Labonovum
Innovative Laboratory Medicine

SER COL STORAGE

1. INTENDED USE

Ser-Col storage can be used to store 200-300 µL of blood/ serum/plasma from a tube. Blood collected with the Ser-Col device is separated in blood cells and plasma within the device. After drying the blood in the Ser-Col device for at least one hour at RT, the Ser-Col can be stored at -20°C (see figure 1).

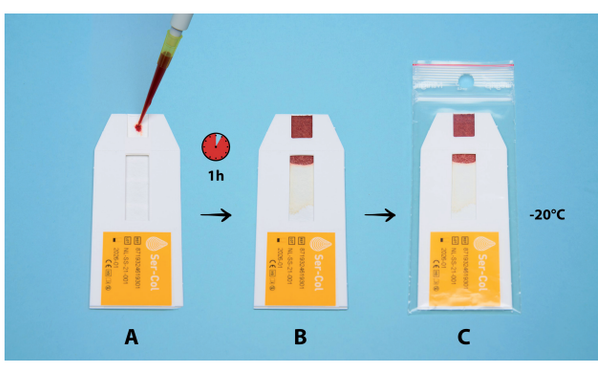

Figure 1: Use and storage of Ser-Col. (A) transfer 200-300 µL blood, plasma or serum on the Ser-Col, (B) drying at RT for at least 1 hour and (C) place the Ser-Col in a bag before storage at -20°C.

2. SER-COL ELUTION BUFFER PREPARATION

Prepare the Ser-Col elution buffer by dissolving the elution buffer pill in 300 mL demineralized water. The Ser-Col elution buffer pill must be completely dissolved, no residue must be visible. Store aliquots of Ser-Col elution buffer at –20°C.

3. PRINCIPLES OF ELUTION PROCEDURE

See next page

4. EXPIRATION

Refer to labels of individual Ser-Cols for expiration date.

5. SPECIMEN COLLECTION AND HANDLING

Recommended specimen types: capillary blood collected from a fingerstick. Blood collected by venipuncture can be transferred to Ser-Col for storage purposes.

6. CALCULATION OF DILUTION FACTOR

Serum in the Ser-Col device is dissolved in elution buffer and is therefore diluted. To correct the concentration of the analytes determined in the eluted serum, the following formula can be used to calculate the dilution factor:

$$\text{Dilutionfactor Na} = \frac{140\ \text{mmol/L}}{[\text{Na}]\ \text{eluate} - [\text{Na}]\ \text{elutionbuffer}}$$

$$\text{Dilutionfactor Cl} = \frac{102\ \text{mmol/L}}{[\text{Cl}]\ \text{eluate} - [\text{Cl}]\ \text{elutionbuffer}}$$

$$\text{Mean Dilutionfactor} = \frac{\text{Dilutionfactor Na} + \text{Dilutionfactor Cl}}{2}$$

Figure 2: Formula for calculating the dilution factor

The calculation of the dilution factor is based on the assumption that the average sodium concentration in bloodis 140 mmol/L and the average chloride concentration is 102 mmol/L. By measuring the sodium and chloride concentration in both the eluate and elution buffer the dilution factor can be calculated.

7. ANALYTICAL VALIDATION OF SER-COL

Regression analysis was investigated by comparing the results of total protein, albumin, IgA, IgG and IgM tested in blood collected by conventional venipuncture and blood from a fingerstick collected with Ser-Col. The results are summarized in table 1.

Test	R	Slope	Intercept	Bias	n
Total Protein	0.957	0.806	-3.058	-15.581	29
Albumin	0.965	0.852	-2.140	-7.342	29
IgA	0.997	0.742	0.029	-0.676	29
IgG	0.987	0.736	0.053	-2.677	29
IgM	0.999	0.892	0.013	-0.177	29

Table 1: Regression analysis results of Ser-Col compared to venipuncture.

