

sebia

HYDRAGEL 7 LIPOPROTEIN(E)

Ref. 4114

HYDRAGEL 15 LIPOPROTEIN(E)

Ref. 4134

HYDRAGEL 30 LIPOPROTEIN(E)

Ref. 4138

IVD

CE

2004/11

INTENDED USE

The HYDRAGEL 7, 15 and 30 LIPOPROTEIN(E) kits are designed for determination of lipoprotein profiles in human serum.

Each agarose gel is intended to run:

- 7 samples with the HYDRAGEL 7 LIPOPROTEIN(E) kit,
- 15 samples with the HYDRAGEL 15 LIPOPROTEIN(E) kit,
- 30 samples with the HYDRAGEL 30 LIPOPROTEIN(E) kit.

For *In Vitro* Diagnostic Use.

PRINCIPLE OF THE TEST ¹⁻¹¹

The analysis is performed by electrophoresis on buffered (pH 8.5) agarose gels on the semi-automated HYDRASYS instrument. The separated lipoproteins are stained with a lipid specific Sudan black stain. The excess of stain is removed with an alcoholic solution. The resulting electrophoregrams can be evaluated visually for pattern abnormalities or by densitometry to obtain relative quantification of individual zones.

The lipoproteins are circulating complexes constituted of lipids and proteins. The classification of lipoproteins is based on their properties that lend themselves to the techniques for their separation ^(1,6):

- density (ultracentrifugation),
- charge (zone electrophoresis),
- size (molecular filtration by polyacrylamide gel electrophoresis).

On agarose gels, the major lipoproteins separate into the following fractions (in the order of increasing mobility) :

- the chylomicrons : these are very large molecules with high triglycerides content, present as small particles in the serum and responsible for its opalescence. They normally remain at the application point.
- the beta lipoproteins or Low Density Lipoproteins (LDL): they normally migrate in beta globulins position.
- the pre-beta lipoproteins or Very Low Density Lipoproteins (VLDL): they have molecular weight higher and density lower than LDL. They are more mobile than LDL and migrate in front of beta globulins position.
- the alpha lipoproteins or High Density Lipoproteins (HDL): they are the fastest fraction of lipoproteins. They migrate in alpha-2 globulins position.

Electrophoresis is a simple and useful technique for the assessment of lipoprotein abnormalities and coronary disease risk factors in serum ^(2,4,5,7,9,10). The differentiation of lipoproteins according to their mobility in zone electrophoresis is the basis of the Fredrickson classification of hyperlipemia⁽³⁾. This classification readily allows application of dietary measures or therapeutic treatment ⁽⁸⁾.

REAGENTS AND MATERIALS SUPPLIED IN THE HYDRAGEL 7, 15 AND 30 LIPOPROTEIN(E) KITS

ITEMS	PN 4114	PN 4134	PN 4138
Agarose Gels (ready to use)	10 gels	10 gels	10 gels
Buffered Strips (ready to use)	10 packs of 2 each	10 packs of 2 each	10 packs of 2 each
Sudan Black Stain (stock solution)	1 vial, 20 mL	1 vial, 20 mL	1 vial, 20 mL
Applicators (ready to use)	1 pack of 10 (7 teeth)	1 pack of 10 (15 teeth)	2 packs of 10 (15 teeth)
Filter Papers - Thin	1 pack of 10	1 pack of 10	1 pack of 10

FOR OPTIMAL RESULTS

All reagents from the same kit must be always used together and according to the package insert instructions.

PLEASE READ THE PACKAGE INSERT CAREFULLY.

1. AGAROSE GELS**Preparation**

Agarose gels are ready to use. Each gel contains: agarose, 0.8 g/dL ; buffer pH 8.5 ± 0.1 ; additives, nonhazardous at concentrations used, necessary for optimum performance.

Use

Support medium for lipoprotein electrophoresis.

