

Wellion® LEONARDO



Wellion® LEONARDO CHOL Teststreifen

WICHTIG: BITTE LESEN SIE DIESE INFORMATION UND IHR WELLION LEONARDO GLU/CHOL HANDBUCH BEVOR SIE WELLION LEONARDO CHOL TESTSTREIFEN VERWENDEN.
FÜR FRAGEN UND HILFESTELLUNGEN KONTAKTIEREN SIE BITTE DEN HERSTELLER.

Bestimmungsgemäße Verwendung

Die Wellion LEONARDO CHOL Teststreifen werden gemeinsam mit dem Wellion LEONARDO GLU/CHOL Messgerät verwendet, um die Konzentration des Blutcholesterins im Kapillarblut aus den Fingerspitzen zu messen.
Wellion LEONARDO CHOL Teststreifen sind plasmakalibriert, um den Vergleich mit Laborergebnissen zu erleichtern. Sie sind zur Selbstmessung für Personen zu Hause oder zur Verwendung in medizinischen Einrichtungen durch Fachpersonal gedacht.

Einführung

Der Wellion LEONARDO CHOL Teststreifen misst das Gesamtcholesterin im Blut mittels einer enzymatischen Reaktion, wobei eine bestimmte Strommenge entsteht. Eine Blutprobe aus der Fingerspitze wird durch Kapillarwirkung zur Reaktionszone eingesaugt, wo sich das Enzym befindet. Die durch die Reaktion produzierte Strommenge wird vom Gerät gemessen und steht in direkter Korrelation zu der Konzentration des Gesamtcholesterins im Blut. Das Messgerät zeigt das Messergebnis nach 90 Sekunden an.

Zusammensetzung des Reagens

Jeder cm² des Teststreifens enthält:
Cholesterin Esterase 10%
Cholesterin Oxidase 12%
Enzymstabilisator 59%
Enzymaktivator 19%

Warnungen und Vorsichtsmaßnahmen

Der Wellion LEONARDO CHOL Teststreifen wird außerhalb des Körpers angewendet. (IN VITRO -diagnostische Verwendung.)
[1] Verwenden Sie die Teststreifen nicht nach deren Ablaufdatum. Bitte überprüfen Sie das Ablaufdatum auf der Teststreifenpackung.
[2] Verwenden Sie keine nassen oder beschädigten Teststreifen.
[3] Teststreifen dürfen nicht wiederverwendet werden.
[4] Die Ergebnisse mit den Teststreifen sollten nicht als Basis einer Diagnose für die Erkrankung eines erhöhten Cholesterinspiegels im Blut oder Fett- und Proteinstoffwechselstörungen dienen.
[5] Nehmen Sie keinesfalls Änderungen an Ihrer Behandlung vor und ignorieren Sie Symptome ohne Ihren Arzt zu konsultieren.
[6] Die Betriebstemperatur für das Messgerät und die Teststreifen liegt zwischen 18°C–38°C (64°F–100°F).
[7] Für eine korrekte Kalibrierung müssen Sie den Code Chip bei der Verwendung einer neuen Schachtel Teststreifen in Ihr Messgerät stecken. Der Code Chip ist in jeder Teststreifenschachtel enthalten und ist chargenspezifisch. Stellen Sie sicher, dass der Code, der am Gerätedisplay angezeigt wird, mit dem Code, der auf der Teststreifenpackung aufgedruckt ist, übereinstimmt.

Lagerung und Handhabung

[1] Lagern Sie die Teststreifen zwischen 4°C–30°C (39°F–86°F). Nicht einfrieren. [2] Vermeiden Sie direktes Sonnenlicht. [3] Ungeöffnete Teststreifen sind bei korrekter Lagerung bis zum auf der Teststreifenpackung gedruckten Ablaufdatum haltbar. [4] Das Ablaufdatum gilt bis zum Ende des Monats, der auf die Packung gedruckt ist. [5] Verwenden Sie die Teststreifen nicht mit nassen oder schmutzigen Händen.

Probentnahme und Vorbereitung

Die Messung muss sofort nach der Gewinnung der Blutprobe durchgeführt werden.

Messvorgang

Sehen Sie das Kapitel „Messen Ihres Blutzuckers“ im Wellion LEONARDO GLU/CHOL Handbuch.

Zielbereich für Cholesterin

Konsultieren Sie Ihren Arzt oder medizinisches Fachpersonal, um den geeigneten Cholesterinbereich für Sie festzulegen.

Gesamtcholesterinwert:
< 200 mg/dL erstebenswert
200–239 mg/dL grenzwertig
≥ 240 mg/dL hoch

Referenz: 1 "High Blood Cholesterol - What You Need to Know". NHLBI. Publication No. 05-3290

Qualitätskontrolle

Führen Sie Level 1 oder Level 2 Kontrolllösungstests durch. Folgen den Anweisungen im Handbuch. Führen Sie Kontrollmessungen in folgenden Fällen durch:

- [1] Mindestens einmal pro Woche, um sicherzustellen, dass das Messgerät und die Teststreifen korrekt funktionieren.
- [2] Wenn Ihre Teststreifen außerhalb der Lageretemperatur oder des Luftfeuchtigkeitsbereiches gelagert wurden.
- [3] Wenn Sie das Messgerät zum ersten Mal verwenden. [4] Um Ihre Messtechnik zu üben. [5] Wenn Sie Ihr Messgerät fallen gelassen haben.

