CytoFlora™ Decreases Serum IgA and IgM against LPS of Enteric Bacteria and Improves ATEC Scores in Immune Compromised Children

By BioRay, Inc.
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CytoFlora™, a cell wall broken host of multi strain probiotics, corrects dysbiosis, delivering both an immune strengthening impact and the competitive exclusion effect which drives pathogens out of the gastro-intestinal tract without killing them and allows normal bowel flora to recolonize.

Ten autistic and immune-deficient children, ranging in age from 4 to 15 years old, were placed on a 3-week protocol of CytoFlora™. All pre-existing supplements and medications remained unchanged and no new supplements or medications, with the exception of CytoFlora™, were added during the study.

Immunobilan laboratory testing was completed by Redlabs U.S.A. and measured the serum IgA and IgM immune response levels to enteric bacteria present in the participant's blood samples. The testing measured IgA and IgM levels of Kiebsiella pneumoniae, Proteus mirabilis, Citrobacter koseri, Pseudomonas aeruginosa, Pseudomonas putida, Morganella morganii, and Hafnia alvei. Baseline results showed most levels elevated above 2.0, or normal range, with a mean IgA level of 4.22 and a mean IgM level of 1.86.

Participant benchmarks included parental completion of the Autism Treatment Evaluation Checklist (ATEC) in addition to Immunobilan laboratory testing. The ATEC was developed by Bernard Rimland and Stephen M. Edelson of the Autism Research Institute, and features a one-page form designed to be completed by parents, teachers, or caretakers. It consists of 4 subtests: Speech/Language Communication, Sociability, Sensory/ Cognitive Awareness, and Health/Physical/Behavior. Baseline testing showed eight of the fifteen children scoring in moderate to severe ranges on the ATEC, with a mean total score of 42.10.

In addition, parents reported a variety of symptoms at the start of the study, including food sensitivities, yellow teeth, hyperactivity/lethargy, irrational tempers/moods, constipation/diarrhea, anxiety, violent/destructive behaviors, distant and disconnected attitudes, lack of concern/interest in others or their environment, and an inability and disinclination to communicate, both verbally and nonverbally.

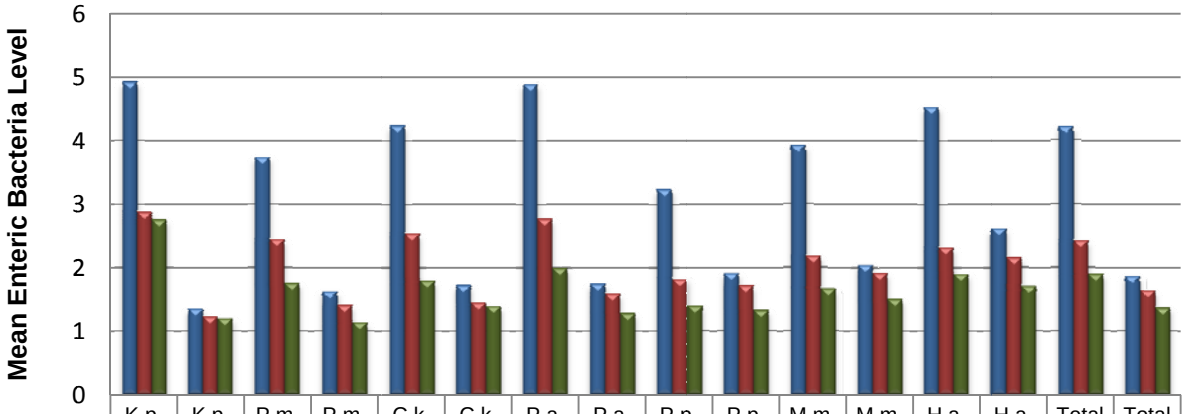
CytoFlora™ was administered to the children twice a day, at 5 dropperfuls per dose for a period of 21 days, at which point another blood test and ATEC was completed. Immunobilan testing revealed that 100% of the IgA markers had a statistically significant decrease, with a mean IgA level decrease of 1.79, 43%. IgM markers, however, seemed relatively unaffected, with no significant decrease recorded.