Storage, stability and signs of deterioration

Store the gels horizontally in the original protective packaging at room temperature (15 to 30 °C) or refrigerated (2 to 8 °C). (The arrow on the front of the kit box must be pointing upwards). DO NOT FREEZE. Avoid obvious temperature fluctuations during storage (e.g., do not store close to a window or to a heat source). The gels are stable until the expiration date indicated on the kit package or the gel package labels.

Discard when:

- crystals or precipitate form on the gel surface or the gel texture becomes very soft (all these result from freezing the gel),
- bacterial or mold growth is indicated,
- abnormal quantity of liquid is present in the gel box (as a result of buffer exudation from the gel due to improper storage conditions).

2. BUFFERED STRIPS

Preparation

Buffered sponge strips are ready to use. Each contains: buffer pH 8.5 ± 0.1 ; sodium azide ; additives, nonhazardous at concentrations used, necessary for optimum performance.

WARNING: The buffer in the strips contains 0.20 % sodium azide. Harmful if swallowed. Do not ingest ! If ingested consult physician immediately ! When disposing, prevent contact with acids, lead or copper, as these are known to form explosive or toxic compounds with sodium azide. After contact with skin, wash immediately with plenty of water.

Use

Buffered strips function as electrophoresis buffer reservoir and ensure contact between the gel and electrodes.

Storage, stability and signs of deterioration

Store the buffered strips horizontally in the original protective packaging at room temperature or refrigerated. (The arrow on the front of the kit box must be pointing upwards).

They are stable until the expiration date indicated on the kit package or buffered strips package label.

DO NOT FREEZE.

Discard buffered strips if the package is opened and the strips dry out.

3. SUDAN BLACK STAIN

Preparation

Prepare the working Sudan black stain solution at least 30 minutes before use. Add exact volumes of the individual components in the following order, under gentle stirring:

1) Pure ethanol (96 %), 120 mL ; Sudan Black Stain, stock solution (6.6 g/dL in dimethylformamide), 1.45 mL. Wait until the Sudan Black is completely dissolved and then add distilled or deionized water, 100 mL. Stir for 30 minutes minimum.

or

2) Pure isopropanol (100 %), 100 mL ; Sudan Black Stain, stock solution (6.6 g/dL in dimethylformamide), 1.45 mL. Wait until the Sudan Black is completely dissolved and then add distilled or deionized water, 120 mL. Stir for 30 minutes minimum.

Keep these solutions away from any source of heat. Discard after each staining procedure.

IMPORTANT: The use of another alcohol or denatured ethanol, may lead to atypical results. If lower concentrations than indicated of pure alcohol are used, adjust accordingly the volumes of alcohol and water.

WARNING: The vial of Sudan black contains dimethylformamide. Harmful by inhalation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not ingest ! If ingested, consult physician immediately ! After contact with eyes or skin, rinse immediately with plenty of water and seek medical advice.

Use

For staining gels with electrophoretic lipoprotein separations.

Storage, stability and signs of deterioration

Store the stock stain solution at room temperature or refrigerated. It is stable until the expiration date indicated on the kit package or stain vial labels.

The working stain solution is stable for 12 hours maximum at room temperature in a closed container to prevent evaporation.

4. APPLICATORS

Use

Precut, single use applicators for sample application.

Storage

Store applicators in a dry place at room temperature or refrigerated.

5. FILTER PAPERS - THIN

Use

Single use absorbent pads for blotting excessive moisture from off the gel surface before sample application.

Storage

Store the thin filter papers in a dry place at room temperature or refrigerated.

REAGENTS REQUIRED

1. DESTAINING SOLUTION (& WASH SOLUTION No. 1)

Preparation

At least 15 minutes before use, prepare 440 mL of solution containing (vol./vol.):

- 1) 45 % pure ethanol (96 %) and 55 % distilled or deionized water, or,
- 2) 30 % pure isopropanol (100 %) and 70 % distilled or deionized water.

IMPORTANT: The use of another alcohol or denatured ethanol, may lead to atypical results. If lower concentrations than indicated of pure alcohol are used, adjust accordingly the volumes of alcohol and water.

