Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Combination Probiotic in Pediatric Gastroenteritis: A Multicenter Trial

Supplementary Material

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Institute, University of Alberta, Edmonton, AB, Canada; 11 Provincial Laboratory for Public Health, and Department of Laboratory Medicine and Pathology, University of Alberta, Edmonton, AB, Canada; 12 Division of Pediatric Emergency Medicine, Washington University School of Medicine, St. Louis, MO, USA; 13 Children's Minnesota and Department of Pediatrics, University of Minnesota School of Medicine, Minneapolis, MN, USA; 14 Division of Paediatric Emergency Medicine and Research Institute, The Hospital for Sick Children, University of Toronto, Toronto, ON, Canada.
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References
List of Investigators and Study Sites/Research Ethics Boards

All study sites recruited participants in the emergency departments of their respective institutions. The lead investigators at each site are shown in bold.

<table>
<thead>
<tr>
<th></th>
<th>Investigators</th>
<th>Site &amp; Location</th>
<th>Average Emergency Department Annual Number of Visits</th>
<th>Number of Participants Enrolled</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Stephen B. Freedman MDCM, MSc, Sarah Williamson-Urquhart BScKIN, David Johnson MD</strong></td>
<td>Alberta Children’s Hospital, University of Calgary, Calgary, Alberta, Canada</td>
<td>75,000</td>
<td>196</td>
</tr>
<tr>
<td>2</td>
<td><strong>Suzanne Schuh MD, Yaron Finkelstein MD, Judy Sweeney RN, Maggie Rumatir MD</strong></td>
<td>The Hospital for Sick Children, University of Toronto, Toronto, Ontario, Canada</td>
<td>70,000</td>
<td>133</td>
</tr>
<tr>
<td>3</td>
<td><strong>Ken Farion MD, Amy Plint MD, MSc, Dale Dalgleish RN</strong></td>
<td>Children’s Hospital of Eastern Ontario, University of Ottawa, Ottawa, Ontario, Canada</td>
<td>75,000</td>
<td>265</td>
</tr>
<tr>
<td>4</td>
<td><strong>Serge Gouin MDCM, Marie-Christine Auclair RN</strong></td>
<td>Centre Hospitalier Universitaire Sainte-Justine, Université du Québec à Montréal,</td>
<td>85,000</td>
<td>183</td>
</tr>
<tr>
<td></td>
<td>Name</td>
<td>Institution</td>
<td>Participants</td>
<td>Division</td>
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<td>---</td>
<td>-----------------------------</td>
<td>--------------------------------------------------</td>
<td>--------------</td>
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<td>5</td>
<td>Katrina Hurley MD, Karen Black MD, Eleanor Fitzpatrick RN</td>
<td>IWK Health Centre, Dalhousie University, Halifax, Nova Scotia, Canada</td>
<td>33,000</td>
<td>41</td>
</tr>
<tr>
<td>6</td>
<td>Naveen Poonai MD</td>
<td>London Children’s Hospital, University of Western Ontario, London, Ontario, Canada</td>
<td>37,000</td>
<td>68</td>
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**Study Conduct**

An independent Data Safety Monitoring Committee (DSMC) provided oversight. The principal investigative site (Alberta Children’s Hospital – The University of Calgary) conducted periodic quality assurance audits at all sites. The Principal Investigator contracted with the study drug manufacturer (Lallemand Health Solutions, Montreal, Quebec) to prepare the investigational product and placebo. Study drug kits were prepared and distributed by the Alberta Health Services Research Support Pharmacy (Calgary, Alberta). Randomization services were provided by [www.randomize.net](http://www.randomize.net). Study data management was contracted out to the Women and Children’s Health Research Institute (WCHRI) Data Coordinating Centre at the University of Alberta (Edmonton, Alberta). All authors assume responsibility for the manuscript’s accuracy and vouch for its completeness and fidelity to the study protocol.
Probiotic

Quantitative Bacterial Culture

<table>
<thead>
<tr>
<th>Batch #</th>
<th>Expiration Date</th>
<th>Testing Date</th>
<th>Colony Forming Unit Count/Gm</th>
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<tr>
<td>1</td>
<td>June 2015</td>
<td>November 28, 2016</td>
<td>6.19 x 10^9</td>
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<td>2</td>
<td>July 2016</td>
<td>November 28, 2016</td>
<td>9.36 x 10^9</td>
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<tr>
<td>3</td>
<td>December 2017</td>
<td>May 30, 2017</td>
<td>6.13 x 10^9</td>
</tr>
</tbody>
</table>

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The probiotic preparation (Lacidofil® STRONG) is a lyophilized powder containing 4.0 x 10^9 CFU of two-bacterial strains – *Lactobacillus rhamnosus* R0011 and *Lactobacillus helveticus* R0052 in a 95:5 ratio. Both the probiotic and placebo sachets contained maltodextrin, magnesium stearate and ascorbic acid as inert excipients. The strains are registered at the Institut Pasteur Collection Nationale de Cultures de Microorganismes (CNCM, Paris, France) as I-1720 and I-1722, respectively.

