

Evaluation of a new Konelab LDH IFCC assay

Katajamäki T. (1), Mattila K. (1), Keurulainen M. (2), Lampinen H. (2)

- 1) Turku University Hospital, Turku, Finland
- 2) Thermo Clinical LabSystems, Vantaa, Finland

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Abstract

Lactate dehydrogenase (LDH) is a hydrogen transfer enzyme catalyzing the oxidation of L-lactate to pyruvate with the mediation of NAD⁺ as hydrogen acceptor. The reaction is reversible and the equilibrium strongly on the reversed reaction, the reduction of pyruvate to lactate. The reaction started from pyruvate, Scandinavian recommendation (SCE) or NADH The German Society for Clinical Chemistry recommendation (DGKC), have been widely used in clinical laboratories. The new measurement for LDH recommended by IFCC is the oxidation from Lactate to Pyruvate. LDH catalyzes the oxidation of lactate to pyruvate reducing nicotinamide adenine dinucleotide (NAD⁺) to NADH. The activity of LDH can be determined by the rate of increase in absorbance at 340 nm. In this study we evaluated the performance of new Konelab assay kit for LDH IFCC, and especially the correlation to the existing Konelab SCE and Roche DGKC methods. The within run variation coefficient for low level was 1.4%, for medium 0.4% and for high 1.0%. The respective total variations were 3,6%, 2.8% and 2.7%. The correlation to the Konelab SCE method was $y=0.52x+15.0$, $r=0.995$, $n=52$ and to Hitachi/Roche DGKC method $y=0.54x-10.9$, $r=0.998$, $n=119$. The new Konelab LDH assay following IFCC recommendation is precise and reliable. The correlation coefficient between SCE or DGKC and IFCC is excellent. The average observed bias with patient samples is about 50% for both methods which have to be recognised by physicians.

Materials and methods

Instruments

Konelab 60i, Thermo Clinical LabSystems, Vantaa, Finland
Hitachi 917, Hitachi Ltd, Tokyo, Japan

Application

Konelab LDH (IFCC) application consists of two reagents on-board, kinetic measurement and theoretical factor used for result calculation. The used dispensing volumes and incubations: LDH Reagent 1, 100 µl; sample 6 µl; incubation in 37 °C, 300 s; LDH Reagent 2, 25 µl; incubation 180 s; kinetic measurement at 340 nm.

Reagents, controls and samples

Reagents

LDH (IFCC), Thermo Clinical LabSystems, Cat no 981782
LDH (SCE), Thermo Clinical LabSystems, Cat no 981383
LDH (DGKC) Optimized, Roche Diagnostics GmbH, Cat no 1876961

Controls

Nortrol, Thermo Clinical LabSystems, Cat no 981043
Abtrol, Thermo Clinical LabSystems, Cat no 981044
C.f.a.s. ; Calibrator for automated systems, Roche Diagnostics GmbH, Cat no 759350
Multi-enzyme Lin-Trol, Sigma, Cat no M2266
Zero dilution matrix, Sigma, Cat no L1401

Samples

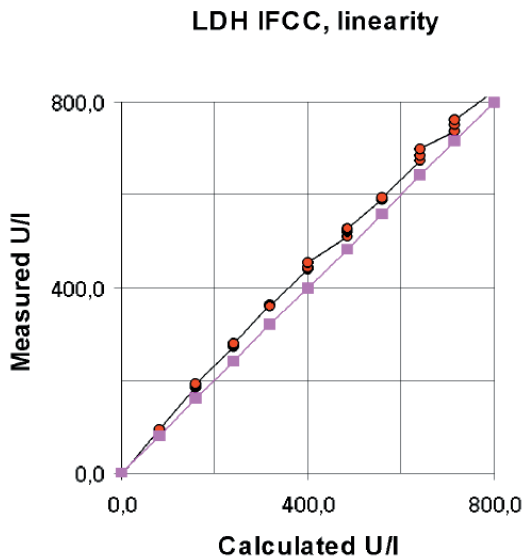
The used patient samples in correlation study were serum samples when running between IFCC and SCE and plasma samples collected in lithium heparin tubes when running between IFCC and DGKC. All patient samples were centrifuged properly and assayed as soon as possible or stored maximum for 1 day at +2...+8 °C.

