

Vibrant Food Sensitivity IgG & IgA Validation Report

1 Intended Use

Vibrant Food SensitivityTM kit is designed for the *in vitro* measurement of specific IgG and IgA autoantibodies against 96 food allergens present in the human serum. The test system could be used as an aid in the determination of sensitivity to specific varieties of food.

2 Test Principle

The Vibrant Food Sensitivity platform is a microarray of 96 food allergens tested on a pillar plate. Food antibodies if present in the serum will recognize the antigens coupled on the specific chips and form an antibody-antigen complex. Unbound antibody and other substances are removed by washing using the wash buffer. The chips are then incubated with anti-human IgG HRP and antihuman IgA HRP antibodies and the unbound HRP antibodies are then removed using the wash buffer. The plate is then immersed in a chemiluminescent substrate solution and is imaged using a Bio CCD chemiluminescence imager. The intensity of specific chips are then calculated and converted into qualitative and semi-quantitative results for IgG and IgA for all the components of food tested. This interpretation is performed by comparison with calibrators, controls and cut-off values. The sample is considered to be negative if the concentration of the antibody is less than the cut-off value chosen. The sample is considered to be positive if the concentration of the antibody is greater than the cut-off value chosen.

3 Performance Characteristics

A. Precision

The total precision of Food Sensitivity[™] IgG & IgA kit was assayed in 2 replicates of 3 samples twice daily over 5 days. One positive and one negative control were included in each assay run. The data were analyzed and percent coefficient of variation are summarized below:

Test Name	Sample 1 CV	Sample 2 CV	Sample 3 CV	Test Name	Sample 1 CV	Sample 2 CV	Sample 3 CV
Sesame IgG	1.47%	1.10%	1.02%	Corn IgG	2.48%	5.02%	4.14%
Shrimp IgG	2.17%	1.48%	1.28%	Codfish IgG	1.28%	2.20%	2.84%
Vanilla Bean IgG	0.50%	1.24%	2.37%	Ginger IgG	3.20%	1.26%	1.35%
Black Walnut IgG	2.07%	1.63%	0.80%	Cucumber IgG	2.32%	0.89%	1.61%
Oats IgG	3.43%	3.63%	3.69%	Carrot IgG	9.13%	1.68%	0.84%
Watermelon IgG	1.87%	0.96%	1.37%	Blueberry IgG	7.12%	1.12%	1.29%
Soybean IgG	0.55%	1.09%	0.95%	Grapefruit IgG	6.33%	4.23%	3.98%
Tomato IgG	8.98%	0.89%	0.64%	English Walnut IgG	4.30%	5.11%	7.15%
Rosemary IgG	3.07%	2.16%	2.01%	Halibut IgG	2.75%	1.38%	2.16%
Squash IgG	1.68%	0.94%	1.11%	Lake Trout IgG	9.19%	1.45%	1.01%