Administration

To optimize probiotic viability, carbonated and highly acidic beverages were avoided, doses were administered at meal time, and ingested as quickly as possible after preparation.
Specimen Processing and Testing

Acquisition

If a stool specimen was unavailable in the emergency department, two rectal swabs [nylon swab (Copan, Italy) in liquid Amies media for bacterial culture; FLOQSwabs\textsuperscript{TM} (Copan, Italy) for molecular testing] were performed prior to discharge.\textsuperscript{1} In addition, families that consented to participate in additional sub-studies collected the first available stool at home which was retrieved by a courier who transported it to the laboratory for analysis. Stool samples and flocked swabs were frozen at -80°C and stored in Universal Transport Media (Copan, Italy) until they were shipped for additional testing.

Testing

Routine enteric bacterial culture was initially performed locally at each participating institution. Subsequently, specimens were shipped to the ProvLab Alberta for additional testing employing the Luminex xTAG Gastrointestinal Pathogen Panel (GPP). The latter is a bead-based syndromic assay that incorporates a multiplex reverse transcription – polymerase chain reaction with a hybridization-based universal tag sorting system panel that tests for adenovirus 40/41, norovirus genogroup I/II, rotavirus A, Clostridium difficile toxin A/B, Campylobacter sp., Escherichia coli O157, Enterotoxigenic E. coli, heat-labile enterotoxin/heat-stable enterotoxin, Salmonella sp., Shiga-toxin producing E. coli, Shiga-like toxin 1/2, Shigella sp., Vibrio cholerae, Yersinia enterocolitica, Cryptosporidium sp., Entamoeba histolytica and Giardia sp.\textsuperscript{2}

Processing

100-150 mg of solid stool, 100 µL of liquid stool, or 300 µL of the phosphate-buffered saline-rectal swab suspension was added to Bertin SK38 soil grinding lysis bead tubes along
with 10 μL of bacteriophage MS2 (both from Luminex Molecular Diagnostics, Toronto) to a final volume of 1000 μL. Total nucleic acid was extracted and eluted in 70 μL using the NucliSENS® easyMag® extractor (bioMérieux, Marcy-l'Étoile, France) according to manufacturer’s instructions and stored at -80°C. Ten μL of nucleic acids was used in GPP testing. The GPP test was performed as per manufacturer’s instructions.
Rationale for Selection of the Modified Vesikari Scale (MVS)

Score as the Primary Outcome

The primary outcome is the development of moderate-severe disease in the 2 weeks after the index ED visit as measured by the MVS.\textsuperscript{3} The original 20 point Vesikari Score has been employed as a dichotomous variable in many clinical studies.\textsuperscript{4-12} It has been shown to correlate with measures such as caregiver anxiety, helplessness, and stress.\textsuperscript{13} Increasing severity scores were associated with higher parental worry, greater changes in the child’s behavior, and trends towards greater impact on the parents’ daily activities and higher parental distress.\textsuperscript{14}

Percent dehydration, an element of the original score,\textsuperscript{12} is challenging to determine. While using baseline and rehydrated weights is the gold standard,\textsuperscript{15} this is often of limited value, especially in infants and toddlers, due to difficulties in ensuring follow-up, determining when rehydration has occurred, and the variation related to timing of voiding, stooling, eating, and drinking. Moreover, clinical estimates of dehydration are highly inaccurate.\textsuperscript{16} Thus, this element is omitted or incorrectly assigned in most studies. The MVS score includes an important and easy to obtain outcome that reflects global disease severity – need for unscheduled future health care visits within 2 weeks of the index visit.\textsuperscript{3} This is supported by evidence that the utilization of professional medical care correlates with disease severity.\textsuperscript{13} Unscheduled future health care visits is a powerful marker that has the capacity to alter clinical practice and influence decision makers. Similar modifications have been performed previously when percent dehydration has been unavailable.\textsuperscript{13,17} Furthermore, because ED care does not alter the disease process in AGE, ED revisits are very common.\textsuperscript{18,19}
Characteristics of the MVS: The MVS was prospectively evaluated in an 11 center (455 children) ED study \(^3\) which found that it effectively measures global disease severity. Factor analysis revealed that item correlations were acceptable and supported the appropriateness of retaining all factors. Multi-collinearity was not a problem and the correlations between the MVS and other measures of clinical significance were in the expected direction. Disease severity was associated with prolonged daycare (P = 0.01) and work absenteeism (P = 0.002). The MVS had a normal distribution with minimal kurtosis (-0.14; SE: 0.24) and skewing (0.39; SE: 0.12). There was good variation across severity ranges (49% mild; 21% moderate; 30% severe). Variation between institutions was insignificant (P = 0.11) and complete follow-up was achieved in 91% of participants.

How was the MVS Calculated?: Following enrollment (Time 0), follow-up occurred daily until both the diarrhea and vomiting had resolved. Each variable was scored, as appropriate, based on the clinically most severe 24-hour period (e.g. maximal number of vomiting or diarrhea episodes in a 24-hour period), the total symptom duration (e.g. number of days of vomiting or diarrhea) or event occurrence (e.g. health-care visits, treatments administered). Once follow-up was completed (Day 14) each variable was assigned a score for the entire study period (Time 0 to Day 14). The points associated with each of the seven elements are then added together to provide a total score.