Results

Measuring range

Konelab LDH (IFCC) method has linearity range from 10 to 600 U/l. Extended range after automatic secondary dilution is 10 – 3000 U/l.

Fig 1. Linearity study made by Lin-Trol Multi-enzyme control serum.



Determination limit

The determination limit is the lowest concentration that can be measured quantitatively. For Konelab LDH (IFCC) test the determination limit is 10 U/l.

Imprecision

Table 1. Imprecision of Konelab LDH (IFCC) on low, medium and high level of samples.

| | Mean 172 U/l | | Mean 240 U/l | | Mean 507 U/l | |
|-------------|--------------|-----|--------------|-----|--------------|-----|
| | SD | CV% | SD | CV% | SD | CV% |
| Within run | 2.4 | 1.4 | 0.9 | 0.4 | 5.3 | 1.0 |
| Between day | 5.6 | 3.1 | 6.4 | 2.6 | 13.1 | 2.5 |
| Total | 6.4 | 3.6 | 6.9 | 2.8 | 14.2 | 2.7 |

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 Konelab LDH SCE method as well as the Hitachi/Roche LDH DGKC method as a reference.

Fig 2. Method comparison between Konelab LDH (IFCC) and Konelab LDH (SCE) with serum samples.

$$Y = 0.52x + 15.0; R = 0.995; N = 52.$$

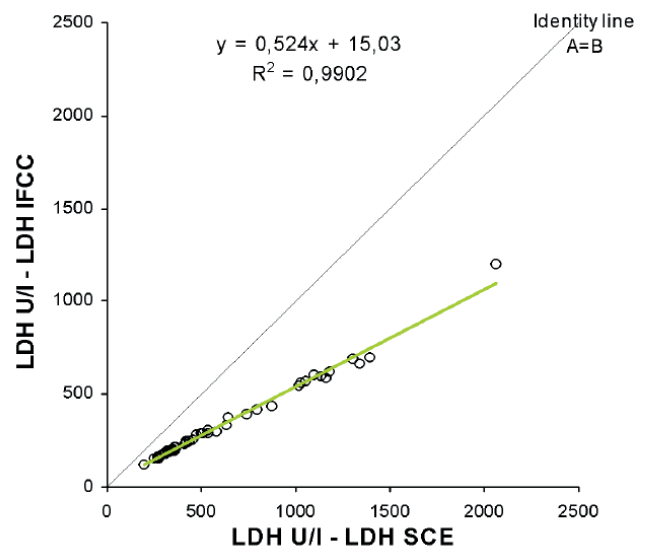


Fig 3. Difference (%) between Konelab LDH (IFCC) and Konelab LDH (SCE).

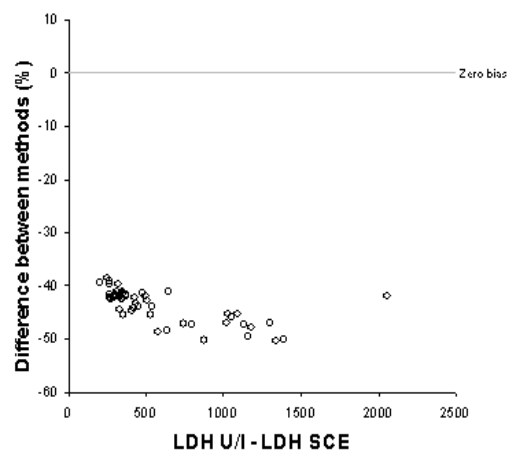


Fig 4. Method comparison between Konelab LDH (IFCC) and Hitachi/Roche LDH (DGKC) with plasma samples.

