For In Vitro Diagnostic Use

Rx Only

ANNUAL REVIEW

<table>
<thead>
<tr>
<th>Reviewed by</th>
<th>Date</th>
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PRINCIPLE

INTENDED USE

UniCel DxC SYNCHRON Systems HDL Cholesterol reagent (HDL), when used in conjunction with UniCel DxC 600/800 SYNCHRON System(s) and UniCel DxC SYNCHRON Systems HDL Calibrator, is intended for quantitative determination of HDL cholesterol in the high density lipoprotein fraction of human serum or plasma.

CLINICAL SIGNIFICANCE

Many epidemiological investigations have demonstrated the strong and independent inverse association between HDL-Cholesterol and the risk of coronary artery disease.\(^1\),\(^2\) It has been proposed that HDL particles, through the uptake and transport of Cholesterol from peripheral tissue to the liver (reverse Cholesterol transport), protects against the development of atheromatous plaques.\(^3\)

The guidelines issued by The National Cholesterol Education Program Adult Treatment Panel 3 (NCEP ATP 3),\(^4\) recommends lipoprotein analysis (total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides) as the preferred initial test, rather than screening for total cholesterol and HDL alone.

In 2001, the NCEP increased the high-risk medical decision point to <40 mg/dL.\(^5\)

The guidelines classify HDL- C levels as follows:

1. < 40 mg/dL as indicative of a major risk factor for Coronary Heart Disease.
2. ≥ 60 mg/dL as a negative risk factor for Coronary Heart Disease.

METHODOLOGY

This HDL cholesterol test is a two reagent homogenous system for the selective measurement of serum or plasma HDL cholesterol in the presence of other lipoprotein particles. The assay is comprised of two distinct phases. In phase one,
free cholesterol in non-HDL-lipoproteins is solubilized and consumed by cholesterol oxidase, peroxidase, and DSBmT to generate a colorless end product. In phase two, a unique detergent selectively solubilizes HDL. The HDL cholesterol is released for reaction with cholesterol esterase and cholesterol oxidase, in the presence of chromogens, to produce a colour product.

The HDL reagent measures the HDL cholesterol concentration by a timed-endpoint method. The system automatically proportions the appropriate HDL cholesterol sample and reagent volumes into a cuvette. The ratio used is one part sample to 93 parts reagent. The system monitors the change in absorbance at 560 nanometers. This change in absorbance is directly proportional to the concentration of cholesterol in the sample and is used by the system to calculate and express the HDL cholesterol concentration.

**CHEMICAL REACTION SCHEME**

![Chemical Reaction Scheme](image)

**SPECIMEN**

**TYPE OF SPECIMEN**

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum or plasma are the preferred specimens. Refer to the PROCEDURAL NOTES section of this chemistry information sheet for information on anticoagulants.

**SPECIMEN STORAGE AND STABILITY**

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.
2. Use fresh samples for analysis when possible. HDL cholesterol is stable in serum and plasma for 8 hours at +15°C to +30°C and 7 days at +2°C to +8°C. If longer storage is required, samples can be frozen for up to 30 days at ≤ -20°C. Frozen samples should be thawed only once.

Additional specimen storage and stability conditions as designated by this laboratory:

**SAMPLE VOLUME**

The optimum volume, when using a 0.5 mL sample cup, is 0.3 mL of sample. For optimum primary sample tube volumes and minimum volumes, refer to the Primary Tube Sample Template for your system.
CRITERIA FOR UNACCEPTABLE SPECIMENS

Refer to the PROCEDURAL NOTES section of this chemistry information sheet for information on unacceptable specimens.

Criteria for sample rejection as designated by this laboratory:

PATIENT PREPARATION

Special instructions for patient preparation as designated by this laboratory:

SPECIMEN HANDLING

Special instructions for specimen handling as designated by this laboratory:

REAGENTS

CONTENTS

Each kit contains the following items:
Two HDL Reagent Cartridges (2 x 200 tests)

WARNING AND PRECAUTIONS

For in vitro diagnostic use. Do not ingest. Harmful if swallowed.