The primary outcome (the presence of moderate-severe disease, as defined by a MVS of \( \geq 9 \) during the 2 week follow-up period) only included symptoms and outcomes that occurred following the ED visit (i.e. after randomization) and it was not directly impacted by the pre-enrollment score.
Why a cut-point of 9?: With the original score, severe disease was defined as $\geq 11$, moderate as $\geq 9$. In the MVS derivation study, construct validity was proven by using scores of $\geq 9$ to define moderate and $\geq 11$ to define severe disease. These cut-points were associated with significant increases in other measures of disease severity [e.g. daycare (P=0.01) and work absenteeism (P=0.002)].

What if at baseline the pre-enrollment MVS was $\geq 9$?: Regardless of the score assigned at Time 0 (i.e. pre-enrollment score), all participants reverted to a score of 0 at enrollment (i.e. only symptoms occurring after randomization are included in the outcome measures of disease severity).
Data Safety Monitoring Committee Members

Dr. Terry Klassen, Chair
Chief Executive Officer and Scientific Director, The Children’s Hospital Research Institute of Manitoba, Head of the Department of Pediatrics and Child Health, University of Manitoba and Medical Director, Child Health Program, Winnipeg Regional Health Authority

Dr. Mark Roback
Professor and Co-Director, Division of Pediatric Emergency Medicine, University of Minnesota

Dr. Nick Barrowman, Biostatistician
Senior Statistician, Clinical Research Unit, Department of Pediatrics Children’s Hospital of Eastern Ontario
Statistical Analysis – Exploratory Analyses

Exploratory analyses evaluated interactions between treatment assignment and (1) duration of symptoms pre-enrollment; (2) identification of bacterial pathogens; and (3) pre-enrollment Modified Vesikari Scale score. The analyses were repeated employing an outcome of severe disease (i.e. Modified Vesikari Scale score ≥11).

SF designed the study, vouches for the data, the analysis, and he wrote and decided to publish the paper. Data was gathered by study site research staff. JX analyzed the data.
### Table S1

**Index Visit Discharge Diagnoses**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Total N=827</th>
<th>Probiotic n=414</th>
<th>Placebo n=413</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastroenteritis</td>
<td>587 (71.0%)</td>
<td>301 (72.7%)</td>
<td>286 (69.2%)</td>
<td>0.28</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>111 (13.4%)</td>
<td>50 (12.1%)</td>
<td>61 (14.8%)</td>
<td>0.26</td>
</tr>
<tr>
<td>Viral illness</td>
<td>61 (7.4%)</td>
<td>26 (6.3%)</td>
<td>35 (8.5%)</td>
<td>0.23</td>
</tr>
<tr>
<td>Enteritis</td>
<td>18 (2.2%)</td>
<td>6 (1.4%)</td>
<td>12 (2.9%)</td>
<td>0.16</td>
</tr>
<tr>
<td>Bronchiolitis</td>
<td>6 (0.7%)</td>
<td>5 (1.2%)</td>
<td>1 (0.2%)</td>
<td>0.22</td>
</tr>
<tr>
<td>Acute Otitis Media</td>
<td>6 (0.7%)</td>
<td>4 (1.0%)</td>
<td>2 (0.5%)</td>
<td>0.69</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>6 (0.7%)</td>
<td>3 (0.7%)</td>
<td>3 (0.7%)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Vomiting</td>
<td>5 (0.6%)</td>
<td>5 (1.2%)</td>
<td>0</td>
<td>0.062</td>
</tr>
<tr>
<td>Urinary Tract Infection</td>
<td>5 (0.6%)</td>
<td>2 (0.5%)</td>
<td>3 (0.7%)</td>
<td>0.69</td>
</tr>
<tr>
<td>Dehydration</td>
<td>4 (0.5%)</td>
<td>2 (0.5%)</td>
<td>2 (0.5%)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Fever</td>
<td>4 (0.5%)</td>
<td>1 (0.2%)</td>
<td>3 (0.7%)</td>
<td>0.37</td>
</tr>
<tr>
<td>Coxsackie</td>
<td>4 (0.5%)</td>
<td>1 (0.2%)</td>
<td>3 (0.7%)</td>
<td>0.37</td>
</tr>
<tr>
<td>Asthma</td>
<td>2 (0.2%)</td>
<td>2 (0.5%)</td>
<td>0</td>
<td>0.50</td>
</tr>
<tr>
<td>Herpangina</td>
<td>2 (0.2%)</td>
<td>1 (0.2%)</td>
<td>1 (0.2%)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Abdominal Pain</td>
<td>1 (0.1%)</td>
<td>1 (0.2%)</td>
<td>0</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Colitis</td>
<td>1 (0.1%)</td>
<td>1 (0.2%)</td>
<td>0</td>
<td>&gt; 0.99</td>
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<tr>
<td>Enterovirus</td>
<td>1 (0.1%)</td>
<td>1 (0.2%)</td>
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<td>&gt; 0.99</td>
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<td>Diaper dermatitis</td>
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<td>1 (0.2%)</td>
<td>0.50</td>
</tr>
<tr>
<td>Influenza</td>
<td>1 (0.1%)</td>
<td>1 (0.2%)</td>
<td>0</td>
<td>&gt; 0.99</td>
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<tr>
<td>Wheezing</td>
<td>1 (0.1%)</td>
<td>1 (0.2%)</td>
<td>0</td>
<td>&gt; 0.99</td>
</tr>
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</table>
Table S2