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Spinach IgG	2.37%	3.84%	3.44%	Catfish IgG	4.46%	1.21%	1.74%
Turkey IgG	2.56%	0.87%	1.10%	Strawberry IgG	3.37%	4.29%	3.34%
Salmon IgG	2.84%	1.03%	1.42%	Celery IgG	4.36%	4.23%	4.71%
Raspberry IgG	2.53%	1.75%	1.50%	Cherry IgG	9.42%	3.04%	4.85%
Seaweed(Kelp) IgG	1.74%	2.18%	1.90%	Cinnamon IgG	2.82%	0.96%	0.87%
Brown Rice IgG	4.08%	0.98%	1.25%	Clam IgG	3.53%	1.39%	1.80%
Tuna IgG	8.82%	1.51%	1.48%	Coffee IgG	0.19%	1.19%	0.94%
Scallops IgG	2.28%	3.22%	3.70%	Garlic IgG	4.84%	2.89%	1.65%
Black pepper IgG	0.54%	6.29%	5.12%	Crab IgG	1.19%	0.33%	0.20%
Perch IgG	9.02%	1.16%	1.98%	Grape IgG	8.55%	1.30%	1.54%
Beta-Casein IgG	1.51%	0.54%	0.42%	Lamb IgG	6.33%	1.38%	1.82%
Sweet Potato IgG	6.70%	3.46%	9.76%	Buckwheat IgG	9.89%	2.11%	2.74%
Avocado IgG	2.03%	6.81%	1.10%	Broccoli IgG	8.82%	1.48%	2.97%
Amaranth IgG	5.39%	9.47%	4.90%	Chicken IgG	9.48%	3.34%	1.24%
Pork IgG	3.88%	2.72%	1.75%	Cashews IgG	7.51%	3.04%	2.82%
Casomorphin IgG	6.61%	1.35%	2.50%	Green Bean IgG	2.48%	7.22%	9.34%
Blackberry IgG	5.90%	1.58%	3.15%	Cantaloupe IgG	4.91%	2.90%	2.36%
White Potato IgG	8.43%	3.13%	2.91%	Cauliflower IgG	7.23%	1.81%	1.62%
Mustard IgG	1.63%	2.97%	2.95%	Apple IgG	8.79%	2.77%	2.40%
Navy Bean IgG	1.01%	1.64%	1.69%	Beef IgG	6.33%	2.42%	1.92%
Onion IgG	7.26%	1.69%	1.43%	Goat's Milk IgG	6.58%	6.87%	6.38%
Orange IgG	8.04%	1.33%	1.32%	Cow's Milk IgG	5.81%	7.14%	6.99%
Oyster IgG	2.06%	4.19%	4.50%	Pineapple IgG	2.01%	2.91%	3.17%
Green Peas IgG	1.11%	5.06%	5.36%	Rye IgG	1.69%	1.14%	0.89%
Peach IgG	9.24%	1.35%	0.92%	Yeast IgG	0.43%	1.41%	1.02%
Peanut IgG	4.29%	0.96%	1.34%	Whey Protein IgG	8.68%	1.81%	1.59%
Pear IgG	6.99%	6.01%	6.51%	Lima Bean IgG	0.42%	0.57%	0.44%
Pecan IgG	2.06%	1.23%	1.67%	Coconut IgG	3.12%	4.99%	3.71%
Hops IgG	3.75%	4.45%	5.86%	Apricot IgG	9.97%	0.50%	0.59%
Green Pepper IgG	0.59%	0.62%	0.65%	Cabbage IgG	2.73%	0.72%	1.18%
Lettuce IgG	3.45%	1.29%	1.23%	Almond IgG	1.97%	2.06%	2.39%
Lobster IgG	2.91%	1.52%	0.60%	Banana IgG	0.44%	0.29%	0.26%
Mackerel IgG	5.33%	1.73%	1.12%	Barley IgG	0.91%	1.23%	1.02%
Malt IgG	8.69%	4.95%	3.62%	Wheat IgG	1.21%	8.95%	1.09%
Kidney Bean IgG	0.49%	3.52%	5.36%	Cocoa IgG	0.97%	1.57%	0.58%
Mushrooms IgG	5.31%	9.42%	8.58%	Cranberry IgG	1.89%	1.06%	1.29%
Nutmeg IgG	4.23%	0.86%	0.74%	Egg White IgG	1.09%	1.15%	0.91%
Olive IgG	4.81%	5.03%	5.34%	Egg Yolk IgG	4.46%	0.63%	0.52%

