

Vibrant Gut Commensal Panel Validation Report

1 Intended Use

The Vibrant Gut Commensal panel assay is a microarray chip-based assay that analyzes a patient's gut genetic profile to identify the relative abundance of gut microbiome. This test is measured on a proprietary microarray platform to detect the presence/absence and identify the relative abundance of species/sub-species of bacteria from genomic DNA extracted from stool samples.

2 Test Principle

The Vibrant Gut Commensal microarray consists of unique probe sequence to identify 153 unique gut microorganisms. The sample DNA is extracted from the stool sample provided and amplified using 16s rDNA and other gene segments to identify the organisms. The amplified DNA is then hybridized to the probe sequences on the array based on the complementary sequences in the sample which will bind to the probe sequences thus forming a double stranded structure on the array. This is followed by stringent wash cycles to remove any non-specific hybridization. Labelling is done using biotin-labelled nucleotides followed by detection using an enzyme based chemiluminescent substrate. The array is scanned using a Chemiluminescence imager and the raw intensity for each probe is calculated. The test relative abundance results are then determined by comparison with calibrators, known standards and cut-off values.

3 Performance Characteristics

1. Performance Characteristics

The kit comprises of calibrators, positive and negative controls which are used for each assay performed. The validation studies are analyzed after each plate tested passes the acceptance criteria for controls and calibrators ranges assigned during assay design.

2. Precision

A. Accuracy/Trueness

Accuracy of this assay will be inferred from determining the concordance between the known blinded culture samples obtained from commercial sources and the gut commensal microarray chip. The test results of 14688 data points with known specimen types are unblinded and compared to the expected results to determine the total concordance.

Specimen Type	Vibrant Gut Zoomer Array	Expected Result		Total
		Positive	Negative	
Known Culture samples	Positive	153	0	153
	Negative	0	14535	14535
	Total	153	14535	14688
Positive concordance % = 100 % (91.23%-100%) Negative concordance % = 100 % (96.66%-100%)				

B. Repeatability/Reproducibility

Precision study was performed over 6 days, with two runs per day (one each by 2 operators), for a total of 12 runs. The Precision panel tested were divided into two concentration categories, based upon organism concentration relative to the LoDs established for each Array (Samples were spiked in stool matrix) and 2 samples with unknown results. Results were summarized by organism tested and Variance Component (SD and % CV), Percent Agreement was also calculated.

Array Probe Index	High Positive Sample 1	Low Positive Sample 1	High Positive Sample 2	Low Positive Sample 2	Stool Sample		% Agreement With Expected Result
	3X LOD	1X LOD	3X LOD	1X LOD	Sample 1	Sample2	
Variance Component (SD and % CV)							
Probe001	0.3%	0.7%	2.6%	2.5%	1.1%	0.5%	100%
Probe002	2.7%	0.5%	1.0%	1.1%	1.1%	1.6%	100%
Probe003	0.5%	0.7%	1.1%	0.9%	7.9%	9.1%	100%
Probe004	1.7%	1.7%	1.0%	9.5%	0.7%	0.8%	100%
Probe005	3.7%	0.9%	0.9%	3.2%	1.1%	1.2%	100%
Probe006	1.0%	3.2%	2.1%	0.8%	1.0%	1.1%	100%
Probe007	0.9%	2.4%	0.9%	0.6%	0.4%	0.8%	100%
Probe008	3.7%	1.0%	1.0%	3.1%	1.0%	0.7%	100%
Probe009	6.4%	4.1%	2.3%	1.1%	1.6%	0.4%	100%
Probe010	1.2%	6.8%	0.6%	1.4%	1.1%	3.3%	100%
Probe011	1.4%	1.0%	0.9%	4.4%	1.1%	0.7%	100%
Probe012	0.8%	1.0%	5.1%	0.6%	0.8%	1.3%	100%
Probe013	1.1%	3.6%	2.7%	0.8%	1.6%	6.8%	100%
Probe014	7.6%	1.5%	3.6%	1.1%	0.9%	0.7%	100%
Probe015	1.0%	1.5%	13.1%	0.7%	1.2%	1.1%	100%
Probe016	1.7%	0.9%	1.6%	4.5%	0.7%	9.5%	100%