Co-Administered Medications

A) Index Visit

<table>
<thead>
<tr>
<th>Medication</th>
<th>Total N=827</th>
<th>Probiotic n=414</th>
<th>Placebo n=413</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ondansetron</td>
<td>183 (22.1%)</td>
<td>94 (22.7%)</td>
<td>89 (21.5%)</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>100 (12.1%)</td>
<td>52 (12.6%)</td>
<td>48 (11.6%)</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>84 (10.2%)</td>
<td>39 (9.4%)</td>
<td>45 (10.9%)</td>
</tr>
<tr>
<td>Salbutamol</td>
<td>8 (1.0%)</td>
<td>6 (1.4%)</td>
<td>2 (0.5%)</td>
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<tr>
<td>Ceftriaxone</td>
<td>7 (0.9%)</td>
<td>4 (1.0%)</td>
<td>3 (0.7%)</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>4 (0.5%)</td>
<td>4 (1.0%)</td>
<td>0</td>
</tr>
<tr>
<td>Midazolam</td>
<td>3 (0.4%)</td>
<td>0</td>
<td>3 (0.7%)</td>
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<td>Dexamethasone</td>
<td>2 (0.2%)</td>
<td>1 (0.2%)</td>
<td>1 (0.2%)</td>
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<tr>
<td>Eutectic Mixture of Local Anesthetics</td>
<td>2 (0.2%)</td>
<td>1 (0.2%)</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Amoxicillin-Clavulanic Acid</td>
<td>1 (0.1%)</td>
<td>1 (0.2%)</td>
<td>0</td>
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<tr>
<td>Cefprozil</td>
<td>1 (0.1%)</td>
<td>1 (0.2%)</td>
<td>0</td>
</tr>
<tr>
<td>Cephalexin</td>
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<td>1 (0.2%)</td>
<td>0</td>
</tr>
<tr>
<td>Diphenhydramine</td>
<td>1 (0.1%)</td>
<td>1 (0.2%)</td>
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</tr>
<tr>
<td>Prednisolone</td>
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<td>1 (0.2%)</td>
<td>0</td>
</tr>
<tr>
<td>Epinephrine</td>
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<td>1 (0.2%)</td>
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</tr>
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<td>Heparin</td>
<td>1 (0.1%)</td>
<td>1 (0.2%)</td>
<td>0</td>
</tr>
<tr>
<td>Vancomycin</td>
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<td>0</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Ampicillin</td>
<td>1 (0.1%)</td>
<td>0</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Prednisone</td>
<td>1 (0.1%)</td>
<td>0</td>
<td>1 (0.2%)</td>
</tr>
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</table>
### B) Prescribed at Discharge

<table>
<thead>
<tr>
<th>Drug</th>
<th>Total N=827</th>
<th>Probiotic n=414</th>
<th>Placebo n=413</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin</td>
<td>7 (0.9%)</td>
<td>2 (0.5%)</td>
<td>5 (1.2%)</td>
</tr>
<tr>
<td>Ondansetron</td>
<td>5 (0.6%)</td>
<td>4 (1.0%)</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Salbutamol</td>
<td>2 (0.2%)</td>
<td>1 (0.2%)</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Nystatin cream</td>
<td>2 (0.2%)</td>
<td>1 (0.2%)</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>2 (0.2%)</td>
<td>1 (0.2%)</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Azithromycin</td>
<td>1 (0.1%)</td>
<td>0</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>1 (0.1%)</td>
<td>0</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Cefprozil</td>
<td>1 (0.1%)</td>
<td>0</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Diphenhydramine</td>
<td>1 (0.1%)</td>
<td>0</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Clarithromycin</td>
<td>1 (0.1%)</td>
<td>0</td>
<td>1 (0.2%)</td>
</tr>
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<td>Iron supplement</td>
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<td>0</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Cephalexin</td>
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<td>0</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Fluticasone Propionate</td>
<td>1 (0.1%)</td>
<td>0</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Ihle’s Paste</td>
<td>1 (0.1%)</td>
<td>0</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Zinc Oxide paste</td>
<td>1 (0.1%)</td>
<td>0</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Prednisolone</td>
<td>1 (0.1%)</td>
<td>1 (0.2%)</td>
<td>0</td>
</tr>
<tr>
<td>Clotrimazole cream</td>
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<td>1 (0.2%)</td>
<td>0</td>
</tr>
<tr>
<td>Desonide cream</td>
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<td>1 (0.2%)</td>
<td>0</td>
</tr>
<tr>
<td>Hydroxyzine</td>
<td>1 (0.1%)</td>
<td>1 (0.2%)</td>
<td>0</td>
</tr>
<tr>
<td>Trimethoprim Sulfamethoxazole</td>
<td>1 (0.1%)</td>
<td>1 (0.2%)</td>
<td>0</td>
</tr>
<tr>
<td>Hydrocortisone Cream</td>
<td>1 (0.1%)</td>
<td>1 (0.2%)</td>
<td>0</td>
</tr>
</tbody>
</table>
C) Antibiotics Received During the 14-Day Follow-Up Period