Verwenden Sie ausschließlich Wellion LEONARDO CHOL Kontrolllösung. Die Messwerte sollten innerhalb des Bereiches liegen, der auf der Teststreifenpackung aufgedruckt ist. Wiederholen Sie Messungen mit der Kontrolllösung, wenn Messwerte außerhalb des Kontrollbereichs liegen. Messwerte können aus folgenden Gründen außerhalb des Kontrollbereichs liegen:

- [1] Fehler beim Messen mit der Kontrolllösung [2] Abgelagerte oder kontaminierte Kontrolllösung. [3] Beschädigter Teststreifen. [4] Fehlfunktion des Messgeräts

WICHTIG: WENN DAS MESSERGEBNIS WEITERHIN AUSSERHALB DES AUFGEDRUCKTEN BEREICHES LIEGT, KONTAKTIEREN SIE BITTE DEN HERSTELLER, DER AM ENDE DIESES INSERTS GENANNT WIRD.

Problemebehebung

- [1] Fehler Stellen Sie sicher, dass die Teststreifen nicht abgelaufen sind. [2] Stellen Sie sicher, dass genügend Blut in die Reaktionszone aufgesaugt wird. Bei zu wenig Blut **E 2** angezeigt. Versuchen Sie auch, einen zweiten Blutstreifen auf den Teststreifen aufzutragen. Entfernen Sie den Teststreifen aus dem Gerät und testen Sie erneut mit einem neuen Teststreifen.
- [3] Prüfen Sie das System mit einem Kontrolllösungstest. [4] Wenden Sie sich an das Kapitel „Problemebehebung“ im Handbuch für weitere Hinweise.

Einschränkungen

- [1] Messen Sie NICHT mit Plasma- oder Serumproben. [2] Messen Sie NICHT bei Neugeborenen. [3] Messen Sie KEINE venösen oder arteriellen Blutproben. [4] Höhen bis zu 3150m (10335 feet) beeinflussen das Testergebnis nicht. [5] Hämatokritbereich: 30–55%. [6] Ein hoher Anteil Ascorbinsäure (>1,5 mg/dL) kann falsche Resultate verursachen. Um korrekte Resultate zu erhalten, testen Sie Ihren Cholesterinspiegel morgens nachdem Sie 8 Stunden nüchtern waren. [7] L-DOPA (>0,5 mg/dL) kann falsch-niedrige Ergebnisse in therapeutischen Konzentrationen liefern (1 mg/dL).

Folgende Stoffe können den Messwert beeinflussen, wenn die therapeutische oder physiologische Konzentration überschritten ist:

Störstoffe	Störstoffkonzentrationen	Therapeutische Konzentration/Referenzintervall
Dopamin	> 0,5 mg/dL	0,03 mg/dL
Methyl-Dopa	> 0,75 mg/dL	0,1–0,75 mg/dL
Triglyceride	> 308 mg/dL	30–300 mg/dL

Leistungsbewertung

Genauigkeit

Drei Chugens von Wellion LEONARDO CHOL Teststreifen wurden im Zuge des Genauigkeitstests für das Wellion LEONARDO GLU/CHOL Messsystem verwendet. Eine Vergleichsstudie mit Kapillarblut zwischen dem Wellion LEONARDO GLU/CHOL Messsystem und Hitachi 717 Chemistry Analyzer liefert folgende Daten:

Anzahl der Messungen: 327
Bereich der Blutcholesterinkonzentration: 101 bis 390 mg/dL

Gesamt innerhalb +/- 20 %
314/327 (96,0%)

Präzision

1 Charge Wellion LEONARDO CHOL Teststreifen wurden für die Reproduzierbarkeitsstudie verwendet. Venöses Blut in Heparin-Röhrchen wurde in 3 verschiedenen Konzentrationen verwendet. Blutcholesterinmessungen wurden für einen Tag aufgezichnet und ergaben 100 Datenpunkte pro Konzentration; wie in der folgenden Tabelle zu sehen:

Reproduzierbarkeitsstudie			
Anzahl der Messungen	100	100	100
Mittelwert (mg/dL)	137	193	255
CV%	6,5	5,8	6,3
mCV%	NA	6,2	NA



Testovacie prížky na meranie hladiny cholesterolu v krvi Wellion® LEONARDO

UPOZORNENIE: PRED POUŽITÍM TESTOVACÍCH PRÍŽKOV NA MERANIE HLADINY CHOLESTEROLU V KRVÍ WELLION LEONARDO SI PROSÍM PŘEČITAJTE TIETO INFORMÁCIE A NÁVOD NA POUŽITIE VĚŠTÍCH MERAČŮ WELLION LEONARDO. AK MÁTE OTÁZKY ALEBO POTRBUJETE POMOČ, KONTAKTUJTE PROSÍM AUTORIZOVANÉO ZÁSTUPČÍ UVEDENÉHO NA KONCI TĚTO INFORMÁCIE PŘE POUŽÍVATELE.

ZAMÝŠĽANÉ POUŽITIE

Testovacie prížky na meranie hladiny cholesterolu v krvi Wellion LEONARDO sú určené na použitie s meračom hladiny cholesterolu v krvi Wellion LEONARDO na kvantitatívne meranie hladiny cholesterolu v kapilárnej cely krvi odovbranej z konečkov prstov. Testovacie prížky na meranie hladiny cholesterolu v krvi Wellion LEONARDO sú kalibrované na plazmu pre jednoduché porovnanie s laboratornými výsledkami. Sú určené na domáce samostatovanie osôb a na používanie zdravotníckym personálom v zdravotníckych zariadeniach.