Probe017	1.5%	0.5%	10.3%	9.7%	1.3%	1.0%	100%
Probe018	1.5%	11.0%	1.4%	0.7%	0.7%	0.6%	100%
Probe019	4.6%	1.7%	1.7%	1.3%	4.1%	2.0%	100%
Probe020	1.4%	4.0%	0.6%	0.8%	6.0%	0.7%	100%
Probe021	1.1%	4.9%	0.8%	0.8%	0.5%	1.2%	100%
Probe022	5.6%	2.4%	1.1%	0.8%	0.8%	2.9%	100%
Probe023	0.7%	1.2%	0.5%	0.7%	6.0%	1.2%	100%
Probe024	1.4%	1.0%	0.9%	4.4%	1.1%	0.7%	100%
Probe025	0.7%	1.0%	4.4%	1.2%	0.8%	1.2%	100%
Probe026	2.6%	1.3%	0.9%	0.9%	1.2%	1.3%	100%
Probe027	2.0%	14.2%	0.6%	0.9%	0.5%	1.4%	100%
Probe028	1.7%	0.7%	0.9%	1.3%	1.1%	0.6%	100%
Probe029	0.8%	4.3%	2.7%	0.9%	2.5%	0.5%	100%
Probe030	0.8%	0.7%	1.2%	0.7%	3.7%	0.5%	100%
Probe031	2.3%	0.8%	0.8%	5.9%	2.4%	0.7%	100%
Probe032	1.3%	1.4%	5.5%	1.4%	6.3%	6.8%	100%
Probe033	3.3%	0.6%	3.0%	2.7%	6.8%	6.9%	100%
Probe034	1.0%	2.7%	0.9%	1.3%	0.6%	2.1%	100%
Probe035	9.8%	0.8%	0.9%	1.4%	0.7%	1.3%	100%
Probe036	0.6%	4.6%	1.8%	1.3%	3.8%	0.8%	100%
Probe037	1.3%	1.1%	2.3%	10.5%	2.4%	1.2%	100%
Probe038	1.2%	1.6%	0.9%	2.9%	2.2%	0.6%	100%
Probe039	1.1%	0.6%	4.3%	2.3%	0.6%	0.8%	100%
Probe040	1.5%	1.1%	1.3%	0.8%	0.6%	0.6%	100%
Probe041	1.1%	4.9%	0.8%	0.8%	0.5%	1.2%	100%
Probe042	1.6%	0.9%	7.0%	1.0%	1.4%	1.6%	100%
Probe043	0.8%	1.6%	1.5%	4.3%	1.4%	0.6%	100%
Probe044	1.0%	8.1%	15.3%	7.8%	0.6%	1.5%	100%
Probe045	0.8%	1.7%	1.3%	0.7%	4.1%	1.7%	100%
Probe046	0.9%	0.7%	1.3%	1.2%	0.9%	2.8%	100%
Probe047	0.9%	1.1%	1.9%	4.2%	0.7%	2.2%	100%
Probe048	3.1%	1.5%	2.2%	0.8%	1.8%	1.7%	100%
Probe049	1.1%	4.0%	0.9%	5.9%	0.9%	0.8%	100%
Probe050	0.9%	0.8%	1.7%	0.7%	1.6%	0.9%	100%
Probe051	1.0%	3.4%	1.3%	2.6%	0.6%	4.3%	100%
Probe052	12.7%	1.0%	1.2%	1.7%	0.5%	5.2%	100%
Probe053	0.9%	1.2%	2.7%	1.0%	1.6%	0.6%	100%
Probe054	1.0%	0.9%	0.6%	0.7%	0.6%	1.0%	100%
Probe055	1.4%	0.4%	1.3%	0.9%	4.4%	0.9%	100%

