Sheet is available upon request.
- **Waste disposal**: Respect legislation in force in the country. All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

CALIBRATION VALUES AND UNCERTAINTY

<table>
<thead>
<tr>
<th>BATCH</th>
<th>Calibration Values</th>
<th>Uncertainty</th>
</tr>
</thead>
<tbody>
<tr>
<td>CK-MB (immuno-inhibition)</td>
<td>( )</td>
<td></td>
</tr>
<tr>
<td>HDL-Cholesterol (Direct method)</td>
<td>mmol/L</td>
<td></td>
</tr>
<tr>
<td>IS units</td>
<td>( )</td>
<td></td>
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<tr>
<td>Conventional units</td>
<td>mg/dL</td>
<td></td>
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<tr>
<td>HDL-Cholesterol (PTA method)</td>
<td>mmol/L</td>
<td></td>
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<tr>
<td>IS units</td>
<td>( )</td>
<td></td>
</tr>
<tr>
<td>Conventional units</td>
<td>mg/dL</td>
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<tr>
<td>LDL-Cholesterol (Direct method)</td>
<td>mmol/L</td>
<td></td>
</tr>
<tr>
<td>IS units</td>
<td>( )</td>
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<tr>
<td>Conventional units</td>
<td>mg/dL</td>
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</tbody>
</table>

Calibration values were determined in several independent laboratories in our laboratory using:
- BIOLABO procedure and International Standards for HDL and LDL cholesterol (SRM® 1951b: Standard Reference Material®) which values were determined at CDC (Center for Disease Control) and a BIOLABO mastermix calibrator for the determination of CK-MB activity.
- Recommended and validated statistical techniques.
- Metrologically controlled instrument.

Assigned value is the median of values obtained for each analyte. The assigned value with PTA method is traceable to SRM® 1951b and is obtained with pre-treated calibrator. It is not necessary to multiply the obtained results by calculation factor. Refer to package insert Ref 86516 and 86536.

Values in brackets indicate the enlarged uncertainty taking into account all the sources of error which may influence the result.

REFERENCES
(9) National Institutes of Health publication No. 93-3095, September, (1993).

Made in France

Latest Revision: www.biolabo.fr

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