



*UAS Labs' Superstrain*  
*Lactobacillus acidophilus* DDS<sup>®</sup>-1



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## Summary

The DDS<sup>®</sup>-1 strain of *Lactobacillus acidophilus* has been used in numerous laboratory, animal, and human clinical studies, and has been shown to have a positive effect on digestion, immune function, and skin conditions.

The aim of this white paper is to present a review of literature regarding the clinical and laboratory evidence behind *Lactobacillus acidophilus* on supporting health. It will focus on the DDS<sup>®</sup>-1 strain, supplied exclusively by UAS Labs, and its benefits across the age spectrum.

## The Opportunity

Over the past several years, there has been an explosion of information regarding the role that the human microbiota plays in both health and disease. Projects such as the National Institutes of Health Human Microbiome Project,<sup>1</sup> the European Meta-Hit Project,<sup>2</sup> the Belgian Flemish Gut Flora Project,<sup>3</sup> as well as the creation of the International Human Microbiome Consortium are collecting data on the human microbiota from large populations that will contribute to increased knowledge about the microbes inhabiting the body. These projects will also offer information on the impact of host and environmental factors on microbiota variations within average, healthy populations and provide information on microbiome-associated variables that may point to disease risks as well.

One of the growing areas of interest regarding the microbiome is diversity across all age groups. Probiotics are being used with increasing frequency worldwide, and as such, the safety and efficacy of probiotics for use in males and females of all ages, from infants and children to adults, have been reviewed by experts in food safety.<sup>4-8</sup> All reviews support the safety and sustainability of lactobacilli and bifidobacteria for use as oral probiotics, a conclusion largely based on their long history of safe use in food and as dietary supplements.

## The History

As one of the pioneering probiotic scientists, Dr. Khem Shahani began his landmark research on *L. acidophilus* at the University of Nebraska in the late 1950's. There, he discovered a strain of *L. acidophilus* (now known as DDS<sup>®</sup>-1) that showed superior growth, stability, health potential. Dr. Shahani would spend the rest of his career unlocking the strain's potential for improving overall health.

Providing DDS<sup>®</sup>-1 to the food and dietary supplement market for almost 40 years, UAS Labs continues to build on its probiotic industry leadership, with multiple state-of-the-art facilities dedicated to manufacturing probiotic solutions. This passion for probiotic perfection is exemplified by UAS' ability to create probiotic products in an optimal environment, its expertise in the field with a continual focus on advancing probiotic science and offering superior, clinically-studied probiotics, including *Lactobacillus acidophilus* DDS<sup>®</sup>-1. DDS<sup>®</sup>-1 research has over 28 peer-reviewed publications, and we continue to unlock the benefits by investing in human trials on multiple continents.

## DDS<sup>®</sup>-1 Introduction

The DDS<sup>®</sup>-1 strain of *Lactobacillus acidophilus* is a unique strain of *L. acidophilus* known to have a high tolerance to acidity, making it ideal for passage through the stomach and into the bowel where it can colonize. A recent study compared *L. acidophilus* to autochthonous species *L. reuteri* and *L. mucosae* in the ability to colonize the human GI tract. All three organisms were found to successfully colonize the GI tract, as quantified by assessment of fecal samples.<sup>9</sup> Naturally, the autochthonous species demonstrated higher quantities in fecal stool compared with *L. acidophilus*, and only one of the twelve human subjects was found to have detectable bacteria 8 days after the end of consumption. These findings indicate that while these probiotics successfully colonize the GI tract, even preparations of autochthonous species must continue to be consumed on a regular basis to ensure persistence in the gut.

## Probiotic Properties

### Gastrointestinal Survival and Adherence

*L. acidophilus* DDS<sup>®</sup>-1 has been assessed *in vitro* and shown to have several important probiotic characteristics, including:

- High resistance to low pH conditions and pepsin present in the stomach.
- High resistance to bile salts and pancreatin at physiological concentrations present in the duodenum.
- Strong adherence potential to representative human intestinal cell lines, including Caco-2 and HT-29. Attachment to these cell lines is considered a good indicator of adherence potential in the GI tract.

### Inhibitory Properties against Common Pathogens

*L. acidophilus* DDS<sup>®</sup>-1 has been shown to inhibit a range of gastrointestinal pathogens *in vitro*, an important attribute of a probiotic. Mechanistically, probiotics may be able to inhibit, displace and compete with pathogens and thus positively modulate the intestinal microflora. *L. acidophilus* DDS<sup>®</sup>-1 is also unique due to its ability to produce a compound, acidophilin, with natural anti-pathogenic potential.



