

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

A. 510(k) Number:

k134013

B. Purpose for Submission:

New device

C. Measurand:

Immunoglobulin E specific (sIgE) for allergen components from House Dust Mite (*Dermatophagoides pteronyssinus*), Cat dander (*Felis domesticus*), Horse dander (*Equus caballus*), Dog dander (*Canis familiaris*), Egg white (*Gallus spp.*), Cow's milk (*Bos spp.*), Peanut (*Arachis hypogaea*), Bermuda grass (*Cynodon dactylon*), Orchard Grass (*Dactylis glomerata*), Timothy grass (*Phleum pratense*), Mold (*Aspergillus fumigatus*), Mold (*Alternaria tenuis*), Birch (*Betula*), and Mugwort (*Artemisia vulgaris*)

D. Type of Test:

Not applicable

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Lyphocheck Allergen sIgE Control Negative
Lyphocheck Allergen sIgE Control Panel A

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.1660 Quality Control Material (assayed and unassayed)
2. Classification:
Class I, reserved
3. Product code:
JJY – Multi-analyte controls, all kinds (assayed)
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
Lyphocheck Allergen sIgE Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

2. Indication(s) for use:
Same as intended use
3. Special conditions for use statement(s):
For in vitro diagnostic use
4. Special instrument requirements:
Values are listed in the labeling for several analyzers. Values were assigned on these analyzers: Siemens IMMULITE 2000/2000 XPi, Phadia ImmunoCAP Series, Hycor HYTEC 288.

I. Device Description:

Lyphocheck Allergen sIgE Controls are packaged as lyophilized vials of Allergen sIgE Control Negative and Allergen sIgE Control Panel A. Control Panel A contains IgE antibodies specific for the listed analytes. The Negative and Panel A controls are either packaged as six vials, two mL per vial, or as a MiniPak of a two mL vial.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Ventrex Laboratories
2. Predicate 510(k) number(s):
k832218
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Matrix	Human serum	Human serum
Levels	Two levels	Two levels
Shelf life storage	2-8°C until expiration date	2-8°C until expiration date

Differences		
Item	Device	Predicate
Intended Use	Lyphocheck Allergy Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.	Baseline Allergen Controls are human serum based system for use in evaluating accuracy and precision of allergen specific IgE testing procedures, using either the radioallergosorbent or the enzyme immunoassay method.
Form	Lyophilized	Liquid
Open vial stability	28 days at 2-8°C	No claims made

Differences		
Item	Device	Predicate
Fill volume	2 mL	1 mL
Two Control Level contents	<p>Lyphocheck Allergen sIgE Control, Negative</p> <p>Lyphocheck Allergen sIgE Control, Panel A (Inhalants and Food)</p>	<p>Baseline Allergen Control – Negative</p> <p>Baseline Allergen Control – Inhalants</p>
Allergens Contained in Device:	<p>D1: House dust mite (<i>Dermatophagoides pteronyssinus</i>)</p> <p>D2: House dust mite (<i>Dermatophagoides farinae</i>)</p> <p>E1: Cat dander (<i>Felis domesticus</i>)</p> <p>E3: Horse dander (<i>Equus caballus</i>)</p> <p>E5: Dog dander (<i>Canis familiaris</i>)</p> <p>F1: Egg white (<i>Gallus spp.</i>)</p> <p>F2: Cow's milk (<i>Bos. spp.</i>)</p> <p>F13: Peanut (<i>Arachis hypogaea</i>)</p> <p>G2: Bermuda grass (<i>Cynodon dactylon</i>)</p> <p>G3: Orchard Grass (<i>Dactylis glomerata</i>)</p> <p>G6: Timothy grass (<i>Phleum pratense</i>)</p> <p>M3: Mold (<i>Aspergillus fumigatus</i>)</p> <p>M6: Mold (<i>Alternaria tenuis</i>)</p> <p>T3: Birch (<i>Betula</i>)</p> <p>W6: Mugwort (<i>Artemisia vulgaris</i>)</p>	<p>E1: Cat Epithelium</p> <p>E2: Dog Epithelium</p> <p>E3: Horse Dander</p> <p>E4: Cow Dander</p> <p>G1: Sweet Vernal Grass</p> <p>G2: Bermuda grass</p> <p>G3: Orchard Grass</p> <p>G4: Meadow Fescue</p> <p>G5: Perennial Rye Grass</p> <p>G6: Timothy Grass</p> <p>G7: Common Reed</p> <p>G8: Kentucky Blue Grass</p> <p>G9: Red Top (Bent Grass)</p> <p>G10: Johnson Grass</p> <p>G11: Brown Grass</p> <p>G12: Cultivated Rye</p> <p>G13: Velvet Grass</p> <p>G14: Cultivated Oat</p> <p>Pollen</p> <p>G15: Cultivated Wheat</p> <p>Pollen</p> <p>G16: Meadow Foxtail</p> <p>G17: Bahia Grass</p> <p>H1: House dust (Greer)</p> <p>H2: House dust (Hollister-Stier) <i>Dermatophagoides farinae</i></p> <p>I6: Cockroach</p> <p>T1: Maple (Box Elder)</p> <p>T2: Alder</p> <p>T3: Birch</p> <p>T4: Hazelnut</p> <p>T5: Beech</p> <p>T6: Mountain Cedar</p> <p>T7: Oak</p> <p>T8: Elm</p>

Differences		
Item	Device	Predicate
		T9: Olive Tree T11: Sycamore T12: Willow T14: Cottonwood T16: White Pine T20: Mesquite T21: Pecan Tree W1: Common Ragweed W2: Western Ragweed W3: Giant Ragweed W4: False Ragweed W5: Wormwood W6: Mugwort (common) W7: Oxeye Daisy W8: Dandelion W9: English Plantain W10: Lamb's Quarter W11: Russian Thistle W12: Goldenrod W16: True (Rough) Marsh Elder W17: Kochia (Firebrush) W22: Careless Weed W23: Yellow Dock

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

None

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Value assignment: The mean values and the corresponding $\pm 3SD$ ranges printed in this insert were derived from replicate analyses and are specific for this lot of

product. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. The sponsor recommends that each laboratory establish its own acceptable ranges and the values provided be used only as guides.

Stability: The sponsor's unopened, lyophilized shelf-life and reconstituted open-vial stability protocols and acceptance criteria were reviewed and found to be acceptable.

Shelf-life stability studies: Accelerated stability studies: control materials were stored at three different elevated temperatures then periodically reconstituted and tested against vials stored under normal conditions (2-8°C). Accelerated stability study model and data supports shelf life claim of 37 months at 2-8°C storage. Real time testing is ongoing.

Open-vial stability studies: the reconstituted controls were tested at periodic intervals at day 0, 3, 28 and 35. The results support the claim of 28 days open vial stability when stored at 2-8°C.

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

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:
Not applicable

N. Proposed Labeling:

The labeling is sufficient and it 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.