LDL-CHOLESTEROL, DIRECT

LDL-KOLESTEROL, DİREKT

REF	CONT	REF	CONT
LDL-30080	R1: 2 x 30 mL R2: 2 x 10 mL	LDL-30240M	R1: 4 x 45 mL R2: 2 x 24 mL
LDL-30200	R1: 3 x 50 mL R2: 1 x 50 mL	LDL-30240P	R1: 4 x 45 mL R2: 2 x 24 mL
LDL-30400	R1: 4 x 75 mL R2: 2 x 50 mL		
LDL-30128A	R1: 4 x 24 mL R2: 4 x 8 mL		

: 2-8 °C CE IVD

INTENTED USE

This reagent is intended for the *in vitro* quantitative determination of low-density lipoprotein cholesterol (LDL-C) in human serum.

METHODOLOGY

The assay is based on a modified polyvinyl sulfonic acid (PVS) and polyethylene-glycol methyl ether (PEGME) coupled classic precipitation method with the improvements in using optimized quantities of PVS/PEGME and selected detergents. LDL, VLDL, and chylomicron (CM) react with PVS and PEGME and the reaction results in inaccessibility of LDL, VLDL and CM by cholesterol oxidase (CHOD) and cholesterol esterase (CHER), whereas HDL reacts with the enzymes. Addition of R2 containing a specific detergent releases LDL from the PVS/PEGME complex. The released LDL reacts with the enzymes to produce H_2O_2 which is quantified by the Trinder reaction.

REAGENT COMPOSITION

Reagent 1: MES buffer (pH 6.5), Polyvinyl sulfonic acid, 4-aminoantipyrine, Cholesterol esterase, Cholesterol oxidase, Peroxidase, Polyethylene-glycol-methyl ester, $MgCl_2$, Detergent, EDTA

Reagent 2: MES buffer (pH 6.5), TODB N,N-Bis(4-sulfobutyl)-3- methylaniline, Detergent, EDTA

REAGENT PREPARATION

Reagent 1 and Reagent 2 are ready to use.

Precautions and Warnings:

1. For in vitro diagnostic use only.
2. DO NOT pipette by mouth.
3. Avoid contact with skin and eyes. If spilt, thoroughly, wash affected areas with water.
4. All specimens used in the test should be considered potentially infectious.
5. Do not use the reagent after the expiration date printed on the kit.

REAGENT STORAGE

1. Store the reagent at 2-8°C.
2. The reagent is stable until the expiration date printed on the label when stored at 2-8°C protected from light and contamination prevented during their use.

REAGENT DETERIORATION:

Do Not Use Reagent If:

1. The reagent develops turbidity.
2. The reagent fails to recover control values within the assigned range.

SPECIMEN COLLECTION AND HANDLING

Use fresh patient serum or plasma samples (EDTA, Citrate). Fasting and non-fasting samples can be used.

Storage: If not analyzed promptly, specimens may be stored at 2-8°C for up to 7 days.

INTERFERENCES

The following substances normally present in serum produced less than 10% deviation at the listed concentrations: Triglyceride at 1000 mg/dL, Ascorbic Acid at 10 mM, Bilirubin at 40 mg/dL, Bilirubin Conjugate at 30 mg/dL, Hemoglobin at 1000 mg/dL.

Materials Required but not Provided

1. A clinical chemistry analyzer or photometre.
2. Analyzer specific consumables, eg: sample cups.
3. Control and calibrator materials.

PROCEDURE

Primary Wavelength	: 600 nm
Secondary Wavelength	: 700 nm
Working temperature	: 37°C
Optical path	: 1 cm
Assay type	: Endpoint/sample blank
Direction	: Increasing

1. Bring reagent to room temperature (15-30°C).

	Standard	Sample
Reagent 1	300 µL	300 µL
Standard	4 µL	--
Sample	--	4 µL

2. Mix and then incubate for 5 min at 37°C, read the absorbance of the sample (Abs.1 sample) and standard (Abs.1 standard) against distilled water.

	Standard	Sample
Reagent 2	100 µL	100 µL

3. Return tube to 37° C and after 5 min. read the final absorbance of the sample (Abs.2 sample) and standard (Abs.2 standard) against distilled water.
4. Determine the Δ Abs. for Sample and Standard.