# Pre-clinical Studies

## Intestinal Colonization

Two trials were conducted to determine the impact of *L. acidophilus* DDS<sup>®</sup>-1 in gnotobiotic and conventional pigs. In a first trial with 24 gnotobiotic pigs (12 treated and 12 control), the *L. acidophilus* DDS<sup>®</sup>-1 treated group was found to have a significantly higher population of *L. acidophilus* ( $p < 0.001$ ).<sup>16</sup> Elevated *L. acidophilus* populations were maintained for up to 9 days post-inoculation. In a second trial with 4 conventional pigs (2 treatment and 2 control), *Lactobacillus* populations increased linearly ( $p < 0.05$ ) and *E. coli* populations decreased linearly ( $p < 0.01$ ) with treatment, however no significant differences were demonstrated between groups.<sup>16</sup>

In a follow-up study, seventy-two crossbred pigs were utilized to study the effect of *L. acidophilus* DDS<sup>®</sup>-1 in starter diets on weight gain, feed conversion, fecal *Lactobacillus* and coliform counts.<sup>17</sup> *L. acidophilus* DDS<sup>®</sup>-1 administration was shown to increase fecal *Lactobacillus* counts. Further, pigs receiving lactose in combination with *L. acidophilus* DDS<sup>®</sup>-1 had the highest *Lactobacillus* counts as well as most pronounced average daily weight gain.

## Intestinal Activity and Probiotic Functionality

*L. acidophilus* DDS<sup>®</sup>-1 has also been assessed for its impact on intestinal activity and functionality in multiple pre-clinical studies.

- Rats administered *L. acidophilus* DDS<sup>®</sup>-1 milk showed a higher protein digestibility than their control counterparts.<sup>18</sup>
- *L. acidophilus* DDS<sup>®</sup>-1 has been suggested to possess potential anti-tumor and anti-carcinogenic properties, as a result of its intestinal activity *in vivo*.<sup>19,20</sup>
- *L. acidophilus* DDS<sup>®</sup>-1 demonstrated cholesterol lowering efficacy in a rat model. Relative to control milk, milk fortified with *L. acidophilus* DDS<sup>®</sup>-1 achieved significant reduction in cholesterol levels in rats.<sup>21</sup>