Probe056	3.1%	1.5%	2.2%	0.8%	1.8%	1.7%	100%
Probe057	2.0%	0.9%	1.2%	0.7%	2.3%	2.9%	100%
Probe058	0.7%	3.0%	0.8%	3.8%	0.6%	0.9%	100%
Probe059	0.7%	0.7%	1.0%	2.0%	0.6%	0.6%	100%
Probe060	1.5%	1.2%	0.8%	0.8%	0.7%	0.5%	100%
Probe061	0.9%	1.6%	1.0%	1.2%	0.5%	0.9%	100%
Probe062	0.9%	1.3%	0.8%	0.9%	1.2%	1.3%	100%
Probe063	3.5%	4.2%	2.1%	1.3%	2.6%	2.1%	100%
Probe064	0.7%	12.3%	1.5%	2.4%	1.3%	0.4%	100%
Probe065	4.2%	0.9%	1.7%	0.9%	0.9%	3.0%	100%
Probe066	1.3%	0.6%	2.5%	1.1%	1.2%	1.4%	100%
Probe067	6.0%	2.4%	1.2%	1.7%	0.7%	3.3%	100%
Probe068	0.7%	0.7%	0.9%	1.1%	2.4%	2.1%	100%
Probe069	0.6%	0.5%	0.9%	1.8%	0.7%	0.7%	100%
Probe070	0.6%	2.5%	1.2%	1.9%	0.6%	0.9%	100%
Probe071	0.9%	0.7%	10.3%	0.8%	1.3%	0.4%	100%
Probe072	1.0%	1.9%	2.0%	10.5%	1.5%	13.3%	100%
Probe073	1.8%	2.7%	0.7%	0.9%	0.6%	1.9%	100%
Probe074	1.4%	4.3%	2.6%	0.9%	0.6%	0.8%	100%
Probe075	0.8%	0.8%	4.5%	2.2%	1.7%	2.4%	100%
Probe076	2.3%	1.1%	1.2%	8.7%	1.6%	0.9%	100%
Probe077	5.0%	1.1%	14.6%	1.7%	0.9%	0.8%	100%
Probe078	4.8%	15.4%	9.0%	3.5%	0.8%	0.7%	100%
Probe079	2.1%	2.0%	2.8%	6.2%	0.6%	4.3%	100%
Probe080	7.0%	6.1%	14.9%	3.7%	0.9%	3.4%	100%
Probe081	0.8%	1.2%	2.9%	6.9%	3.7%	0.6%	100%
Probe082	1.3%	1.6%	2.9%	0.7%	2.2%	1.6%	100%
Probe083	1.3%	2.7%	1.1%	1.1%	0.8%	0.9%	100%
Probe084	2.9%	0.7%	0.8%	5.1%	0.9%	0.9%	100%
Probe085	0.8%	2.0%	2.0%	1.1%	1.8%	10.0%	100%
Probe086	0.7%	0.9%	14.8%	1.9%	0.6%	14.1%	100%
Probe087	1.3%	0.6%	2.5%	1.1%	1.2%	1.4%	100%
Probe088	2.5%	1.4%	1.0%	0.9%	0.6%	2.6%	100%
Probe089	1.4%	1.0%	0.9%	4.4%	1.1%	0.7%	100%
Probe090	3.9%	7.1%	0.8%	2.1%	0.6%	0.7%	100%
Probe091	1.0%	0.7%	1.6%	1.1%	0.5%	0.7%	100%
Probe092	6.3%	5.3%	0.7%	0.8%	0.6%	1.0%	100%
Probe093	1.0%	1.5%	1.5%	1.2%	1.2%	0.9%	100%
Probe094	1.2%	0.7%	0.5%	2.3%	0.9%	0.9%	100%