ÚVOD

Testovacie prížky na meranie hladiny cholesterolu v krvi Wellion LEONARDO merajú hladinu celkového cholesterolu v krvi pomocou enzýmovej reakcie, počas ktorej vzniká elektrický prúd. Pasívnu kapillaritu je krv z konečca prsta natiahnutá do reakčnej zóny, ktorá obsahuje enzým. Merač potom zmeria elektrický prúd, ktorý vznikne počas reakcie, a ktorý je v priamej korelácii s koncentráciou celkového cholesterolu v krvnej vzorke.

Zloženie reagencie

Každý cm² testovacieho prížky obsahuje:
Cholesterin esteráza 10%
Cholesterin oxidáza 12%
Stabilizátor enzýmu 59%
Aktivátor enzýmu 19%

Upozornenia a opatrenia pri používaní

Testovacie prížky na meranie hladiny cholesterolu v krvi Wellion LEONARDO sú určené na vonkajšie použitie (použitie na diagnostiku IN VITRO).

- [1] Nepoužívajte testovacie prížky po uplynutí dátumu expirácie. Skontrolujte prosím dátum expirácie uvedené na nádobke s testovacími prížkami. [2] Nepoužívajte vlhké alebo poškodené testovacie prížky. [3] Nepoužívajte prížky opakovane. [4] Testovacie prížky by sa nemali používať ako základ pre diagnózu ochoreni, pri ktorých dochádza k zvýšeniu hladiny cholesterolu v krvi a porúch metabolizmu tukov a bielkovin. [5] Nikdy výrazne nemeňte svoju liečbu ochorenia, ani nieignorujte žiadne príznaky bez toho, aby ste sa poradili s lekárom. [6] Prevádzková teplota merača a testovacích prížok je v rozmedzí 18°C–38°C (64°F–100°F). [7] Pre správnu kalibráciu je potrebné pre každé nové balenie testovacích prížok vložiť do merača kódovací čip. Kódovací čip je priložený k testovacím prížkom v balení a je špecifický pre danú šaržu. Uistite sa, že kód zo zobrazený na displeji merača je v súlade s kódovacím čipom, ktorý je rovnaký, ako kód uvedený na balení testovacích prížok.

Skladovacie podmienky

- [1] Testovacie prížky skladujte pri teplote 4°C–30°C (39°F–86°F). Nezmrazujte. [2] Chráňte pred priamym slnečným žiarením. [3] Pri správnom uchovávaní sú neotvorené testovacie prížky stabilné až do dátumu expirácie s vztahom na balenie. [4] Údaj o mesiaci uvedený na štitku sa vzťahuje na KONIEC DANÉHO mesiaca. [5] Nepinanulujte s testovacími prížkami, ak máte moriako alebo špeciálne ruky.

Odber vzorky a príprava

Meranie musí prebehnúť ihneď po odobraní vzorky.

Postup merania

Prečítajte si časť „Meranie hladiny cholesterolu v krvi“ v návode na použitie merača Wellion LEONARDO.

Oráčkové ošetrovanie

Oráčkové ošetrovanie alebo zdravotníckym pracovníkom o vhodnom rozmedzí cieľových hladín cholesterolu vo Vašom prípade.

Hladina celkového cholesterolu:
< 200 mg/dL Zrieduče
200–239 mg/dL Hranična vysoká
≥ 240 mg/dL Vysoká

Referenčná: 1 "High Blood Cholesterol - What You Need to Know". NHLBI. Publication No. 05-3290

Kontrola kvality

Vykonať meranie s kontrolným roztokom úrovne 1 alebo úrovne 2. Riadte sa pokynmi uvedenými v návode na použitie. Kontrolné meranie vykonajte:

- [1] Aspoň raz do týždňa, aby ste sa uistili, že meracie a testovacie prížky fungujú správne. [2] Ak ste uchovávali testovacie

prížky pri teplote a vlhkosti, ktoré nezodpovedajú vhodným podmienkam uchovávania. [3] Keď merač použíivate prvýkrát. [4] Aby ste si naučili techniku merania. [5] Ak Vám merač padá.

Používajte iba kontrolný roztok pre cholesterol Wellion LEONARDO. Výsledky merania by mali spadať do kontrolného rozmedzia uvedeného na balení testovacích prížok. Ak výsledky nepodajú do tohto rozmedzia, zapožikujte meranie s kontrolným roztokom. Výsledky môžu spadať mimo rozmedzia z nasledujúcich dôvodov:

- [1] Chyby pri testovaní s kontrolným roztokom. [2] Kontrolným roztoku uplynul dátum expirácie alebo bol kontaminovaný. [3] Poškodený testovací prížok. [4] Porucha merača.

DŮLEŽITÉ: AK VÝSLEDEK AJ NĚDAĹEJ SPĀDĀ MIMO VYTĹČĀENĚHO ROZMEDZĪ, KONTAKTUJTE AUTORIZOVANĚHO ZĀSTUPČÍ UVEDENĚHO NA KONCI TĚTO INFORMĀCIE PŘE POUŽÍVATELE.