# Clinical Studies

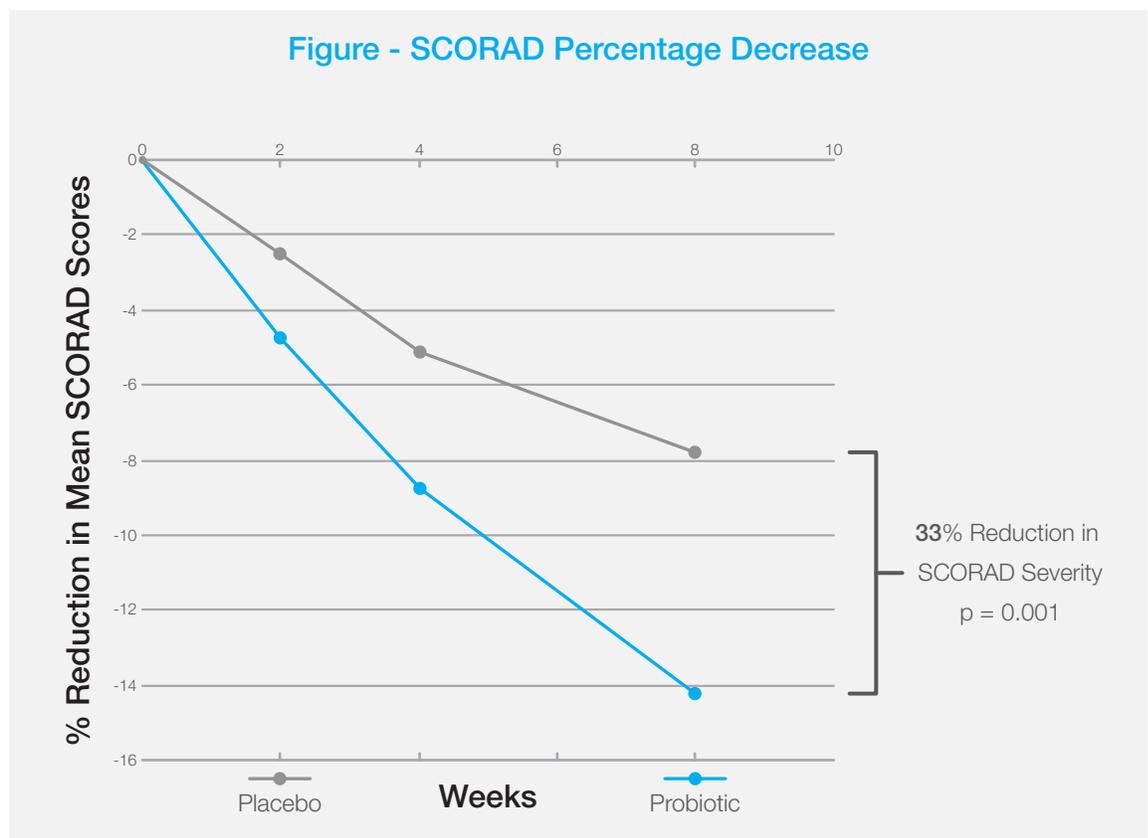
## Atopic Dermatitis

The clinical efficacy of *L. acidophilus* DDS<sup>®</sup>-1, combined with *B. lactis* UABla-12 was assessed in preschool children with atopic dermatitis (AD). In a randomized, double-blind, placebo-controlled clinical trial, 90 children ages 1 to 3 years old with moderate to severe AD were given either the probiotic at a dosage of 5 billion CFU twice daily or placebo for 8 weeks.<sup>22</sup>

The primary outcome measure was the percentage change in the Scoring of Atopic Dermatitis (SCORAD) value. Secondary outcome measures included changes in the Infant Dermatitis Quality Of Life (IDQOL) and Dermatitis Family Impact (DFI) scores, frequency of topical corticosteroid used, and lymphocyte subsets (CD3, CD4, CD8, CD16, CD22 and CD25) in the peripheral blood were measured by laser flow cytometry. CD4 and CD25 lymphocytes are often elevated in AD while CD8 is reduced.<sup>23</sup>

At week 8, the percentage decrease in SCORAD was 33.7% for the probiotic group, compared to 19.4% in the placebo group ( $p = 0.001$ ; see Figure below). At week 8, children in the probiotic group also showed a greater decrease in the mean [SD] SCORAD score compared to those in the placebo group (-14.2 [9.9] vs -7.8 [7.7], respectively;  $p = 0.001$ ). IDQOL and DFI scores decreased significantly from baseline by 33% and 35.2% in the probiotic group compared to 19% and 23.8% in the placebo group ( $p = 0.013$  and  $p = 0.010$ , respectively). Use of topical corticosteroids during the 8-week trial period averaged 7.7 g less in the probiotic group ( $p = 0.006$ ).