Test Name	Sample 1 CV	Sample 2 CV	Sample 3 CV	Test Name	Sample 1 CV	Sample 2 CV	Sample 3 CV
Almond IgA	1.25%	1.04%	0.75%	Halibut IgA	1.09%	1.50%	0.94%
Amaranth IgA	1.20%	0.81%	0.66%	Hops IgA	0.96%	5.25%	1.04%
Apple IgA	2.09%	2.21%	1.96%	Kidney Bean IgA	1.17%	2.00%	1.36%
Apricot IgA	2.67%	2.60%	1.21%	Lake Trout IgA	0.74%	1.80%	1.27%
Avocado IgA	2.09%	1.41%	6.08%	Lamb IgA	1.03%	2.85%	0.87%
Banana IgA	2.70%	0.99%	2.58%	Lettuce IgA	3.00%	0.93%	6.47%
Barley IgA	3.26%	0.98%	4.36%	Lima Bean IgA	9.20%	4.13%	0.57%
Beef IgA	2.58%	1.63%	0.99%	Lobster IgA	1.81%	1.75%	1.27%
Beta-Casein IgA	2.49%	1.13%	1.48%	Mackerel IgA	1.45%	3.35%	1.54%
Black pepper IgA	0.83%	0.88%	1.73%	Malt IgA	1.73%	3.52%	1.85%
Black Walnut IgA	1.63%	2.93%	2.87%	Mushrooms IgA	1.22%	1.01%	1.22%
Blackberry IgA	4.57%	1.46%	1.73%	Mustard IgA	2.14%	1.39%	5.19%
Blueberry IgA	0.98%	1.46%	1.14%	Navy Bean IgA	1.28%	1.10%	1.58%
Broccoli IgA	2.87%	1.04%	1.57%	Nutmeg IgA	1.62%	0.84%	1.80%
Brown Rice IgA	1.36%	4.97%	1.65%	Oats IgA	1.46%	1.70%	1.17%
Buckwheat IgA	3.20%	0.51%	1.58%	Olive IgA	6.11%	0.82%	1.68%
Cabbage IgA	2.55%	0.90%	1.12%	Onion IgA	3.86%	0.62%	1.07%
Cantaloupe IgA	1.62%	1.26%	1.80%	Orange IgA	9.75%	0.85%	0.72%
Carrot IgA	8.77%	0.90%	1.10%	Oyster IgA	1.61%	1.11%	7.79%
Cashews IgA	0.84%	2.56%	1.20%	Peach IgA	1.67%	2.89%	1.20%
Casomorphin IgA	2.21%	0.83%	1.62%	Peanut IgA	0.88%	0.77%	1.01%
Catfish IgA	1.59%	4.02%	1.56%	Pear IgA	1.46%	1.16%	1.12%
Cauliflower IgA	0.87%	1.92%	1.73%	Pecan IgA	3.68%	1.42%	4.92%
Celery IgA	6.69%	3.78%	0.82%	Perch IgA	8.01%	6.87%	1.60%
Cherry IgA	2.24%	0.97%	1.42%	Pineapple IgA	1.16%	1.44%	3.54%
Chicken IgA	1.79%	2.94%	1.28%	Pork IgA	1.28%	2.21%	1.17%
Cinnamon IgA	1.14%	1.79%	2.46%	Raspberry IgA	3.28%	1.18%	2.82%
Clam IgA	0.83%	1.14%	4.36%	Rosemary IgA	2.16%	6.62%	1.14%
Cocoa IgA	0.96%	1.29%	0.96%	Rye IgA	4.47%	4.16%	0.97%
Coconut IgA	1.31%	0.94%	1.00%	Salmon IgA	2.22%	2.59%	1.28%
Codfish IgA	1.99%	1.15%	4.78%	Scallops IgA	2.61%	0.97%	1.33%
Coffee IgA	1.35%	0.88%	2.79%	Seaweed(Kelp) IgA	1.14%	1.33%	2.89%
Corn IgA	1.42%	1.19%	1.48%	Sesame IgA	9.20%	1.00%	0.79%
Cow's Milk IgA	5.96%	3.58%	1.25%	Shrimp IgA	1.90%	1.44%	0.95%
Crab IgA	1.83%	1.83%	2.36%	Soybean IgA	1.04%	1.84%	5.98%
Cranberry IgA	3.52%	1.27%	1.95%	Spinach IgA	1.66%	0.73%	1.19%