Use

It serves for cleaning of the HYDRASYS Staining Compartment before staining the HYDRAGEL 7 LIPOPROTEIN(E) and HYDRAGEL LIPOPROTEIN(E) 15/30 gels.

For destaining, i.e., removal of excess and background stain from the gels.

Storage, stability and signs of deterioration

Store destaining solution at room temperature tightly capped to prevent evaporation. It is stable for one month at room temperature.

Discard destaining solution if it changes its appearance, e.g., becomes cloudy due to microbial contamination.

2. WASH SOLUTION No. 2

Preparation

Prepare 1 liter of a solution containing (vol./vol.):

- 1) 75 % pure ethanol (96 %) and 25 % distilled or deionized water, or,
- 2) 70 % pure isopropanol (100 %) and 30 % distilled or deionized water.

Denatured ethanol may also be used. If lower concentrations than indicated of alcohol are used, adjust accordingly the volumes of alcohol and water.

Use

For washing of the HYDRASYS staining compartment after staining the gels.

Storage, stability and signs of deterioration

Store wash solution No. 2 at room temperature tightly capped to prevent evaporation. It is stable for three months at room temperature. Discard destaining solution if it changes its appearance, e.g., becomes cloudy due to microbial contamination.

3. FLUIDIL

Preparation

Fluidil (SEBIA, PN 4587, 1 vial, 5 mL) is ready to use.

Use

To treat viscous or turbid samples, e.g., sera containing cryoglobulin or cryogel. Fluidil does not clarify samples where the turbidity is caused by triglycerides.

Storage, stability and signs of deterioration

Store at room temperature or refrigerated. It is stable until the expiration date indicated on the Fluidil vial label. Fluidil must be free of precipitate.

EQUIPMENT AND ACCESSORIES REQUIRED

1. HYDRASYS System SEBIA, PN 1210 or PN 1211.
2. Micropipettor, either manual or automated, such as HYDRAPLUS SEBIA, PN 1215, for an alternative way of loading the sample applicators.
3. Wet Storage Chamber PN 1270 supplied with HYDRASYS.
4. Accessory Kit HYDRASYS LIPOPROTEINS SEBIA, PN 1263.
5. Pipettes: 10 µL, 200 µL and 1000 µL.
6. HYDRASYS Gel holder for 82 x 51 mm gels, SEBIA, PN 10043110.
7. Densitometer / scanner capable of scanning 82 x 51 mm or 82 x 102 mm gel plates at 570 nm or with a yellow filter such as HYDRASYS SEBIA, DVSE SEBIA or PHORESIS software for flat-bed scanner. Refer to manufacturer's instructions for operation and calibration procedures.

SAMPLES FOR ANALYSIS

Sample collection and storage

Fresh serum samples are recommended for analysis. It is recommended to collect samples on fasting patients for at least 12 hours. They must be collected according to established procedures used in clinical laboratory testing. Store samples refrigerated (2 to 8 °C) as soon as possible after collection.

Samples can be stored at 2 to 8 °C for 10 days maximum or 3 days maximum at room temperature.

Do not freeze the samples.

Do not use samples collected on heparin.

The pre-beta lipoprotein (VLDL) is the lipoprotein fraction that could be most affected by storage. Storage causes slow-down of pre-beta lipoprotein mobility, and therefore, under-evaluation of this fraction ; this becomes most apparent with samples low in VLDL (<10 %).

Sample preparation

Use undiluted serum samples.

Upon storage at 2 to 8 °C, some samples (particularly those containing cryoglobulin or cryogel) may become viscous or develop turbidity. Such samples might present application problems due to hindered diffusion through the sample applicator teeth. In such case, add 25 µL Fluidil to 75 µL serum and vortex for 15 seconds. Then follow the standard procedure.

PROCEDURE

The HYDRASYS system is a semi-automated multi-parameter instrument. The automated steps include processing of HYDRAGEL agarose gels in the following sequence: sample application, electrophoretic migration, drying, staining, destaining and final drying. The manual steps include handling samples and gels, and setting up the instrument for operation.