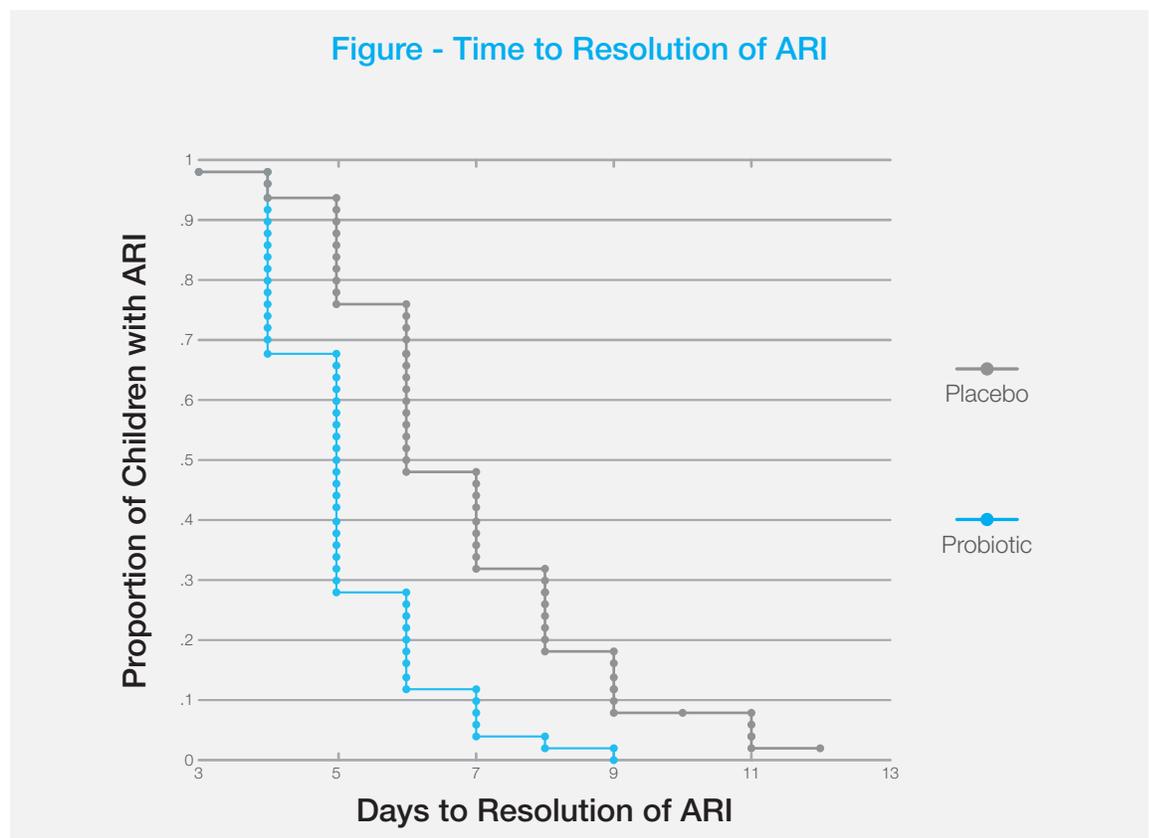
The percentage of CD4, and the percentage and absolute count of CD25 lymphocyte subsets decreased while the absolute count of CD8 increased significantly in the probiotic group compared to the placebo group at week 8 ( $p < 0.007$ ). There was a significant correlation between CD4 percentage, CD25 percentage, CD25 absolute count, and SCORAD values in the probiotic group at week 8 ( $p < 0.05$ ). The investigators suggest this may represent a positive influence on the balance of T helper-1/T helper-2 ratio in the probiotic group. There were no clinically significant adverse events in either group.



## Acute Respiratory Infections

In a randomized, double-blind, placebo-controlled clinical trial, 240 children ages 3 to 12 years old were enrolled to assess the short-term use of probiotics in ARIs.<sup>24</sup> On the first day of appearance of a sick household member, the otherwise healthy subject was randomized to receive *L. acidophilus* DDS®-1, in combination with *B. lactis* UABLa-12, at a dose of 5 billion CFU per day or placebo. The primary outcome measure was the incidence of ARIs. The secondary outcomes were time to resolution and severity of the ARIs.

In all, 64 of 113 children in the probiotic group (57%) and 73 of 112 children in the control group (65%) developed ARIs ( $p = 0.261$ ). However, time to resolution of the secondary ARI was significantly shorter in the probiotic group (5 days vs. 7 days, respectively;  $p < 0.001$  [See Figure below]). The median severity of ARIs was significantly less in the probiotic group compared to the placebo group ( $p < 0.001$ ). Comparing the probiotic and placebo groups, there was a 2-day decrease in the median number of days or daycare/school missed 7 vs. 9, respectively;  $p < 0.001$ ) or workdays missed by a caregiver (5 vs. 7, respectively;  $p < 0.001$ ). As in the study above, there were no clinically significant adverse events in either group.



## Symptoms of Lactose Intolerance

A randomized, double-blind, placebo-controlled, crossover study evaluated the effect of *L. acidophilus* DDS<sup>®</sup>-1, taken once daily for 4 weeks, on relieving discomfort related to lactose intolerance.<sup>25</sup> The study enrolled healthy volunteers between 18 and 75 years of age who complained of lactose intolerance. Screening visits included a lactose challenge visit to confirm eligibility. Qualified subjects participated in a crossover design, with each arm consisting of 4 weeks of intervention of either active or placebo product, with a 2-week washout period during crossover. Data collected included subjective symptom scores related to lactose intolerance. While no significant changes were observed in hydrogen breath tests (HBT), *L. acidophilus* DDS<sup>®</sup>-1 demonstrated statistically significant reductions, as compared to placebo, in abdominal symptom scores during the 6-h lactose challenge at week 4 for diarrhea ( $p = 0.033$ ), abdominal cramping ( $p = 0.012$ ), vomiting ( $p = 0.0002$ ) and overall symptom score ( $p = 0.037$ ).

