

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

k032251

B. Analyte:

Total IgE

C. Type of Test:

Quantitative flow-cytometry

D. Applicant:

ImmuneTech Corporation

E. Proprietary and Established Names:

ImmuneTech™ Total IgE System

F. Regulatory Information:

1. Regulation section:
21 CFR §866.5510 Immunoglobulins A, G, M, D and E Immunological Test System
2. Classification:
Class II
3. Product Code:
DGC
4. Panel:
IM 82

G. Intended Use:

The ImmuneTech™ Total IgE System is a quantitative *in vitro* diagnostic test that measures total IgE in human serum. The ImmuneTech™ Total IgE System is intended for clinical laboratory use. The ImmuneTech Total IgE System may be run only on the Luminex™ 100 Integrated System.

1. Indication(s) for use:
The ImmuneTech™ Total IgE System is a quantitative *in vitro* diagnostic test system used as an aid in the clinical diagnosis of IgE mediated allergic disorders.
2. Special condition for use statement(s):
The device is for prescription use only.
3. Special instrument Requirements:
Luminex™ 100

H. Device Description:

The ImmuneTech Total IgE System consists of two components: ImmuneTech Total IgE System reagents and the ImmuneTech Total IgE System support software for the Luminex™ 100. A serum sample is mixed with anti-human IgE coupled microspheres. IgE in the sample will bind with the microspheres and form an anti-human IgE-IgE complex. This complex is sequentially incubated with biotin-labeled anti-human IgE antibody and fluorescent-labeled streptavidin reporter reagent. If IgE is present in the sample, the final sandwich complex of anti-human IgE-IgE-biotin-anti-IgE-

fluorescent-streptavidin will form. Measurement of the fluorescent signal from the final reaction complex is directly proportional to the concentration of total IgE in the sample. The Luminex 100 instrument with the ImmuneTech Total IgE System software provides a quantitative measurement of total IgE concentrations.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Pharmacia CAP System IgE FEIA
2. Predicate K number(s):
K991945
3. Comparison with predicate

Similarities		
Item	Device	Predicate
Indications for Use	Aid in the diagnosis of IgE mediated allergic disorders	Same
Sample type	Serum	Same
Calibration- WHO 2 nd International Reference Preparation 75/502	Six standards 2-2000 IU/mL	Same
Cut-off	>100 IU/mL	Same
Differences		
Item	Device	Predicate
Instrument	Luminex TM 100 IS Version 2.0	Pharmacia CAP System
Assay principle	Fluorescence (flow-cytometry)	Fluoroenzymeimmunoassay (FEIA) by fluorometer
Capture antibody	Anti-human IgE coupled to microspheres	Monoclonal anti-human IgE coupled to β -galactosidase
2 nd antibody	Biotinylated goat anti-human IgE	None
Label (reporter)	R-phycoerythrin-labeled streptavidin	4-methylumbelliferyl- β -D-galactoside

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

None referenced

K. Test Principle:

Fluorescent signal flow-cytometry

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. Precision/Reproducibility:
Within-run and between-run precision was determined by running 6 replicates of 3 levels (8, 129, and 858 IU/mL) over a period of 5 days using standard assay procedures. For within-run, the statistics were done on Mean Fluorescent Intensity (MFI) and %CV ranged from 1.4 to 2.4% for the high end sample, from 2.1-2.8% for the

medium sample and from 7.8 to 10.2% for the low end sample. The between run calculations showed the %CV was 3.6% for the high end sample, 5.3% for the medium sample and 9.9% for the low end sample with results ranging as follows: high average 858 IU/mL +/- 155 IU/mL, medium average 129.2 IU/mL +/- 7.3 IU/mL and the low average 7.6 IU/mL +/- 1.6 IU/mL.

Lot-to-lot studies using three manufacturing lots showed no difference observed between the three lots.

Summary:	Lot 1 to Lot 2	Lot 1 to Lot 3	Lot 2 to Lot 3
Correlation	0.9999	0.9999	0.9999
Slope	1.0652	1.0324	1.0316

b. Linearity/assay reportable range:

Recovery studies were performed using the following protocol: Three replicates of 3 serum samples were spiked with an equal volume of WHO International Standard 75/202. The expected concentrations were 23.9 IU/mL, 80.5 IU/mL, and 358.2 IU/mL. The samples were then run following standard assay procedures and the Total IgE values were interpolated from the curve. The percent recovery ranged from 88.2% to 106.2%.

c. Traceability (controls, calibrators, or method):

The standards used for calibration of the assay are standardized against the WHO 2nd International Reference Preparation 75/502 Serum IgE.

d. Detection limit:

Ten replicates of the blanking solution and 10 replicates of the lowest standard at 2 IU/mL were run following standard procedures. The analytical sensitivity (detection limit) studies characterized the lowest detectable quantity for the assay to be 2 IU/mL. The results showed that the 95% confidence level for 2 IU/mL is above the 95% confidence level for the blank solution.

e. Analytical specificity:

The polyclonal IgE antibody is commercially available and was obtained from a vendor. Characterization of the antibody showed no cross-reactivity to IgA, IgG or IgM.

f. Assay cut-off:

Serum from normal (n=21) and atopic (n=37) individuals were run following standard assay procedures. The results showed that normal individuals had total IgE levels from <2 to 81 IU/mL. The average total IgE value for non-atopic individuals was 19 IU/mL. Total IgE levels for atopic individuals ranged from 24 IU/mL to >2000 IU/mL, and 89% had levels >100 IU/mL (assay cut-off). The average total IgE value for the atopic population was >1000 IU/mL.

2. Comparison studies:

a. Method comparison with predicate device:

The comparison study included 117 serum samples with total IgE concentrations spread over the complete measuring range of the assay. Linear regression analysis for all samples yielded $y = 1.00x + 6.03$ with a correlation coefficient of 0.97. Further linear regression analysis of the samples with concentrations less than or equal to 50 IU/mL yielded $y = 1.10x - 1.94$ with a correlation coefficient of 0.94. The overall agreement (positive versus negative) was 98%.

b. Matrix comparison:

Not applicable.

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):

None

4. Clinical cut-off:

See assay cut-off.

5. Expected values/Reference range:

The expected value in the general population (non-atopic) is <100 IU/mL.

ImmuneTech studies showed 76% of non-atopic individuals were <25 IU/mL and 89% of atopic individuals were >100 IU/mL.

M. Conclusion:

The ImmuneTech™ Total IgE System is substantially equivalent to other devices regulated under 21 CFR §866.5510, product code DGC, Class II