READ CAREFULLY HYDRASYS INSTRUCTION MANUAL.

I. MIGRATION SET UP

1. Switch on HYDRASYS instrument.
2. Place one applicator for HYDRAGEL 7 LIPOPROTEIN(E) (7 samples) and HYDRAGEL LIPOPROTEIN(E) 15/30 (15 samples), or two applicators for HYDRAGEL LIPOPROTEIN(E) 15/30 (30 samples), on a flat surface with the well numbers in the right-side-up position (Fig. 1).
 - Apply 10 µL neat sample in each well. Load each applicator within 2 minutes.
 - Place the applicator(s) into the wet storage chamber with the teeth up. Handle it (them) by the plastic tooth protection frame. Let the samples diffuse into the teeth for 5 minutes after the last sample application.

See wet chamber package insert for further details.

3. Open the lid of the Migration Module and raise the electrode and applicator carriers.
WARNING: Never close the lid while the carriers are raised!
4. Select «7&15/30 LIPO» migration program for both HYDRAGEL 7 LIPOPROTEIN(E) and for HYDRAGEL LIPOPROTEIN(E) 15/30 from the instrument menu (left side of the keyboard).
5. Remove buffered strips from the package ; handle them by the plastic ends. Engage the punched ends of the strip's plastic backing to the pins on the electrode carrier ; the strip's plastic backing must face the carrier (Fig. 2).

6. Unpack the HYDRAGEL plate.
 - Roll quickly and uniformly one thin filter paper onto the gel surface to absorb the excess of liquid. Remove the paper immediately.

WARNING: Do not leave the filter paper for a too long contact with the gel to avoid its dehydration.

 - Pool 120 µL distilled or deionized water for HYDRAGEL 7 LIPOPROTEIN(E) gel, or 200 µL for HYDRAGEL LIPOPROTEIN(E) 15/30 gel, on the lower third of the frame printed on the Temperature Control Plate of the migration module.
 - Place the gel plate (the gel side up) with its edge against the stop at the bottom of the printed frame (Fig. 3).
 - Bend the gel and ease it down onto the water pool (Fig. 3). Ensure that no air bubbles are trapped, water is spread underneath the entire gel plate and the gel is lined up with the printed frame.
7. Lower both carriers down. In this position, the buffered strips do not touch the gel. DO NOT FORCE THE CARRIERS ALL THE WAY DOWN.
8. Remove the applicator(s) from the wet chamber. Handle it (them) by the protection frame.
 - Snap off the applicator teeth's protection frame.
 - For 7 and 15 samples analysis, place the applicator into position No 4 on the carrier.
 - For 30 samples analysis, place the two applicators each into position No 2 and 8.

IMPORTANT: The numbers printed on the applicator(s) must face the operator (Fig. 4).
9. Close the lid of the migration module.
10. Start the procedure immediately by pressing the green arrow «START» key on the left side of the keyboard.

During the migration, run the wash cycle of the processing / staining module (see paragraph no. II).

IMPORTANT: Make sure that the ventilation air inlet on the right side of the instrument is not blocked.

MIGRATION - DESCRIPTION OF THE AUTOMATED STEPS

- The two carriers are lowered so that buffered strips and applicator(s) contact the gel surface.
- Sample applicator carrier rises up.
- Migration is carried out under 160 V constant voltage for HYDRAGEL 7 LIPOPROTEIN(E) and for HYDRAGEL LIPOPROTEIN(E) 15/30, until 65 Vh have accumulated, at 20 °C controlled by Peltier effect, for about 25 minutes.
- The electrode carrier rises to disconnect the electrodes.
- The temperature of the control plate rises to 60 °C for 15 minutes to dry the gel.
- The control plate is cooled down ; when it reaches 50 °C, an audible beep signals that the migration module lid unlocks. The plate temperature remains at 50 °C until the lid is opened. Then, the temperature keeps decreasing until it reaches 20 °C (in less than 5 minutes) after which a new migration run may start.

NOTE: The migration module lid remains closed during all migration steps.