CALCULATIONS

(ΔAbs. = Abs.2 – Abs.1)

$$\frac{\Delta \text{Abs. Sample}}{\Delta \text{Abs. Standard}} \times \text{Concentration of standard} = \text{LDL-Cholesterol (mg/dL)}$$

Limitations

1. Anticoagulants containing heparin should not be used.
2. Protect the reagents from direct sunlight.
3. Store the reagents as per instructions..

CALIBRATION

bt products Chem-Calibrator or HDL/LDL Calibrator is required for calibration. If control results are found to be out of range, the procedure should be recalibrated.

QUALITY CONTROL

Reliability of test results should be routinely monitored with control materials that reasonably emulate performance of patient specimens. Quality control materials are intended for use only as monitors of accuracy and precision. Controls should be run with every working shift in which LDL-Cholesterol assays are performed.

RESULTS

LDL-Cholesterol concentration is expressed as mg/dL.

To convert from conventional units to S.I.units, multiply the conventional units by 0.02586.

mg/dL x 0.02586 = mmol/L LDL-Cholesterol

mmol/L x 38.66 = mg/dL

EXPECTED VALUES

<100 mg/dL Optimal

100 - 129 mgldL Near optimal / above optimal

130 - 159 mg/dL Borderline high

160 - 189 mg/dL High

≥190 mg/dL Verv high

Each laboratory must establish its own range of expected values.

PERFORMANCE

1. Linearity: 4 – 250 mg/dL

If samples contain LDL cholesterol greater than 250 mg/dL, they should be diluted with saline and retested.

2. Accuracy:

The performance of this assay was compared with the performance of a legally marketed LDL-Cholesterol assay using serum samples. Seventy nine serum samples ranging from 4.0 - 232.0 mg/dL gave a correlation coeffıcient of 0.9804. Linear regression analysis gave the following equation: y = 1.0883x + 0.6078

3. Precision:

The precision of the **bt products** LDL-Cholesterol Reagent was evaluated according to Clinical LaboratorY Standards Institute EP5-A guideline. In the study, three serum specimens containing 95 mg/dL,146 mg/dL and 210 mg/dL LDL-Cholesterol were tested on Hitachi 917 with 2 runs per day with duplicates over 20 working days. This method has not been tested or certified by the Cholesterol Reference Method Laboratory Network.

Within- Run Precision :	Level 1 95 mg/dL LDL	Level 1 146 mg/dL LDL	Level 1 210 mg/dL LDL
N	80	80	80
Mean	97,14	147,37	211,47
SD	1,00	1,19	1,38
CV %	1,0%	0,8%	0,7%

Within- Laboratory Precision :	Level 1 95mg/dL LDL	Level 1 146 mg/dL LDL	Level 1 210 mg/dL LDL
N	80	80	80
Mean	97,14	147,37	211,47
SD	1,55	2,23	2,98
CV %	1,6%	1,5%	1,4%

REFERENCES

1. "Executive Summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult treatment Panel III)", JAMA, 285:2486 (2001).
2. Crouse JR et aL, Studies of low density lipoprotein molecular weight in human beings with coronary artery disease, J. Lipid Res., 26; 566 (1985).
3. Badimon 11, Badimon L., Fuester V., Regression of Atherosclerotic Lesions by High-Density Lipoprotein Plasma Fraction in the Cholesterol-Fed Rabbit, Journal of Clinical Investigation, 85: i 234-4 i (I 990).
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7. William P., Robinson D., Baily A., High density lipoprotein and coronary risk factor, Lancet, 1;72 (I 979).
8. Kannel WB, Castelli WP, Gordon T., Cholesterol in the prediction of atherosclerotic disease; New perspectives based on the Framingham study, Am. Intern. Med.90;85 (1979).
9. Hongbing Xiao Method and composition for determining low density lipoprotein cholesterol, Chinese Patent CNI379234A (2002).
10. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of the High Blood Cholesterol in Adults (Adult Treatment Panel III).
11. Pisani T, Gebski CP, Leary Et, et aL. Accurate Direct Determination of Low-Density Lipoprotein Cholesterol Assay. Arch Pathdl Lab Med 1995; 119:1127.

Caution, refer to accompanying documents.
Beraberindeki dokümanları inceleyiniz.

Consult instructions for use.
Kullanım için prospektüsü okuyun.

