

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k063766

B. Purpose for Submission:

New device

C. Measurand:

Transferrin

D. Type of Test:

Turbidimetric immunoassay (TIA)

E. Applicant:

Good Biotech Corp.

F. Proprietary and Established Names:

Good Biotech Corp. Transferrin TIA, Transferrin Calibrator Set and Transferrin Control-L, Control-M, and Control-H

G. Regulatory Information:

1. Regulation sections:

21 CFR 866.5880 Transferrin immunological test system

21 CFR 862.1150 Calibrator

21 CFR 862.1660 Quality control material (assayed and unassayed)

2. Classifications:

Class II (Device and calibrator set)

Class I (Controls)

3. Product codes:

DDG Transferrin, antigen, antiserum, control

JIT Calibrator, secondary

JJX Single (specified) analyte controls (assayed and unassayed)

4. Panel:

Immunology (82) (Device)

Chemistry (75) (Calibrator and control)

H. Intended Use:

1. Intended use(s):

Good Biotech, Corp. Transferrin test system is intended to be used for the quantitative determination of transferrin in human serum by turbidimetric immunoassay (TIA). Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders, such as iron deficiency anemia.

Good Biotech, Corp. Transferrin Calibrator Set is intended to be used with Transferrin TIA for the quantitative determination of transferrin in serum samples.

Good Biotech, Corp. Transferrin Controls are intended to be used as the assayed quality control material for transferrin analysis.

2. Indication(s) for use:
Same as the Intended Use
3. Special conditions for use statement(s):
Prescription use
4. Special instrument requirements:
The GBC Transferrin TIA assay is a ready to use reagent kit for chemistry analyzers capable of running an immunoturbidimetric assay. Performance was established by testing the reagents on the Hitachi 917 chemistry analyzer.

I. Device Description:

The GBC Transferrin reagent assay consists of Reagent 1 (R1), Reactive Tris Buffer solution and Reagent 2 (R2), a solution of duck anti-transferrin antibody. The assay is to be run in conjunction with the 6 levels of calibrators: 0, 50, 100, 200, 400 and 700 mg/dL, and 3 levels of controls: low, moderate, and high.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Roche Diagnostics Tina-quant Transferrin ver. 2; C.f.a.s. (Calibrators for automated systems) Protein Calibrators; and controls: Precinorm Protein and Precipath Protein
2. Predicate 510(k) number(s):
k012393
3. Comparison with predicate:

Similarities		
Item	New Device	Predicate
	GBC Transferrin	Roche Tina-quant V. 2 Transferrin
Indications for use	Aid in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders, such as iron deficiency anemia	Same
Methodology	Immunoturbidimetric	Same
Reference Interval	200-360 mg/dL	Same
	GBC Transferrin	Roche Tina-quant v. 2 Transferrin
Calibrators	Six levels: 0, 50, 100, 200, 400, 700 mg/dL traceable to CRM-470	Six levels [concentration factors based on lot assigned values] traceable to CRM-470

Differences		
Item	New Device	Predicate
	GBC Transferrin	Roche Tina-quant v. 2 Transferrin
Reagents	Reagent 1 (Tris buffer) Reagent 2 (duck anti-transferrin)	Reagent 1 (phosphate buffer, Reagent 2 (rabbit anti-transferrin)
Control materials	Low, medium and high	Normal and abnormal
Measuring Range	10-700 mg/dL	10-520 mg/dL
Reagent Stability	Unopened: 12 months (2°C - 10°C), Opened: 30 days (2°C - 10°C)	Unopened: up to the stated expiration (2°C - 8°C), Opened: 84 days refrigerated on the analyzer
Sample type	Serum	Serum and plasma
Sample volume	2 µL/test	3 µL/test

K. Standard/Guidance Document Referenced (if applicable):

Replacement Reagent and Instrument Family Policy; Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Shelf Life of Medical Devices, FOD Number 415; CLSI EP14-A Evaluation of Matrix Effects, Approved Guideline.

