**INTENDED USE**

The QuickGel Cholesterol System is intended for in vitro use for the quantitation of cholesterol in plasma. The system and the kit are calibrated using the QuickGel cholesterol gels and the reagents provided in the Kit. The system is method-based and does not require wet chemistry controls or manual adjustments. The system is intended for the separation and quantitation of lipoproteins in plasma and serum in a clinical laboratory setting. The system is intended for the measurement of total cholesterol, HDL cholesterol, and LDL cholesterol.

The system is linear to 400 mg/dL total cholesterol, with sensitivity down to 10 mg/dL. The system is intended for use in laboratories where the NCEP guidelines are followed. The system is intended for use with the QuickGel Chamber and the SPIFE 2000/3000.

**SUMMARY**

- **LEAD COMPOUNDS**
  - Cholesterol Esterase (EC 3.1.1.11)
  - Lipoprotein Lipase (EC 3.1.1.37)

- **REAGENT COMPONENTS**
  - The QuickGel Chamber contains agarose in a sodium barbital buffer.
  - The lipid bands are stained with enzymic reagent and their cholesterol content quantitated.

- **STORAGE AND STABILITY**
  - The gels are ready for use as packaged.
  - The reagent strips are stable for at least 1 year.

- **APPLICATIONS**
  - Lipoprotein electrophoresis
  - Lipoprotein analysis
  - Lipoprotein phenotyping

**LIMITATIONS**

The system is intended for the separation and quantitation of lipoprotein cholesterol by agarose gel electrophoresis. The lipoprotein bands are stained with enzymic reagent and their cholesterol content quantitated.

- **QUALITY CONTROL**
  - The Helena Laboratories Quality Control Program is designed to ensure the quality of the results obtained with this system.

- **PRECISION**
  - The following items, needed for the performance of the QuickGel Chamber method, must be ordered individually.

- **METHOD**
  - The method is based on the separation of lipoproteins by agarose gel electrophoresis. The lipoprotein bands are stained with enzymic reagent and their cholesterol content quantitated.

- **REAGENTS**
  - The following reagents are included in the kit:
    - Cholesterol Esterase (EC 3.1.1.11)
    - Lipoprotein Lipase (EC 3.1.1.37)

- **SERVICES**
  - The Helena Laboratories Quality Control Program is designed to ensure the quality of the results obtained with this system.

- **DATA SHEET**
  - The data sheet provides detailed instructions on how to use the reagents and perform the analysis.

**STORAGE AND STABILITY**

- The gels are ready for use as packaged.
- The reagent strips are stable for at least 1 year.
- The system is intended for use in laboratories where the NCEP guidelines are followed.

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- **DATA SHEET**
  - The data sheet provides detailed instructions on how to use the reagents and perform the analysis.

**STORAGE AND STABILITY**

- The gels are ready for use as packaged.
- The reagent strips are stable for at least 1 year.
- The system is intended for use in laboratories where the NCEP guidelines are followed.
Discard the diluent if it shows signs of deterioration.

2. For effects of various drugs, refer to Young et al. 1994.

Patient Preparation:

SPECIMEN COLLECTION AND HANDLING

3. Informed consent should be obtained.

SPECIMEN COLLECTION AND HANDLING

4. A blood sample should be collected in a clean vacutainer tube.

III. Preparation of Reagent

5. The following materials are required for the procedure:

IV. Preparation of Reagent

6. Place the diluent in the appropriate room temperature environment immediately before use, and refrigerate after use.

V. Blotting and Staining

7. Place the gel in the blower at 30°C while performing the blotting procedure.

VI. Procedure

8. Using the gel, perform the blotting procedure. After blotting, the gel is ready for use.

VII. Procedure

9. Place the gel in the appropriate environment to allow the gel to set. After setting, the gel is ready for use.

VIII. Procedure

10. Place the gel in the appropriate environment to allow the gel to set. After setting, the gel is ready for use.

IX. Procedure

11. Place the gel in the appropriate environment to allow the gel to set. After setting, the gel is ready for use.

X. Procedure

12. Place the gel in the appropriate environment to allow the gel to set. After setting, the gel is ready for use.

XI. Procedure

13. Place the gel in the appropriate environment to allow the gel to set. After setting, the gel is ready for use.

XII. Procedure

14. Place the gel in the appropriate environment to allow the gel to set. After setting, the gel is ready for use.

XIII. Procedure

15. Place the gel in the appropriate environment to allow the gel to set. After setting, the gel is ready for use.

XIV. Procedure

16. Place the gel in the appropriate environment to allow the gel to set. After setting, the gel is ready for use.

XV. Procedure

17. Place the gel in the appropriate environment to allow the gel to set. After setting, the gel is ready for use.

XVI. Procedure

18. Place the gel in the appropriate environment to allow the gel to set. After setting, the gel is ready for use.

XVII. Procedure

19. Place the gel in the appropriate environment to allow the gel to set. After setting, the gel is ready for use.

XVIII. Procedure

20. Place the gel in the appropriate environment to allow the gel to set. After setting, the gel is ready for use.

XIX. Procedure

21. Place the gel in the appropriate environment to allow the gel to set. After setting, the gel is ready for use.

XX. Procedure

22. Place the gel in the appropriate environment to allow the gel to set. After setting, the gel is ready for use.

XXI. Procedure

23. Place the gel in the appropriate environment to allow the gel to set. After setting, the gel is ready for use.

XXII. Procedure

24. Place the gel in the appropriate environment to allow the gel to set. After setting, the gel is ready for use.

XXIII. Procedure

25. Place the gel in the appropriate environment to allow the gel to set. After setting, the gel is ready for use.
In statu nulli the expiration data indicated on the label.

4. Interfering Substances:

- Most of the lipoprotein fractions contain proteins, amino acids, and other substances which have a wide range of migration rates.

5. Preparation of Reactant:

- The reaction of the serum with the reagent should be allowed to proceed until the expiration date on the reagent package is reached.

6. Procedure:

- After dissolution, the destain contains 0.3% (w/v) citric acid.

7. Washing of Cholesterol Gels:

- After electrophoresis, this wash cycle should be initiated at least 4 hours after the end of electrophoresis and continued for 15 minutes.

8. PREPARATION REAGENT (REP) PREP

- The REP Prep is dispensed for use and is not to be refrigerated.

9. Incubation:

- The incubator capable of maintaining 30°C should be used for all incubation steps.

10. Electrophoresis:

- Electrophoresis should be performed on 50 gels. Unscrew the endcaps from the old electrode and replace them with new ones if necessary.

11. Incubation:

- After incubation, carefully remove the gel from the electrophoresis unit and place in the destain solution using a gentle rocking and swirling technique.

12. Staining:

- Place the gel in the destain solution using a gentle rocking and swirling technique. Allow the gel to remain in the destain solution for 15 minutes.

13. The two small notches in the backing must fit over the small pins (not touching the gel) so that, when the lid closes, the Blotter X's do not interfere with the electrodes.
Discard the diluent if it shows signs of

2. For best results, scan the QuickGel-

SPIFE QuickGel Gel Holder 3358

Cat. No.

QuickGel Blotter X (20)

Materials Provided: are necessary.

ably alter the lipoprotein separation.