Riešenie problémov

- [1] Skontrolujte, či testovaciemu prížky neuplynul dátum expirácie. [2] Uistite sa, že krv vyplnila reakčnú zónu. Ak je krvi málo, zobrazí sa „E 2“. NEPRIDĀVAJTE ďalšiu vzorku krvi. Odstráňte prížok z merača a meranie opakujte s novým testovacím prížkom. [3] Skontrolujte meraci systém pomocou testu s kontrolným roztokom. [4] Pre viac tipov si prečítajte časť „Riešenie problémov“ v návode na použitie.

Obmedzenia

- [1] NEPOUŽÍVAJTE vzorky plazmy alebo séra. [2] NEPOUŽÍVAJTE na meranie s krvnými vzorkami novorodencov. [3] NEPOUŽÍVAJTE na meranie so vzorkami krvi zo žíl alebo z artérií. [4] Nadmorská výška do 3150 m (10335 stóp) nemá vplyv na výsledky meraní. [5] Rozsah hematokritu: 30–55%. [6] Vysoká hladina kyseliny askorbovej (>1,5 mg/dL) môže spôsobiť nesprávne výsledky. Aby Vaše výsledky boli správne, merajte si hladinu cholesterolu ráno, najmenej po 8 hodinách nalačno. [7] L-DOPA (>0,5 mg/dL) v terapeutickú koncentráciu (1 mg/dL) môže spôsobovať nesprávne nížke výsledky.

Nasledujúce interferenty môžu ovplyvniť výsledky meraní, ak je ich koncentrácia vyššia ako terapeutická alebo fyziologická koncentrácia:

Interferenty	Koncentrácia interferentov	Terapeutická koncentrácia/Referenčný interval
Dopamin	> 0,5 mg/dL	0,03 mg/dL
Metyldopa	> 0,75 mg/dL	0,1–0,75 mg/dL
Triglycerid	> 308 mg/dL	30–300 mg/dL

Údaje o hodnotení výkonnosti

Presnosť

Pri testovaní presnosti meračieho systému Wellion LEONARDO GLU/CHOL boli použité tri šarže testovacích prížok na meranie hladiny cholesterolu v krvi Wellion LEONARDO.
Štúdia pre kapilárnu krv, v ktorej sa porovnával merač systém Wellion LEONARDO GLU/CHOL a chemický analyzátor Hitachi 717, priniesla nasledujúce údaje:
Počet meraní: 327
Rozsah vzorky: 101 to 390 mg/dL

Celkovo v rámci +/- 20 %			
314/327 (96,0%)			

Presnosť

Na štúdiu opakovateľnosti v rámci jednej série bola použitá 1 šarža testovacích prížok na meranie hladiny cholesterolu v krvi Wellion LEONARDO. Bola použitá žilová krv 3 rôznych koncentrácií v heparinových skúmavkách. Hladina cholesterolu v krvi sa zaznamenáva počas 1 kaži, vďaka čomu bolo zozbieraných 100 údajových bodov pre každú koncentráciu tak, ako je uvedené v nasledujúcich tabuľkách:

Štúdia opakovateľnosti

Počet výsledkov	100	100	100
Priemer (mg/dL)	137	193	255
CV %	6,5	5,8	6,3
mCV %	NA	6,2	NA



Wellion® LEONARDO Cholesterol Test trip

IMPORTANT: PLEASE READ THIS INFORMATION AND YOUR WELLION LEONARDO GLU/CHOL USER'S GUIDE BEFORE USING WELLION LEONARDO CHOLESTEROL TEST STRIP.
FOR QUESTIONS AND ASSISTANCE, PLEASE CONTACT THE AUTHORIZED REPRESENTATIVE FOUND AT THE END OF THIS INSERT.

INTENDED USE

The Wellion LEONARDO Cholesterol Test Strip is intended to be used with the Wellion LEONARDO GLU/CHOL Cholesterol Meter to quantitatively measure cholesterol in capillary whole blood drawn from fingertips. The Wellion LEONARDO Cholesterol Test Strip is plasma-calibrated for easy comparison to lab results. It is intended for self-testing by individuals at home or for clinical settings by healthcare professionals.

INTRODUCTION

The Wellion LEONARDO Cholesterol Test Strip measures total cholesterol in blood via enzymatic reaction which produces a current. Blood from a finger tip is drawn into the reaction area which contains the enzyme through passive capillary action. The current produced by the reaction is measured by the meter and is in direct correlation to the concentration of the total cholesterol in the blood sample. The meter shows the test result in 90 seconds.

Reagent Composition

Each cm² of test strip contains:
Cholesterol Esterase 10%
Cholesterol Oxidase 12%
Enzyme Stabilizer 59%
Enzyme Activator 19%

Warnings and Precautions

The Wellion LEONARDO Cholesterol Test Strip is for use outside the body (IN VITRO diagnostic use).

- [1] Do not use test strip after their expiration date. Please check the expiration date on the test strip box. [2] Do not use strips that are wet or damaged. [3] Do not reuse the strips. [4] The test strip should not be used as the basis for diagnosis of disorders involving excess cholesterol in the blood and lipid protein metabolism disorders. [5] Never make any changes in your treatment program or ignore symptoms without consulting your physician. [6] Operation temperature for meter and test strip is between 18°C–38°C (64°F–100°F). [7] You must insert a code chip into the meter for each new box of test strips for proper calibration. The code chip is packaged inside the test strip box and is lot specific. Make sure that both code numbers as shown on the meter after the code chip has been inserted and the code number printed on the test strip box match each other.

