

DEVELOPMENT AND EVALUATION OF A NEW KONELAB SOLUBLE TRANSFERRIN RECEPTOR (sTfR) ASSAY

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INTRODUCTION

Cellular iron uptake is mediated by transferrin receptor (TfR) which is a transmembrane receptor and present on virtually all mammalian cells. A soluble form of TfR, called soluble transferrin receptor (sTfR), can be found in serum. sTfR is reported to be a good marker for the diagnosis of iron deficiency. It is especially useful parameter to assess iron stores when iron metabolism is influenced by acute or chronic inflammatory state because sTfR concentration is not influenced by the acute phase response. Elevated sTfR concentrations have been also observed in various haematological disorders such as haemolytic anemia, polycythaemia and thalassaemia. Decreased sTfR levels have been found in e.g. chronic renal failure and aplastic anemia.

The purpose of this study was to develop and evaluate the performance of a new Konelab sTfR assay, which is based on the particle enhanced immunoturbidimetry, measurement being performed at 660 nm.

The measurement range of the sTfR assay is from 0.7 to 8 mg/l and up to 40 mg/l with automatic dilution. Within run imprecision (CV%) was below 2.5% and 3.5% at the level of 1.4 mg/l and 4.5 mg/l respectively.

The new Konelab sTfR kit includes sTfR reagent (lyophilized, microparticles coated with anti-human sTfR), sTfR Buffer (ready for use) and sTfR calibration set (ready for use).

For the method two level ready for use controls, sTfR Control and sTfR Control High, will be available.

The performance characteristics of the assay were analyzed by Konelab 20, 30 and 60 analyzers and showed good precision and correlation to other commercially available method.

MATERIALS AND METHODS

Instruments

Konelab 20, 30 and 60, Thermo Electron Oy, Vantaa, Finland

Hitachi 917, Hitachi Ltd, Tokyo, Japan

Application

Konelab sTfR application consists of two reagents on-board with additional diluent, two-point measurement and nonlinear calibration curve used for result calculation. The used dispensing volumes and incubations: sTfR Buffer, 125 µl; sample 10 µl; incubation in 37 °C, 200 s; sTfR Reagent, 10 µl; incubation 40 s; two-point measurement with time interval 180 seconds at 660 nm.

Reagents, controls and samples

Reagents

Soluble Transferrin Receptor (sTfR), Thermo Electron, Cat No 981853.

Calibrators are included in the assays kit.

IdeA sTfR IT, Cat No 67968 Orion Diagnostica.

Controls

sTfR Control, Thermo Electron, Cat No 981854

sTfR Control High, Thermo Electron, Cat No 981855

Samples

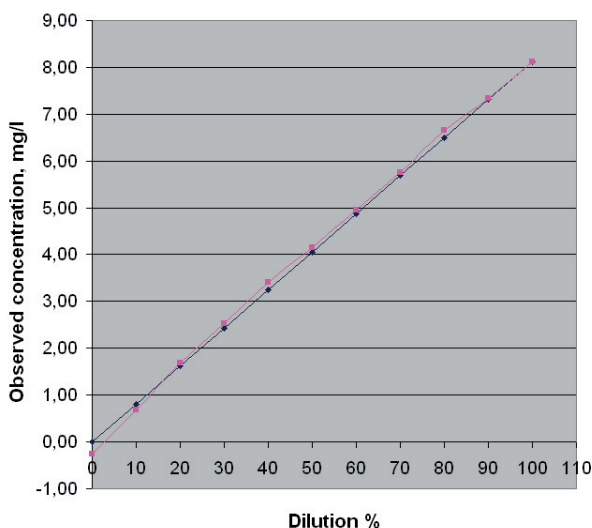
The used patient samples in both precision and correlation study were serum samples.

RESULTS

Measuring range

Konelab sTfR method has measurement range from 0.7 to 8.0 mg/l. Extended range after automatic secondary dilution is up to 40 mg/l.

Fig 1. Linearity of Konelab sTfR assay, measured by Konelab 20XT.



Determination limit

Determination limit is the lowest concentration that can be measured quantitatively. For Konelab sTfR test the determination limit is 0.7 mg/l.

Imprecision

Table 1. Imprecision of Konelab sTfR on low and high level of samples, measured on Konelab 30. Patient samples are used for within day, and control samples for between days study.

	Mean 1.54 mg/l		Mean 4.57 mg/l		Mean 1.39 mg/l		Mean 5.37 mg/l	
	SD	CV%	SD	CV%	SD	CV%	SD	CV%
Within day (n=12)	0.029	1.86	0.13	2.85				
Between days (n=20)					0.024	1.73	0.117	2.19

Method comparison

A comparison study was performed using the sTfR method from Orion Diagnostica on Hitachi 917 as a reference.

Linear regression (result unit mg/l):

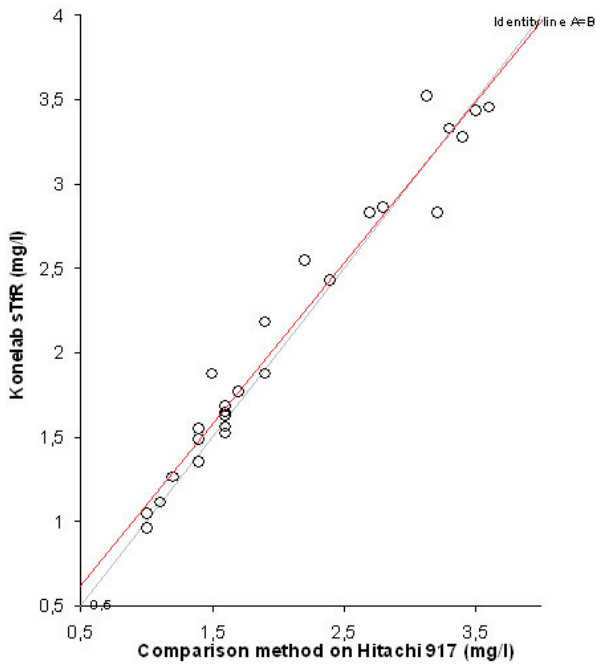
$$Y = 0.956 x + 0.14$$

$$R = 0.981$$

$$N = 26$$

The sample concentrations were between 1.0 and 3.6 mg/l.

Figure 2. Method comparison



CONCLUSIONS

Precision of the evaluated sTfR method proved to be good on both low and high level. Correlation study between Konelab sTfR and sTfR test from Orion Diagnostica on Hitachi 917 showed very good correlation.

We conclude that the performance characteristics of the new Konelab sTfR test are excellent. It is an easy to use, stable and cost efficient new marker for the diagnosis of iron deficiency on fully automated Konelab analyzer.

Figure 3. Difference (%) in method comparison study