<table>
<thead>
<tr>
<th></th>
<th>Total N=827</th>
<th>Probiotic n=414</th>
<th>Placebo n=413</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotic, Unspecified</td>
<td>13 (1.6%)</td>
<td>8 (1.9%)</td>
<td>5 (1.2%)</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>12 (1.5%)</td>
<td>9 (2.2%)</td>
<td>3 (0.7%)</td>
</tr>
<tr>
<td>Clarithromycin</td>
<td>2 (0.1%)</td>
<td>0</td>
<td>2 (0.5%)</td>
</tr>
<tr>
<td>Azithromycin</td>
<td>1 (0.1%)</td>
<td>0</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Ceftriaxone</td>
<td>1 (0.1%)</td>
<td>1 (0.2%)</td>
<td>0</td>
</tr>
</tbody>
</table>
Table S3

Primary Outcome – Modified Vesikari Scale Score, Logistic Regression Model,
Adjusted for Site and Pre-Defined Covariates

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Odds Ratio (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probiotic</td>
<td>1.06 (0.76, 1.49)</td>
<td>0.74</td>
</tr>
<tr>
<td>Placebo</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Alberta Children’s Hospital</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>The Hospital for Sick Children</td>
<td>0.69 (0.37, 1.29)</td>
<td>0.25</td>
</tr>
<tr>
<td>Children’s Hospital of Eastern Ontario</td>
<td>1.10 (0.68, 1.78)</td>
<td>0.69</td>
</tr>
<tr>
<td>Centre Hospitalier Universitaire Sainte-Justine</td>
<td>0.67 (0.40, 1.14)</td>
<td>0.14</td>
</tr>
<tr>
<td>IWK Health Centre</td>
<td>0.82 (0.34, 1.99)</td>
<td>0.14</td>
</tr>
<tr>
<td>London Children’s Hospital</td>
<td>1.63 (0.82, 3.21)</td>
<td>0.16</td>
</tr>
<tr>
<td>Age, Months</td>
<td>0.97 (0.95, 0.99)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Vomit Episodes, 24 hours pre-enrollment</td>
<td>1.09 (1.05, 1.13)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Diarrhea Episodes, 24 hours pre-enrollment</td>
<td>1.05 (1.01, 1.09)</td>
<td>0.009</td>
</tr>
<tr>
<td>Rotavirus Positive</td>
<td>1.48 (0.95, 2.30)</td>
<td>0.09</td>
</tr>
<tr>
<td>Rotavirus Negative</td>
<td>Reference</td>
<td></td>
</tr>
</tbody>
</table>
### Table S4

**Subgroup Analyses, of the Primary Outcome - Modified Vesikari Scale Score ≥ 9,**

Employing Logistic Regression Models, Adjusted for Site

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Number of Participants</th>
<th>Odds Ratio (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &lt; 1 year</td>
<td>284</td>
<td>1.01 (0.60, 1.71)</td>
<td>0.97</td>
</tr>
<tr>
<td>Exclusively Breastfed</td>
<td>40</td>
<td>0.82 (0.18, 3.61)</td>
<td>0.79</td>
</tr>
<tr>
<td>Antibiotics Used in Past 14 Days</td>
<td>105</td>
<td>0.86 (0.35, 2.11)</td>
<td>0.74</td>
</tr>
<tr>
<td>Compliance &gt; 70%</td>
<td>598</td>
<td>1.16 (0.79, 1.71)</td>
<td>0.45</td>
</tr>
</tbody>
</table>
Table S5

Primary Outcome – Modified Vesikari Scale Score, Logistic Regression Model, Adjusted for Site, Pre-Defined Covariates Including Interaction Terms for: 1) treatment groups and age; 2) treatment groups and exclusive breastfeeding; 3) treatment groups and antibiotic use in past 14 days; and 4) treatment group and >70% compliance.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Odds Ratio (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probiotic</td>
<td>0.82 (0.29, 2.26)</td>
<td>0.69</td>
</tr>
<tr>
<td>Placebo</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Alberta Children’s Hospital</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>The Hospital for Sick Children</td>
<td>0.72 (0.37, 1.39)</td>
<td>0.33</td>
</tr>
<tr>
<td>Children’s Hospital of Eastern Ontario</td>
<td>1.05 (0.63, 1.75)</td>
<td>0.86</td>
</tr>
<tr>
<td>Centre Hospitalier Universitaire Sainte-Justine</td>
<td>0.69 (0.39, 1.22)</td>
<td>0.20</td>
</tr>
<tr>
<td>IWK Health Centre</td>
<td>0.49 (0.17, 1.44)</td>
<td>0.20</td>
</tr>
<tr>
<td>London Children’s Hospital</td>
<td>1.55 (0.76, 3.20)</td>
<td>0.23</td>
</tr>
<tr>
<td>Age, Months</td>
<td>0.97 (0.94, 1.00)</td>
<td>0.03</td>
</tr>
<tr>
<td>Vomit Episodes, 24 hours pre-enrollment</td>
<td>1.10 (1.06, 1.14)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diarrhea Episodes, 24 hours pre-enrollment</td>
<td>1.05 (1.01, 1.09)</td>
<td>0.03</td>
</tr>
<tr>
<td>Antibiotic Use in Preceding 14 Days</td>
<td>1.02 (0.49, 2.14)</td>
<td>0.95</td>
</tr>
<tr>
<td>Exclusive Breastfeeding</td>
<td>0.83 (0.29, 2.37)</td>
<td>0.73</td>
</tr>
<tr>
<td>&gt;70% Compliance</td>
<td>0.76 (0.40, 1.46)</td>
<td>0.42</td>
</tr>
<tr>
<td>Rotavirus positive</td>
<td>1.29 (0.65, 2.53)</td>
<td>0.47</td>
</tr>
<tr>
<td>Treatment Group * Age</td>
<td>1.01 (0.97, 1.05)</td>
<td>0.72</td>
</tr>
<tr>
<td>Treatment Group * Antibiotic Use</td>
<td>0.87 (0.29, 2.63)</td>
<td>0.80</td>
</tr>
<tr>
<td>Treatment Group * Exclusively Breastfed</td>
<td>1.57 (0.34, 7.38)</td>
<td>0.57</td>
</tr>
<tr>
<td>Treatment Group * &gt;70% Compliance</td>
<td>1.28 (0.52, 3.12)</td>
<td>0.59</td>
</tr>
<tr>
<td>Treatment Group * Rotavirus Positive</td>
<td>1.00 (0.43, 2.36)</td>
<td>0.99</td>
</tr>
</tbody>
</table>