II. WASH No. 1: THE PROCESSING / STAINING MODULE

1. Place the empty Gel Holder into the gel Processing / Staining Module.

IMPORTANT: Before starting the washing program, check the following :

 - the destaining container contains at least 220 mL of destaining solution ;
 - the waste container is empty.

For reagent line connection: refer to the information displayed on the screen of the instrument (select key: **Reagent Lines**).

IMPORTANT: Do not forget to block up the unused lines.
2. Select the «LIPO + Lp(a) & LIPO» washing/staining program from the instrument menu. Start the run by pressing the «START» key (green arrow on the right side of the keyboard).

During the washing step, the compartment remains locked.
 After the wash, an audible beep signals that the compartment unlocks.
 Remove the gel holder from the processing / staining module.

III. GEL PROCESSING SET-UP

1. Open the lid of the migration module.
2. Remove the applicator(s) and discard.
3. Raise both carriers, remove the buffered strips by their plastic ends and discard.
4. Remove the dried gel for further processing.
5. After each use, wipe the electrodes and the temperature control plate with a soft wet tissue.
6. Open the gel holder. Lay it flat and position the dried gel (with gel side facing up and **name HYDRAGEL 7 LIPOPROTEIN(E) or HYDRAGEL LIPOPROTEIN(E) 15/30 oriented upside down**) into the grooves of the two rods and close the holder. Make sure that the film is correctly positioned inside the holder and blocked at the lowest point (Fig. 5).
7. Place the gel holder into the gel processing / staining module.

IMPORTANT: Before starting the gel processing / staining program, check the following:

 - the staining container is filled with 220 mL of staining solution ;
 - the destaining container contains at least 220 mL of destaining solution ;
 - the waste container is empty.

For reagent line connection: refer to the information displayed on the screen of the instrument (select key: **Reagent Lines**).

IMPORTANT: Do not forget to block up the unused lines.
8. Start the run by pressing the «START» key (green arrow on the right side of the keyboard).

During gel staining, destaining, rinsing and drying steps, the compartment remains locked.
 After cooling step, an audible beep signals that the compartment unlocks (the ventilation is maintained until the gel holder is removed).

IV. GEL PROCESSING COMPLETION

1. Remove the gel holder from the compartment ; open the clips and remove the dried gel film.

If needed, clean the back side (the plastic support side) of the dry film with a tissue paper soaked with a 70 % alcoholic solution.
2. Scan using a densitometer / scanner with a yellow filter or at 570 nm, adjust the background to zero at the lowest point.

NOTE : The lengths of electrophoretic migrations may be slightly different with gels containing 2 or 3 analysis rows, without any adverse effects on performance.

V. WASH No. 2: THE STAINING COMPARTMENT

1. Place the empty gel holder into the gel processing / staining module.

IMPORTANT: Before starting the washing program, check the following:

- the wash container No. 2 contains at least 250 mL of wash solution No. 2 ;
- the waste container is empty.

For reagent line connection: refer to the information displayed on the screen of the instrument (select key: **Reagent Lines**).

IMPORTANT: Do not forget to block up the unused lines.

2. Start the run by pressing the «START» key (green arrow on the right side of the keyboard).

During washing step, the compartment remains locked.

After drying, an audible beep signals that the compartment unlocks.

RESULTS

Quality Control

It is advised to include an assayed serum with normal triglycerides and cholesterol levels into each run of samples.

Values

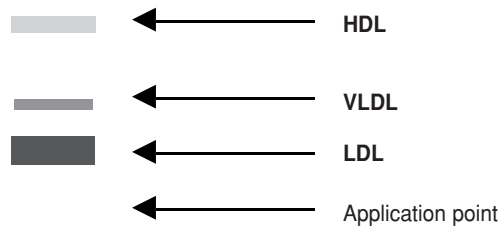
Densitometry of stained electrophoregrams at 570 nm or with yellow filter yields relative concentrations (percentages) of each fraction.