Probe095	9.4%	0.9%	1.2%	3.9%	0.5%	0.8%	100%
Probe096	3.6%	1.4%	12.1%	1.8%	0.8%	1.9%	100%
Probe097	2.4%	8.0%	0.3%	0.4%	0.7%	0.6%	100%
Probe098	0.9%	6.5%	1.6%	1.1%	0.8%	1.3%	100%
Probe099	1.3%	0.6%	1.0%	1.1%	9.3%	6.9%	100%
Probe100	0.5%	11.7%	2.9%	5.9%	1.2%	0.7%	100%
Probe101	1.1%	1.6%	1.8%	4.1%	1.1%	2.1%	100%
Probe102	1.9%	1.3%	7.2%	0.9%	1.0%	1.0%	100%
Probe103	1.2%	14.8%	1.2%	1.6%	2.4%	1.1%	100%
Probe104	1.1%	3.0%	1.0%	3.0%	0.9%	0.7%	100%
Probe105	2.4%	0.8%	0.6%	0.8%	0.7%	0.7%	100%
Probe106	0.8%	1.2%	0.6%	1.2%	1.7%	2.6%	100%
Probe107	0.7%	2.3%	0.8%	4.8%	1.0%	0.8%	100%
Probe108	5.7%	0.8%	4.8%	0.9%	0.6%	1.2%	100%
Probe109	2.7%	6.6%	0.7%	1.2%	2.2%	11.6%	100%
Probe110	4.5%	0.9%	0.8%	1.3%	1.0%	0.6%	100%
Probe111	15.0%	1.8%	0.9%	1.0%	1.1%	1.2%	100%
Probe112	1.7%	2.0%	1.2%	5.3%	0.7%	7.0%	100%
Probe113	13.7%	0.7%	2.5%	9.2%	1.4%	1.2%	100%
Probe114	0.9%	2.4%	0.9%	0.6%	0.4%	0.8%	100%
Probe115	1.7%	5.7%	1.0%	1.4%	4.4%	1.5%	100%
Probe116	0.9%	1.2%	3.9%	1.0%	5.3%	0.7%	100%
Probe117	1.0%	0.7%	3.2%	0.9%	2.0%	1.8%	100%
Probe118	0.7%	2.0%	1.1%	0.9%	0.6%	2.8%	100%
Probe119	0.8%	1.2%	9.8%	0.7%	5.2%	1.2%	100%
Probe120	4.6%	1.7%	1.7%	1.3%	4.1%	2.0%	100%
Probe121	5.5%	0.9%	1.3%	1.2%	0.7%	0.9%	100%
Probe122	0.9%	0.9%	2.0%	1.2%	0.8%	1.6%	100%
Probe123	1.1%	4.9%	0.8%	0.8%	0.5%	1.2%	100%
Probe124	0.9%	1.7%	1.0%	1.3%	1.2%	0.7%	100%
Probe125	3.1%	1.9%	1.5%	1.0%	3.4%	0.6%	100%
Probe126	1.3%	1.1%	3.5%	0.7%	4.5%	0.8%	100%
Probe127	0.9%	0.7%	0.8%	5.2%	2.3%	0.5%	100%
Probe128	7.8%	0.7%	1.0%	1.4%	6.5%	7.7%	100%
Probe129	3.2%	1.0%	1.5%	3.0%	9.0%	3.7%	100%
Probe130	1.0%	1.4%	1.8%	1.6%	0.5%	2.2%	100%
Probe131	0.9%	1.2%	6.1%	1.5%	0.6%	1.4%	100%
Probe132	2.1%	2.8%	3.2%	1.1%	3.4%	0.5%	100%
Probe133	2.1%	2.4%	1.6%	12.6%	3.5%	1.4%	100%