Manufacturer / Üretici
Bilimsel Tıbbi Ürünler Paz.San.Tic.Ltd.Şti.

Biological risk.
Biyolojik risk

Do not dispose of in environment.
Çevreyi kirletmeyin çöpe atınız.

Rev.Date / No: 02.12.2014 / 5

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KULLANIM AMACI

Bu reaktif insan serumundaki Düşük Dansiteli Lipoprotein (LDL) Kolesterol miktarının in vitro olarak belirlenmesini amaçlamıştır.

PRENSİP

Bu metod polivinil sulfonik asit (PVS)ve polietilenglikol metil eter (PEGME) çiftinin kullanıldığı klasik çöktürme metodunun PVS/PEGME miktarlarının optimize edilerek ve deterjan seçimi yapılarak geliştirilen şeklidir. LDL, VLDL, ve şilomikronlar(CM), PVS ve PEGME ile reaksiyon verir ve reaksiyon sonucunda LDL,VLDL ve CM lara ulaşılamaz.Kolesterol oksidaz ve kolesterol esteraz enzimleri seçimli olarak HDL ile reaksiyon verir.Spesifik deterjan içeren R2 ilavesinden sonra PVS/PEGME kompleksine bağlı olan LDL serbest kalır.Ayrılan LDL enzimlerle trinder reaksiyonunu izleyerek H_2O_2 oluşturan bir reaksiyon verir.

REAKTİF BİLEŞİMİ

Reaktif 1: MES tampon (pH 6.5), Polivinilsulfonik asit, 4-aminoantipirin, Kolesterol esteraz, Kolesterol oksidaz, Peroksidaz, Polietilen glikol metilester, $MgCl_2$, Deterjan, EDTA

Reaktif 2: MES tampon (pH 6.5), TODB N,N-Bis(4-sulfobutil)-3- metilanilin, Deterjan, EDTA

REAKTİFİN HAZIRLANMASI

Reaktif 1 ve Reaktif 2 kullanıma hazırdır.

UYARILAR:

1. Yalnız invitro diagnostik kullanım içindir.
2. Ağzınızla pipetlemeyiniz
3. Deri ve gözle temastan sakınınız, temas halinde bol suyla yıkayınız.
4. Bu testte kullanılan bütün materyaller potansiyel olarak enfeksiyonlu gibi düşünülmelidir..
5. Reaktifi kit üzerinde basılı olan son kullanma tarihinden sonra kullanmayınız.

REAKTİFİN DEPOLANMASI VE STABİLİTE

1. Reaktifi 2-8°C de depolayın.
2. Reaktif 2-8°C de ışıktan ve kontaminasyondan korunarak saklandığında etiket üzerinde basılı olan son kullanma tarihine kadar stabildir..

REAKTİFİN BOZULMASI

Aşağıdaki durumlarda reaktifi kullanmayınız:
1.Bulanıklık oluşmuş ise,
2.Reaktif kontrol değerlerini belirtilen değerlerin dışındaysa.

ÖRNEK TOPLANMASI VE SAKLANMASI

Taze hasta serumu ve plazma örnekleri (EDTA'lı Sitratlı) kullanınız. Açlık ve tokluk kan örnekleri kullanılabilir.
Saklama: Hemen çalışılmayacaksa 2-8°C de 7 gün bekletilebilir.

İNTERFERAN ETKİ

Aşağıda listesi verilen maddeler serumda belirtilen konsantrasyonlarda %10 ve daha az sapma göstermiştir: Trigliserid 1000 mg/dL, Askorbik asit 10 mM, Bilirubin 40 mg/dL, Konjuge Bilirubin 30 mg/dL, Hemoglobin 1000 mg/dL.

GEREKLİ OLUP TEMİN EDİLMESİ GEREKEN İLAVE DONANIM

1. Klinik kimya analizörü veye fotometre.
2. Analizöre spesifik sarf malzemeleri
3. Kontrol ve kalibratör materyalleri.

PROSEDÜR

Birinci dalga boyu	: 600 nm
İkinci dalga boyu	: 700 nm
Çalışma sıcaklığı	: 37°C
Optik yol	: 1 cm
Yöntem tipi	: Endpoint/Numune körlü
Yön	: artan

1. Reaktifleri oda sıcaklığına getiriniz (15-30°C).

	Standart	Numune
Reaktif 1	300 µL	300 µL
Standart	4 µL	--
Numune	--	4 µL

2. Karıştırın ve 5 dak. 37°Cde bekletiniz,distile suya karşı numunenin absorbansını(Abs.1 numune)standartın absorbansını (Abs.1 standard) okuyunuz.