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Cucumber IgA	2.19%	1.71%	6.38%	Squash IgA	1.68%	1.28%	1.81%
Egg White IgA	3.86%	1.65%	1.44%	Strawberry IgA	1.57%	5.48%	5.61%
Egg Yolk IgA	1.91%	2.43%	4.29%	Sweet Potato IgA	1.03%	0.92%	1.22%
English Walnut IgA	3.40%	2.56%	1.63%	Tomato IgA	1.90%	1.45%	5.00%
Garlic IgA	1.02%	0.95%	2.61%	Tuna IgA	0.95%	2.55%	0.98%
Ginger IgA	1.32%	3.45%	2.97%	Turkey IgA	1.10%	3.46%	4.12%
Goat's Milk IgA	1.85%	2.48%	1.77%	Vanilla Bean IgA	1.84%	8.42%	1.62%
Grape IgA	1.19%	1.28%	1.35%	Watermelon IgA	1.17%	1.00%	1.13%
Grapefruit IgA	5.46%	2.71%	1.43%	Wheat IgA	4.05%	1.86%	2.70%
Green Bean IgA	1.74%	1.69%	1.61%	Whey Protein IgA	1.07%	0.91%	1.06%
Green Peas IgA	0.79%	5.10%	3.72%	White Potato IgA	2.70%	1.01%	0.78%
Green Pepper IgA	7.36%	1.55%	1.99%	Yeast IgA	1.41%	1.97%	1.65%

B. Analytical sensitivity

The limit of detection for each assay was determined by running a blank sample in 21 replicates per run to determine the standard deviation of each assay in order to determine the limit of detection and the results are summarized below:

Test Name	LOD	Test Name	LOD	Test Name	LOD
Almond IgG	0.522338	Corn IgG	0.759001	Onion IgG	0.505174
Amaranth IgG	0.61123	Cow's Milk IgG	0.669788	Orange IgG	0.578593
Apple IgG	0.645884	Crab IgG	0.807196	Oyster IgG	0.614631
Apricot IgG	0.554914	Cranberry IgG	0.64568	Peach IgG	0.65614
Avocado IgG	0.444506	Cucumber IgG	0.505412	Peanut IgG	0.721538
Banana IgG	0.586502	Egg White IgG	0.775981	Pear IgG	0.500915
Barley IgG	0.706694	Egg Yolk IgG	0.751315	Pecan IgG	0.619785
Beef IgG	0.64666	English Walnut IgG	0.52343	Perch IgG	0.657027
Beta-Casein IgG	0.581488	Garlic IgG	0.622558	Pineapple IgG	0.586864
Black pepper IgG	0.42782	Ginger IgG	0.40278	Pork IgG	0.652986
Black Walnut IgG	0.821756	Goat's Milk IgG	0.607752	Raspberry IgG	0.724381
Blackberry IgG	0.553383	Grape IgG	0.487595	Rosemary IgG	0.371099
Blueberry IgG	0.511117	Grapefruit IgG	0.777015	Rye IgG	0.594127
Broccoli IgG	0.534006	Green Bean IgG	0.594058	Salmon IgG	0.612246
Brown Rice IgG	0.366641	Green Peas IgG	0.750138	Scallops IgG	0.431211
Buckwheat IgG	0.506527	Green Pepper IgG	0.64703	Seaweed(Kelp) IgG	0.751992
Cabbage IgG	0.478583	Halibut IgG	0.534483	Sesame IgG	0.756143
Cantaloupe IgG	0.548153	Hops IgG	0.500005	Shrimp IgG	0.513229
Carrot IgG	0.620965	Kidney Bean IgG	0.48592	Soybean IgG	0.513755
Cashews IgG	0.512751	Lake Trout IgG	0.777432	Spinach IgG	0.698168

