Development of a Human Soluble Transferrin Receptor ELISA

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Introduction

Soluble Transferrin receptor (sTfR) is a circulating, cleaved form of a membrane receptor protein. The serum concentration of sTfR reflects the amount of the cellular receptor (1,2). As Transferrin expression increases with decrease in iron concentrations, measurement of its soluble form can be a valuable indicator of iron deficiency. sTfR level is elevated in iron deficiency, but not in anemia associated with chronic disease (3-5). Therefore, measurement of sTfR is particularly useful, when trying to distinguish between iron deficient individuals and anemic individuals with chronic disease (6). DRG International, Inc. developed a sandwich ELISA assay, to measure sTfR levels

Assay characteristics

Sample Type	Serum and Plasma
Cross-Reactivity	No cross reactivity with human Transferrin, Albumin, and Ferritin
Interfering Substances: the assay is not affected by:	Hemoglobin (up to 4 mg/mL), Bilirubin (up to 0.25 mg/mL) and Triglyceride (up to 7.5 mg/mL) have no influence on the assay results
Lower Limit of Detection	0.01 µg/ml
Sample Volume Required	10 µl
Assay Dynamic Range	0.01 – 8.0 µg/ml
Expected Normal Values (1% - 99% Percentile)	Female: 1.15 - 6.04 µg/ml; Male: 0.98 - 5.62 µg/ml
sTfR Stability	Serum: 5 days at 2-8° C or 12 month at -20°C Plasma: 12 month at -20°C
Freeze – Thaw Stability	All types of samples should be frozen only once at -20° C prior to assay

Conclusions

- DRG International, Inc. developed a rapid sandwich ELISA assay, to measure sTfR levels in serum and plasma
- Our standard curve is set to World Health Organization reference material.
- The results correlate well to a commercially available reference Elisa.
- The advantages of the DRG sTfR ELISA are shorter total assay time, as well the option to measure both serum and plasma samples.
- DRG International, Inc. sTfR ELISA is currently available as RUO in the USA.

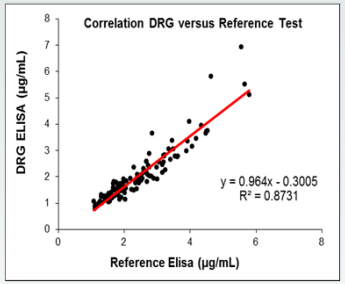
Intra Assay Precision

Sample	n	Mean (µg/mL)	CV (%)
1	20	1.0	5.0
2	20	2.3	5.8
3	20	4.7	5.4

Reference Ranges

General Population	N	5-95th Percentile (µg/mL)	Mean (µg/mL)	Median (µg/mL)
Females	49	0.81 - 2.96	1.47	1.29
Males	60	0.87 – 1.96	1.33	1.30

Correlation to a Reference Test



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Inter Assay Precision

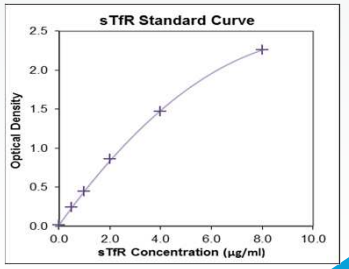
Sample	n	Mean (µg/mL)	CV (%)
1	20	1.6	6.9
2	20	3.7	11.6
3	20	3.2	11.9

Linearity and Spike Recovery

Linearity		Sample 1	Sample 2	Sample 3
Conc. µg/mL]		1.3	2.8	4.7
Average Recovery		93.0	103.7	105.9
Recovery [%]	from	86.3	96.1	92.5
	to	101.0	114.2	112.5

Spike Recovery		Sample 1	Sample 2	Sample 3
Concentration [µg/mL]		1.7	2.2	4.5
Average Recovery		105.5	108.3	95.9
Range of Recovery [%]	from	98.3	102.9	90.3
	to	109.8	112.6	98.7

Representative Standard Curve



Inter – Lot Precision

Sample	n	Mean (µg/mL)	Inter Lot CV (%)
1	18	1.03	11.0
2	18	5.7	8.5
3	18	2.5	9.4