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TECHNICAL NOTE

Method Comparison of Two Test Kits  
for the Determination of Elastase/ $\alpha_1$ -Proteinase-Inhibitor Complex

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**Summary:** A method comparison of the 4 h-elastase/ $\alpha_1$ -proteinase-inhibitor test kit with a newly developed 2 h-version was performed. The within-run and between-days coefficients of variation as well as the recovery of the assigned values were satisfactory for both test kits. Good agreement was found between the 2 h- and 4 h-test kits using specimens from 160 patients. In conclusion, the 2 h-test kit can be used as an alternative for the determination of elastase/ $\alpha_1$ -proteinase-inhibitor complex.

**Introduction**

Elastase/ $\alpha_1$ -proteinase-inhibitor complex is a marker for inflammatory disease activity in patients with rheumatic diseases (1), active *Crohn* disease (2), postoperative infections after major abdominal surgery (3) and multiple trauma (4) as well as for monitoring therapy (5). The present study was undertaken to verify the performance criteria of the 2 h-test kit versus the 4 h-test kit.

**Material and Methods**

**Origin of specimen**

K<sub>2</sub>-EDTA blood samples (3 ml) were drawn randomly from 160 hospitalized patients (male/female ratio: 78/82, age range: 3–80 years) and immediately centrifuged at 150 g for 10 min at 20 °C. The plasma supernatants were stored at –30 °C until use.

**2 h- and 4 h-test kits of elastase/ $\alpha_1$ -proteinase-inhibitor**

The elastase/ $\alpha_1$ -proteinase-inhibitor test kits (2 h-test: lot. No. F0; 4 h-test: No. 75366927) were kindly supplied by Dr. S. Neumann, Biochemische Forschung Merck, D-6100 Darmstadt (6). The 2 h-test kit differed from the 4 h-test kit only in the shorter incubation times of antibody-alkaline-phosphatase-conjugate (30 min) and substrate (30 min). To assess the linearity of the 2 h-test kit version, a plasma sample from one patient (elastase/ $\alpha_1$ -proteinase-inhibitor concentration: 1746 µg/l) was

Tab. 1. Imprecision within-run, between-days and accuracy for the 2 h- and 4 h-test kits of elastase/ $\alpha_1$ -proteinase-inhibitor-enzyme-linked-immunosorbent assay (CV = coefficient of variation)

	Imprecision within run					Imprecision between days					Accuracy	
	Concentration $\bar{x}$ (µg/l)	Dilution	Sample volume (ml)	Test series (n)	CV (%)	Concentration $\bar{x}$ (µg/l)	Dilution	Sample volume (ml)	Test series (n)	CV (%)	Found concentration (µg/l)	Assigned value (µg/l)
2 h- version	178.7	1:51	0.5	10	5.8	86.1	1:51	0.5	10	9.1	296.0	305.0
	353.6	1:51	0.5	10	4.6						300.3	
											303.7	
											308.9	
											309.4	
4 h- version	176.0	1:51	0.5	10	5.3	80.8	1:51	0.5	10	8.7	139.0	139.0
	362.9	1:51	0.5	10	4.0						141.0	
											144.0	

diluted with sample diluent (phosphate, 0.01 mol/l, pH 7.5; NaCl, 0.15 mol/l; EDTA, 20 mmol/l; bovine serum albumin, 1 g/l) (6) in a ratio from 1/100 to 1/1500.

#### Statistical analysis

For evaluation of results, imprecision within-run and between-days, coefficient of correlation ( $r$ ), standard principle component analysis and paired t-test ( $p < 0.025$ ) were performed as described elsewhere (7–9).

#### Results and Discussion

Table 1 shows the condensed data for the imprecision of both test kits. From these data it can be deduced that the highest within-run and between-days coefficients of variation for the 2 h-/4 h-test kits were 5.8%/5.3% and 9.1%/8.7% respectively. The recovery data of the assigned values of control materials varied within the  $\pm 3.5\%$  range for both test kits (tab. 1). The range of linearity for the 2 h-test kit version was between 1.2  $\mu\text{g/l}$  and 9.9  $\mu\text{g/l}$ .

The detection limit, defined as the mean absorbance of the reagent blank plus three times its standard deviation, was about 1.0  $\mu\text{g/l}$ . Because of the wide measuring range it was necessary to repeat analyses only in exceptional cases. The comparison of elastase/ $\alpha_1$ -proteinase-inhibitor in plasma samples from 160 patients showed a good agreement ( $r = 0.97$ ) between both test kits (fig. 1).

The findings suggest that the 2 h-elastase/ $\alpha_1$ -proteinase-inhibitor test kit is able to replace the 4 h-test kit version.

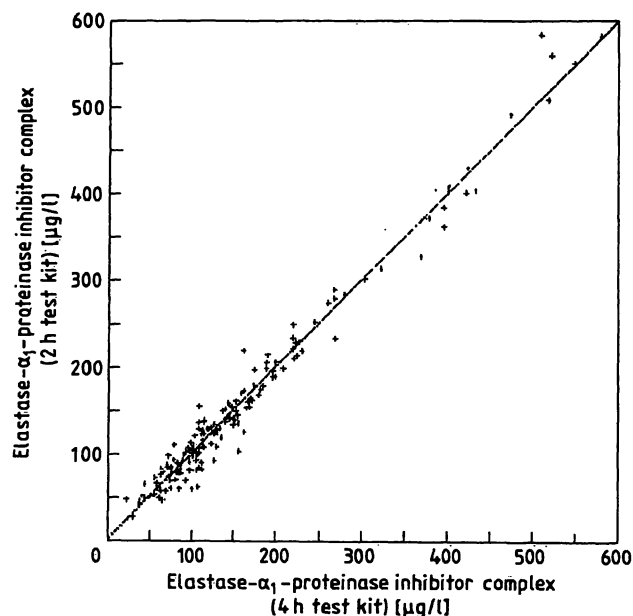


Fig. 1. Correlation between the elastase/ $\alpha_1$ -proteinase-inhibitor concentrations using a 2 h- and 4 h-test kit version.

Standard principle component analysis:

$$y = 1.01x - 0.55$$

Regression line according to *Passing & Bablok*:

$$y = 0.99x + 2.45$$

Coefficient of correlation:

$$r = 0.97 \quad n = 160$$

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