* Indicates an interaction term.
Table S6

Pathogen Specific Subgroup Analysis.

Includes all participants who had an enteropathogen identified AND completed follow-up. Analyses were performed employing logistic regression adjusted for study site with the outcome dependent variable being moderate to severe disease (i.e. Modified Vesikari Scale score ≥ 9). Includes only pathogens identified in a minimum of 5 participants in each group.

<table>
<thead>
<tr>
<th>Pathogen Identified</th>
<th>Probiotic N=408</th>
<th>Placebo N=408</th>
<th>OR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>MVS ≥ 9</td>
<td>N (%)</td>
<td>N</td>
</tr>
<tr>
<td>Norovirus GI/GII</td>
<td>99</td>
<td>28 (28.3)</td>
<td></td>
<td>117</td>
</tr>
<tr>
<td>Rotavirus A</td>
<td>116</td>
<td>38 (32.8)</td>
<td></td>
<td>79</td>
</tr>
<tr>
<td>Clostridium difficile, Toxin A/B</td>
<td>47</td>
<td>16 (34.0)</td>
<td></td>
<td>60</td>
</tr>
<tr>
<td>Adenovirus 40/41</td>
<td>50</td>
<td>9 (18.0)</td>
<td></td>
<td>44</td>
</tr>
<tr>
<td>Salmonella sp.</td>
<td>11</td>
<td>4 (36.4)</td>
<td></td>
<td>9</td>
</tr>
</tbody>
</table>
Table S7

Adverse events coded employing definitions from the *Medical Dictionary for Regulatory Activities*, version 19.0.*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Probiotic</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Participants = 414</td>
<td>Participants = 413</td>
</tr>
<tr>
<td></td>
<td>Total Adverse Events = 204</td>
<td>Total Adverse Events = 230</td>
</tr>
<tr>
<td></td>
<td><strong>Relationship</strong></td>
<td><strong>no. of events (% of total participants)</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Not</strong></td>
<td><strong>Unlikely</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Associated</strong></td>
<td></td>
</tr>
<tr>
<td>Any Grade</td>
<td>59 (14.3)</td>
<td>124 (30.0)</td>
</tr>
<tr>
<td>Mild</td>
<td>48 (11.6)</td>
<td>116 (28.0)</td>
</tr>
<tr>
<td>Moderate</td>
<td>11 (2.7)</td>
<td>8 (1.9)</td>
</tr>
<tr>
<td>Severe</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Life Threatening</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*Adverse Events Reported by ≥2% of Patients in Either Trial Group*

<p>| Dermatitis, diaper   | 94 (22.7)                 | 95 (23.0)                |</p>
<table>
<thead>
<tr>
<th>Rash</th>
<th>28 (6.8)</th>
<th>18 (4.4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other</td>
<td>82 (19.8)</td>
<td>117 (28.3)</td>
</tr>
</tbody>
</table>

*Patients with multiple adverse events had each event included as an independent entity.

### Moderate Severity Adverse Events by Treatment Group*

<table>
<thead>
<tr>
<th>Moderate severity adverse event</th>
<th>Probiotic Participants = 414</th>
<th>Placebo Participants = 413</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of moderate severity adverse events=20</td>
<td>Number of moderate severity adverse events=11</td>
</tr>
<tr>
<td>no. of events (% of total participants)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermatitis diaper</td>
<td>4 (1.0)</td>
<td>3 (0.7)</td>
</tr>
<tr>
<td>Cough</td>
<td>2 (0.5)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Acidosis</td>
<td>1 (0.2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Bronchospasm</td>
<td>1 (0.2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Dehydration</td>
<td>1 (0.2)</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Hypoglycaemia</td>
<td>1 (0.2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Condition</td>
<td>Count</td>
<td>Probability</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-------</td>
<td>-------------</td>
</tr>
<tr>
<td>Ketosis</td>
<td>1 (0.2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Mouth ulceration</td>
<td>1 (0.2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>1 (0.2)</td>
<td>2 (0.5)</td>
</tr>
<tr>
<td>Oliguria</td>
<td>1 (0.2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Oropharyngeal pain</td>
<td>1 (0.2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Otitis media</td>
<td>1 (0.2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>1 (0.2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>1 (0.2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Rash</td>
<td>1 (0.2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Stridor</td>
<td>1 (0.2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Dermatitis allergic</td>
<td>0 (0)</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Febrile convulsion</td>
<td>0 (0)</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Irritability</td>
<td>0 (0)</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Kawasaki's disease</td>
<td>0 (0)</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Swelling</td>
<td>0 (0)</td>
<td>1 (0.2)</td>
</tr>
</tbody>
</table>