Probe134	0.6%	7.5%	0.9%	2.0%	1.9%	0.5%	100%
Probe135	5.7%	1.1%	1.0%	1.8%	0.6%	0.9%	100%
Probe136	1.4%	11.2%	2.5%	0.8%	0.6%	0.5%	100%
Probe137	7.7%	1.1%	0.7%	1.2%	1.1%	0.9%	100%
Probe138	8.4%	2.5%	1.6%	1.3%	1.6%	1.0%	100%
Probe139	2.1%	6.8%	0.8%	3.0%	1.2%	0.8%	100%
Probe140	13.1%	0.5%	2.8%	5.0%	0.8%	1.6%	100%
Probe141	1.8%	11.5%	1.3%	0.8%	4.1%	1.8%	100%
Probe142	1.4%	3.1%	0.7%	1.3%	0.8%	2.4%	100%
Probe143	1.4%	1.2%	2.4%	3.0%	0.6%	3.3%	100%
Probe144	2.5%	0.8%	11.7%	1.6%	0.4%	1.5%	100%
Probe145	1.0%	8.6%	0.8%	4.4%	1.2%	0.8%	100%
Probe146	1.1%	0.8%	4.5%	0.7%	1.9%	1.1%	100%
Probe147	1.7%	0.8%	0.9%	2.7%	0.7%	4.6%	100%
Probe148	1.3%	2.5%	3.0%	1.8%	0.4%	4.5%	100%
Probe149	2.1%	1.1%	4.7%	0.8%	1.5%	0.7%	100%
Probe150	0.5%	0.6%	0.8%	0.7%	0.8%	1.2%	100%
Probe151	1.7%	0.6%	1.1%	0.9%	3.8%	1.7%	100%
Probe152	3.0%	0.8%	1.3%	0.8%	1.8%	1.2%	100%
Probe153	4.0%	0.5%	1.6%	0.2%	1.7%	3.2%	100%

C. Analytical Specificity / Interference substances

6 different samples were tested for cross-reactivity with the following compounds with varying concentrations to analyze the analytical specificity of Gut Zoomer assay.

Interference study	Result
Endogenous and Commercial Exogenous Substances	
Human DNA 2.4ng/ml	NI
Mucus 2.2 mg/ml + Fecal Fat 2.5mg/ml	NI
Whole Human Blood (1:1)	NI
Microorganisms Tested For interference	
Shigella	NI
Escherichia Coli 0157	NI
Candida sp.	NI

NI: No Reportable Change in Result

D. Analytical Sensitivity / Limit of Detection

Analytical sensitivity (LoD), defined as the lowest concentration at which greater than 95% of all replicates are expected to have detectable range. LOD data were collected using three lots of reagents for Gut commensal assay. One sample was serially diluted 3 times and was

tested with reagents from three lots to calculate the LoD for each organism.

Organism	LOD (CFU/ml)
Enterobacteriaceae	8.50e1
Bifidobacterium	6.52e2
Propionibacterium	7.07e2
Eubacterium	7.02e2
Lactobacillus	1.81e2
Roseburia	6.43e2
Eubacterium rectale	5.46e2
Butyrivibrio	4.65e2
Akkermansia muciniphila	4.50e1
Lactobacillus reuteri	9.17e2
Lactobacillus rhamnosus	8.01e2
Lactobacillus plantarum	8.49e2
Streptococcus thermophilus	4.87e2
Lactobacillus bulgaricus	5.72e2
Lactobacillus acidophilus	1.52e2
Bifidobacterium longum	1.03e2
Streptococcus species	1.37e2
Escherichia coli	1.43e2
Staphylococcus species	3.00e1
Micrococcus	7.33e2
Acinetobacter	9.37e2
Bacteroides	7.79e2
Clostridium	1.01e2
Peptostreptococcus	7.54e2
Enterococcus species	2.12e2
Methanobrevibacter smithii	7.46e2
Lactobacillus casei	3.07e2
Collinsella	5.40e1
Lactobacillus ruminis	5.85e2
Atopobium	2.67e2
Lactobacillus sakei	5.87e2
Enterobacter aerogenes	2.73e2
Solobacterium moorei	8.53e2
Atopobium parvulum	5.45e2
Roseburia intestinalis	5.79e2
Faecalibacterium prausnitzii	4.11e2
Prevotella copri	1.02e2
Alloprevotella	7.89e2