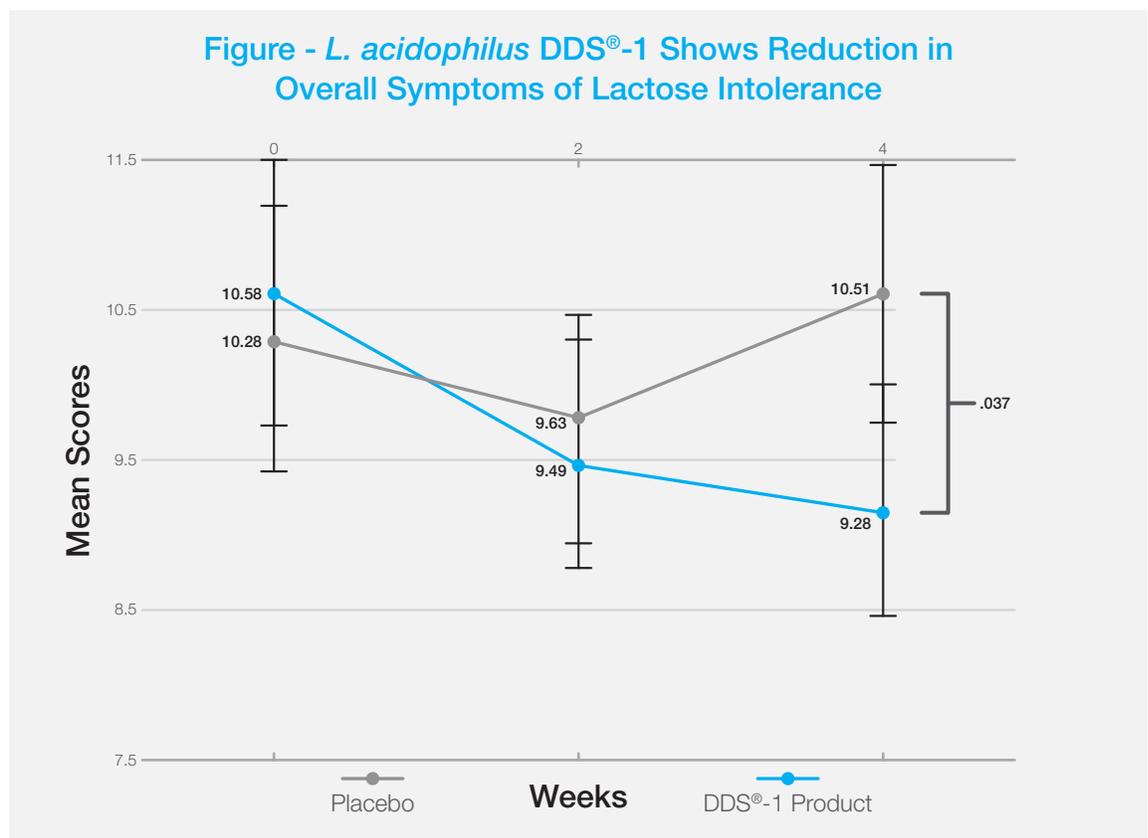


Figure - *L. acidophilus* DDS<sup>®</sup>-1 Shows Reduction in Vomiting Symptoms of Lactose Intolerance