The ranges of normal values (mean \pm 2 SD) for individual zones on HYDRAGEL 7 LIPOPROTEIN(E) and HYDRAGEL LIPOPROTEIN(E) 15/30 gels have been established from a healthy population of 97 adults (men and women):

Beta lipoproteins (LDL) : 42.3 - 69.5 %
 Pre-beta lipoproteins (VLDL) : 2.0 - 31.2 %
 Alpha lipoproteins (HDL) : 15.1 - 39.9 %

It is recommended each laboratory establish its own normal values.

Migration pattern



Interpretation of lipoprotein patterns

The lipoprotein pattern of a clinical sample must be interpreted visually by comparing it with a control or a normal serum pattern. Densitometry provides accurate relative percentage of individual lipoprotein fractions. Such quantitation may be useful for the follow up of the patient by monitoring the fractions' changes. The relative (%) values obtained by densitometry, however can not be used to type hyperlipemia. Qualitative (presence of abnormal or absence of normal fractions) or semi-quantitative (relative increase or decrease of fractions) abnormalities necessitate further lipoprotein analyses. Further aid in the interpretation of lipoprotein patterns is the Fredrickson classification of lipoproteins.

Lipoprotein electrophoresis interpretation - Fredrickson classification

TYPE OF HYPERLIPEMIA	TYPE I	TYPE II a	TYPE II b	TYPE III	TYPE IV	TYPE V
TOTAL CHOLESTEROL						
g/L.....	2 - 4	3 - 10	2.8 - 3.5	3 - 5	< 2.7	\leq 5
mmol/L.....	5.2 - 10.4	7.8 - 26	7.3 - 9.1	7.8 - 13	< 7	\leq 13
TRIGLYCERIDES						
g/L.....	30 - 70	< 1.6	2 - 5	2 - 9	2 - 10	\leq 30
mmol/L.....	34 - 79	< 2	2.3 - 5.6	2.3 - 10.2	2.3 - 11.3	\leq 34
SERUM APPEARANCE	milky	clear	clear to slightly turbid	clear to slightly turbid	turbid	milky
CHYLOMICRONS	++++	0	0	0	\pm	++++
LDL	---	+++	++	++ coupled	-	--
VLDL	normal to ---	normal	++	++	+++	++
HDL	---	normal to -	normal to -	-	-	-

Particular cases

- Chylomicrons and triglycerides stay at application point.
- In the absence of chylomicrons, a fraction with a cathodic mobility may be seen between application point and LDL indicating a special lipoprotein called LP X. It is found in icteric sera and in case of cholestasis and biliary disease.
- Lipoprotein remnants and Lp(a) migrate between LDL and VLDL and generally do not present themselves as a band.

Interference and limitations

- Do not use frozen samples.
- Storage causes slow-down of pre-beta lipoprotein mobility, and therefore, under-evaluation of this fraction ; this becomes most apparent with samples low in VLDL (<10 %).
- In some sera, a more or less diffuse trail may appear in front of alpha lipoprotein fraction (HDL). This zone corresponds to partially delipidated HDL and it has to be included in the HDL percentage.
- The procedure is qualitative ; detected changes necessitate further analysis.

Troubleshooting

Call Technical Service of the supplier when the test fails to perform while the instruction for the preparation and storage of materials, and for the procedure were carefully followed.

Kit reagent Safety Data Sheets and informations on waste products elimination are available from the Technical Service of the supplier.

PERFORMANCE DATA

SEBIA's HYRYS densitometer was used for all densitometric evaluation. All electrophoregrams were also interpreted visually. The results showed below have been obtained with Sudan black staining solution prepared with ethanol.

Reproducibility

In all reproducibility studies, the electrophoregrams were scanned and relative per cent concentration of each lipoprotein fraction recorded. Means, SD and CV were calculated with respect to the parameters examined. Upon visual examinations of the electrophoregrams, no visual differences were observed among the repeats. Good reproducibility (precision) was obtained : 4.1 % was the mean CV % value.

