READ HIGHLIGHTED CHANGES

quantex sTfR (II)

3000-2334

1 x 13 ml sTfR (II) R1 (Buffer)
1 x 6 ml sTfR (II) R2 (Reagent)

Intended use

The reagents **quantex sTfR (II)** are intended for the quantitative determination of soluble transferrin receptor (sTfR) in human serum or plasma using the ILab™ Clinical Chemistry Systems. Check with your distributor or with the Technical Department of BIOKIT, S.A. for other available applications. Refer to the Clinical Chemistry publication "Effects of Disease on Clinical Laboratory Tests"[1] for a summary of causes of increased sTfR concentration.

Summary/Principle

Transferrin receptor (TfR) is a cell membrane glycoprotein with a molecular mass of 190 kDa. It consists of two identical subunits linked with disulfide bridges. Both subunits can be separated by proteolysis giving a soluble form of TfR of 85 kDa. The concentration of soluble transferrin receptor (sTfR) in serum is proportional to the concentration of the TfR membrane associated.

Cellular iron uptake is mediated by TfR. TfR binds plasma diferric transferrin and internalizes the TfR-transferrin complex, where transferrin provides its iron to the cytosol. The receptor-bound transferrin recycles to the cell surface and is able to bind another diferric transferrin.

The prime determinants of sTfR concentration are cellular iron requirements and the erythrocyte proliferation rate. The measurement of sTfR has been introduced as a powerful tool for the diagnosis of iron deficiency in a variety of clinical situations. Basically, the concentration of serum sTfR increases in iron deficiency anemia and in conditions of high turnover erythropoiesis (i.e. hemolytic anemia). Decreased concentrations of sTfR have been detected in aplastic anemia and chronic renal failure.[2]

The sTfR concentration has also been shown to be a more sensitive and less variable index of iron status than the more conventional serum iron, transferrin and total iron-binding capacity.[2]

The **quantex sTfR (II)** reagent is a suspension of polystyrene latex particles of uniform size coated with monoclonal antibodies anti-human sTfR. When a sample containing sTfR is mixed with the reagent, a clear agglutination occurs, which can be measured by turbidimetry.[3] Results are expressed in mg/l or nmol/l of sTfR.

Reagents

- sTfR (II) R1 (Buffer):
  Tris buffer 20 mM pH 8.2. Contains < 0.1% sodium azide.
- sTfR (II) R2 (Reagent):
  Suspension of polystyrene latex particles coated with monoclonal antibodies anti-human sTfR in a buffer.

Precautions

The **quantex** reagents are intended for IN VITRO diagnostic use.

For professional use only.

Sodium azide may react with lead or copper pipes and plumbing creating highly explosive metal azides. Flush drains with water thoroughly after disposing of the remains of reagents.

Because no test method can offer complete assurance of the absence of infectious agents, this product should be handled with caution.[4]

Dispose all used materials in a suitable biohazardous waste container.

Reagent preparation

- sTfR (II) R1 (Buffer) : Ready to use. Place container in reagent tray.
- sTfR (II) R2 (Reagent): Ready to use. Invert gently to mix well before first use. Avoid foam formation. Place container in reagent tray.

Reagent storage and stability

Reagents from unopened vials are stable until the expiration date shown on the vial when stored at 2-8°C. Do not freeze.

For optimal stability remove reagents from the system and store them at 2-8°C in the original vial securely closed. Once opened the vials, the reagents are stable for 30 days on-board the instrument.

Samples

Use fresh serum or plasma (Li-heparin). Other anticoagulants should be evaluated before use. Samples can be stored at 2-8°C for 7 days. For longer periods, samples should be frozen (-20°C). Avoid repeated freezing and thawing. Homogenize the samples before analysis.

Calibration
Use **quantex sTfR (II) standard multipoint** REF 3000-2338. The concentrations in mg/l and nmol/l are indicated in the insert data sheet. Recalibrate every 14 days, when a new lot of reagents is used, when control recovery falls out of the expected range or when adjustments are made to the instrument.

Quality control
It is recommended to use two levels of controls such as **quantex sTfR (II) control I/II** REF 3000-2339. Analyze controls at least once each day. Expected ranges can be found on the control insert sheet. The control values should be within the established range. Otherwise, corrective measures should be taken by the user. For identification and resolution of out-of-control situations, references such as Westgard *et al.* are recommended.[5]
Changes in typical reagent blank absorbance may indicate reagent deterioration.
If expected results are not obtained, do not use the kit.

Interferences
Interference up to 10% is observed from lipemia up to concentrations of 400 mg/dl of intralipis and for the rheumatoid factor up to 800 IU/ml. No significant interference from bilirubin up to concentrations of 20 mg/dl, hemoglobin up to concentrations of 500 mg/dl and ascorbic acid up to 3 mg/dl. For a comprehensive review of interfering substances, refer to the publication by Young et al.[6]

Reference range
The normal values for adults are about 0.90 - 2.30 mg/l (10.5 - 27.0 nmol/l).
These values may be exceeded up to 20 times in iron deficiency. Serum sTfR may also be elevated in hemolytic anemia, polycythaemia and thalasemia without iron deficiency.
In any case, these concentrations are only indicatives and each laboratory should establish its own reference range.

Precision

ILab 600	n Replicates/runs day/days	Mean (nmol/l)	CV (%)	n Replicates/runs day/days	Mean (nmol/l)	CV (%))
Within run	2/2/20	17.6	3.03	2/2/20	65.0	1.80
Total	2/2/20	17.6	3.02	2/2/20	65.0	2.62

Method comparison
Studies performed using serum samples:

Test reagent (y)	**quantex sTfR (II)**
Test instrument (y)	Olympus AU600
Comparison reagent (x)	ELISA assay
Slope	0.906
y intercept	1.972
Mean X (nmol/l)	24.8
Mean Y (nmol/l)	24.7
r	0.981
n	70

Linearity
ILab 600/650: 0.18 to 21.28 mg/l (2.1 to 250 nmol/l) without the automatic rerun capability.
0.18 to 212.8 mg/l (2.1 to 2500 nmol/l) with the automatic rerun capability.