Casomorphin IgG	0.652628	Lamb IgG	0.559532	Squash IgG	0.62761
Catfish IgG	0.378261	Lettuce IgG	0.800837	Strawberry IgG	0.663782
Cauliflower IgG	0.213357	Lima Bean IgG	0.556504	Sweet Potato IgG	0.608335
Celery IgG	0.655079	Lobster IgG	0.471037	Tomato IgG	0.770991
Cherry IgG	0.885147	Mackerel IgG	0.636541	Tuna IgG	0.621992
Chicken IgG	0.602419	Malt IgG	0.872764	Turkey IgG	0.733031
Cinnamon IgG	0.700434	Mushrooms IgG	0.48535	Vanilla Bean IgG	0.656388
Clam IgG	0.659547	Mustard IgG	0.615264	Watermelon IgG	0.745183
Cocoa IgG	0.617851	Navy Bean IgG	0.74047	Wheat IgG	0.836773
Coconut IgG	0.441323	Nutmeg IgG	0.562534	Whey Protein IgG	0.710206
Codfish IgG	0.495052	Oats IgG	0.603731	White Potato IgG	0.499358
Coffee IgG	0.684739	Olive IgG	0.450435	Yeast IgG	0.798324

Test Name	LOD	Test Name	LOD	Test Name	LOD
Almond IgA	0.551774	Corn IgA	0.56145	Onion IgA	0.67775
Amaranth IgA	0.531977	Cow's Milk IgA	0.67363	Orange IgA	0.645022
Apple IgA	0.803337	Crab IgA	0.603874	Oyster IgA	0.592189
Apricot IgA	0.410953	Cranberry IgA	0.504405	Peach IgA	0.642272
Avocado IgA	0.658279	Cucumber IgA	0.601789	Peanut IgA	0.565377
Banana IgA	0.594026	Egg White IgA	0.436598	Pear IgA	0.68566
Barley IgA	0.652382	Egg Yolk IgA	0.481877	Pecan IgA	0.867397
Beef IgA	0.542333	English Walnut IgA	0.628917	Perch IgA	0.686303
Beta-Casein IgA	0.863901	Garlic IgA	0.499623	Pineapple IgA	0.690917
Black pepper IgA	0.540832	Ginger IgA	0.51731	Pork IgA	0.623856
Black Walnut IgA	0.366529	Goat's Milk IgA	0.553515	Raspberry IgA	0.248646
Blackberry IgA	0.695078	Grape IgA	0.476934	Rosemary IgA	0.769608
Blueberry IgA	0.544931	Grapefruit IgA	0.523807	Rye IgA	0.684236
Broccoli IgA	0.70596	Green Bean IgA	0.747877	Salmon IgA	0.403023
Brown Rice IgA	0.407291	Green Peas IgA	0.528592	Scallops IgA	0.750534
Buckwheat IgA	0.41452	Green Pepper IgA	0.639648	Seaweed(Kelp) IgA	0.618607
Cabbage IgA	0.715595	Halibut IgA	0.591254	Sesame IgA	0.325766
Cantaloupe IgA	0.76006	Hops IgA	0.675558	Shrimp IgA	0.309209
Carrot IgA	0.672096	Kidney Bean IgA	0.499156	Soybean IgA	0.286458
Cashews IgA	0.642462	Lake Trout IgA	0.873277	Spinach IgA	0.708472
Casomorphin IgA	0.552533	Lamb IgA	0.586976	Squash IgA	0.538583
Catfish IgA	0.649989	Lettuce IgA	0.71349	Strawberry IgA	0.708597
Cauliflower IgA	0.598602	Lima Bean IgA	0.681882	Sweet Potato IgA	0.674439
Celery IgA	0.481588	Lobster IgA	0.548006	Tomato IgA	0.713977