Within gel reproducibility

Three serum samples (sample A with elevated HDL, sample B with elevated VLDL, sample C, normal serum) were analyzed using HYDRAGEL 15 & 30 LIPOPROTEIN(E) procedure on gels from the same lot. Each sample was applied in 14 tracks of a single gel and a normal control serum was applied on the 15th track of each gel. The following table shows the within gel data for the three samples.

FRACTION	HDL (A – B – C)	VLDL (A – B – C)	LDL (A – B – C)
MEAN (%)	48.2 - 14.6 - 33.9	9.7 - 43.2 - 12.2	42.2 - 42.1 - 53.9
SD	1.4 - 1.1 - 0.4	0.7 - 0.7 - 0.3	1.3 - 0.7 - 0.4
CV %	3.0 - 7.6 - 1.2	7.6 - 1.7 - 2.7	3.0 - 1.6 - 0.7

Gel-to-gel reproducibility

Fifteen different samples were analyzed using HYDRAGEL 15 & 30 LIPOPROTEIN(E) procedure. Each sample was applied in one track in each of the 10 gels from the same lot. The mean, SD and CV % (n = 15) were calculated for each sample and each lipoprotein fraction. The following table shows the limit values for means, SD and CV % and a mean CV % representing all samples.

FRACTION	HDL	VLDL	LDL
MEAN (%)	14.6 - 37.6	5.0 - 41.4	43.1 - 66.1
SD	1.1 - 1.9	0.3 - 1.0	1.1 - 2.3
CV %	3.6 - 8.2	1.8 - 8.5	2.1 - 4.0
MEAN CV %	5.3	4.7	3.0

Linearity and Sensitivity

Relative concentrations of lipoprotein fractions were determined with serial dilutions of two different serum samples in saline. The densitometric concentrations were found independent of the dilution factor. The highest dilution providing a scannable pattern was 1 : 8 (i.e., essentially the same as obtained with the neat serum sample). The test was found linear in the entire range studied.

The sensitivity of HYDRAGEL LIPOPROTEIN(E) 15/30 was determined by assaying two mixtures of two different samples in different proportions ; the minimum mean variation detected for the three lipoprotein fractions was 2.8 %.

Accuracy

One hundred and seventy three (173) different serum samples (normal and pathological) were analyzed using SEBIA's HYDRAGEL 7, 15 and 30 LIPOPROTEIN(E) kits and another, commercially available test for electrophoretic quantification of HDL, VLDL and LDL lipoproteins.

The following table shows the results of linear regression analysis of the densitometric values by both procedures.

Fraction	Correlation coefficient	Y-Intercept**	Slope	Range of % values of samples used*
HDL	0.945	6.245	0.802	7.4 - 54.6
VLDL	0.977	2.730	0.905	4.6 - 65.0
LDL	0.955	1.233	0.948	15.4 - 89.9

* The % values are determined in the HYDRAGEL 7, 15 & 30 LIPOPROTEIN(E) system.