VOLUMES PER TEST
Sample Volume: 3 µL
Total Reagent Volume: 280 µL
Cartridge Volumes:
A: 210 µL
B: 70 µL
C: – –

REACTIVE INGREDIENTS

REAGENT CONSTITUENTS

- Cholesterol esterase (Pseudomonas): 375 U/L
- Cholesterol oxidase (E. coli): 750 U/L
- Peroxidase (Horseradish): 975 U/L
- Ascorbate oxidase (Cucurbita sp.): 2,250 U/L
- DSBmT: 0.75 mmol/L
- 4-aminoantipyrine: 0.25 mmol/L
- Detergent: 0.375%
- Preservative: 0.05%

Also non-reactive chemicals necessary for optimal system performance.

GHS HAZARD CLASSIFICATION
HDL Cholesterol Reagent  (Compartment A)  

DANGER

H317  May cause an allergic skin reaction.
H334  May cause allergy or asthma symptoms or breathing difficulties if inhaled.
P261  Avoid breathing vapours.
P280  Wear protective gloves, protective clothing and eye/face protection.
P284  In case of inadequate ventilation, wear respiratory protection.
P304+P340  IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.
P342+P311  If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
P362+P364  Take off contaminated clothing and wash it before use.

Peroxidase 0.1 - 1%
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

HDL Cholesterol Reagent  (Compartment B)  

WARNING

H317  May cause an allergic skin reaction.
P280  Wear protective gloves, protective clothing and eye/face protection.
P333+P313  If skin irritation or rash occurs: Get medical advice/attention.
P362+P364  Take off contaminated clothing and wash it before use.

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

SOS  Safety Data Sheet is available at techdocs.beckmancoulter.com

EUROPEAN HAZARD CLASSIFICATION
HDL Cholesterol Reagent (Compartment A) Xi;R43
R43 May cause sensitization by skin contact.
S24 Avoid contact with skin.
S28 After contact with skin, wash immediately with plenty of water.
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

HDL Cholesterol Reagent (Compartment B) Xi;R43
R43 May cause sensitization by skin contact.
S24 Avoid contact with skin.
S28 After contact with skin, wash immediately with plenty of water.
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

UniCel DxC SYNCHRON Systems HDL Calibrator
Deionized Water
At least two levels of control material
Saline

REAGENT PREPARATION

The HDL reagent is ready for use. No preparation is required.

ACCEPTABLE REAGENT PERFORMANCE

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within your facility's acceptance criteria.

REAGENT STORAGE AND STABILITY

HDL Cholesterol Reagent when stored unopened at +2°C to +8°C, will attain the shelf-life indicated on the cartridge label. Once opened, the reagent is stable for 60 days at +2°C to +8°C unless the expiration date is exceeded. DO NOT FREEZE.

Reagent storage location:
CALIBRATION

CALIBRATOR REQUIRED

UniCel DxC SYNCHRON Systems HDL Calibrator PN B23634
Deionized water (Level 1 calibrator)

CALIBRATOR PREPARATION

1. Use deionized water as the Level 1 calibrator.
2. Remove the metal cap around the HDL calibrator bottle and gently tap the bottle on the table to remove powder at the top of the stopper. Open the HDL calibrator bottle carefully, avoiding loss of lyophilizate.
3. Add exactly 1.00 mL of deionized water to the bottle of calibrator. Replace the stopper and let stand for 5 minutes at room temperature.
4. Gently invert until the contents are dissolved avoiding the formation of foam. DO NOT SHAKE.

CALIBRATOR STORAGE AND STABILITY

The unopened, UniCel SYNCHRON Systems HDL Calibrator may be stored at +2°C to +8°C until the expiration date printed on the label. Reconstituted calibrators that are resealed are stable for 14 days at +2°C to +8°C or for 30 days at ≤ -20°C unless the expiration date is exceeded. Frozen calibrator should be thawed only once.

Visible signs of microbial growth, gross turbidity, or precipitate in the calibrator may indicate degradation and warrant discontinuation of use.

CAUTION

BIOHAZARD: Because this calibrator is of human origin, it should be handled as though capable of transmitting infectious diseases. Each serum or plasma donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV-Ag, HIV-1/2 and HCV and nonreactive for HbsAg. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples to be handled as specified in Centers for Disease Control's Biosafety Level 2 guidelines.10

Calibrator storage location:

CALIBRATION INFORMATION

1. The system must have valid calibration factors in memory before controls or patient samples can be run.
2. Under typical operating conditions the HDL assay must be calibrated every 28 days or with each new lot of reagent and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 System
Instructions for Use (IFU) manual. Alternatively, this assay can use the within-lot calibration feature available on the UniCel DxC 600/800 System. The within-lot calibration option allows loading of a reagent cartridge of the same lot number without the need for recalibration up to and including 90 days. Refer to the UniCel DxC 600/800 System Instruction for Use manual for information on this feature.