Storage and Handling

- [1] Store the test strips between 4°C–30°C (39°F–86°F). Do not freeze. [2] Store out of direct sunlight. [3] Unopened test strips are stable until the expiration date printed on the box when stored properly. [4] The month printed on the label refers to the END of that month. [5] Do not handle the test strip with wet or dirty hands.

Sample Collection and Preparation

Testing must be performed immediately after the sample is obtained.

Test Procedure

See „Testing Your Blood Cholesterol“ in the Wellion LEONARDO GLU/CHOL User's Guide.

Expected Values

Consult with your physician or healthcare professional to determine an appropriate cholesterol target range for you.

Total cholesterol levels:
< 200 mg/dL Desirable
200–239 mg/dL Borderline high
≥ 240 mg/dL High

Reference: 1 "High Blood Cholesterol - What You Need to Know". NHLBI. Publication No. 05-3290

Quality Control

Run Level 1 or Level 2 control solution test. Follow the User's Guide instructions. Do control tests:

- [1] At least once per week to make sure the meter and test strip are working properly. [2] If your test strips were stored at temperature and humidity outside proper storage conditions. [3] When you use your meter for the first time. [4] To practice your testing technique. [5] If you drop your meter.

Use only Wellion LEONARDO Cholesterol Control Solution. Your test results should fall within the control range printed on the test strip bottle. Repeat control solution testing if results fall out of range. Results may fall out of range due to:

- [1] Errors in control solution testing [2] Expired or contaminated control solution [3] Damaged test strip [4] Meter malfunction

IMPORTANT: IF THE RESULT CONTINUES TO FALL OUTSIDE OF THE PRINTED RANGE; CONTACT THE AUTHORIZED REPRESENTATIVE FOUND AT THE END OF THIS INSERT.

Problem Solving

- [1] Confirm the test strip is not expired. [2] Make sure the blood fits the reaction zone. "E 2" will show if there is too little blood. DO NOT add a second drop of blood. Discard the test strip from the meter and retest with a new test strip. [3] Check the system with a control solution test. [4] Refer to "Solving Problems" in the User's Guide for more hints.

Limitations

[1] DO NOT use plasma or serum samples. [2] DO NOT test on neonatal blood samples. [3] DO NOT test on venous or arterial blood samples. [4] Altitudes up to 3150m (10335 feet) will not affect test results. [5] Hematocrit range: 30–55%. [6] High level of ascorbic acid (>1.5 mg/dL) may cause incorrect results. To get correct result, test your cholesterol level in the morning after fasting for at least 8 hours. [7] L-DOPA (>0.5 mg/dL) can give falsely reduced results in therapeutic concentration (1 mg/dL).

The following intererents may affect test results if concentration is greater than therapeutic or physiological concentration:

Interferents	Interference Concentration	Therapeutic Concentration/ Reference Interval
Dopamine	> 0,5 mg/dL	0,03 mg/dL
Methyl-Dopa	> 0,75 mg/dL	0,1–0,75 mg/dL
Triglyceride	> 308 mg/dL	30–300 mg/dL

Performance Evaluation Data

Accuracy

Three lots of Wellion LEONARDO Blood Cholesterol Test Strips were used in the accuracy test of the Wellion LEONARDO GLU/CHOL System.

A capillary blood comparison study between the Wellion LEONARDO CHOL System and Hitachi 717 Chemistry Analyzer yields the following data:

Number of Readings: 327
Sample Range: 101 to 390 mg/dL

Total within +/- 20 %			
314/327 (96,0%)			

Precision

1 lot of Wellion LEONARDO Cholesterol Test StripS was used for within-run repeatability study. Venous blood in heparin-tubes was spiked to 3 kinds of concentration. Blood cholesterol readings were recorded for 1 day resulting in 100 data points for each concentration; as shown in the following tables:

Number of Readings	100	100	100
Mean (mg/dL)	137	193	255
CV%	6,5	5,8	6,3
mCV%	NA	6,2	NA



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not be used as the basis for diagnosis of disorders involving excess cholesterol in the blood and lipid protein metabolism disorders. [5] Never make any changes in your treatment program or ignore symptoms without consulting your physician. [6] Operation temperature for meter and test strip is between 18°C–38°C (64°F–100°F). [7] You must insert a code chip into the meter for each new box of test strips for proper calibration. The code chip is packaged inside the test strip box and is lot specific. Make sure that both code numbers as shown on the meter after the code chip has been inserted and the code number printed on the test strip box match each other.

Storage and Handling

- [1] Store the test strips between 4°C–30°C (39°F–86°F). Do not freeze. [2] Store out of direct sunlight. [3] Unopened test strips are stable until the expiration date printed on the box when stored properly. [4] The month printed on the label refers to the END of that month. [5] Do not handle the test strip with wet or dirty hands.
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Wellion® LEONARDO Cholesterol Test strip

IMPORTANT: PLEASE READ THIS INFORMATION AND YOUR WELLION LEONARDO GLU/CHOL USER'S GUIDE BEFORE USING WELLION LEONARDO CHOLESTEROL TEST STRIP. FOR QUESTIONS AND ASSISTANCE, PLEASE CONTACT THE AUTHORIZED REPRESENTATIVE FOUND AT THE END OF THIS INSERT.