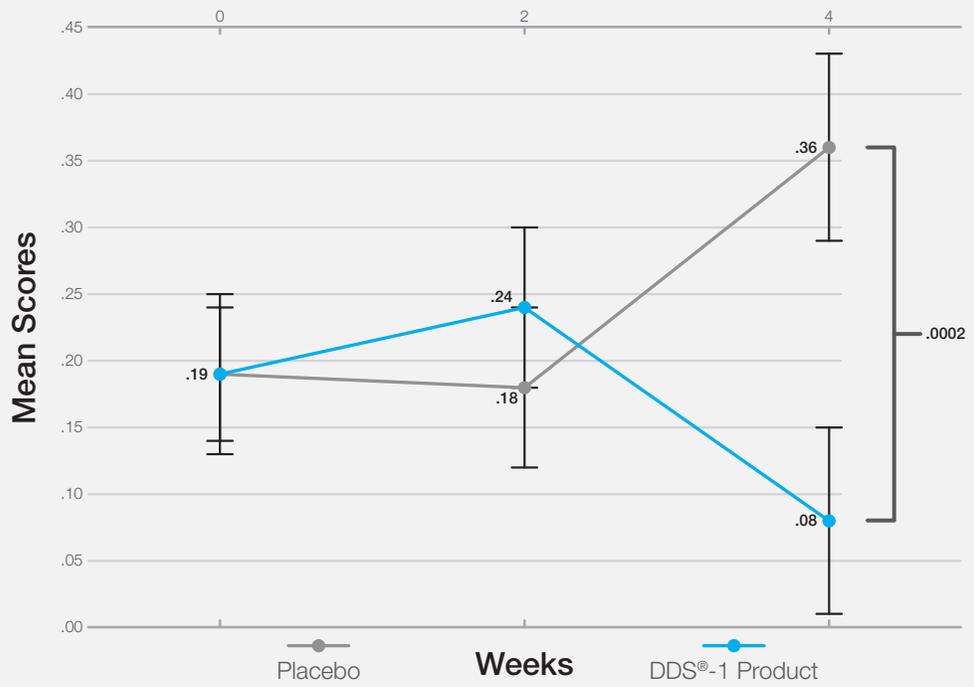
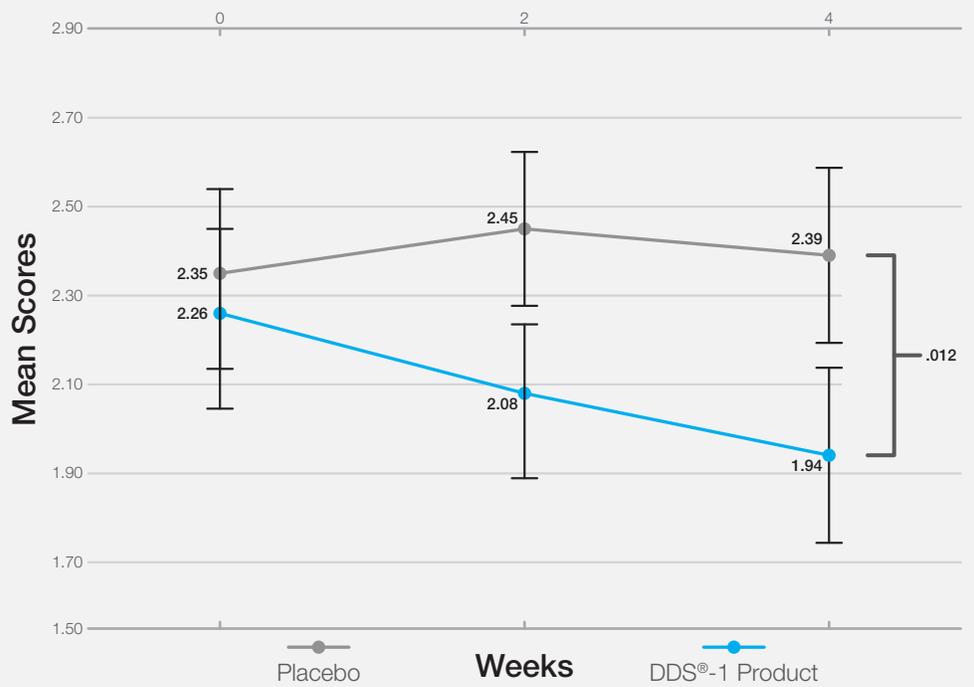


Figure - *L. acidophilus* DDS<sup>®</sup>-1 Shows Reduction in Abdominal Cramping Symptoms of Lactose Intolerance



## Functional Constipation

A probiotic blend, which included *L. acidophilus* DDS<sup>®</sup>-1 as a primary strain, was assessed in a randomized double-blind, placebo-controlled, parallel arm study in adults with symptoms of functional constipation.<sup>26</sup> Briefly, 100 healthy men and women, with constipation symptoms, were randomized to receive a four strain probiotic, at a dose of 15 billion CFU daily, or placebo over a 4-week intervention period.

Subjects receiving the probiotic demonstrated a faster normalization in their bowel habits, including stool frequency and consistency. Between groups, there was a significant difference in the average stool consistency after the first week of intervention ( $p = 0.03$ ); during that week, the probiotic group had a significantly higher Bristol Stool Scale (BSS) score than placebo. A 20% improvement over the placebo in stool consistency was observed as participants supplemented with the probiotic moved from being constipated at baseline to within normal stool consistency after week-1 of supplementation. The BSS scores of participants receiving the probiotic showed significant increases in average stool consistency from baseline to weeks 2, 3 and 4 ( $p < 0.001$ ) as well, however no significant between group differences were demonstrated at these timepoints due to a large placebo response. Within 1 week of intervention, as measured by Complete Spontaneous Bowel Movements (CSBM) per week, the probiotic group demonstrated a trend to a greater increase in stool frequency as compared to the placebo group ( $p=0.057$ ).