3. For detailed calibration instructions, refer to the UniCel DxC 600/800 System Instructions For Use (IFU) manual.

4. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the UniCel DxC 600/800 System Instructions For Use (IFU) manual.

TRACEABILITY

For Traceability information refer to the Calibrator instructions for use.

QUALITY CONTROL

At least two levels of control material should be analyzed daily. In addition, these controls should be run with each new calibration, with each new reagent cartridge, and after specific maintenance or troubleshooting procedures as detailed in the appropriate system manual. More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws.

The following controls should be prepared and used in accordance with the package inserts. Discrepant quality control results should be evaluated by your facility.

<table>
<thead>
<tr>
<th>CONTROL NAME</th>
<th>SAMPLE TYPE</th>
<th>STORAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1.0 Quality Control Material

TESTING PROCEDURE(S)

1. If necessary, load the reagent onto the system.
2. After reagent load is completed, calibration may be required.
3. Program samples and controls for analysis.
4. After loading samples and controls onto the system, follow the protocols for system operations.

For detailed testing procedures, refer to the UniCel DxC 600/800 System Instructions For Use (IFU) manual.

CALCULATIONS

The UniCel DxC 600/800 SYNCHRON System(s) performs all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.
REPORTING RESULTS

REFERENCE INTERVALS

Each laboratory should establish its own reference intervals based upon its patient population. The reference interval listed below was taken from literature.

Table 2.0 REFERENCE INTERVALS\textsuperscript{1,4}

<table>
<thead>
<tr>
<th>INTERVALS</th>
<th>CARDIOVASCULAR RISK</th>
<th>CONVENTIONAL UNITS</th>
<th>S.I. UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Literature</td>
<td>Low</td>
<td>≥ 60 mg/dL</td>
<td>≥ 1.55 mmol/L</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>&lt; 40 mg/dL</td>
<td>&lt; 1.03 mmol/L</td>
</tr>
</tbody>
</table>

Laboratory

Refer to References (11, 12, 13) for guidelines on establishing laboratory-specific reference intervals.

Additional reporting information as designated by this laboratory:

PROCEDURAL NOTES

ANTICOAGULANT TEST RESULTS

The following anticoagulants were assessed by Deming regression analysis with a minimum of 60 paired serum and plasma samples. Values of serum (X) ranging from 17 mg/dL to 127 mg/dL were compared with the values for plasma (Y) yielding the following results.

Table 3.0 Anticoagulant Test Results

<table>
<thead>
<tr>
<th>ANTICOAGULANT</th>
<th>LEVEL OF ANTICOAGULANT TESTED</th>
<th>DEMING REGRESSION ANALYSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lithium Heparin</td>
<td>17 Units/mL</td>
<td>Y = 0.995X - 0.3; r = 0.998</td>
</tr>
<tr>
<td>Sodium Heparin</td>
<td>17 Units/mL</td>
<td>Y = 0.994X - 0.3; r = 0.998</td>
</tr>
</tbody>
</table>

INTERFERENCES

1. The following substances were tested for interference with this methodology using CLSI EP07-A2\textsuperscript{14}:

Table 4.0 Interferences

<table>
<thead>
<tr>
<th>SUBSTANCE</th>
<th>SOURCE</th>
<th>LEVEL TESTED</th>
<th>OBSERVED EFFECT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin</td>
<td>Hemolysate</td>
<td>500 mg/dL</td>
<td>NSI\textsuperscript{a}</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>Mixed Isomers</td>
<td>40 mg/dL</td>
<td>NSI</td>
</tr>
</tbody>
</table>
Table 4.0 Interferences, Continued

<table>
<thead>
<tr>
<th>SUBSTANCE</th>
<th>SOURCE</th>
<th>LEVEL TESTED</th>
<th>OBSERVED EFFECT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triglyceride</td>
<td>Human</td>
<td>900 mg/dL</td>
<td>NSI</td>
</tr>
<tr>
<td>Lipemia</td>
<td>Intralipidb</td>
<td>1,500 mg/dL</td>
<td>NSI</td>
</tr>
<tr>
<td>Ascorbic Acid</td>
<td>NAc</td>
<td>20 mg/dL</td>
<td>NSI</td>
</tr>
<tr>
<td>Immunoglobin IgG</td>
<td>Human</td>
<td>5,000 mg/dL</td>
<td>NSI</td>
</tr>
</tbody>
</table>

a Criteria for no significant interference (NSI) is recovery within 10% of the initial result.
b Company and product names are the property of their respective owners.
c NA = Not applicable.