Organism	LOD (CFU/ml)
Catenibacterium	8.99e2
Tyzzereella	1.26e2
Tyzzereella 4	8.56e2
Porphyromonas gingivalis	6.39e2
Bifidobacteria	6.48e2
Proteobacteria	1.67e2
Staphylococcaceae	4.93e2
Staphylococcus epidermidis	5.08e2
Staphylococcus pasteurii	5.52e2
Coprococcus	2.99e2
Akkermansia	6.17e2
Pseudobutyrvibrio	8.94e2
Proteus mirabilis	7.80e1
Enterococcus gallinarum	7.93e2
Clostridia clusters XIVa	4.54e2
Clostridia clusters IV	3.50e1
Clostridia clusters XVIII	1.73e2
Bifidobacterium bifidum	7.85e2
Bifidobacterium animalis	2.75e2
Oscillospira	2.32e2
Christensenella minuta	5.67e2
Bacteroides caccae	1.12e2
Clostridium hathewayi	7.45e2
Clostridium ramosum	8.30e1
Clostridium symbiosum	1.81e2
Eggerthella lenta	2.12e2
Blautia hydrogenotrophica	1.19e2
Ruminococcus obeum	7.59e2
Bifidobacterium adolescentis	5.90e2
Lactobacillus paracasei	9.62e2
Bacillus subtilis	4.07e2
Propionibacterium freudenreichii	4.27e2
Bifidobacterium animalis subspecies lactis	3.80e1
Lactobacillus animalis	9.12e2
Ruminococcus bromii	8.21e2
Lactobacillus murinus	5.57e2
Methanobrevibacter	4.94e2
Butyricimonas	4.34e2
Lactobacillaceae	1.97e2
Bradyrhizobiaceae	5.38e2

Organism	LOD (CFU/ml)
Clotridiales Incertae Sedis IV	9.49e2
Desulfovibrio	6.88e2
Bacteroides vulgatus	1.64e2
Bacteroidetes	7.44e2
Firmicutes	1.01e2
Bacteroidales	8.70e1
Lachnospiraceae	2.18e2
Pseudomonas	5.20e1
Mycoplana	5.58e2
Haemophilus	3.94e2
Blautia	4.07e2
Dorea	8.79e2
Prevotella	8.93e2
Veillonellaceae	4.93e2
Lactobacillus fermentum	5.00e1
Lactobacillus brevis	1.41e2
Bifidobacterium dentium	5.55e2
Bifidobacterium animalis subsp lactis	1.48e2
Streptococcus	7.48e2
Lactococcus	1.31e2
Pediococcus	5.49e2
Leuconostoc	2.90e2
Fusobacteria	1.60e2
Veillonella	6.33e2
Ruminococcaceae	2.47e2
Clostridiales Family XIV Incertae Sedis	7.23e2
Streptococci	1.37e2
Enterobacteria	8.87e2
Ruminococcus	3.92e2
Enterococcus	7.50e2
Fusobacterium	5.74e2
Lactobacillus rhamnosus GG	8.54e2
Phascolarctobacterim	8.47e2
Faecalibacterium	6.98e2
Desulfovibrio piger	3.20e1
Dialister invisus	4.36e2
Ruminococcus gnavus	1.65e2
Saccharomyces boulardii	7.23e2
Lactobacillus salivarius	2.48e2
Bifidobacterium breve	9.18e2

Organism	LOD (CFU/ml)
Escherichia coli Nissle	8.00e1
Bifidobacterium catenulatum	2.81e2
Bacillus coagulans	6.34e2
Bifidobacterium infantis	4.38e2
Bifidobacterium lactis	5.16e2
Edwardsiella	9.29e2
Alistipes	6.77e2
Citrobacter	5.28e2
Dermabacter	4.73e2
Escherichia	9.22e2
Marvinbryantia	4.12e2
Tannerella	8.90e2
Actinomyces	8.35e2
Anaerostipes	1.67e2
Barnesiella	6.02e2
Butyricoccus	2.28e2
Cedecea	2.14e2
Cetobacterium	6.51e2
Coprobacillus	3.16e2
Dysgonomonas	5.45e2
Enterobacter	6.10e1
Hafnia	2.58e2
Holdemania	5.50e2
Megamonas	4.37e2
Mitsuokella	1.89e2
Odoribacter	7.99e2
Paenibacillus	6.42e2
Parabacteroides	1.92e2
Paraprevotella	2.22e2
Porphyromonas	3.93e2
Pseudoflavonifractor	5.50e2
Subdoligranulum	5.36e2
Turicibacter	7.60e2
Weissella	4.68e2
Yokenella	4.77e2

E. Reference Range and Interpretation

Calibration - The calibrator within this test system are prepared using known standards of bacteria spiked in a stool matrix and has been assigned a Correction Factor (CF) for the generation of calibrator value and spike recovery.