** y = HYDRAGEL 15 & 30 LIPOPROTEIN(E)

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SCHÉMAS / FIGURES

Figure 1

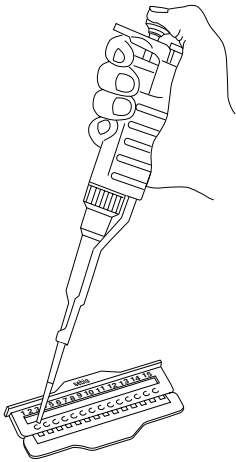


Figure 2

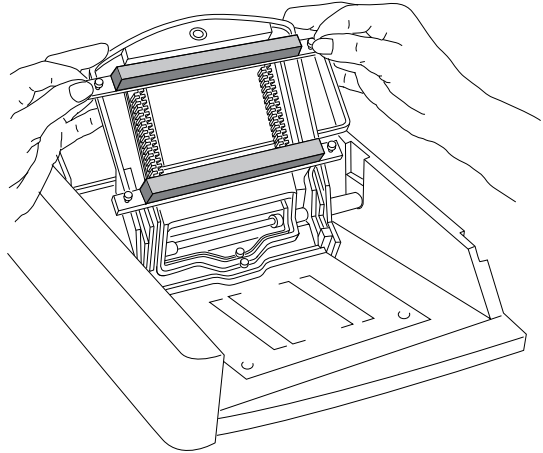


Figure 3

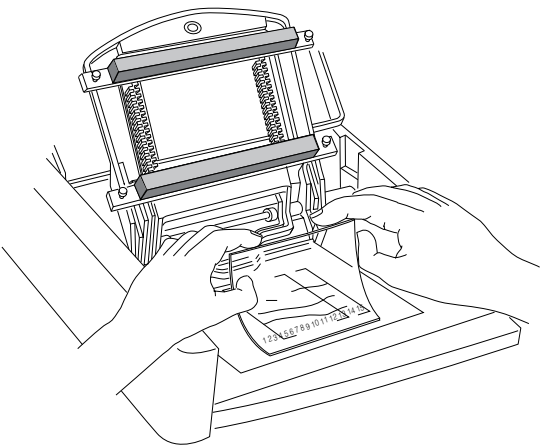


Figure 4

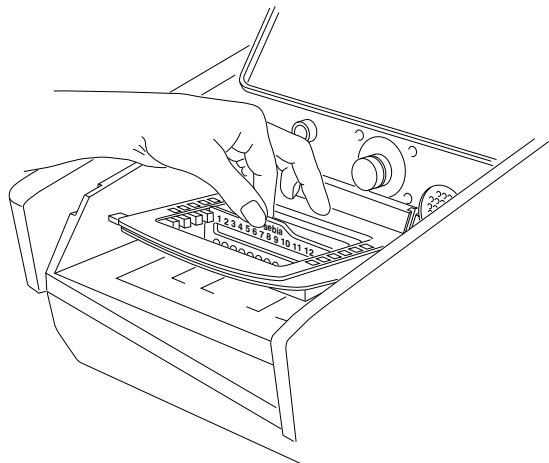
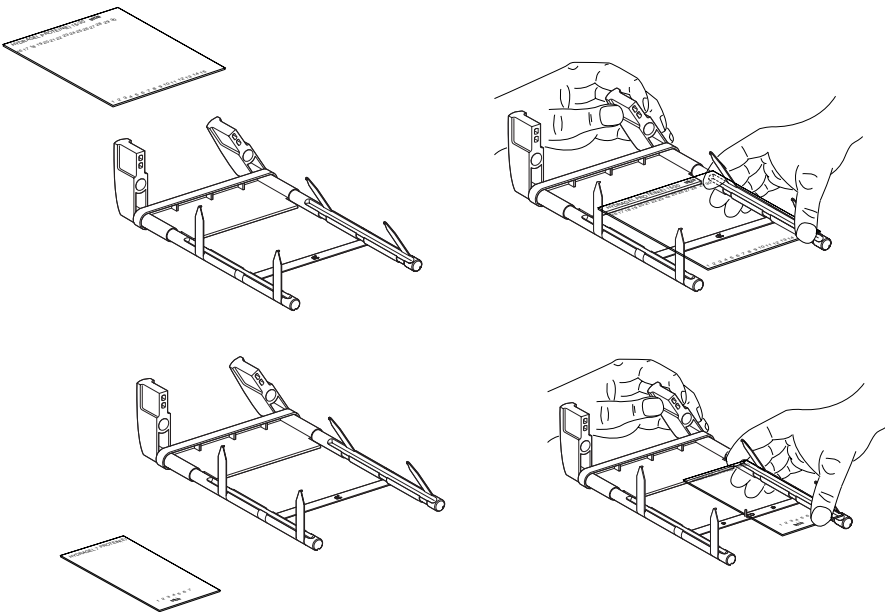


Figure 5



sebia

Parc Technologique Léonard de Vinci
Rue Léonard de Vinci
CP 8010 Lisses
91008 EVRY CEDEX - FRANCE



sebia Benelux s.a. / n.v.

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