21-day ATEC scores also showed statistically significant decreases across the board, with a mean total score of 29.4, indicating an overall 30% improvement. Results revealed a 14% improvement in Speech/Language Communication, 27% improvement in Sociability, 20% improvement in Sensory/ Cognitive Awareness, and a 45% improvement in Health/Physical/Behavior.

Following the 21-day testing, the participants were monitored during a two-week washout period, during which CytoFlora™ was discontinued and no new supplements or medications were added to the child's protocol. At the end of the washout period, a 35-day Immunobilan blood test was administered.

The 35-day Immunobilan testing revealed a further decrease in IgA and IgM levels, with 12 of the 14 markers showing statistically significant results. All IgA markers continued to significantly decline, with a mean IgA level of 1.89, indicating an overall drop of 2.32, a 55% decrease. All IgM markers also declined, with a mean IgM level was 1.37, indicating an overall drop of .49, a 27% decrease.

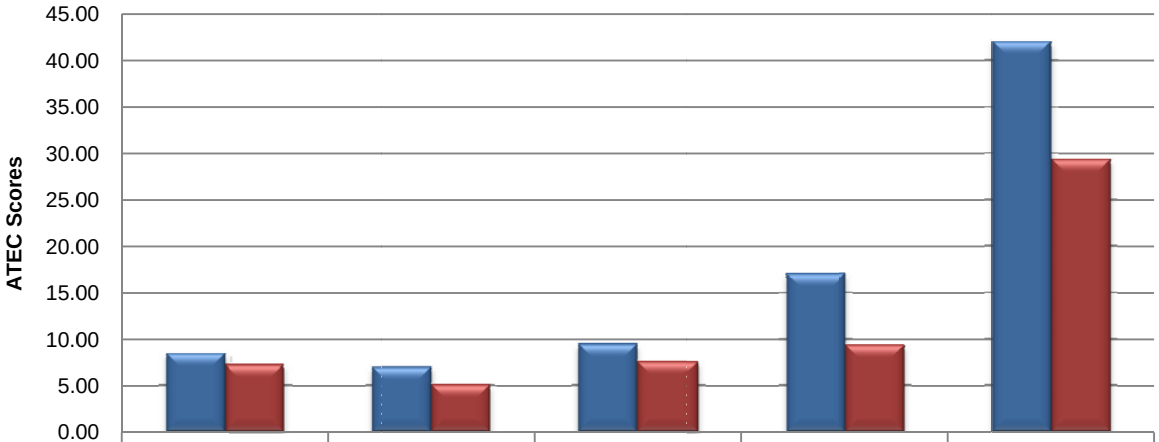
Mean Immunobilan Lab Results



	K.p. IgA	K.p. IgM	P.m. IgA	P.m. IgM	C.k. IgA	C.k. IgM	P.a. IgA	P.a. IgM	P.p. IgA	P.p. IgM	M.m. IgA	M.m. IgM	H.a. IgA	H.a. IgM	Total IgA	Total IgM
Day 1	4.92	1.35	3.73	1.62	4.24	1.72	4.9	1.75	3.24	1.90	3.91	2.04	4.54	2.61	4.22	1.86
Day 21	2.87	1.22	2.44	1.40	2.54	1.45	2.77	1.59	1.82	1.71	2.17	1.91	2.32	2.15	2.42	1.64
Day 35	2.75	1.2	1.75	1.13	1.79	1.4	1.99	1.28	1.39	1.32	1.66	1.50	1.90	1.70	1.89	1.37

Mean Immunobilan Lab Results show a 55% overall decrease in IgA levels and a 27% overall decrease in IgM levels after 31 days. Normal Range is considered to be below 2.0 and an extreme positive/high range is considered to be above 3.0.

Mean ATEC Scores



	Speech/Language Communication	Sociability	Sensory/Cognitive Awareness	Health/Physical Behavior	Total Score
Day 1	8.50	7.00	9.50	17.10	42.10
Day 21	7.30	5.10	7.60	9.40	29.40

Mean scores from the Autism Treatment Evaluation Checklist (ATEC) show a 30% overall improvement after 21 days.