

EVALUATION OF A NEW KONELAB MYOGLOBIN ASSAY

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INTRODUCTION

Myoglobin is an oxygen-binding heme protein present in cardiac and skeletal muscle. In case of a damage of these muscles, as in the case of an acute myocardial infarction (AMI) or muscle trauma, myoglobin is released in the blood circulation. The determination of myoglobin represents a rapid and sensitive laboratory test which complements the ECG during the early phase of AMI.

The purpose of this study was to evaluate the performance of a new Konelab Myoglobin system assay (Thermo Electron Corp, Vantaa, Finland), which is based on the particle enhanced immunoturbidimetry and end-point measurement at 700 nm.

The performance characteristics of the assay were analyzed by Konelab 20, 30 and 60 analyzers. The Myoglobin levels in the serum and plasma measured by Konelab Myoglobin assay were compared with those analyzed by Hitachi 917 using DiaSys (DiaSys Diagnostic Systems GmbH, Holzheim, Germany) Myoglobin test kit.

The precision study was performed using the NCCLS Document EP5-A as a guideline, during 10 days including 40 measurements. Within run imprecision (CV %) was 2.4%, and 1.1% at the level of 91.3 and 140 µg/l, respectively. Total imprecision (CV %) was 6.4% and 4.7% at the level of 91.3 and 140 µg/l, respectively.

The observed measurement range was from 40 to 520 µg/l and up to 2600 µg/l with automatic dilution. Detection limit of the assay was 12 µg/l. Correlation coefficient between the Konelab and comparison method was 1.000 (n=91) and linear regression curve $y=1.08x-7.0$. The new Konelab Myoglobin test showed a good precision and measurement range. The measured patient samples were in good correlation with the comparison method.

MATERIALS AND METHODS

Instruments

Konelab 20, 30 and 60, Thermo Electron Oy, Vantaa, Finland
Hitachi 917, Hitachi Ltd, Tokyo, Japan

Application

Konelab MYOGLOBIN application consists of two reagents on-board, end-point measurement with sample blank and nonlinear calibration curve used for result calculation.

The used dispensing volumes and incubations:

MYO Reagent A (Buffer), 106 µl; sample 10 µl; incubation in 37 °C, 300 s;
MYO Reagent B (Latex), 77 µl; incubation 600 s; end-point measurement at 700 nm.

Reagents, controls and samples

Reagents

MYOGLOBIN, Thermo Electron, Cat no 981847

Myoglobin Calibration Set, Thermo Electron, Cat no 981849

Myoglobin FS, DiaSys Diagnostic Systems GmbH, Cat no 1 7039 99 10 730

TrueCal Myoglobin Calibrator set, DiaSys Diagnostic Systems GmbH, Cat no 1 7039 99 10 058

Controls

Myoglobin Control, Thermo Electron, Cat no 981880

Myoglobin Control High, Thermo Electron, Cat no 981881

Samples

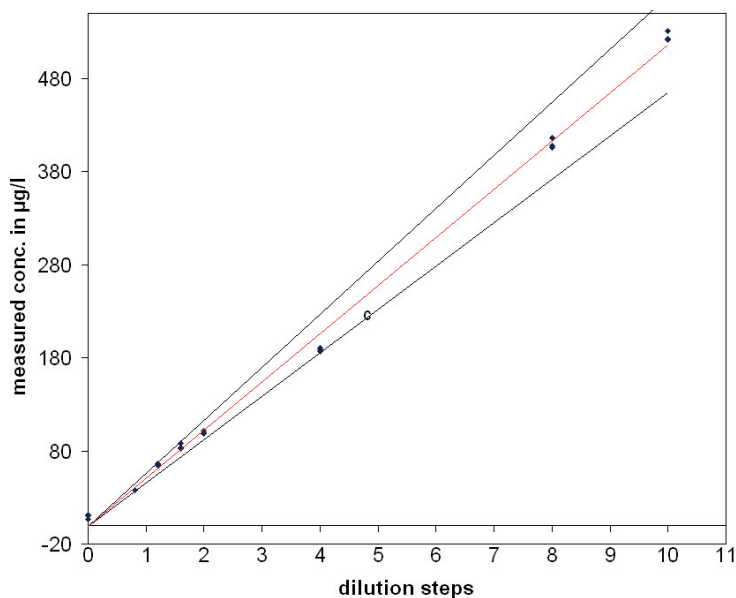
The used patient samples in correlation study were serum samples.

RESULTS

Measuring range

Konelab MYOGLOBIN method has measurement range from 40 to 520 µg/l. Extended range after automatic secondary dilution is up to 2600 µg/l.

Fig 1. Linearity study.



Detection and determination limit

The detection limit is measured repeating zero sample 20 times and calculating three standard deviation from the observed mean value. For Konelab MYOGLOBIN test the detection limit is 12 µg/l. Determination limit is the lowest concentration that can be measured quantitatively. For Konelab MYOGLOBIN test the determination limit is 40 µg/l.

Imprecision

Table 1. Imprecision of Konelab MYOGLOBIN on low and high level of samples.

	Mean 91.32 U/l		Mean 140 U/l	
	SD	CV%	SD	CV%
Within run	2.20	2.4	1.6	1.1
Between day	4.3	4.7	4.9	3.5
Total	5.8	6.4	6.6	4.8

A precision study was performed according to the guidelines in the NCCLS Document EP5-A during 20 days with the number of measurements being n = 80.

Method comparison

A comparison study was performed using the NCCLS Document EP9-A as a guideline and the Myoglobin FS method from DiaSys on Hitachi 917 as a reference.

Linear regression (result unit µg/l):

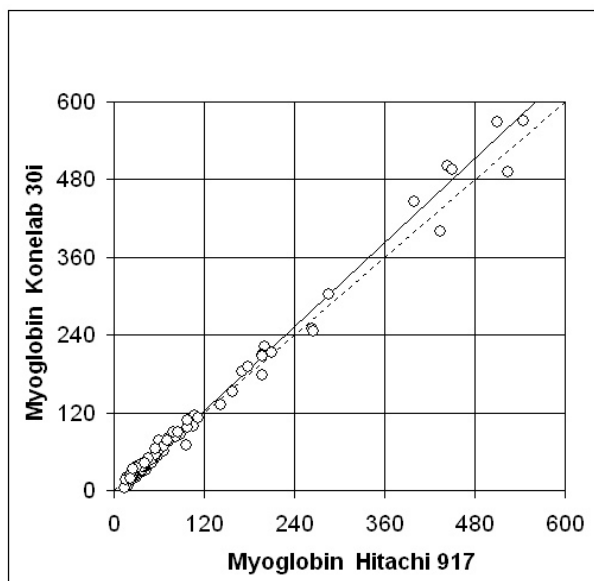
$$Y = 1.08 x - 7,0$$

$$R = 0.995$$

$$N = 91$$

The sample concentrations were between 40 and 500 µg/l.

Figure 2. Method comparison study



CONCLUSIONS

Precision of the evaluated Myoglobin method proved to be good on both low and high level. Correlation study between Konelab Myoglobin and Myoglobin test from DiaSys on Hitachi 917 showed very good correlation. We conclude that the performance characteristics of the new Konelab Myoglobin test are excellent. It is an easy to use and cost efficient assay on fully automated Konelab analyzer.

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