*Patients with multiple adverse events had each event included as an independent entity.*
Table S8

Study End-Points Employing Modified Vesikari Scale score ≥ 11 (Severe Disease) as the Outcome. *

<table>
<thead>
<tr>
<th>End-Point</th>
<th>Number Included in Analysis</th>
<th>Probiotic N (%)</th>
<th>Placebo N (%)</th>
<th>Odds Ratio (95%CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Efficacy End-Point: MVS Score ≥ 11†</td>
<td>827</td>
<td>67/414 (16.2)</td>
<td>62/413 (15.0)</td>
<td>1.08 (0.73, 1.61)</td>
<td>0.70</td>
</tr>
<tr>
<td>All Participants – no. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age &lt; 1 yr – no. (%)</td>
<td>284</td>
<td>27/134 (20.1)</td>
<td>30/150 (20.0)</td>
<td>0.91 (0.48, 1.72)</td>
<td>0.77</td>
</tr>
<tr>
<td>Exclusively Breast Fed – no. (%)‡</td>
<td>53</td>
<td>5/22 (22.7)</td>
<td>7/31 (22.6)</td>
<td>0.71 (0.15, 3.25)</td>
<td>0.66</td>
</tr>
<tr>
<td>Antibiotics, 14 Days pre-Index Visit – no. (%)§</td>
<td>110</td>
<td>9/51 (14.4)</td>
<td>9/59 (17.5)</td>
<td>1.64 (0.54, 4.99)</td>
<td>0.38</td>
</tr>
<tr>
<td>Greater Than 70% Compliance – no. (%)</td>
<td>598</td>
<td>42/295 (14.2)</td>
<td>35/303 (11.6)</td>
<td>1.26 (0.76, 2.07)</td>
<td>0.37</td>
</tr>
</tbody>
</table>

* MVS denotes Modified Vesikari Scale.

† Analyzed employing logistic regression with model adjusted for participant enrollment site.

‡ Regression excluding sites of HSC (n= 5), IWK (n=6) due to no case with MVS>=11; excluded STJ (n=2) due to no case of MVS<11.

§ Regression excluding sites of IWK (n= 5), due to the 5 all had MVS <11.
Table S9

Supplement to Table 2 including complete demographics, baseline disease characteristics, and index visit interventions.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Probiotic (N=440^*)</th>
<th>Placebo (N=437^*)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (IQR) – mo</td>
<td>16.0 (10.0, 24.8)</td>
<td>15.0 (9.5, 24.0)</td>
</tr>
<tr>
<td>3 – &lt; 12 mo – no. (%)</td>
<td>140 (31.8)</td>
<td>159 (36.4)</td>
</tr>
<tr>
<td>12 – &lt; 24 mo – no. (%)</td>
<td>175 (39.8)</td>
<td>163 (37.3)</td>
</tr>
<tr>
<td>24 – &lt; 36 mo – no. (%)</td>
<td>77 (17.5)</td>
<td>70 (16.0)</td>
</tr>
<tr>
<td>36 – &lt; 48 mo – no. (%)</td>
<td>48 (10.9)</td>
<td>45 (10.3)</td>
</tr>
<tr>
<td>Male sex – no. (%)</td>
<td>243 (55.2)</td>
<td>252 (57.7)</td>
</tr>
<tr>
<td><strong>Season</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>January 1 to March 31– no. (%)</td>
<td>176 (40.0)</td>
<td>174 (39.8)</td>
</tr>
<tr>
<td>April 1 to June 30– no. (%)</td>
<td>129 (29.3)</td>
<td>126 (28.8)</td>
</tr>
<tr>
<td>Parameter</td>
<td>July 1 to September 30 – no. (%)</td>
<td>October 1 to December 31 – no. (%)</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>----------------------------------</td>
<td>------------------------------------</td>
</tr>
<tr>
<td>Weight – kg – median (IQR)</td>
<td>10.6 (9.0, 13.0)</td>
<td>10.7 (8.8, 12.6)</td>
</tr>
<tr>
<td>Primary care physician – no. (%)</td>
<td>398 (90.5)</td>
<td>403 (92.2)</td>
</tr>
<tr>
<td>Attends Daycare – no. (%)†</td>
<td>228 (51.8)</td>
<td>225 (51.5)</td>
</tr>
<tr>
<td>Exclusively Breastfed – no. (%)</td>
<td>23 (5.2)</td>
<td>32 (7.3)</td>
</tr>
<tr>
<td>Electronic Follow-Up – no. (%)</td>
<td>348 (79.1)</td>
<td>352 (80.5)</td>
</tr>
<tr>
<td>Antibiotic Usage within 14 Days Preceding Enrollment – no. (%)</td>
<td>56 (12.7)</td>
<td>63 (14.4)</td>
</tr>
<tr>
<td>Rotavirus Vaccine – no. (%)</td>
<td>214 (48.6)</td>
<td>213 (48.7)</td>
</tr>
</tbody>
</table>