Cherry IgA	0.544245	Mackerel IgA	0.534041	Tuna IgA	0.511892
Chicken IgA	0.582819	Malt IgA	0.566436	Turkey IgA	0.806526
Cinnamon IgA	0.315585	Mushrooms IgA	0.649967	Vanilla Bean IgA	0.580739
Clam IgA	0.329751	Mustard IgA	0.696801	Watermelon IgA	0.695485
Cocoa IgA	0.630634	Navy Bean IgA	0.44767	Wheat IgA	0.755237
Coconut IgA	0.459745	Nutmeg IgA	0.617994	Whey Protein IgA	0.506326
Codfish IgA	0.627534	Oats IgA	0.560696	White Potato IgA	0.48891
Coffee IgA	0.578854	Olive IgA	0.796539	Yeast IgA	0.541898

C. Analytical sensitivity

An interfering substances study was conducted to evaluate the potential interference of specific endogenous and exogenous substances with Food Sensitivity IgG & IgA kit. No interference was observed with any of the substances tested. The substances and the maximum levels tested are shown in the table below:

Substance	Concentration
Bilrubin	40mg/dl
Hemoglobin	500mg/dl
Triglycerides	1000mg/dl

D. Reference Range and Interpretation

Results Interpretation - The calibrator within this test system has been assigned a Correction Factor (CF) for the generation of calibrator value and the unit values. Based on testing of specimens, a maximum normal unit value has been determined and correlated to the calibrator.

Calculation - All calculations are based on raw chemiluminescent signal intensity. Correction Factor (CF) - The lab determines a cutoff value for positive samples by running 192 healthy control samples and correlated it to the calibrator using 2.5 to 97.5% percentile. The Correction Factor allows for the determination of the cutoff value for positive samples. It will also correct for slight day-to-day variations in test results. The CF is determined for each different lot of components. To obtain the cutoff value, the CF is multiplied by the mean signal of the calibrators determined for each assay.

Interpretations - Index values are interpreted as follows-

Result	Index Value
Negative	<10
Borderline	11 – 20
Positive	>20

E. Accuracy/ Method comparison

Accuracy study - A total of 40 individual serum samples were tested using Vibrant Food Sensitivity (IgG and IgA) assay on the Bio CCD Imager and compared to values obtained from the results run at a reference laboratory and the agreement results are summarized below -

Test Name	N	Agreement	Test Name	Ν	Agreement
Almond IgA	40 of 40	100.00%	Cabbage IgA	40 of 40	100.00%
Almond IgG	40 of 40	100.00%	Cabbage IgG	40 of 40	100.00%
Amaranth IgA	40 of 40	100.00%	Cantaloupe IgA	40 of 40	100.00%
Amaranth IgG	40 of 40	100.00%	Cantaloupe IgG	40 of 40	100.00%
Apple IgA	40 of 40	100.00%	Carrot IgA	40 of 40	100.00%
Apple IgG	40 of 40	100.00%	Carrot IgG	40 of 40	100.00%
Apricot IgA	40 of 40	93.80%	Cashews IgA	40 of 40	100.00%
Apricot IgG	40 of 40	100.00%	Cashews IgG	40 of 40	100.00%
Avocado IgA	40 of 40	100.00%	Casomorphin IgA	40 of 40	100.00%
Avocado IgG	40 of 40	100.00%	Casomorphin IgG	40 of 40	100.00%
Banana IgA	40 of 40	100.00%	Catfish IgA	40 of 40	100.00%
Banana IgG	40 of 40	100.00%	Catfish IgG	40 of 40	100.00%
Barley IgA	40 of 40	100.00%	Cauliflower IgA	40 of 40	100.00%
Barley IgG	40 of 40	100.00%	Cauliflower IgG	40 of 40	100.00%
Beef IgA	40 of 40	100.00%	Celery IgA	40 of 40	95.80%
Beef IgG	40 of 40	100.00%	Celery IgG	40 of 40	100.00%
Beta-Casein IgA	40 of 40	100.00%	Cherry IgA	40 of 40	93.90%
Beta-Casein IgG	40 of 40	100.00%	Cherry IgG	40 of 40	100.00%
Black pepper IgA	40 of 40	100.00%	Chicken IgA	40 of 40	93.90%
Black pepper IgG	40 of 40	100.00%	Chicken IgG	40 of 40	100.00%
Black Walnut IgA	40 of 40	100.00%	Cinnamon IgA	40 of 40	100.00%
Black Walnut IgG	40 of 40	100.00%	Cinnamon IgG	40 of 40	100.00%
Blackberry IgA	40 of 40	100.00%	Clam IgA	40 of 40	100.00%
Blackberry IgG	40 of 40	100.00%	Clam IgG	40 of 40	100.00%
Blueberry IgA	40 of 40	100.00%	Cocoa IgA	40 of 40	93.30%
Blueberry IgG	40 of 40	100.00%	Cocoa IgG	40 of 40	100.00%
Broccoli IgA	40 of 40	100.00%	Coconut IgA	40 of 40	100.00%
Broccoli IgG	40 of 40	100.00%	Coconut IgG	40 of 40	96.60%
Brown Rice IgA	40 of 40	100.00%	Codfish IgA	40 of 40	100.00%
Brown Rice IgG	40 of 40	100.00%	Codfish IgG	40 of 40	100.00%
Buckwheat IgA	40 of 40	100.00%	Coffee IgA	40 of 40	100.00%
Buckwheat IgG	40 of 40	100.00%	Coffee IgG	40 of 40	100.00%