2. Inaccurate results (usually negative interference) may be produced in patient samples with elevated serum immunoglobulin levels.15 In very rare cases gammopathy, especially monoclonal IgM (Waldenström's macroglobulinemia), may cause unreliable results.

3. Falsely low results may be obtained in patients with Type III hyperlipidemia.16

4. Venipuncture immediately after or during the administration of Metamizole (Dipyrone) may lead to falsely low results for HDL. Venipuncture should be performed prior to the administration of Metamizole.

5. Refer to References (17, 18, 19) for other interferences caused by drugs, disease and preanalytical variables.

PERFORMANCE CHARACTERISTICS

ANALYTIC RANGE

The UniCel DxC 600/800 System method for the determination of this analyte provides the following analytical ranges, which have been verified using CLSI EP06-A20.

Table 5.0 Analytical Range

<table>
<thead>
<tr>
<th>SAMPLE TYPE</th>
<th>CONVENTIONAL UNITS</th>
<th>S.I. UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum or Plasma</td>
<td>5 – 135 mg/dL</td>
<td>0.13 – 3.49 mmol/L</td>
</tr>
</tbody>
</table>

Samples with concentrations exceeding the high end of the analytical range should be diluted with saline and reanalyzed.

REPORTABLE RANGE (AS DETERMINED ON SITE):

Table 6.0 Reportable Range

<table>
<thead>
<tr>
<th>SAMPLE TYPE</th>
<th>CONVENTIONAL UNITS</th>
<th>S.I. UNITS</th>
</tr>
</thead>
<tbody>
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DETECTION LIMIT

Limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) data analysis was performed in accordance with the CLSI EP17-A2 guideline.21 The LoB corresponds to the concentration below which analyte-free samples are found with 95% confidence. The LoD corresponds to the sample concentration above the LoB which is detectable with 95% confidence. The LoQ is defined as the lowest amount of analyte in the sample that can be quantitatively determined with stated acceptable precision and trueness, under stated experimental conditions. A properly operating UniCel DxC 600/800 System should exhibit detection limit values equal to the following:
The detection limit results using serum samples support the LoB, LoD, and LoQ specifications in the table below using the HDL reagent on a UniCel DxC 600/800 System.

Table 7.0 DETECTION LIMIT & RESULTS

<table>
<thead>
<tr>
<th>Specifications</th>
<th>Results</th>
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<tbody>
<tr>
<td>LoB ≤ 3 mg/dL (0.08 mmol/L)</td>
<td>0.43 mg/dL (0.01 mmol/L)</td>
</tr>
<tr>
<td>LoD ≤ 5 mg/dL (0.13 mmol/L)</td>
<td>0.66 mg/dL (0.02 mmol/L)</td>
</tr>
<tr>
<td>LoQa ≤ 5 mg/dL (0.13 mmol/L)</td>
<td>3.26 mg/dL (0.08 mmol/L)</td>
</tr>
</tbody>
</table>

a LoQ data is based on a total error of ≤13%.22

EQUIVALENCY

Equivalency was assessed by Deming regression analysis of patient samples to accepted clinical methods.

Serum (in the range of 8.1 to 123.7 mg/dL):

\[
\begin{align*}
Y & \text{ (UniCel DxC 800 System)} = 1.015X - 0.9 \\
N & = 131 \\
\text{MEAN } Y & = 56.0 \\
\text{MEAN } X & = 56.1 \\
\text{CORRELATION COEFFICIENT } (r) & = 0.999
\end{align*}
\]

Performance data obtained on the UniCel DxC 800 System is representative of the data obtained on the UniCel DxC 600 System.

Refer to Reference (23) for guidelines on performing equivalency testing.

