



ASX ANNOUNCEMENT

Sant Joan de Déu finds FebriDx® to be a useful tool for optimising antibiotic prescription in paediatric patients with febrile Acute Respiratory Infection

MELBOURNE, Australia (8 April 2024) – Lumos Diagnostics (ASX: LDX), (“Lumos” or the “Company”) a leader in rapid point-of-care (POC) diagnostic technologies, is pleased to announce that respected international journal, *Infectious Diseases and Clinical Microbiology*, has published results of a FebriDx study in 216 paediatric patients. The study and subsequent peer-reviewed publication were conducted by collaborators at Sant Joan de Déu Hospital, Barcelona, one of Spain’s largest paediatric hospitals.

The publication, by de la Matta Farrando, P, et al is titled "Evaluación de FebriDx® para el manejo de niños con infección respiratoria aguda febril" - Evaluation of FebriDx® for the management of children with acute febrile respiratory infection. A copy of the peer-reviewed publication [is available via this link](#).

A portion of the study funding was provided by Lumos and the study was conducted by Principal Investigator, Director of the pediatric emergencies service and Associate Professor Dr. Carles Luaces Cubells, a pediatrician and researcher with global impact (200+ peer reviewed publications.)

Key Highlights

- FebriDx® peer reviewed clinical paper by collaborators at Sant Joan de Déu Hospital, Barcelona, one of Spain’s largest paediatric hospitals, published in *Infectious Diseases and Clinical Microbiology* journal
- The study enrolled 216 paediatric patients and aimed to determine FebriDx’s impact on the management of antibiotics in paediatric patients presenting to the emergency department with Acute Respiratory Infection
- The study concluded FebriDx® could be a useful tool for optimising antibiotic use in children with acute febrile respiratory infections. FebriDx® may also decrease the need for unnecessary chest X-rays, improving the management of febrile respiratory illnesses in children

- The work by Dr. Luaces Cubells et al adds to the growing body of evidence supporting FebriDx use in the management of Acute Respiratory Infection and is the largest published study to date in children.

Study highlights

A single centre prospective clinical study, entitled “*Evaluation of FebriDx® for the management of children with acute febrile respiratory infection*” was conducted to evaluate the impact of FebriDx on antibiotic prescription (ATB) when managing febrile pediatric patients who presented to the emergency department with acute respiratory infection (ARI). The study enrolled 216 children (1-17 years) who presented to the emergency department with febrile ARI between November 2022 and August 2023. FebriDx® was performed and the impact on management of antibiotics was evaluated at follow-up.

- FebriDx agreed with the clinician’s diagnosis in the majority of cases (>80%)
- When FebriDx results were not in agreement with the clinician’s diagnosis,
 - FebriDx detected bacterial infections that may have been missed (~80% received appropriate antibiotic therapy as a result)
 - FebriDx detected viral infections that were initially thought to be bacterial (40% of these patients did not receive antibiotics that were not needed)
- FebriDx® was shown to have great utility in pneumonia, where antibiotic prescription usage was reduced by 35%
- FebriDx® was shown to be is a great tool to optimize management of ARI in patients where etiologic assessment can be difficult
- FebriDx® may help reduce additional testing, such as chest x-rays, which has the potential to reduce time and cost to diagnosis

Two excerpts from the paper’s conclusion are as follows:

“To our knowledge, this is the study with the largest sample size that evaluates the usefulness of FebriDx® for the management of pediatric patients with febrile ARI in daily clinical practice. The results obtained support that FebriDx® could be a useful tool in the ED to optimize the prescription of ATB in these patients. In our series, FebriDx® is especially useful in patients with suspected ARI of bacterial etiology, modifying this etiological orientation in almost 3 out of 4 cases. This result is in line with that described in the pilot studies by Davidson and Onrubia and González, in which this proportion is around 80%. It should be noted that, in this sense, pneumonia was the clinical entity in which a greater impact was observed, with ATB not being prescribed in one out of every 3 cases, showing a good clinical evolution with symptomatic treatment. Several studies have analysed different biomarkers for the etiological differentiation of pneumonia, with controversial results, so FebriDx® could be especially useful in the evaluation of this entity.”

“In conclusion, FebriDx® could be a useful tool in the management of paediatric patients with febrile ARI to optimise antibiotic prescription, especially in those entities, such as pneumonia, which present greater difficulty in its etiological discrimination. In addition, it could also be useful for reducing unnecessary chest X-rays.”

Principal Investigator, Director of the pediatric emergencies service and Associate Professor Dr. Carles Luaces Cubells commented, *“Febrile syndrome is, without a doubt, the most frequent reason for consultation in Paediatric Emergency Departments. Emergency paediatricians know that in most cases these febrile processes correspond to viral conditions. Despite this, the correct diagnosis is still a major and frequent challenge.*

FebriDx, with its two biomarkers (MxA and CRP) has shown that it is a rapid diagnostic test, with results available in 10 minutes, capable of helping in the possible identification of the infectious agent (virus vs bacteria), contributing to a much more adequate antibiotic prescription and thus considerably limiting the negative effects mentioned above. It should also be reiterated that the simple sample processing and its low harm/pain causing technique represent an added value for paediatric patients.

Based on our experience, we understand that the incorporation of FebriDx in the diagnostic arsenal for febrile patients, along with a good clinical evaluation, is useful for improving the indication of complementary tests such as X-rays and favors a more accurate antibiotic prescription.”

Lumos CEO and Managing Director, Doug Ward commented, *“We are highly encouraged by the results of this paediatric study and I commend Associate Professor Dr. Carles Luaces Cubells and his team for their excellent work. We are also grateful to all the patients who agreed to participate – their contributions are invaluable in helping us to achieve our goal of reducing antibiotic overuse.*

“If FebriDx can be useful as an aid in diagnosing conditions in children like pneumonia quickly and accurately, it means we can use the right treatment tools straight from diagnosis, potentially reducing recovery times and stress for these kids and their families. It may also mean less load on other hospital resources, such as imaging, in those markets where use is permitted.”

Intended use

FebriDx is indicated for paediatric patient use in some markets, including Europe, Canada, and Australia, but is not indicated for use in patients under 12 years of age in the U.S.

In the United States, FebriDx is indicated for use in patients in patients aged 12-64 who present to urgent care or emergency care settings for evaluation of acute respiratory infection who have had symptoms for less than 7 days and within 3 days of fever onset. FebriDx test results are intended to be used in conjunction with other clinical and diagnostic findings as an aid in the diagnosis of bacterial acute respiratory infection and differentiation from non-bacterial etiology.

-Ends-

This announcement has been approved by the Lumos Disclosure Committee.

About Lumos Diagnostics

Lumos Diagnostics specializes in rapid and complete point-of-care (POC) diagnostic test technology to help healthcare professionals more accurately diagnose and manage medical conditions. Lumos offers customized assay development and manufacturing services for POC tests and proprietary digital reader platforms. Lumos also directly develops, manufactures, and commercializes novel Lumos-branded POC tests that target infectious and inflammatory diseases.

For more information visit lumosdiagnostics.com.

Forward-Looking Statements

This announcement contains forward-looking statements, including references to forecasts. Forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions, and other important factors, many of which are beyond Lumos' control and speak only as of the date of this announcement. Readers are cautioned not to place undue reliance on forward-looking statements.

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