

## 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

**A. 510(k) Number:**

K032254

**B. Analyte:**

Circulating Immune Complex

**C. Type of Test:**

Quantitative, ELISA

**D. Applicant:**

Immuno-Biological Laboratories (IBL)

**E. Proprietary and Established Names:**

IBL C1q-CIC EIA Test

**F. Regulatory Information:**

1. Regulation section:  
21CFR 866.5240
2. Classification:  
Complement C1q, Antigen, Antiserum, Control
3. Product Code:  
DAK
4. Panel:  
82 Immunology

**G. Intended Use:**

1. Indication(s) for use:  
The IBL-C1q-CIC test is a quantitative enzyme immunoassay for the *in vitro* diagnostic detection of circulating immune complex that bind C1q in serum. The measurement is performed as an aid in the diagnosis of various autoimmune and other CIC related diseases. Levels of these complexes are one indicator in a multi-factorial diagnostic regime.
2. Special condition for use statement(s):  
NA
3. Special instrument Requirements:  
Microtiter plate reader capable of reading absorbance at 450 nm (reference wavelength 600-650 nm)

**H. Device Description:**

The *in vitro* diagnostic reagent kit contains sufficient reagents for 96 determinations. The reagent consist of the following: 4 each of 3 x 8 antibody coated microwells, 1 vial of ready to use calibrator, 1 vial each of positive and negative controls, 1 vial of ready to use enzyme conjugate, 1 bottle each of ready to use TMB substrate solution and stop solution, 1 bottle of Wash buffer and Sample Diluent.

**I. Substantial Equivalence Information:**

1. Predicate device name(s):  
Scimedx C1q-CIC EIA
2. Predicate K number(s):

K833636

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Quantitative enzyme immunoassay for the in vitro diagnostic detection of C1q - circulating immune complex in human serum	Same
Sample Preparation	1:5 sample dilution	Same
Sample	Serum Only	Same
Component	Monoclonal anti-C1q Antibody coated microplate; Monoclonal Anti-Human IgG-HRP conjugate	Same
Reagent Volumes	100 uL Sample diluent 100 uL per well	Same
Differences		
Item	Device	Predicate
Cut-Off	Negative = <40 ug/mL Equiv. = 40-50 ug/mL Positive >50 ug/mL	Negative 0-34 ug/mL Positive >35 ug/mL
Standards and Controls	Liquid positive and negative controls and 1 level of standard	Lyophilized Positive and negative controls and 3 levels of standards
Incubation Time	30 min/15 min/ 15 min @ R.T.	60 min/ 60 min/ 30 min @32-37°C/R.T./R.T.

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

NA

**K. Test Principle:**

Solid phase enzyme-linked immunosorbent assay (ELISA) based on the sandwich principle. The wells are coated with an antibody, directed towards an epitope of an antigen molecule. The antigen of the sample is incubated in the coated well with enzyme conjugated second antibody (E-Ab), directed towards a different region of the antigen molecule. After the substrate reaction, the intensity of the developed color is proportional to the amount of the antigen. Results of samples can be determined directly using the standard curve.

**L. Performance Characteristics (if/when applicable):**1. Analytical performance:a. *Precision/Reproducibility:*

Studies were performed using 5 sera samples, 4 positives and 1 negative.

**Intra-Assay**

<b>N</b>	<b>mean</b>	<b>CV%</b>
8	6.7	10.7
8	64.0	9.2
8	81.9	7.6
8	86.0	8.7
8	114.9	8.1

**Inter-Assay**

<b>N</b>	<b>mean</b>	<b>CV%</b>
12	6.4	15.5
12	64.8	5.4
12	82.6	8.1
12	88.3	9.4
12	117.6	6.8

*b. Linearity/assay reportable range:*

No negative hook effect was observed through the OD range.

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

The value of the standards was determined against the predicate Scimedx kit. An optimal level of 100 ug/mL was used. New batch of standards were tested against previously approved batches. Controls were run in the assay, typically on three batches of plates, and assign an acceptable range based on the mean +/- 2 standard deviations.

*d. Detection limit:*

2 X SD of zero standard = 10 ug/mL

*e. Analytical specificity:*

Bilirubin up to 0.25 g/L, hemoglobin up to 10 g/L and EDTA up to 10 mM do not have a significant effect on the test results.

A statement regarding potential interferences (heterophile antibodies) is included in the Limitations Section.

*f. Assay cut-off:*

<40 ug/mL The grey zone was established on the basis of 2 and 3 SDs of the mean of the normal population. ROC analysis was also performed, with the summary results shown in the following table:

Assay Upper limit	100
Cut-off Increment	1
N <sup>0</sup> Negatives	44
N <sup>0</sup> Positives	16
Suggested Cut-off	38.0
Sensitivity	93.75%

Specificity	90.91%
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2. Comparison studies:a. *Method comparison with predicate device:*

IBL C1q-CIC	Scimedx C1q-CIC		
	positive	negative	total
Positive	15	1	16
Negative	1	63	64
Total	16	64	

Relative Sensitivity = 93.7%

Relative Specificity = 98.4%

Overall agreement = 97.5%

b. *Matrix comparison:*

Both tests use serum only

3. Clinical studies:a. *Clinical sensitivity:*

NA

b. *Clinical specificity:*

NA

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

NA

4. Clinical cut-off:

NA

5. Expected values/Reference range:

C1q (ug/mL)

Negative = &lt;40

Equivocal = 40-50

Positive = &gt;50

**M. Conclusion:**

Based upon the review of the information provided in this 510(k), The IBL C1q-CIC test appears to be **Substantially Equivalent** to devices regulated under 21CFR 866.5240, product code DAK, Immunology Devices Panel 82, Class II.