LDL-C Select FS*

Diagnostic reagent for quantitative in vitro determination of low density lipoprotein cholesterol (LDL-C) in serum or plasma on Sysmex BX-Series

Order information

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Kit size</th>
<th>Number of tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 4121 99 10 972</td>
<td>R1</td>
<td>3 x 12.3 mL</td>
</tr>
<tr>
<td></td>
<td>BX-3010</td>
<td>3 x 80 tests</td>
</tr>
<tr>
<td></td>
<td>BX-4000</td>
<td>3 x 61 tests</td>
</tr>
<tr>
<td></td>
<td>BX-3010</td>
<td>3 x 80 tests</td>
</tr>
<tr>
<td></td>
<td>BX-4000</td>
<td>3 x 61 tests</td>
</tr>
</tbody>
</table>

Method

Previous LDL-cholesterol determinations were performed indirectly by calculation from the combined results of total cholesterol, HDL cholesterol and triglycerides using the Friedewald equation [1]. LDL-C Select FS is a homogeneous method without centrifugation steps for the direct measurement of LDL-cholesterol. In a first step, LDL is selectively protected while non-LDL-lipoproteins are enzymatically processed. In a second step, LDL is released and LDL-cholesterol selectively determined in a color producing enzymatic reaction.

Principle

1) LDL + reagent 1 → protected LDL
   HDL, VLDL, Chylomicrons → Cholestene + H2O2
   H2O2 + Cholestane + O2
   2) Protected LDL + reagent 2 → LDL
   Cholestene + H2O2 + 4-Aminoantipyrine + H2DAOS → POD → Color

Reagents

Components and Concentrations

R1: Good’s buffer pH 6.8 20 mmol/L
   Cholesterol esterase (CHE) ≥ 2.5 kU/L
   Cholesterol oxidase (CHO) ≥ 2.5 kU/L
   N-(2-hydroxy-3-sulfophenyl)-3,5-dimethoxyaniline (H2DAOS)
   Catalase ≥ 50 kU/L

R2: Good’s buffer pH 7.0 25 mmol/L
   4-Aminoantipyrine 3.4 mmol/L
   Peroxidase (POD) ≥ 15 kU/L

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2–8°C and contamination is avoided. Do not freeze the reagents! Reagents must be protected from light.

Warnings and Precautions

1. Reagent 2 contains sodium azide (0.95 g/L). Do not swallow! Avoid contact with skin and mucous membranes.
2. Reagent 1 contains animal material. Handle the product as potentially infectious according to universal good clinical laboratory practices.
3. Artificial lipid mixtures (e.g. Intralipid®) may interfere with the test. Serum samples from patients treated with such solutions should not be used.
4. Patient samples with a rare type of Hyperlipoproteinemia (Hyperlipoproteinemia Type III) can bring false results.
5. In very rare cases, samples of patients with gompathepathy might give falsified results [7].
6. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
7. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient’s medical history, clinical examination and other findings.
8. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent trays.

Specimen

Serum or heparin plasma

Stability [2]:
1 day at 20 – 25°C
7 days at 4 – 8°C
3 months at –20°C

Discard contaminated specimens. Only freeze once.

Calibrators and Controls

For calibration, DiaSys TruCal Lipid calibrator is recommended. The assigned values of the calibrator have been made traceable to NIST-SRM®-1951 Level 2. For internal quality control a DiaSys TruLab L control should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

Calibrators

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Kit size</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>TruCal Lipid</td>
<td>1 3570 99 10 045</td>
<td>3 x 2 mL</td>
</tr>
<tr>
<td>TruLab L Level 1</td>
<td>5 9030 99 10 065</td>
<td>3 x 3 mL</td>
</tr>
<tr>
<td>TruLab L Level 2</td>
<td>5 9030 99 10 065</td>
<td>3 x 3 mL</td>
</tr>
</tbody>
</table>

Performance Characteristics

Measuring range up to 340 mg/dL (8.79 mmol/L) LDL (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).

Limit of detection** 0.5 mg/dL (0.013 mmol/L) LDL

On-board stability 3 weeks

Calibration stability 3 weeks

For further information on interfering substances refer to Young DS [5].