L. Test Principle:

When a sample containing transferrin is mixed with the duck anti-transferrin antibodies, the resulting agglutination based on the antigen-antibody reaction increases the turbidity of the sample. The value of the absorbance change at 505nm is proportional to the transferrin concentration of the sample and is recorded by the instrument. The transferrin concentration of the serum sample is determined by comparison to a standard curve. The calibration curve is generated by running 6 standards with known concentrations.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Three samples with three different levels of transferrin were prepared. For within run precision, each level was assayed 10 times.

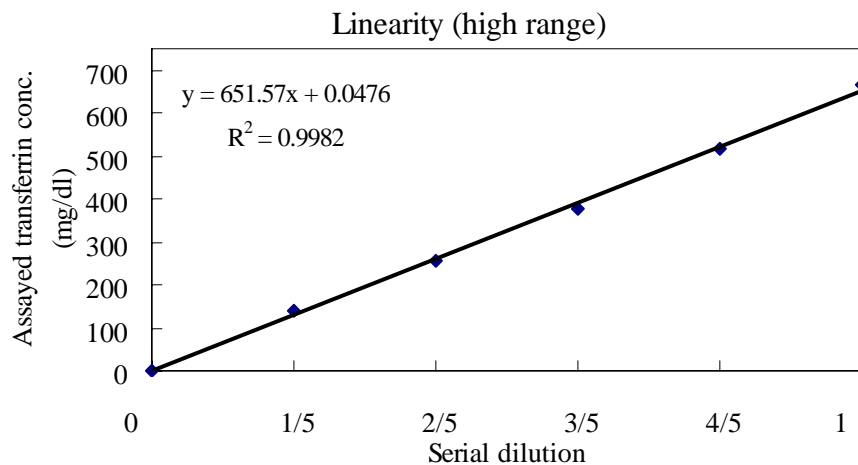
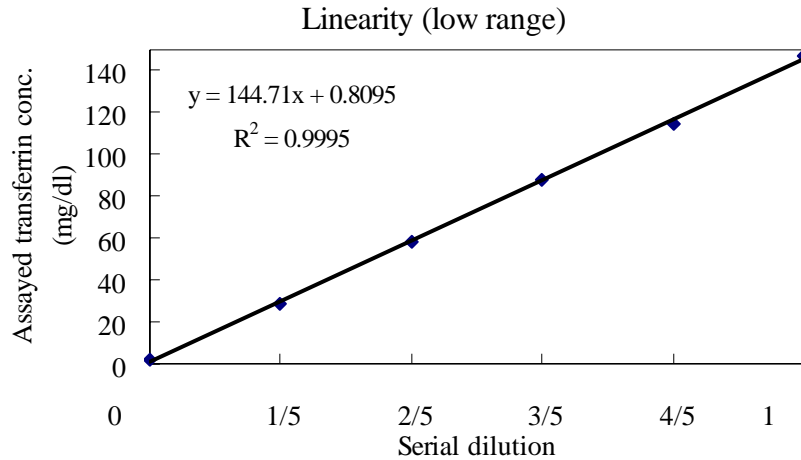
Within-run			
Replicates	10	10	10
Mean (mg/dL)	65.1	143	377.2
SD	0.57	2.87	6.53
CV %	0.87	2.01	1.73

Three samples measured in duplicate for 14 days were used to determine total precision.

Total			
Replicates	14	14	14
Mean (mg/dL)	107.5	210.91	452.07
SD	4.48	13.70	13.91
CV %	4.17	6.49	3.08

b. Linearity/assay reportable range:

Linearity: To cover the low and high ends of the measuring range, dilutions were made of the 100 and the 700 mg/dL calibrators. Linear regression analyses yielded R^2 values of 0.9995 and 0.9982 for the low range and the high range respectively.



