Rotavirus Infections Decline More than 70 Percent in Children in U.S.

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Quest Diagnostics Health Trends(TM) Report shows declines vary widely by state

MADISON, N.J., Oct. 25 /PRNewswire-FirstCall/ -- The largest study of rotavirus laboratory data developed since an oral rotavirus vaccine was introduced in the U.S. in early 2006 shows that cases of rotavirus infection have decreased significantly, suggesting the vaccine is preventing infection in infants and young children. The latest Quest Diagnostics Health Trends(TM) Report also provides evidence for the first time that cases of infection decreased in children up to the age of six, suggesting that herd immunity may have reduced rates of infection in children age two and over who were unlikely to have been vaccinated. However, the report shows that while cases of infection decreased nationally, rates varied by state, indicating possible geographic differences in use of the vaccine.

Rotavirus is the most common cause of severe, dehydrating gastroenteritis among infants and young children worldwide, and one of the leading causes of emergency department visits, physician visits and hospitalizations of children in the United States.

The findings were presented today by Jay M. Lieberman, M.D., medical director, infectious diseases, Quest Diagnostics Incorporated (NYSE: DGX) at the Joint Meeting of the 48th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) and the 46th Annual Meeting of the Infectious Disease Society of America (ISDA) in Washington, D.C. The Quest Diagnostics Health Trends(TM) Report is the largest assessment of rotavirus laboratory-test results since the Advisory Committee on Immunization Practices of the U.S. Centers for Disease Control and Prevention recommended routine vaccination in August 2006 for infants at 2, 4, and 6 months of age.

The analysis was performed on de-identified diagnostic test results from September 2003 through June 2008 from data of more than 132,000 patients in the Quest Diagnostics database.

The analysis showed a 76 percent reduction in positive test results during the most recent peak season, December 2007 through June 2008, compared to the three years before the rotavirus vaccine was available, December 2003 to June 2006. In addition, the positivity rate (the number of individuals who test positive in proportion to the total number of tests taken) decreased 70 percent during the study period.

"Our analysis suggests that the oral rotavirus vaccine has been highly effective at reducing the incidence of rotavirus. Our findings reinforce those from a preliminary report issued by the CDC earlier this year. Considering the toll this disease has traditionally taken on children and their families each year in the U.S., this is exciting and welcome news for physicians and parents," said Dr. Lieberman. "Our report also may have important implications for public health efforts in developing parts of the world, where rotavirus tragically is a frequent cause of childhood death."

Rotavirus causes severe acute gastroenteritis among infants and young children, often resulting in high fever, vomiting and diarrhea. Rotavirus accounts for more than half a million deaths of children under the age of five each year worldwide. In the U.S., the disease causes fewer deaths annually (an average of 20 to 60), but remains a substantial cause of morbidity, resulting in approximately 410,000 physician visits, 205,000 to 270,000 emergency department visits, and 55,000 to 70,000 hospitalizations. Rotavirus infection represents a significant drain on resources, with estimates of $1 billion in societal costs nationally. In the U.S. rotavirus activity follows a distinct winter-spring seasonal pattern.

Decline in Rotavirus Varies Among States

The analysis showed a reduction in rotavirus positivity rates in all 43 states and Puerto Rico that had submitted at least 100 lab specimens during the pre-vaccine period. Some states experienced greater declines than others, which likely reflect differences in vaccine uptake. The majority of states reduced the incidence of rotavirus, as indicated by positivity rates, by more than 60 percent. However, there was substantial variability, with states such as Delaware, North Carolina, and Alabama each experiencing declines of more than 95 percent, while in Washington, Nebraska, New Mexico, and Arizona, the declines were less than 35 percent.

"While our data does not provide insight into why rates of infection varied geographically, we know that multiple factors determine how quickly new vaccines are adopted by physicians, parents and public health agencies," said Dr. Lieberman. "We suspect that much of the variability we see in our data is related to such differences in vaccine uptake. Our analysis suggests the need for further research into the factors influencing uptake and its implications for public health policy."

Herd Immunity Benefits Nonvaccinated Children

The analysis showed that the sharpest decline in positive rotavirus test results, approximately 83 percent, occurred in children younger than 12 months of age, the age group most likely to have been vaccinated. However, the analysis also showed a dramatic decline in positive test results in older children (ranging from 67 to 75 percent), including children ages two to six. Because children older than two years of age in the U.S. are unlikely to have been vaccinated, these data suggest a herd immunity phenomenon, which occurs when enough individuals are vaccinated so as to reduce transmission of a virus, thereby providing some protection to unvaccinated individuals.

"Herd immunity is a significant favorable outcome of a successful vaccination program because it means that even unvaccinated individuals may be benefiting from widespread use of a vaccine," said Dr. Lieberman. "Our analysis provides evidence for the first time that unvaccinated children may also be reaping the benefits of the rotavirus vaccine. Herd immunity is particularly valuable to newborns and other young infants who have not yet started or completed their vaccine series."

Study Methodology

The Quest Diagnostics Health Trends(TM) Report, "Decline in Rotavirus Cases in the U.S. After Licensure of a Live, Oral Rotavirus Vaccine," is based on an analysis of more than 132,000 rotavirus antigen detection test results (by antigen-capture enzyme immunoassay, or EIA) performed from December to June at all Quest Diagnostics regional laboratories, during the period of December 2003 to June 2008. The results were extracted from the Quest Diagnostics Information Data Warehouse (IDW), the largest private database of clinical laboratory tests results in the United States. IDW

contains information on all clinical test results reported by Quest Diagnostics laboratories in the United States, and includes data from all 50 states, the District of Columbia, and Puerto Rico. The database includes information on the ordering physician, patient, tests ordered, and results reported, and data are handled in a HIPAA-compliant manner. The study utilized only de-identified testing data that did not contain any patient- or physician-identifiable health information.

In the study, the pre-vaccine period was defined as the three seasons before vaccine* licensure (December through June 2003-2004, 2004-2005, and 2005-2006). The post-vaccine period was defined as the most recent peak season, December 2007 through June 2008. (The December 2006-June 2007 season was a "transition" year, with limited vaccine use in young infants in the months immediately after the vaccine became available.) In the pre-vaccine period, Quest Diagnostics performed an average of 27,625 tests for rotavirus annually, of which 7,162 (26 percent) were positive. By contrast, of the 21,873 tests conducted by Quest Diagnostics in the post-vaccine period, only 1,703 (7.8 percent) were positive - a 76.2 percent reduction in the total number of positive tests (p