Precision BX-3010

<table>
<thead>
<tr>
<th>Within run (n=20)</th>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [mg/dL]</td>
<td>89.6</td>
<td>125</td>
<td>143</td>
</tr>
<tr>
<td>Mean [mmol/L]</td>
<td>2.92</td>
<td>3.33</td>
<td>3.70</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>1.98</td>
<td>1.49</td>
<td>2.08</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Between run (n=20)</th>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [mg/dL]</td>
<td>85.9</td>
<td>116</td>
<td>142</td>
</tr>
<tr>
<td>Mean [mmol/L]</td>
<td>2.22</td>
<td>3.00</td>
<td>3.67</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>1.86</td>
<td>1.54</td>
<td>1.84</td>
</tr>
</tbody>
</table>

Method comparison (n=120)

<table>
<thead>
<tr>
<th>Test x</th>
<th>DiaSys LDL-C Select FS (BioMajesty BM6010C®)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test y</td>
<td>DiaSys LDL-C Select FS (BX-3010)</td>
</tr>
<tr>
<td>Slope</td>
<td>1.00</td>
</tr>
<tr>
<td>Intercept</td>
<td>-2.23 mg/dL (-0.058 mmol/L)</td>
</tr>
<tr>
<td>Coefficient of correlation</td>
<td>0.997</td>
</tr>
</tbody>
</table>

Conversion factor

LDL-C [mg/dL] x 0.02586 = LDL-C [mmol/L]

Reference Range [3]

Desirable ≤ 130 mg/dL (3.4 mmol/L)
Borderline high risk 130 – 160 mg/dL (3.4 – 4.1 mmol/L)
High risk > 160 mg/dL (> 4.1 mmol/L)

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Clinical Interpretation

The European Task Force on Coronary Prevention recommends to lower TC concentration to less than 190 mg/dL (5.0 mmol/L) and LDL-cholesterol to less than 115 mg/dL (3.0 mmol/L) [4].
Literature

Chemistry Parameters 1

<table>
<thead>
<tr>
<th>Method No.</th>
<th>Method Name</th>
<th>LDL</th>
<th>Reagent Name</th>
<th>Reagent (µL)</th>
<th>Water (µL)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>R1 LDL</td>
<td>120</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>R2 LDL</td>
<td>30</td>
<td></td>
</tr>
</tbody>
</table>

**Print Name**: LDL
**MethodColor**: Method
**Sample Type**: Serum
**Unit**: mg/dL
**Assay Type**: Sample Ppt. Wash

**Measuring points**
- Start: 22
- End: 23
- Stirring Speed R1: Middle
- R2: Middle

**Wave Length**
- Prim.: 600
- Sec.: 700

**Normal Range**
- No.: Male-G1
  - Min: *
  - Max: *
- No.: Male-G2
  - Min: *
  - Max: *
- No.: Male-G3
  - Min: *
  - Max: *
- No.: Female-G1
  - Min: *
  - Max: *

**Technical Range**
- Low
  - Diluent: 0.0 < 1.5 < 0.0
  - Technical Range: (Conc) 0.5 < (mAbs/10) < 340

**Diluent**
- 0.0 < 1.5 < 0.0

**Previous Result Comparison (%)**
- Abnormal Range
  - (Conc) 1
  - Previous Result Comparison (%) 
- Panic Range
  - (Conc) 1

**Decimal Point**: 1
**Profile SI**: Disable

*Entered by user*

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Chemistry Parameters 2

<table>
<thead>
<tr>
<th>Method No.</th>
<th>Method Name</th>
<th>LDL</th>
<th>Sample</th>
<th>Serum</th>
</tr>
</thead>
</table>

**Limit Checks**
- Duplicate Limit 100 mAbs/10
- Sensitivity Limit 2100 mAbs/10
- Linearity Limit
- Prozone Limit Higher %

**Absorbance Limit**
- Abs. in reaction Increase
- Absorbance Limit
- Limit 25000 mAbs/10

**Instrument Factor**
- a: 1.00
- b: 0.00

**Blank measurement**
- Blank measurement:
- Disable reagent blank and C1 blank

**Measurement of Reagent Blank during Run**
- None

**Reagent blank measurement at calibration**
- Reagent blank (No sample)

**The number of measurement**
- Duplicate

**Reagent blank limit checks**
- Duplicate Limit 20 mAbs/10
## LDL-C Select FS

### Analytical Parameters

- **Calibration Registration**
  - Method No.:
  - Method Name: LDL
  - Sample Type: Serum
  - Replication: Duplicate
  - Check Interval: 21
  - Test without calibration: Disable
  - Calibration Type: Linear
  - Reagent Lot: New
  - Calibrator Name: TruCal Lipid

<table>
<thead>
<tr>
<th>Concentration</th>
<th>WORK</th>
<th>MASTER</th>
<th>Calibr. Lot No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C4</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>C5</td>
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<td></td>
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<tr>
<td>C6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C7</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Reagent Lot No.**
  - (R1): [ ]
  - (R2): [ ]

- **Calibration Curve**
  - The calibration curve is lot dependent

- **Reagent Blank**
  - mAbs/10

- **Blank**
  - mAbs/10

- **Calibration Curve**
  - Conc.

