quantex s TfR

CE

Kit Configuration

P/N 3000-2300	1 x 45 mL s TfR R1 1 x 4 mL s TfR R2

Reagent Preparation

P/N 3000-2300 s TfR R1: Ready to use.
s TfR R2: Reconstitute with 4 mL of NCCLS Type II water. Invert to mix before use. Transfer the reagent in an empty vial.
Place the bottles into reagent tray.

In Use Stability

RUBE R1: Until Expiration date.
RUBE R2: 60 days stored at 2-8°C
For optimal stability remove reagents from the system immediately after use, and store them at 2-8°C in the original vial securely closed.

Specimen

Serum.

Calibration

Use quantex sTfR standard multipoint Cat. No 3000-2301. The calibrator concentrations are indicated on the vial labels. Recalibrate every 30 days or when a new lot of reagent is used. A reagent balnk shoul be run daily before sample analysis.

Quality Control

Use quantex sTfR Control I/II Cat. No. 3000-2302.

Calculation of Analytical Results

The results concentration is automatically calculated by the instrument against the Calibration curve. For detailed description, refer to the Instrument settings and to the ILab 600/650 Operator's Manual.

Reference Interval

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

References / Literatur / Bibliografía / Bibliographie / Bibliografia /

See package insert enclosed in the kit

Performance Characteristics

Limitation/Interfering Substances

No significant interference from bilirubin up to concentrations of 20 mg/dL (342 μmol/L) hemoglobin up to concentrations of 500 mg/dL (0.3 mmol/L), triglycerides up to concentrations of 2000 mg/dL (23 mmol/L) and rheumatoid factor up to 500 IU/mL.
For a comprehensive review of interfering substances, refer to the publication by Young *et al*.[1]

Precision

	Samples/Runs	Mean (mg/L)	CV(%)	Mean (mg/L)	CV(%)
Within run	3/10	1.51	1.5	5.75	1.0
Total	3/10	1.51	1.7	5.75	3.0

Linearity

no rerun 0.1- 9.0 mg/L ; with rerun 0.1- 90 mg/L

Quantification Limit

0.1 mg/L

Instrumentation Laboratory
Instrumentation Laboratory SpA – V.le Monza 338 – 20128 Milano (Italy))
Instrumentation Laboratory Company - Lexington, MA 02421-3125 (USA)

quantex s TfR

CE

Instrument Settings

Photometric Test Parameters		***Serum***
Test No.		**
Test Name, Test Code		sTfR, sTfR
Sample Type		Serum
Reporting Unit, Decimal Points		mg/L, 2
Reation Cycle		Standard
Twin Analysis		OFF
Methodology Type, Measuring Point		End Point, 19/33
Photometric Methodology		1 Wavelength
Primary/Secondary Wavelenght		660
Sampling Conditions		
Sampling 1	Sample Vol.	15
	Sample/Diluent Vol.	0/0
Sampling 2	Sample Vol.	15
	Sample/Diluent Vol.	15/135
Sampling 3	Sample Vol.	30
	Sample/Diluent Vol.	0/0
Sampling 4		***
Diluent Code		Saline
Diluent Warning Limit		N/A
First Run		Sampling 1
Below/Above Normal Range		***
Panic L		***
Panic H		Sampling 2
Noise		***
Prozone		N/A
High!, ABS!		Sampling 2
Sample Volume Reduction		**
Reagent Volumes		
R1	Code	01871
	Rgt/Dil. Vol. Stirring	180/0, ON
	Low Vol. Warning Limit	***
	Stability (days)	**
R2	Code	01872
	Rgt/Dil. Vol. Stirring	30/10, ON
	Low Vol. Warning Limit	***
	Stability (days)	**

Ranges and Evaluation Criteria	***Serum***
Normal Range-Male	**
Normal Range-Female	**
Normal Range-Other	**
Valid Range	0 - 9.00
Hemolysis/Icterus/Lipemia Limit	***
Reaction Slope	Positive
Absorbance Limit	Above, 3200
Prozone Limit	N/A
Non Linear Limit	N/A
Slope/Intercept Correction	1/0
Qualitative Report	OFF
Calibration Conditions	
Calibration	6 Points, point to point, 2 Reps
Stability (days)	30
Calibrator Concentration	Std sTfR, * (0 Saline)
R-Blank Limit (mAbs)	2000
Cal. Reps Range (%)	***
Min Cal. Response (mAbs)	***
Cal. Factor Change (%)	***
M-Point Curve Fit (%)	***
Reagent Blank	ON
Auto R-Blank by Bottle	ON

*	Lot dependent
**	operator definable
***	optional
N/A	not applicable to this test

quantex s TfR

CE

Kit Configuration

P/N 3000-2300	1 x 45 mL s TfR R1 1 x 4 mL s TfR R2

Reagent Preparation

P/N 3000-2300 s TfR R1: Ready to use.
s TfR R2: Reconstitute with 4 mL of NCCLS Type II water. Invert to mix before use. Transfer the reagent in an empty vial.
Place the bottles into reagent tray.

In Use Stability

RUBE R1: Until Expiration date.
RUBE R2: 60 days stored at 2-8°C
For optimal stability remove reagents from the system immediately after use, and store them at 2-8°C in the original vial securely closed.

Specimen

Serum.

Calibration

Use quantex sTfR standard multipoint Cat. No 3000-2301. The calibrator concentrations are indicated on the vial labels. Recalibrate every 30 days or when a new lot of reagent is used. A reagent balnk shoul be run daily before sample analysis.

Quality Control

Use quantex sTfR Control I/II Cat. No. 3000-2302.

Calculation of Analytical Results

The results concentration is automatically calculated by the instrument against the Calibration curve. For detailed description, refer to the Instrument settings and to the ILab 600/650 Operator's Manual.

Reference Interval

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

References / Literatur / Bibliografía / Bibliographie / Bibliografia /

See package insert enclosed in the kit

Performance Characteristics

Limitation/Interfering Substances

No significant interference from bilirubin up to concentrations of 20 mg/dL (342 μmol/L) hemoglobin up to concentrations of 500 mg/dL (0.3 mmol/L), triglycerides up to concentrations of 2000 mg/dL (23 mmol/L) and rheumatoid factor up to 500 IU/mL.
For a comprehensive review of interfering substances, refer to the publication by Young *et al*.[1]

Precision

	Samples/Runs	Mean (mg/L)	CV(%)	Mean (mg/L)	CV(%)
Within run	3/10	1.51	1.5	5.75	1.0
Total	3/10	1.51	1.7	5.75	3.0

Linearity

no rerun 0.1- 9.0 mg/L ; with rerun 0.1- 90 mg/L

Quantification Limit

0.1 mg/L

Instrumentation Laboratory
Instrumentation Laboratory SpA – V.le Monza 338 – 20128 Milano (Italy))
Instrumentation Laboratory Company - Lexington, MA 02421-3125 (USA)