$$Y = 0.54x - 10.9; R = 0.998; N = 119.$$

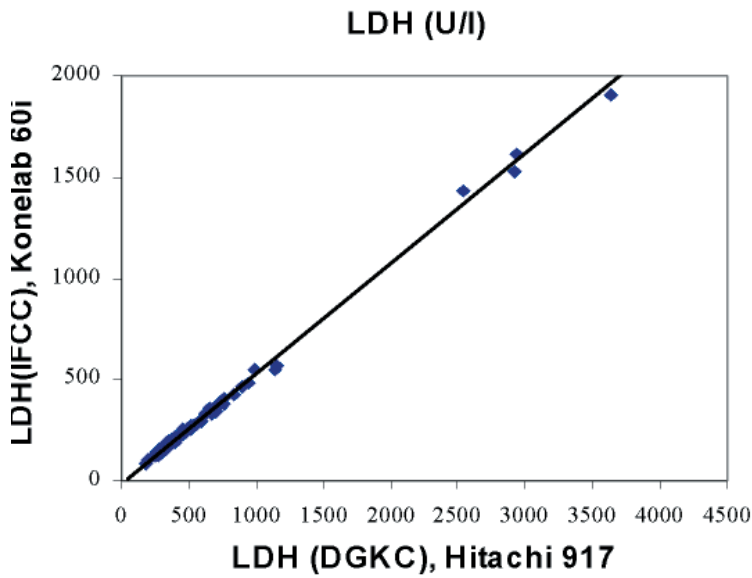
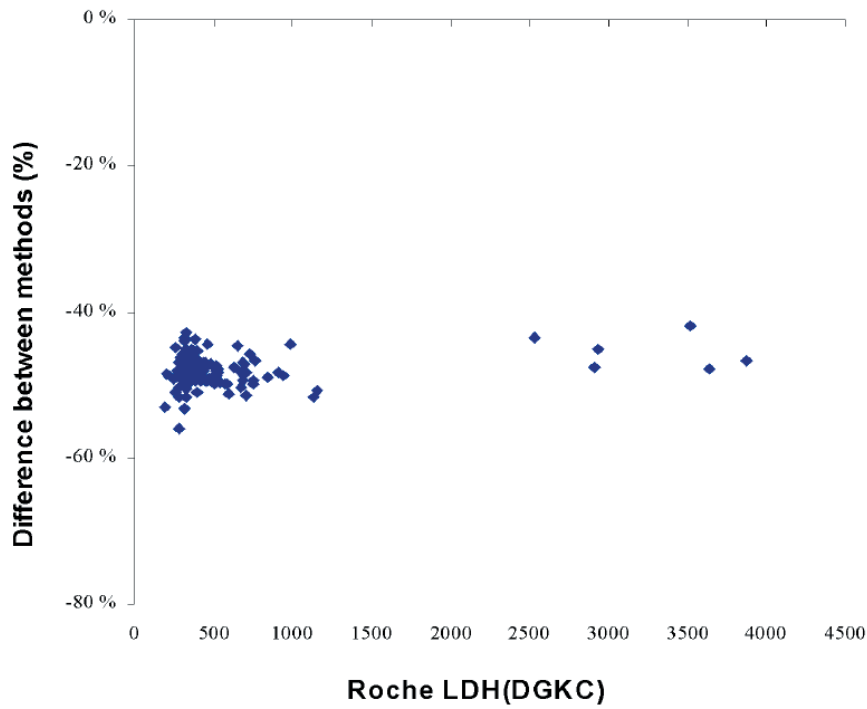


Fig 5. Difference (%) between Konelab LDH (IFCC) and Hitachi/Roche LDH (DGKC).



Conclusions

Precision of the evaluated LDH IFCC method proved to be excellent on low, medium and high level. Correlation between Konelab IFCC method and both of the comparison methods according to SCE or DGKC recommendations showed a good linear relationship with the expected bias known between IFCC and SCE or DGKC assays. The average observed bias with patient samples is about 50 % for both methods which have to be recognised by physicians.

We conclude that the performance characteristics of the Konelab LDH IFCC test are excellent. It is an easy to use and cost efficient LDH assay on fully automated Konelab analyzer.

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