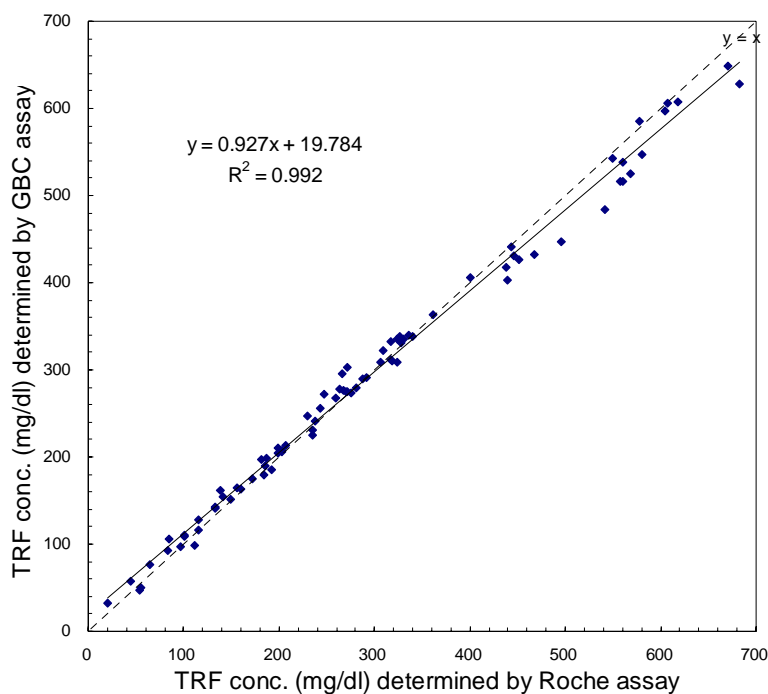
Prozone Effect: Diluted samples were prepared from the transferrin standard (2,000 mg/dL). No hook effect was observed for the tested specimens up to 2,000 mg/dL compared to the upper limit of the measuring range of 700 mg/dL.

The assay reportable range is from 10 to 700 mg/dL.

- c. Traceability, Stability, Expected values (controls, calibrators, or methods):
The recommended calibrators are standardized against the Certified Reference Material, CRM 470. The calibrators are assigned values of 0, 50, 100, 200, 400 and 700 mg/dL. The zero calibrator is stable for 19 months and calibrators 50 – 700 mg/mL are stable for 4 years unopened and at the recommended storage conditions of 2°C - 10°C.
- d. Detection Limit:
The detection limit was calculated as 2 SD above the mean response for the zero calibrator when assayed 20 times and was 0.4 mg/dL. The detection limit claim is 10 mg/dL.
- e. Analytical specificity:
Interference testing was performed by spiking different levels of each interferant into low and high transferrin serum samples. Percent recoveries ranged from 94.4 to 106.6%. The following concentrations of potential interferants were tested.

Potential interferant	Concentration
Bilirubin F	60 mg/dL
Bilirubin C	60 mg/dL
Chyle	2,940 FTU
RF	500 IU/mL
Hemoglobin	1,000 mg/dL

- f. Assay cut-off:
Not applicable
2. Comparison studies:
- a. *Method comparison with predicate device:*
Serum samples from 82 patients were tested with the new device and the predicate. Transferrin values for the samples ranged from 33.0 to 648.5 mg/dL. Linear Regression Analysis showed: $y = 0.927x + 19.784$ mg/dL with a correlation coefficient of $R^2 = 0.992$.



b. Matrix comparison:

Both assays use serum as the recommended matrix.

3. Clinical studies:

a. Clinical Sensitivity:

Not determined

b. Clinical specificity:

Not determined

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The recommended reference interval is 200-360 mg/dL (2.0-3.6 g/L). The interval may vary with the populations studied and individual laboratories should establish their own. The reference range is based on the published article, Dati F, et al. *Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/BCR/CAP reference material (CRM 470)*. Eur J Clin Chem Clin Biochem 1996; 34(6): 517-20.

N. Proposed Labeling:

The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.