INTENDED USE

The Wellion LEONARDO Cholesterol Test Strip is intended to be used with the Wellion LEONARDO GLU/CHOL Cholesterol Meter to quantitatively measure cholesterol in capillary whole blood drawn from fingertips. The Wellion LEONARDO Cholesterol Test Strip is plasma-calibrated for easy comparison to lab results. It is intended for self-testing by individuals at home or for clinical settings by healthcare professionals.

INTRODUCTION

The Wellion LEONARDO Cholesterol Test Strip measures total cholesterol in blood via enzymatic reaction which produces a current. Blood from a finger tip is drawn into the reaction area which contains the enzyme through passive capillary action. The current produced by the reaction is measured by the meter and is in direct correlation to the concentration of the total cholesterol in the blood sample. The meter shows the test result in 90 seconds.

Reagent Composition

Each cm² of test strip contains:
 Cholesterol Esterase 10%
 Cholesterol Oxidase 12%
 Enzyme Stabilizer 59%
 Enzyme Activator 19%

Warnings and Precautions

The Wellion LEONARDO Cholesterol Test Strip is for use outside the body (IN VITRO diagnostic use).

[1] Do not use test strip after their expiration date. Please check the expiration date on the test strip box. [2] Do not use strips that are wet or damaged. [3] Do not reuse the strips. [4] The test strip should not be used as the basis for diagnosis of disorders involving excess cholesterol in the blood and lipid protein metabolism disorders. [5] Never make any changes in your treatment program or ignore symptoms without consulting your physician. [6] Operation temperature for meter and test strip is between 18°C-38°C (64°F-100°F). [7] You must insert a code chip into the meter for each new box of test strips for proper calibration. The code chip is packaged inside the test strip box and is lot specific. Make sure that both code numbers as shown on the meter after the code chip has been inserted and the code number printed on the test strip box match each other.

Storage and Handling

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Sample Collection and Preparation

Testing must be performed immediately after the sample is obtained.

Test Procedure

See „Testing Your Blood Cholesterol“ in the Wellion LEONARDO GLU/CHOL User's Guide.

Expected Values

Consult with your physician or healthcare professional to determine an appropriate cholesterol target range for you.

Total cholesterol levels:

< 200 mg/dL	Desirable
200-239 mg/dL	Borderline high
≥ 240 mg/dL	High

Reference: 1 "High Blood Cholesterol - What You Need to Know". NHLBI. Publication No. 05-3290

Quality Control

Run Level 1 or Level 2 control solution test. Follow the User's Guide instructions. Do control tests:

[1] At least once per week to make sure the meter and test strip are working properly. [2] If your test strips were stored at temperature and humidity outside proper storage conditions. [3] When you use your meter for the first time. [4] To practice your testing technique. [5] If you drop your meter.

Use only Wellion LEONARDO Cholesterol Control Solution. Your test results should fall within the control range printed on the test strip bottle. Repeat control solution testing if results fall out of range. Results may fall out of range due to:

[1] Errors in control solution testing [2] Expired or contaminated control solution [3] Damaged test strip [4] Meter malfunction

IMPORTANT: IF THE RESULT CONTINUES TO FALL OUTSIDE OF THE PRINTED RANGE; CONTACT THE AUTHORIZED REPRESENTATIVE FOUND AT THE END OF THIS INSERT.

Problem Solving

[1] Confirm the test strip is not expired. [2] Make sure the blood fills the reaction zone. "E 2" will show if there is too little blood. DO NOT add a second drop of blood. Discard the test strip from the meter and retest with a new test strip. [3] Check the system with a control solution test. [4] Refer to "Solving Problems" in the User's Guide for more hints.

Limitations

[1] DO NOT use plasma or serum samples. [2] DO NOT test on neonatal blood samples. [3] DO NOT test on venous or arterial blood samples. [4] Altitudes up to 3150m (10335 feet) will not affect test results. [5] Hematocrit range: 30-55%. [6] High level of ascorbic acid (>1,5 mg/dL) may cause incorrect results. To get correct result, test your cholesterol level in the morning after fasting for at least 8 hours. [7] L-DOPA (>0,5 mg/dL) can give falsely reduced results in therapeutic concentration (1 mg/dL).

The following interferents may affect test results if concentration is greater than therapeutic or physiological concentration:

Interferents	Interference Concentration	Therapeutic Concentration/ Reference Interval
Dopamine	> 0,5 mg/dL	0,03 mg/dL
Methyl-Dopa	> 0,75 mg/dL	0,1-0,75 mg/dL
Triglyceride	> 308 mg/dL	30-300 mg/dL

Performance Evaluation Data

Accuracy

Three lots of Wellion LEONARDO Blood Cholesterol Test Strips were used in the accuracy test of the Wellion LEONARDO GLU/CHOL System. A capillary blood comparison study between the Wellion LEONARDO CHOL System and Hitachi 717 Chemistry Analyzer yields the following data:

Number of Readings: 327
 Sample Range: 101 to 390 mg/dL

Total within +/- 20 %	
314/327	(96,0%)

Precision

1 lot of Wellion LEONARDO Cholesterol Test Strip5 was used for within-run repeatability study. Venous blood in heparin-tubes was spiked to 3 kinds of concentration. Blood cholesterol readings were recorded for 1 day resulting in 100 data points for each concentration; as shown in the following tables:

Repeatability Study

Number of Readings	100	100	100
Mean (mg/dL)	137	193	255
CV%	6,5	5,8	6,3
mCV%	NA	6,2	NA



Wellion® LEONARDO strisce per il test del colesterolo

IMPORTANTE: PREGO LEGGA QUESTE INFORMAZIONI E IL SUO MANUALE D'USO WELLION LEONARDO GLU/CHOL PRIMA DI USARE LE STRISCE PER IL TEST DEL COLESTEROLO WELLION LEONARDO.