While microbial profiling did not show appreciable shifts, changes were nevertheless observed within the phylum, family and genus levels. Over the intervention period, the probiotic group demonstrated a significant increase in overall abundance of Ruminococcaceae, a family that has been associated with essential bacteria that produce short chain fatty acids. Further, Ruminococcaceae abundance has been shown to be positively correlated with BSS scores and faster intestinal transit.<sup>27</sup> Simultaneously, a decrease in overall abundance was shown in the Tenericutes phylum and the Erysipelotrichaceae family. Lastly, a targeted qPCR assay identified all four strains of the probiotic blend in fecal samples of subjects supplemented with the probiotic. Significantly more total genome equivalents of all four probiotic strains were observed at endpoint, indicating that all strains were recoverable following oral administration. In comparison, no differences were observed in the placebo group. As in the studies outlined above, there were no clinically significant adverse events in either group.

## Irritable Bowel Syndrome

*L. acidophilus* DDS<sup>®</sup>-1, in combination with *Bifidobacterium* strains, was shown to help alleviate symptoms of Irritable Bowel Syndrome in an open label study.<sup>28</sup> The most significant improvement occurred after two months of treatment with 84% improvement in abdominal pain, 73.9% in bloating, 92% in belching, 88% in flatulence, 90.9% in diarrhea and 86.9% in constipation. There were no clinically significant adverse events in either group.

## Prevention of Traveler's Diarrhea

The effects of *L. acidophilus* DDS<sup>®</sup>-1 on traveler's diarrhea was also investigated. The study examined 70 subjects over three different study periods.<sup>29</sup> In open-label fashion, subjects received *L. acidophilus* DDS<sup>®</sup>-1 capsules, at a dose of (two billion CFU per day), for one week prior to travel, and during the entire duration of travel. Subjects visited a collection of countries, wherein the anticipated incidence of gastrointestinal disturbance during such travel was estimated to be 25-30%. In contrast, only two of the 70 subjects (3%) receiving *L. acidophilus* DDS<sup>®</sup>-1 reported experiencing gastrointestinal disturbance and associated symptoms during their respective trips.

## Gastrointestinal Transit, Modulation of Microbiota and Colonization

A number of pilot clinical trials have evaluated the ability of *L. acidophilus* DDS<sup>®</sup>-1 to either survive gastrointestinal transit and/or positively modulate gastrointestinal ecology.

- In one study, 10 subjects were administered two billion CFU *L. acidophilus* DDS<sup>®</sup>-1 for three weeks.<sup>30</sup> Stool concentrations of *L. acidophilus* DDS<sup>®</sup>-1 were determined before and after the three-week intervention period. The 10 subjects experienced a mean 100-fold increase in fecal concentrations of *L. acidophilus* following three weeks of daily supplementation. This outcome suggests good survival of *L. acidophilus* DDS<sup>®</sup>-1 following oral administration in humans.
- In another study, the effect of ingesting *Lactobacillus acidophilus* DDS<sup>®</sup>-1 milk was assessed on fecal microflora and enzyme activity in humans.<sup>31</sup> Ingestion of normal milk or *L. acidophilus* DDS<sup>®</sup>-1 milk had no significant effect on fecal total aerobic counts, however there was a decrease in fecal coliform counts and an increase in *Lactobacillus* counts when each subjects consumed *L. acidophilus* DDS<sup>®</sup>-1 milk. Additionally, fecal beta-glucuronidase and beta-glucosidase activities appeared to decrease when *L. acidophilus* milk was ingested. These enzymes have been reported to be involved in the conversion of procarcinogens to carcinogens.
- In children, administration of *L. acidophilus* DDS<sup>®</sup>-1, in combination with *B. lactis* UABla-12 reduced fecal counts of opportunistic enterobacteria (*Proteus*, *Klebsiella*, *Cytrobacter*, *Enterobacter*, *Pseudomonas* species).<sup>32</sup> However, in this study, the combination failed to achieve statistically significant increases in either *L. acidophilus* or *B. lactis* in stool samples.
- As mentioned above, the colonization ability of two *Lactobacillus* strains identified as autochthonous to the human gastrointestinal tract was compared with *L. acidophilus* DDS<sup>®</sup>-1 (allochthonous strain).<sup>9</sup> Colonization ability was tested in a single-blinded, cross-over study, with twelve human subjects. All three organisms were found to be successfully recovered post-GI transit, as quantified by assessment of fecal samples. Further, all three strains became undetectable 8 days after the end of consumption with one exception, showing that persistence remains short term in most individuals.