PRECISION

Properly operating UniCel DxC 600/800 System should exhibit precision values less than or equal to the following:

Table 8.0 Precision Values

<table>
<thead>
<tr>
<th>TYPE OF PRECISION</th>
<th>SAMPLE TYPE</th>
<th>1 SD</th>
<th>CHANGEOVER VALUEa</th>
<th>% CV</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>mg/dL</td>
<td>mmol/L</td>
<td>mg/dL</td>
</tr>
<tr>
<td>Within-run</td>
<td>Serum/Plasma</td>
<td>1.3</td>
<td>0.03</td>
<td>42</td>
</tr>
<tr>
<td>Total</td>
<td>Serum/Plasma</td>
<td>1.7</td>
<td>0.04</td>
<td>42</td>
</tr>
</tbody>
</table>

a When the mean of the test precision data is less than the changeover value, compare the test SD to the SD guideline given above to determine the acceptability of the precision testing. When the mean of the test precision data is greater than or equal to the changeover value, compare the test % CV to the guideline given above to determine acceptability. Changeover value = (SD guideline/CV guideline) x 100.

Comparative performance data for the UniCel DxC 600/800 System evaluated using the CLSI Approved Guideline EP5-A2 appears in the table below.24 Each laboratory should characterize their own instrument performance for comparison purposes.
Table 9.0 CLSI EP5-A2 Precision Estimate Method

<table>
<thead>
<tr>
<th>TYPE OF IMPRECISION</th>
<th>SAMPLE TYPE</th>
<th>No. Systems</th>
<th>No. Data Points(^a)</th>
<th>Test Mean Value (mg/dL)</th>
<th>EP5-A2 Calculated Point Estimates</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SD</td>
</tr>
<tr>
<td>Within-run</td>
<td>Human Sample 1</td>
<td>1</td>
<td>80</td>
<td>33.3</td>
<td>0.3</td>
</tr>
<tr>
<td></td>
<td>Human Sample 2</td>
<td>1</td>
<td>80</td>
<td>56.1</td>
<td>0.6</td>
</tr>
<tr>
<td></td>
<td>Human Sample 3</td>
<td>1</td>
<td>80</td>
<td>121.0</td>
<td>1.2</td>
</tr>
<tr>
<td>Total</td>
<td>Human Sample 1</td>
<td>1</td>
<td>80</td>
<td>33.3</td>
<td>0.6</td>
</tr>
<tr>
<td></td>
<td>Human Sample 2</td>
<td>1</td>
<td>80</td>
<td>56.1</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>Human Sample 3</td>
<td>1</td>
<td>80</td>
<td>121.0</td>
<td>1.6</td>
</tr>
</tbody>
</table>

\(^a\) The point estimate is based on the pooled data from one system, run for 20 days, two runs per day, two observations per run on an instrument operated and maintained according to the manufacturer’s instructions.

**ADDITIONAL INFORMATION**

For more detailed information on UniCel DxC 600/800 SYNCHRON System(s), refer to the appropriate system manual.

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**SHIPPING DAMAGE**

If damaged product is received, notify your Beckman Coulter Clinical Support Center.

**REVISION HISTORY**

**Revision AC**

Updates from FDA 510(k) clearance

Added GHS Classification information

**Revision AD**

Added new language requirement: Romanian

**Revision AE**

Updates to comply with requirements per Beckman Coulter Global Labeling Policy.

New statement (item #4) added under INTERFERENCES section.

**Revision AF**

Additional changes to comply with requirements per Beckman Coulter Global Labeling Policy.
### SYMBOLS KEY

<table>
<thead>
<tr>
<th>SYMBOL</th>
<th>Key</th>
<th>Description</th>
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<tbody>
<tr>
<td>🚧</td>
<td>Catalogue Number</td>
<td>IVD</td>
</tr>
<tr>
<td>📚</td>
<td>Contents</td>
<td>Temperature limit</td>
</tr>
<tr>
<td>⚠️</td>
<td>Manufacturer</td>
<td>Expiration Date</td>
</tr>
<tr>
<td>🔄️</td>
<td>Batch code</td>
<td>SDS</td>
</tr>
<tr>
<td>🇪🇺</td>
<td>CE Mark</td>
<td>Safety Data Sheet</td>
</tr>
<tr>
<td>🇫🇷</td>
<td>Authorized Representative in the European Community</td>
<td>Consult Instructions for Use</td>
</tr>
<tr>
<td>📅</td>
<td>Date of Manufacture</td>
<td></td>
</tr>
<tr>
<td>🚧</td>
<td>DANGER</td>
<td>Do not reuse</td>
</tr>
<tr>
<td>🇯🇦</td>
<td>Made in Japan</td>
<td></td>
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</table>
REFERENCES


2. G. Kolovou et al., Cholesteryl Ester Transfer Protein Gene Polymorphisms and Longevity Syndrome Open Cardiovasc Med J. 2010; 4, 14-19


EC REP

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