- **Absorbance**
  - mAbs/10

*Entered by user*
**LDL-C Select FS**

**Chemistry Parameters**

<table>
<thead>
<tr>
<th>Method</th>
<th>Name</th>
<th>Reagent Name</th>
<th>Reagent (µL)</th>
<th>Water (µL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td>LDL</td>
<td>LDL</td>
<td>160</td>
<td></td>
</tr>
</tbody>
</table>

**Print Name**

- LDL

**Sample**

- Serum

**Unit**

- mg/dL

**Assay Type**

- End

**Measuring points**

<table>
<thead>
<tr>
<th>Start</th>
<th>End</th>
<th>Decimal Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>33</td>
<td>34</td>
<td>0</td>
</tr>
<tr>
<td>67</td>
<td>68</td>
<td></td>
</tr>
</tbody>
</table>

**Normal Range**

<table>
<thead>
<tr>
<th>No.</th>
<th>Normal Range Name</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Male-G1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Male-G2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Male-G3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Female-G1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Wave Length**

- Prim.: 600
- Sec: 700

**Dilution**

- Rerun (High): 2.0
- Rerun (Low): 2.0

**Reagent Name**

- SPT Wash

**Stirring Speed**

- R1 Middle
- R2 Middle

*Entered by user*

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**Chemistry Parameters**

<table>
<thead>
<tr>
<th>Method No.</th>
<th>Name</th>
<th>Sample</th>
<th>Serum</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LDL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Limit Checks**

- Duplicate Limit: 100 mAbs/10
- Sensitivity Limit: 2100 mAbs/10
- Linearity Limit: % (mAbs/10)/min
- Prozone Limit: % Upper
- Sensitivity: mAbs/10
- Absorbance Limit: Limit: 25000 mAbs/10

**Blank measurement**

Blank measurement:

- Blank measurement: Disable reagent blank and S1 blank
- Measurement of Reagent Blank during Run: None
- Reagent blank measurement at calibration: Reagent blank (No sample)
- The number of measurement: Duplicate
- Reagent blank limit checks: Duplicate Limit 20 mAbs/10

**Instrument Factor**

- a: 1.00
- b: 0.00
**LDL-C Select FS**  

**Chemistry Code 100 57**

| Registration Calibration | Sysmex BX-4000 Chemistry Analyzer  
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Method</strong></td>
<td><strong>Name</strong></td>
</tr>
<tr>
<td>*</td>
<td>LDL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Sample</strong></th>
<th><strong>Sampling</strong></th>
<th><strong>Check Interval</strong></th>
<th><strong>Auto</strong></th>
<th><strong>Auto Interval</strong></th>
<th><strong>Type</strong></th>
<th><strong>Lot</strong></th>
<th><strong>New</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Duplicate</td>
<td>21 days</td>
<td>Change Lot</td>
<td></td>
<td>Linear</td>
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</table>

<table>
<thead>
<tr>
<th><strong>Material Name</strong></th>
<th><strong>TruCa Lipid</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Conc.</strong></th>
<th><strong>WORK</strong></th>
<th><strong>MASTER</strong></th>
<th><strong>Lot No. (S)</strong></th>
<th><strong>All</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>S1 0</td>
<td>Automatic entry</td>
<td>Automatic entry</td>
<td>Lot No. (S)</td>
<td>All</td>
</tr>
<tr>
<td>S2 *</td>
<td>Automatic entry</td>
<td>Automatic entry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S3 *</td>
<td>Automatic entry</td>
<td>Automatic entry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S4 *</td>
<td>Automatic entry</td>
<td>Automatic entry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S5 *</td>
<td>Automatic entry</td>
<td>Automatic entry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S6 *</td>
<td>Automatic entry</td>
<td>Automatic entry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S7 *</td>
<td>Automatic entry</td>
<td>Automatic entry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>K *</td>
<td>Automatic entry</td>
<td>Automatic entry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- S1 Blank
- Reagent Blank for S1

*Entered by user

The calibration curve is lot dependent

<table>
<thead>
<tr>
<th><strong>Reagent blank</strong></th>
<th>mAbs/10</th>
<th><strong>Last</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Blank</td>
<td>mAbs/10</td>
<td>Last</td>
</tr>
</tbody>
</table>

**Type** | **Conc.** | **Absorbance** | **Recalculation**
---------|----------|----------------|------------------