PER DOMANDE ED ASSISTENZA SI PREGA DI CONTATTARE IL RAPPRESENTANTE AUTORIZZATO CHE SI TROVA ALLA FINE DI QUESTO INSERTO

Destinazione d'uso

Le strisce per il test del colesterolo Wellion LEONARDO devono essere usate con lo strumento Wellion LEONARDO GLU/CHOL Cholesterol per la misurazione quantitativa del colesterolo nel sangue intero capillare prelevato dal polpastrello. Le strisce per il test del colesterolo Wellion LEONARDO Cholesterol Test sono plasma cali brate per una facile comparazione con il dato di laboratorio. E' da intendersi per auto-test individuale a casa o per uso da professionisti del settore sanitario.

Introduzione

Le strisce per il test del colesterolo Wellion LEONARDO misurano il colesterolo totale nel sangue attraverso una reazione enzimatica che produce una corrente. Il sangue dal polpastrello è guidato nella camera di reazione contenente l'enzima attraverso una azione capillare passiva. La corrente prodotta dalla reazione è misurata dallo strumento ed è in correlazione diretta con la concentrazione del colesterolo totale nel campione di sangue. Lo strumento mostra i risultati in 90 secondi.

Composizione del reagente

Ogni cm² di strisce di test contiene:
 Colesterolo Esterasi 10%
 Colesterolo Ossidasi 12%
 Enzima Stabilizzatore 59%
 Enzima Attivatore 19%

Avvertenze e Precauzioni

La striscia per il test del colesterolo Wellion LEONARDO Cholesterol Test Strip è per uso esterno (Uso diagnostic IN VITRO). [1] Non usare le strisce di test dopo la scadenza. Si prega di controllare la data di scadenza sulla confezione delle strisce. [2] Non usare strisce bagnate o danneggiate. [3] Non riutilizzare le strisce. [4] La striscia di test non deve essere utilizzata come base per la diagnosi di disturbi che coinvolgono il colesterolo nel sangue e nei disturbi del metabolismo lipidico. [5] Non apportare cambiamenti al tuo programma di trattamento o ignorare i sintomi senza consultare il tuo medico. [6] La temperatura operativa dello strumento e delle strisce è tra 18°C-38°C (64°F-100°F). [7] È necessario inserire un chip codificatore nel meter per ogni nuova confezione di strisce test per una corretta calibrazione. Il chip codificatore è confezionato dentro la confezione delle strisce test ed è lotto specifico. Assicurarsi che entrambi i numeri di codice, quello mostrato dallo strumento dopo che è stato inserito il chip di codifica e quello stampato sul foglio della striscia di prova coincidano.

Movimentazione e Stoccaggio

[1] Conservare le strisce di test tra 4°C - 30°C (39°F - 86°F). Non congelare. [2] Conservare fuori dal contatto con la luce del sole. [3] Le strisce chiuse sono stabili fino alla data di scadenza indicata sul contenitore se conservato correttamente. [4] Il mese indicato nell'etichetta si riferisce alla fine di quell mese. [5] Non maneggiare le strisce di test con le mani bagnate o sporche.

Raccolta e Preparazione

Il test va effettuato immediatamente appena si è ottenuto il campione.

Procedura di prova

Guarda „misura il tuo colesterolo nel sangue“ nella guida d'uso Wellion LEONARDO GLU/CHOL.

Valori attesi

Consultare il proprio medico o il personale sanitario per determinare un target di range di colesterolo per te.

Livelli di colesterolo totale:

< 200 mg/dL	Desiderabile
200-239 mg/dL	Limite alto
≥ 240 mg/dL	Alto

Reference: 1 "High Blood Cholesterol - What You Need to Know". NHLBI. Publication No. 05-3290

Controllo Qualità

Programma Level 1 or Level 2 test soluzione di controllo. Segui le indicazioni della guida all'uso. Fare il test di controllo:
 [1] Almeno una volta alla settimana per assicurarsi che lo strumento e la striscia reattiva funzionino correttamente. [2] Se le strisce reattive sono state conservate a temperatura ed umidità esterna adeguate alle condizioni di conservazione. [3] Quando usi lo strumento per la prima volta. [4] Per fare pratica con la tecnica. [5] Se ti cade lo strumento.

Usare solo soluzione di controllo colesterolo per Wellion LEONARDO. Il tuo test rientra nel range di controllo stampato sulla confezione di strisce per il test. Ripetere il test con la soluzione di controllo se i risultati sono fuori del range indicato. I risultati possono essere fuori dal range per:
 [1] Errori nel test con la soluzione di controllo. [2] Integrità di controllo scaduta o contaminata. [3] Strisce test danneggiate. [4] Strumento mal funzionante.

IMPORTANTE: SE IL RISULTATO CONTINUA A CADERE FUORI DEL RANGE STAMPATO, CONTATTARE IL RAPPRESENTANTE AUTORIZZATO CHE TROVATE ALLA FINE DI QUESTO INSERTO

Risoluzione dei problemi

[1] Controllare che le strisce di test non siano scadute. [2] Assicurarsi che il sangue riempia la zona di reazione. "E 2" mostrerà se il sangue è insufficiente. NON aggiungere una seconda goccia di sangue. Eliminare la striscia reattiva dallo strumento e ripetere il test con una nuova striscia reattiva. [3] Controllare il Sistema con un test con la soluzione di controllo. [4] Fare riferimento a "risoluzione dei problemi" nella guida per l'utente per ulteriori suggerimenti.