Reference Ranges - Reference ranges have been established using a sample cohort comprising of 192 relatively healthy stool samples. The cut-off for the healthy reference range is set between 2.5% to 97.5% percentile, and the high-risk range is set to greater than 97.5% percentile and less than 2.5% percentile as applicable. For each organism tested, the healthy reference ranges are assigned as follows:

Organism Tested	Reference Range
Enterobacteriaceae	0-20
Bifidobacterium	10-30
Propionibacterium	10-30
Eubacterium	10-30
Lactobacillus	10-30
Roseburia	10-30
Eubacterium rectale	10-30
Butyrivibrio	10-30
Akkermansia muciniphila	10-30
Lactobacillus reuteri	10-30
Lactobacillus rhamnosus	10-30
Lactobacillus plantarum	10-30
Streptococcus thermophilus	10-30
Lactobacillus bulgaricus	10-30
Lactobacillus acidophilus	10-30
Bifidobacterium longum	10-30
Streptococcus species	0-20
Escherichia coli	0-20
Staphylococcus species	0-20
Micrococcus	0-20
Acinetobacter	0-20
Bacteroides	0-20
Clostridium	0-20
Peptostreptococcus	0-20
Escherichia coli	0-20
Enterococcus species	0-20
Methanobrevibacter smithii	0-20
Lactobacillus casei	10-30
Lactobacillus plantarum	10-30
Collinsella	0-20
Lactobacillus ruminis	0-20
Atopobium	0-20
Lactobacillus sakei	10-30
Escherichia coli	0-20
Enterobacter aerogenes	0-20

Organism Tested	Reference Range
Streptococcus species	0-20
Solobacterium moorei	0-20
Atopobium parvulum	0-20
Roseburia intestinalis	10-30
Faecalibacterium prausnitzii	10-30
Prevotella copri	10-30
Alloprevotella	10-30
Catenibacterium	10-30
Tyzzarella	0-20
Tyzzarella 4	0-20
Lactobacillus plantarum	10-30
Streptococcus thermophilus	10-30
Porphyromonas gingivalis	0-20
Lactobacillus	10-30
Bifidobacteria	10-30
Proteobacteria	0-20
Enterobacteriaceae	0-20
Staphylococcaceae	0-20
Staphylococcus epidermidis	0-20
Staphylococcus pasteurii	0-20
Coprococcus	10-30
Akkermansia	10-30
Pseudobutyrvibrio	10-30
Proteus mirabilis	0-20
Enterococcus gallinarum	0-20
Clostridia clusters XIVa	10-30
Clostridia clusters IV	10-30
Clostridia clusters XVIII	10-30
Lactobacillus acidophilus	10-30
Lactobacillus casei	10-30
Bifidobacterium bifidum	10-30
Bifidobacterium animalis	10-30
Oscillospira	0-20
Christensenella minuta	0-20
Bacteroides caccae	0-20
Clostridium hathewayi	0-20
Clostridium ramosum	0-20
Clostridium symbiosum	0-20
Eggerthella lenta	0-20
Escherichia coli	0-20