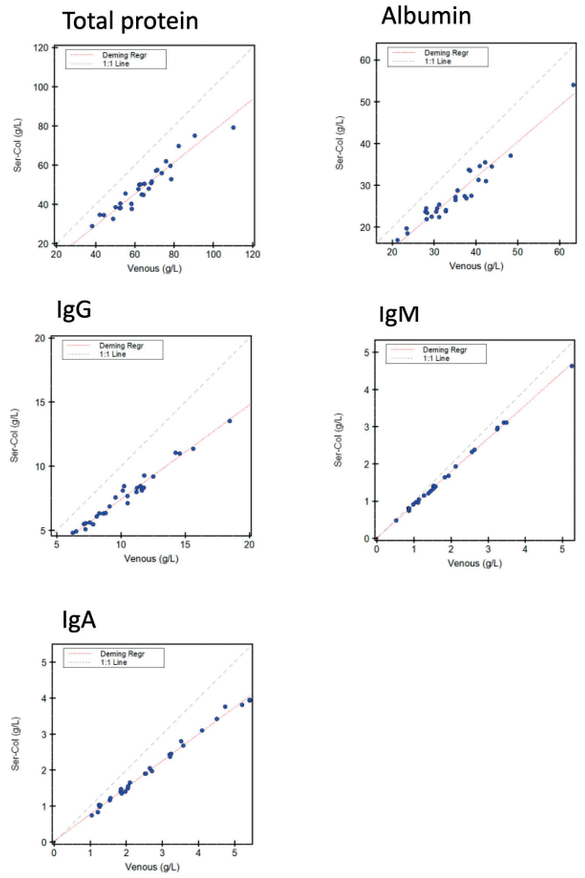

Figure 3: Regression analysis plots of blood analytes in Ser-Col compared to venipuncture.

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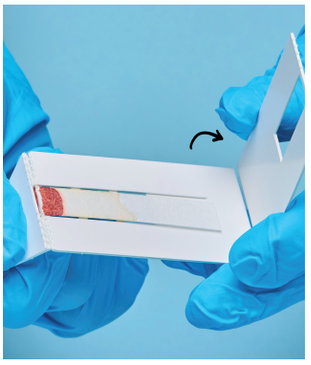
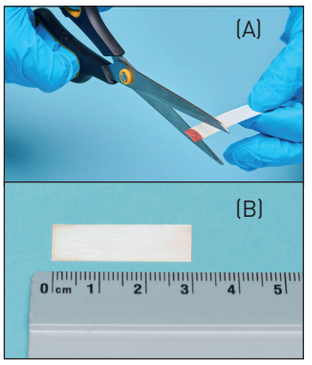
Ser-Col Storage Elution Procedure

1. Ser-Col arrives at the lab

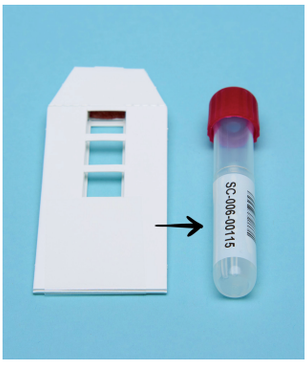
2. Break the top of the Ser-Col at the perforation line



3. Open the Ser-Col and remove the bloodstrip



4. separate the serum part from the bloodcell part by a pair scissors (A) and measure the length of the serum part (B)



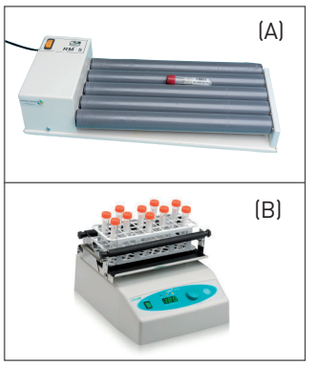
5. Transfer the barcode from Ser-Col to the tube

6. Place the serum part in the tube

7. Push the serum part to the bottom of the tube with the stamper

8. Add 100-150 µl elution buffer/cm serum paper, depending on the LOD of the analysis.

9. Close the tube with the screw cap



10. Incubate for at least 1 hour on a tube roller (A) or tube shaker (B)

11. Push the Ser-Col separator to the bottom of the tube

12. Close the tube with the separator cap until analysis

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