Limitazioni

[1] NON utilizzare campioni di plasma o siero. [2] Non testare su campioni di sangue neonatale. [3] NON testare su campioni di sangue venoso o arterioso. [4] L'altitudine fino a 3150m (10335 feet) non influenzerà i risultati del test. [5]

Range Ematocrito: 30-55%. [6] Altri livelli di acido ascorbico (>1,5 mg/dL) possono causare risultati non corretti. Per avere risultati corretti testa i tuoi livelli di colesterolo alla mattina dopo il digiuno per almeno 8 ore. [7] L-DOPA (>0,5 mg/dL) può dare risultati falsamente ridotti in concentrazioni terapeutiche (1 mg/dL).

I seguenti interferenti possono influenzare il risultato dei test se la concentrazione è maggiore di quella terapeutica o fisiologica:

Interferenti	Concentrazione di interferenza	Concentrazione terapeutica/ intervallo di riferimento
Dopamina	> 0,5 mg/dL	0,03 mg/dL
Metil-Dopa	> 0,75 mg/dL	0,1-0,75 mg/dL
Trigliceridi	> 308 mg/dL	30-300 mg/dL

Performance Dati di valutazione

Accuratezza

Tre lotti di strisce per il test del colesterolo Wellion LEONARDO sono stati usati per il test di accuratezza del sistema Wellion LEONARDO GLU/CHOL.

Uno studio di confronto del sangue capillare tra il Sistema Wellion LEONARDO GLU/CHOL e l'analizzatore chimico Hitachi 717 produce i seguenti dati:

Numero di letture: 327
 Range del campione: 101 a 390 mg/dL

Totalmente entro +/- 20 %	
314/327	(96,0%)

Precisione

1 lotto di Wellion LEONARDO strisce per il test del colesterolo è stato utilizzato per lo studio di ripetibilità a distanza. Il sangue venoso nelle provette con eparina è stato fissato a 3 livelli di concentrazione. Le letture del colesterolo nel sangue sono state registrate per un giorno con 100 punti dati per ciascuna concentrazione come mostrato nelle seguenti tabelle:

Studio di ripetibilità

Numero di letture	100	100	100
Significato (mg/dL)	137	193	255
S.D. (mg/dL)	6,5	5,8	6,3
C.V.%	NA	6,2	NA













SYMBOLE / SYMBOLY / SÍMBOLOS / SYMBOLEN / SYMBOLER / SÚMBOLID / SIMBOLIS:

Beachten Sie die Gebrauchsanweisung / Prečitajte si návod na použitie / Consultar instruções de utilização / Kijk in de gebruikshandleiding / Se bruksanvisning / Vt kasutusjuhendit / Consultare le istruzioni per l'uso

Temperaturbereich / Teplotné obmedzenia / Limites de Temperatura / Temperaturen limieten / Temperaturgränsnings / Temperatuuriirang / Limitazioni della temperatura

Hersteller / Yörobca / Fabricante / Fabrikant / Tilverkare / Tootja / Produttore

In Vitro diagnostisches, medizintechnisches Gerät / Diagnostická zdravotnícka pomôcka in vitro / Dispositivo Médico para Diagnóstico InVitro / In Vitro Diagnostisch Medisch Hulpmiddel / In Vitro Diagnostic Medical Device / In Vitro diagnostiline meditsiinisead / Dispositivo medico per uso diagnostico in vitro

Chargennummer / Kód šarže / Lote / Batchnummer / Partikod / Partikoood / Batch Code

Verwendbar bis /Spotřebuje do / Prazo de Validade / Gebruik tot / Använd senast / Kõlblik kuni / Uso da

Nicht wiederverwenden /Nepoužívajte opakovane / Não Reutilizar / Niet hergebruiken / Återanvänd ej / Mitte korduvalt kasutada / Non riutilizzare

Bei beschädigter Verpackung nicht verwenden / Nepoužívajte, ak je balenie poškodené / Não utilizar se a embalagem se encontrar danificada / Gebruik niet wanneer pakket beschadigd is / Använd inte om förpackningen är skadad / Mitte kasutada, kui pakend on kahjustatud / Non usare se la confezione è danneggiata

Vor /Manter se /Houden /Uchovávat v suchu / Manter seco / Používať vo v suchu / Hoida kuivana / Mantere asciutto

Vorsicht, bitte lesen Sie die beiliegenden Dokumente /Pozor, prečitajte si sprievodné informácie / ATENÇÃO! Consulte os restantes documentos / Waarschuwing, raadpleeg de bijgevoegde documenten / Varning, läs tillhörande dokument / Tähelepanu! Vt seadmega kaasasolevaid juhendeid / Attenzione consultare i documenti di accompagnamento

Bestellnummer /Katalógové číslo / Referencia / Catalogusnummer / Katalognummer / Kataloognummer / Numero di catalogo

Direktes Sonnenlicht vermeiden /Chráňte pred slnečným žiarením / Manter /Astrand da luz solar direta / Niet in zonlicht/direct licht plaatsen / Undvik solljus / Mitte hoida päikesevalguse käes / Tenere lontano dalla luce solare



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