Organism Tested	Reference Range
Blautia hydrogenotrophica	0-20
Ruminococcus obeum	0-20
Akkermansia muciniphila	10-30
Methanobrevibacter smithii	0-20
Bifidobacterium adolescentis	10-30
Lactobacillus paracasei	10-30
Lactobacillus rhamnosus	10-30
Lactobacillus acidophilus	10-30
Lactobacillus casei	10-30
Bifidobacterium animalis	10-30
Bifidobacterium	10-30
Lactobacillus	10-30
Bacillus subtilis	10-30
Propionibacterium freudenreichii	10-30
Bifidobacterium animalis subspecies lactis	10-30
Lactobacillus animalis	10-30
Ruminococcus bromii	10-30
Eubacterium rectale	10-30
Roseburia	10-30
Eubacterium rectale	10-30
Bifidobacteria	10-30
Lactobacillus animalis	10-30
Lactobacillus murinus	10-30
Bifidobacterium animalis	10-30
Methanobrevibacter	0-20
Butyricimonas	10-30
Lactobacillaceae	0-20
Bradyrhizobiaceae	0-20
Clotridiales Incertae Sedis IV	0-20
Enterobacteriaceae	0-20
Desulfovibrio	0-20
Bacteroides vulgatus	0-20
Bacteroidetes	0-20
Firmicutes	10-30
Bifidobacterium	10-30
Bacteroidales	0-20
Lachnospiraceae	10-30
Pseudomonas	0-20
Mycoplana	0-20
Haemophilus	0-20

Organism Tested	Reference Range
Blautia	0-20
Dorea	0-20
Prevotella	10-30
Coprococcus	10-30
Veillonellaceae	10-30
Firmicutes	10-30
Bifidobacterium	10-30
Bacteroidetes	0-20
Bacteroides	0-20
Lactobacillus acidophilus	10-30
Lactobacillus casei	10-30
Lactobacillus fermentum	10-30
Bifidobacterium bifidum	10-30
Lactobacillus brevis	10-30
Bifidobacterium dentium	10-30
Bifidobacterium animalis subsp lactis	10-30
Streptococcus thermophilus	10-30
Lactobacillus bulgaricus	10-30
Streptococcus	10-30
Lactococcus	10-30
Pediococcus	10-30
Lactobacillus	10-30
Leuconostoc	10-30
Proteobacteria	0-20
Fusobacteria	0-20
Veillonella	0-20
Streptococcus species	0-20
Clostridium	0-20
Lachnospiraceae	10-30
Ruminococcaceae	10-30
Clostridiales Family XIV Incertae Sedis	10-30
Enterobacteriaceae	0-20
Escherichia coli	0-20
Streptococci	0-20
Enterobacteria	0-20
Faecalibacterium prausnitzii	10-30
Ruminococcus	0-20
Prevotella	10-30
Enterococcus	0-20
Fusobacterium	0-20

Organism Tested	Reference Range
Streptococcus species	0-20
Veillonella	0-20
Lactobacillus rhamnosus GG	10-30
Lactobacillus	10-30
Bifidobacterium	10-30
Roseburia	10-30
Phascolarctobacterim	0-20
Clostridium	0-20
Ruminococcaceae	10-30
Faecalibacterium	10-30
Desulfovibrio piger	0-20
Faecalibacterium prausnitzii	10-30
Akkermansia muciniphila	10-30
Dialister invisus	10-30
Faecalibacterium prausnitzii	10-30
Bifidobacterium adolescentis	10-30
Ruminococcus gnavus	0-20
Enterococcus	0-20
Veillonella	0-20
Faecalibacterium prausnitzii	10-30
Saccharomyces boulardii	10-30
Lactobacillus reuteri	10-30
Lactobacillus plantarum	10-30
Lactobacillus salivarius	10-30
Bifidobacterium breve	10-30
Bifidobacterium bifidum	10-30
Lactobacillus acidophilus	10-30
Escherichia coli Nissle	10-30
Dorea	0-20
Ruminococcus	0-20
Clostridium	0-20
Lactobacillus	10-30
Veillonella	0-20
Bifidobacterium catenulatum	10-30
Bifidobacterium	10-30
Enterobacteriaceae	0-20
Roseburia	10-30
Eubacterium rectale	10-30
Bacillus coagulans	10-30
Bifidobacterium infantis	10-30

Organism Tested	Reference Range
Lactobacillus acidophilus	10-30
Lactobacillus plantarum	10-30
Lactobacillus rhamnosus	10-30
Bifidobacterium breve	10-30
Bifidobacterium lactis	10-30
Bifidobacterium longum	10-30
Streptococcus thermophilus	10-30
β -glucuronidase producing bacteria	0-20
β -galactosidase producing bacteria	0-20

4 Conclusion

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