Test Name	N	Agreement	Test Name	Ν	Agreement
Corn IgA	40 of 40	100.00%	Halibut IgA	40 of 40	96.70%
Corn IgG	40 of 40	100.00%	Halibut IgG	40 of 40	96.90%
Cow's Milk IgA	40 of 40	100.00%	Hops IgA	40 of 40	100.00%
Cow's Milk IgG	40 of 40	100.00%	Hops IgG	40 of 40	96.90%
Crab IgA	40 of 40	100.00%	Kidney Bean IgA	40 of 40	100.00%
Crab IgG	40 of 40	100.00%	Kidney Bean IgG	40 of 40	96.80%
Cranberry IgA	40 of 40	100.00%	Lake Trout IgA	40 of 40	100.00%
Cranberry IgG	40 of 40	100.00%	Lake Trout IgG	40 of 40	100.00%
Cucumber IgA	40 of 40	100.00%	Lamb IgA	40 of 40	100.00%
Cucumber IgG	40 of 40	100.00%	Lamb IgG	40 of 40	100.00%
Egg White IgA	40 of 40	100.00%	Lettuce IgA	40 of 40	96.70%
Egg White IgG	40 of 40	100.00%	Lettuce IgG	40 of 40	100.00%
Egg Yolk IgA	40 of 40	96.20%	Lima Bean IgA	40 of 40	100.00%
Egg Yolk IgG	40 of 40	100.00%	Lima Bean IgG	40 of 40	100.00%
English Walnut IgA	40 of 40	100.00%	Lobster IgA	40 of 40	96.90%
English Walnut IgG	40 of 40	100.00%	Lobster IgG	40 of 40	100.00%
Garlic IgA	40 of 40	96.30%	Mackerel IgA	40 of 40	100.00%
Garlic IgG	40 of 40	100.00%	Mackerel IgG	40 of 40	100.00%
Ginger IgA	40 of 40	100.00%	Malt IgA	40 of 40	96.90%
Ginger IgG	40 of 40	100.00%	Malt IgG	40 of 40	100.00%
Goat's Milk IgA	40 of 40	100.00%	Mushrooms IgA	40 of 40	96.60%
Goat's Milk IgG	40 of 40	100.00%	Mushrooms IgG	40 of 40	100.00%
Grape IgA	40 of 40	100.00%	Mustard IgA	40 of 40	100.00%
Grape IgG	40 of 40	96.40%	Mustard IgG	40 of 40	100.00%
Grapefruit IgA	40 of 40	96.90%	Navy Bean IgA	40 of 40	100.00%
Grapefruit IgG	40 of 40	100.00%	Navy Bean IgG	40 of 40	100.00%
Green Bean IgA	40 of 40	100.00%	Nutmeg IgA	40 of 40	100.00%
Green Bean IgG	40 of 40	100.00%	Nutmeg IgG	40 of 40	100.00%
Green Peas IgA	40 of 40	100.00%	Oats IgA	40 of 40	100.00%
Green Peas IgG	40 of 40	100.00%	Oats IgG	40 of 40	100.00%
Green Pepper IgA	40 of 40	100.00%	Olive IgA	40 of 40	100.00%
Green Pepper IgG	40 of 40	96.30%	Olive IgG	40 of 40	100.00%