## Probiotic Functionality

*L. acidophilus* DDS<sup>®</sup>-1, in combination with *B. longum* was assessed for its ability to enhance the cholesterol lowering effect of soy in 37 postmenopausal women. The results confirmed a beneficial effect of soy on plasma cholesterol in mildly hypercholesterolemic postmenopausal women independent of equol production status, but did not support an independent or additive effect of these particular probiotic bacteria.<sup>33</sup> In another study with 20 postmenopausal breast cancer survivors and 20 healthy postmenopausal women it was shown that consumption of probiotic capsules containing *L. acidophilus* DDS<sup>®</sup>-1, in combination with *B. longum* did not significantly alter reproductive hormone concentrations, regardless of equol producer status.<sup>34</sup>

## Urinary Tract Health

As described above, an *in vitro* study discussed the potential synergies of *L. acidophilus* DDS<sup>®</sup>-1 combined with bioactive proanthocyanidins, on reducing the invasiveness of Extra-intestinal pathogenic *Escherichia coli*, a common urinary tract pathogen. In a clinical case study, *L. acidophilus* DDS<sup>®</sup>-1, at a dose of two billion CFU twice daily, was shown to be efficacious in the prevention of a pediatric recurrent urinary tract infection.<sup>35</sup>

## The Benefits

The genus *Lactobacillus*, the species *L. acidophilus* and the strain *L. acidophilus* DDS<sup>®</sup>-1 have a documented safe history of use in food.

*Lactobacillus acidophilus* is listed in the International Dairy Federation (IDF) Inventory of Microorganisms with a Documented History of Use in Food.<sup>37,38</sup> Additionally, the European Food Safety Authority (EFSA) found that members of *Lactobacillus acidophilus* species are safe for general use in foods and supplements without restriction and exempt from requirements for pre-market approval of use (Qualified Presumption of Safety, QPS).

To leave no doubt, more recently UAS Labs has consulted the scientific literature, and performed specific safety testing as recommended by Pariza et al.<sup>36</sup> for the determination of the safety of microbial food cultures, including probiotics and has concluded by scientific procedures that *L. acidophilus* DDS<sup>®</sup>-1, is safe for the use as a dietary ingredient. Moreover, numerous *L. acidophilus* DDS<sup>®</sup>-1 human feeding trials in adults and children have not noted any significant adverse effects on study participants.<sup>9,22,24,25,28,31,33,35</sup>

The strain is available in a wide variety of stable supplement and food formats, and benefits from significant continued investment in clinical science.

## Availability

UAS Labs is proud to be the exclusive provider of the DDS<sup>®</sup>-1 strain of *Lactobacillus acidophilus*. As a leader in the industry, we will not rest on the history of the strain but rather focus on its future. DDS<sup>®</sup>-1 is part of our continued clinical investment roadmap and documentation plans.

The DDS<sup>®</sup>-1 strain is commercially available for our preferred partners today. Contact UAS Labs to discuss how this unique strain can be added to your probiotic portfolio today!

Contact a Probiotic Expert at 800-422-3371 or [info@uaslabs.com](mailto:info@uaslabs.com).

## About UAS Labs

At UAS Labs, quality is everything. Their team of probiotic experts has dedicated the past 35+ years to not only producing a quality product, but also to enhancing wellness and quality of life. Where others have merely followed a trend, UAS has continued to invest. Their product development and leadership in gold-standard clinical trials continue to push the probiotic industry forward. From Strain to Solution™, UAS controls every step in the probiotic manufacturing process with precision. Their commitment to excellence starts with strategic probiotic strain selection, continues to cutting-edge fermentation and ends with optimum preservation of the product. The singular focus and dedication to quality make it easy to see how UAS Labs has earned their name as The Probiotic Company<sup>®</sup>.

To learn more visit [www.uaslabs.com](http://www.uaslabs.com).

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