The specimen should never be stored frozen. Freezing may irrevers-

2. For effects of various drugs, refer to Young et al

For best separation of the various lipoproteins, especially the Beta lipoprotein

Preparation for Use:

Pour 11 L of deionized water into the Destain

Store the Destain at 15 to 30°C. It is stable

Procedure for Use:

Place the electrode holders securely into the magnetic posts. Ensure that the electrodes are positioned at the

END OF TEST

Waste 3 1:00 REC=ON VALVE=7

3) No Prompt

11. At the end of incubation, remove the gel from the incubator.

7. Lay a 5 mL serological pipette lengthwise along the cathode

Preparation of Reagent

Apply Reagent 1 30°C 8 cycles

Apply Sample 1 1:00 20°C SPD6 LOC1

Load Sample 1 00:30 20°C SPD6

Apply Sample 1 1:00 20°C SPD6

Electrophoresis 1 25:00 16°C 220 VOLTS

Incubate 1 15:00 30°C

Apply Reagent 1 30°C 8 cycles

For best results, scan the QuickGel-

Patients: The cholesterol content of the serum samples is analyzed by the

For best results, scan the QuickGel-

The operator must be familiar with the QuickGel Chamber and its

Materials Provided: are necessary.

Preparation of Reagent

Apply Reagent 1 30°C 8 cycles

Apply Sample 1 1:00 20°C SPD6 LOC1

Load Sample 1 00:30 20°C SPD6

Apply sample to the cathode of the agarose

Place the gel in the destain solution using a gentle alternately

Same amount of deionized water into the other container.

Remove excess destain.

Procedure for Use:

Pour the contents of the SPIFE Cholesterol Reagent vial

6. Wipe the excess buffer and moisture from around the gel and

5. The QuickGel Chamber must be plugged into a power supply.

In the event that the QuickGel Chamber is not used within

1. The QuickGel Chamber must be plugged into a power supply.

No further buffer or moisture from around the gel.

When the gel is completely dry, remove the gel from the

4. Place the gel in the destain solution using a gentle alternately

Remove excess destain.

Procedure for Use:

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4. Place the gel in the destain solution using a gentle alternately

Remove excess destain.
LDL-Cholesterol

Elevated 200-499 mg/dL

HDL-Cholesterol

< 40 mg/dL

LDL-Cholesterol

< 100 mg/dL

Calculation:

Mild hyperlipidemia is defined as a total cholesterol level above
the upper limit of normal and a LDL cholesterol level above 100
mg/dL. Both conditions are usually present in the same patient.

Mild hypertriglyceridemia is defined as a triglyceride level
above 150 mg/dL. This condition is usually present in the same
patient as mild hypercholesterolemia.

Moderate hypertriglyceridemia is defined as a triglyceride
level above 200 mg/dL. This condition is usually present in the
same patient as mild hypercholesterolemia.

Severe hypertriglyceridemia is defined as a triglyceride
level above 500 mg/dL. This condition is usually present in
the same patient as moderate hypercholesterolemia.


Fig. 1: Schematic of a QuickGel Cholesterol pattern.

INTENDED USE

The SPIFE and QuickGel Chamber systems separate the major lipoprotein classes by electrophoresis and a subsequent colorimetric assay. The NCEP panel concluded that alternative methods are needed for measurement of HDL cholesterol, cholesterol and triglycerides. The QuickGel system is limited to, the implied warranties of merchantability and fitness for a particular purpose.

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The gels should be stored horizontally at 3-6°C. 

INTERPRETATION OF RESULTS

If a band appears between alpha and pre-beta, it is the Lp(a)-C band. This band may not be observed in every specimen. Lp(a)-C may not be present at concentrations that are detectable by agarose electrophoresis on several media. The lipoprotein bands are stained with enzymic reagent and their cholesterol content quantitated by densitometric scanning. The major protein component of LDL is apolipoprotein B-100. It does not appear in every sample at measurable concentrations. It does not appear in every sample at measurable concentrations. The relationship of HDL, Cholesterol to non HDL (CHD) ratio was calculated using (CHD) HDL and VLDL. This work of Castelli et al. used infrared analysis on HDL, measured cholesterol values in the formula. The VLDL is separated by the centrifugal system of the gelator. Neutral Lipid in the serum should be determined by measuring in a centrifugal system using 800 rpm with the QuickGel 2000.