	Standart	Numune
Reaktif 2	100 µL	100 µL

3. Tüpü tekrar 37° C'ye koyun ve 5 dak.sonra distile suya karşı numunenin (Abs.2 numune) ve standardın (Abs.2 standard) final absorbansını okuyun.

4. Numune ve standart için ∆ Abs değerini hesaplayın.

HESAPLAMALAR

(∆Abs. = Abs.2 – Abs.1)

$$\frac{\Delta Abs.\ numune}{\Delta Abs.\ Standart} \times \text{Standart kons.} = \text{LDL-Kolesterol (mg/dL)}$$

Kısıtlamalar

1. Antikoagülan olarak heparin kullanılmamalıdır.
2. Reaktifleri direkt günışığından koruyunuz.
3. Reaktifleri talimatlara göre depolayınız.

KALİBRASYON

Kalibrasyon için **bt products** Chem-Calibrator yada HDL/LDL Calibrator kullanınız. Eğer kontrol değerleri sınırların dışında bulunursa prosedür yeniden kalibre edilmelidir.

KALİTE KONTROL

Test sonuçlarının güvenilirliği için hasta örneklerinden hazırlanmış kontrol materyalleri ile rutin olarak izlenmelidir. Kalite kontrol materyalleri sadece doğruluk ve kesinlik izlenmesi amacıyla kullanılmalıdır. Kontroller her LDL Kolesterol çalışmasıyla birlikte çalışılmalıdır.

SONUÇLAR

LDL-Kolesterol konsantrasyonları mg/dL olarak belirlenir..
S.I. Birim sistemine dönüştürmek için 0.02586 ile çarpın.
mg/dL x 0.02586 = mmol/L.LDL-Kolesterol
mmol/L x 38.66 = mg/dL

BEKLENEN DEĞERLER

<100 mg/dL ideal
100 - 129 mgldL ideale yakın / ideal üstü
130 - 159 mg/dL sınırda yüksek
160 - 189 mg/dL yüksek
≥190 mg/dL çok yüksek
Her laboratuvar kendi referans değerlerini oluşturmalıdır.

PERFORMANS

1. Lineerite : 4 – 250 mg/dL
250 mg/dL 'den büyük LDL Kolesterol sonuçları serum fizyolojik ile dilüe edilerek tekrar çalışılmalıdır.

2. Doğruluk:
Bu yöntemin performansı piyasadaki diğer LDL Kolesterol yöntemlerinin performansı ile serum örnekleri kullanılarak karşılaştırılmıştır. Değerleri 4.0 ile 232 mg/dL arasında değişen 79 serum örneği çalışılmış ve korelasyon katsayısı 0.9804 bulunmuştur. Lineer regresyon analizi sonucunda aşağıdaki eşitlik bulunmuştur:
y = 1.0883x + 0.6078

3. Kesinlik :
bt products LDL Kolesterol reaktifinin kesinliği Klinik Laboratuvar standartları Enstitüsünün EP5 A rehberi dikkate alınarak değerlendirilmiştir. Çalışmada 95 mg/dL,146 mg/dL ve 210 mg/dL LDL içeren serum numuneleri analizörde hergün çiftli 2 tekrar çalışması 20 gün boyunca yapılmıştır. Bu metod Kolesterol Referans metodu Laboratuvar ağı ile test edilmemiş veya sertifikalandırılmamıştır.

Çalışma içinde kesinlik :	Level 1 95 mg/dL LDL	Level 1 146 mg/dL LDL	Level 1 210 mg/dL LDL
Numune sayısı	80	80	80
Ortalama	97,14	147,37	211,47
SD	1,00	1,19	1,38
CV %	1,0%	0,8%	0,7%

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Numune sayısı	80	80	80
Ortalama	97,14	147,37	211,47
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CV %	1,6%	1,5%	1,4%

BİLİMSEL KAYNAKÇA

1. "Executive Summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult treatment Panel III)", JAMA, 285:2486 (2001).
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Biological risk.
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