Test Name	Ν	Agreement	Test Name	Ν	Agreement
Onion IgA	40 of 40	96.40%	Sesame IgA	40 of 40	100.00%
Onion IgG	40 of 40	100.00%	Sesame IgG	40 of 40	100.00%
Orange IgA	40 of 40	100.00%	Shrimp IgA	40 of 40	100.00%
Orange IgG	40 of 40	96.90%	Shrimp IgG	40 of 40	100.00%
Oyster IgA	40 of 40	100.00%	Soybean IgA	40 of 40	100.00%
Oyster IgG	40 of 40	96.90%	Soybean IgG	40 of 40	100.00%
Peach IgA	40 of 40	100.00%	Spinach IgA	40 of 40	100.00%
Peach IgG	40 of 40	100.00%	Spinach IgG	40 of 40	100.00%
Peanut IgA	40 of 40	100.00%	Squash IgA	40 of 40	100.00%
Peanut IgG	40 of 40	100.00%	Squash IgG	40 of 40	100.00%
Pear IgA	40 of 40	100.00%	Strawberry IgA	40 of 40	100.00%
Pear IgG	40 of 40	97.10%	Strawberry IgG	40 of 40	100.00%
Pecan IgA	40 of 40	100.00%	Sweet Potato IgA	40 of 40	100.00%
Pecan IgG	40 of 40	96.60%	Sweet Potato IgG	40 of 40	100.00%
Perch IgA	40 of 40	100.00%	Tomato IgA	40 of 40	100.00%
Perch IgG	40 of 40	100.00%	Tomato IgG	40 of 40	100.00%
Pineapple IgA	40 of 40	100.00%	Tuna IgA	40 of 40	100.00%
Pineapple IgG	40 of 40	100.00%	Tuna IgG	40 of 40	100.00%
Pork IgA	40 of 40	100.00%	Turkey IgA	40 of 40	100.00%
Pork IgG	40 of 40	100.00%	Turkey IgG	40 of 40	100.00%
Raspberry IgA	40 of 40	100.00%	Vanilla Bean IgA	40 of 40	100.00%
Raspberry IgG	40 of 40	100.00%	Vanilla Bean IgG	40 of 40	100.00%
Rosemary IgA	40 of 40	100.00%	Watermelon IgA	40 of 40	100.00%
Rosemary IgG	40 of 40	100.00%	Watermelon IgG	40 of 40	100.00%
Rye IgA	40 of 40	100.00%	Wheat IgA	40 of 40	100.00%
Rye IgG	40 of 40	100.00%	Wheat IgG	40 of 40	100.00%
Salmon IgA	40 of 40	100.00%	Whey Protein IgA	40 of 40	100.00%
Salmon IgG	40 of 40	100.00%	Whey Protein IgG	40 of 40	100.00%
Scallops IgA	40 of 40	100.00%	White Potato IgA	40 of 40	100.00%
Scallops IgG	40 of 40	100.00%	White Potato IgG	40 of 40	100.00%
Seaweed(Kelp) IgA	40 of 40	100.00%	Yeast IgA	40 of 40	100.00%
Seaweed(Kelp) IgG	40 of 40	100.00%	Yeast IgG	40 of 40	100.00%

4 Conclusion

This documents the process results and process parameters obtained during the validation of the standard operating procedure for Vibrant Food Sensitivity assay. All validation assay test results meet their required specifications set by the laboratory.