**Baseline Disease Characteristics**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>July 1 to September 30 – no. (%) § §</th>
<th>October 1 to December 31 – no. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Emergency Department Visit, Current Illness – no. (%) § §</td>
<td>43 (9.8)</td>
<td>44 (10.1)</td>
</tr>
<tr>
<td>Prior Intravenous Fluid Administration, Current Illness – no. (%)</td>
<td>3 (0.7)</td>
<td>3 (0.7)</td>
</tr>
<tr>
<td>Prior Hospitalization, Current Illness – no. (%)</td>
<td>1 (0.2)</td>
<td>0</td>
</tr>
<tr>
<td>Duration of illness at enrollment – hr – median (IQR) ††</td>
<td>42.5 (26.7, 58.1)</td>
<td>43.8 (27.7, 58.8)</td>
</tr>
<tr>
<td>Baseline Modified Vesikari Scale Score † †</td>
<td></td>
<td></td>
</tr>
<tr>
<td>median (IQR)</td>
<td>10 (9, 12)</td>
<td>10 (8, 12)</td>
</tr>
<tr>
<td></td>
<td>No.**</td>
<td>No.***</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-------</td>
<td>--------</td>
</tr>
<tr>
<td>0 – 8 – no. (%)</td>
<td>103 (23.4)</td>
<td>121 (27.7)</td>
</tr>
<tr>
<td>≥ 9 – no. (%)</td>
<td>337 (76.6)</td>
<td>316 (72.3)</td>
</tr>
<tr>
<td>Vomiting – no. (%)</td>
<td>345 (78.4)</td>
<td>327 (74.8)</td>
</tr>
<tr>
<td>Vomiting — no. of episodes in preceding 24 hr – median (IQR)**</td>
<td>5 (3, 8)</td>
<td>5 (2, 8)</td>
</tr>
<tr>
<td>Diarrhea — no. of episodes in preceding 24 hr – median (IQR)</td>
<td>6 (4, 8)</td>
<td>6 (4, 9)</td>
</tr>
<tr>
<td>Febrile – no. (%)***</td>
<td>198 (45.0)</td>
<td>196 (44.9)</td>
</tr>
<tr>
<td>Baseline Clinical Dehydration Scale Score – median (IQR)**</td>
<td>1 (0, 2)</td>
<td>0 (0, 2)</td>
</tr>
</tbody>
</table>

**Index Visit Interventions**

<table>
<thead>
<tr>
<th></th>
<th>No.**</th>
<th>No.***</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ondansetron Administered at Index Visit – no. (%)</td>
<td>100 (22.7)</td>
<td>91 (20.9)</td>
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<tr>
<td>Intravenous Rehydration at Index Visit – no. (%)</td>
<td>37 (8.9)</td>
<td>31 (7.5)</td>
</tr>
<tr>
<td>Admitted at Index Visit – no. (%)</td>
<td>10 (2.4)</td>
<td>10 (2.4)</td>
</tr>
<tr>
<td>Stool Testing Results – no. (%)†††</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Norovirus GI/GII</td>
<td>102 (23.6)</td>
<td>124 (29.0)</td>
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<tr>
<td>Rotavirus A</td>
<td>124 (28.7)</td>
<td>85 (19.9)</td>
</tr>
<tr>
<td>Clostridium difficile, Toxin A/B</td>
<td>51 (11.8)</td>
<td>61 (14.3)</td>
</tr>
<tr>
<td>Adenovirus 40/41</td>
<td>50 (11.6)</td>
<td>45 (10.5)</td>
</tr>
<tr>
<td></td>
<td>Count</td>
<td>Percent</td>
</tr>
<tr>
<td>----------------</td>
<td>-------</td>
<td>---------</td>
</tr>
<tr>
<td><em>Salmonella sp.</em></td>
<td>11 (2.6)</td>
<td>9 (2.1)</td>
</tr>
<tr>
<td><em>Campylobacter sp.</em></td>
<td>10 (2.3)</td>
<td>4 (0.9)</td>
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<tr>
<td>Enterotoxigenic <em>Escherichia coli</em> LT/ST</td>
<td>3 (0.7)</td>
<td>8 (1.9)</td>
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<td><em>Cryptosporidium</em></td>
<td>6 (1.4)</td>
<td>3 (0.7)</td>
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<tr>
<td>Shiga Toxin-Producing <em>Escherichia coli</em> stx1/stx2</td>
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<td>1 (0.2)</td>
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<tr>
<td><em>Shigella sp.</em></td>
<td>2 (0.5)</td>
<td>3 (0.7)</td>
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<tr>
<td><em>Escherichia coli</em> O157</td>
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<tr>
<td><em>Giardia</em></td>
<td>1 (0.2)</td>
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</table>
REFERENCES


