Investor Webinar

Lumos and BARDA Partner to Support FebriDx

11 October 2024

lumosdiagnostics.com

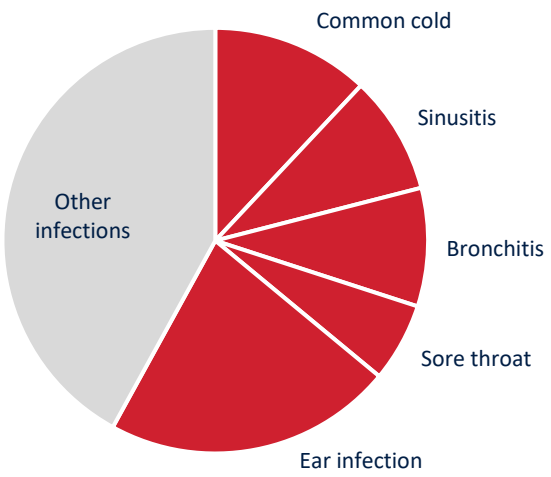
FebriDx - Bacterial / Non-Bacterial Point-of-Care Assay

- A rapid POC test for acute respiratory infections
- Reliable differentiation of bacterial and non-bacterial etiology
- 99% NPV to rule out bacterial Infections[1]
- Results after 10 minutes from a fingerstick
- Easy-to-use procedure
- All-in-one, instrument-free test device
- For use in urgent and emergency care settings

1. Shapiro NI, Filbin MR, Hou PC, Kurz MC, Han JH, Aufderheide TP, Ward MA, Pulia MS, Birkhahn RH, Diaz JL, Hughes TL, Harsch MR, Bell A, Suarez-Cuervo C, Sambursky R. Diagnostic Accuracy of a Bacterial and Viral Biomarker Point-of-Care Test in the Outpatient Setting. JAMA Netw Open. 2022 Oct 3;5(10):e2234588. doi:10.1001/jamanetworkopen.2022.34588. PMID: 36255727; PMCID: PMC9579916.

FebriDx addresses a major need: Antibiotic Overprescription

ANTIBIOTICS PRESCRIBED IN THE U.S. BY TYPE



Acute respiratory infections may account for

58%

of all antibiotics prescribed [4]

ANTIBIOTICS PRESCRIBED

211M antibiotic prescriptions issued in outpatient settings each year [1]

44% of antibiotic prescriptions are written to treat patients with ARIs [2]

40% of these are unnecessary [3]

HOW WE'RE DRIVING MARKET ADOPTION

Marketing and education

- Microbial testing prior to prescribing antibiotics not currently routine
- Assembling Medical Advisory Board of Urgent Care experts
- Program of communication through social media and KOLs

Program of activities includes:

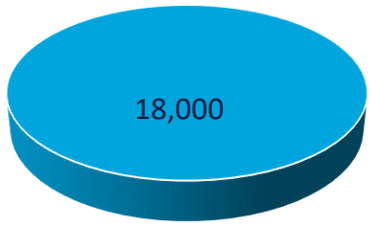
- Sales calls
- Distributor training
- Email campaigns
- Tradeshows
- Digital advertising
- PR
- Strategic partnerships
- Product education
- End user onboarding

[1] Outpatient Antibiotic Prescriptions—United States 2021: https://www.cdc.gov/antibiotic-use/data/report-2021.html
[2] Unnecessary Antibiotics for Acute Respiratory Tract Infections: Associations with Care Setting and Patient Demographics, 2016
[3] Tse, J.; Near, A. *et al*; Antibiotics 2022, 11, 1058. https://doi.org/10.3390/ antibiotics11081.
[4] Centers for Disease Control and Prevention. MMWR, 2011, 60:1153-6

FebriDx Market Opportunity in the US > $1Billion

MODERATE COMPLEXITY LIMITATION

Potential Customer Sites

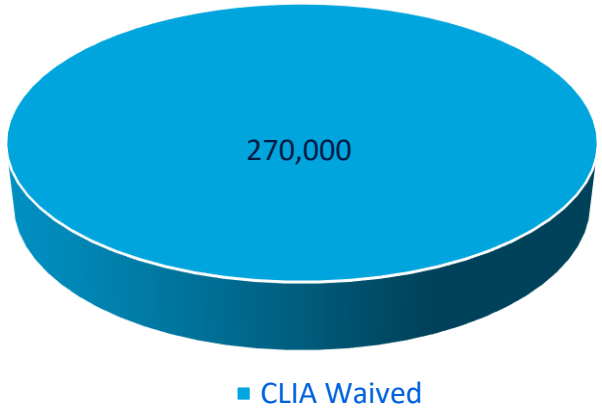


- 18,000[1] potential customer sites in US
- Acute Respiratory Infections (ARI) in US Annually: 80 million (potential FebriDx patient opportunities for use)[1]
- Moderate complex settings ~7% (5.6 million patient interactions)
- Assume distributor sell price to end customers of US$21.00 (CPT codes for reimbursement is US$29.55)
- TAM US$118 million p.a.

15x

CLIA WAIVER EXPANDS ADDRESSABLE MARKET

Potential Customer Sites



- 270,000[2] potential customer sites in US
- Acute Respiratory Infections (ARI) in US Annually: 80 million (potential FebriDx patient opportunities for use)[2]
- CLIA waiver enables 100% market coverage (80 million patient interactions)
- Assume distributor sell price to end customers of US$21.00 (CPT codes for reimbursement is US$29.55)
- TAM US$1.7 billion p.a.

[1] Division of Clinical Laboratory Improvement and Quality Centers for Medicare & Medicaid Services, March 2024 (CMS CLIA Data base)
[2] Source from 2024 Precision Business Insights Report for periods 2026-2030.

BARDA – Promoting Advancement of Medical Countermeasures

About BARDA

(part of the U.S. Department of Health and Human Services)

The Center for the Biomedical Advanced Research and Development Authority (BARDA) provides an integrated, systematic approach to the development of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies such as chemical, biological, radiological, and nuclear (CBRN) accidents, incidents and attacks; pandemic influenza (PI), and emerging infectious diseases (EID).

Together with its industry partners, BARDA promotes the advanced development of medical countermeasures to protect Americans and respond to 21st century health security threats.

Grant Application Process

Lumos was responsive to BARDA AOI (Area of Interest) # 7.2.2 requirements:

Advanced development, clinical evaluation, and FDA clearance/approval of CLIA-waivable/waived, rapid platforms and point-of-care assays that reliably distinguish between viral and bacterial infections to inform appropriate use of antibacterials and antivirals.

FebriDx CLIA Waiver Study

What is the study for…what is CLIA?

- The Clinical Laboratory Improvement Amendment (CLIA) waiver study will demonstrate that the FebriDx test is simple to perform with a low risk of erroneous results when performed by untrained users in expanded user settings.
- A CLIA waiver certificate enables facilities (e.g., physician offices, stand alone urgent care centers) to perform diagnostics without laboratory oversight.

Why?

- A successful study will enable Lumos to market FebriDx to waived settings which expands the TAM 15X and to over $1Billion.

How?

- A method comparison study will be conducted comparing the performance of untrained operators to trained operators in a multi-center study across the US, consisting of physician offices (majority) and standalone urgent care clinics who will enroll around 500-900 patients.

When?

- The study may start in Oct/Nov of 2024 and the submission is planned for May/June 2025. Based on FDA review times, the waived status designation may be expected by Sept/Oct 2025[1].

Risks?

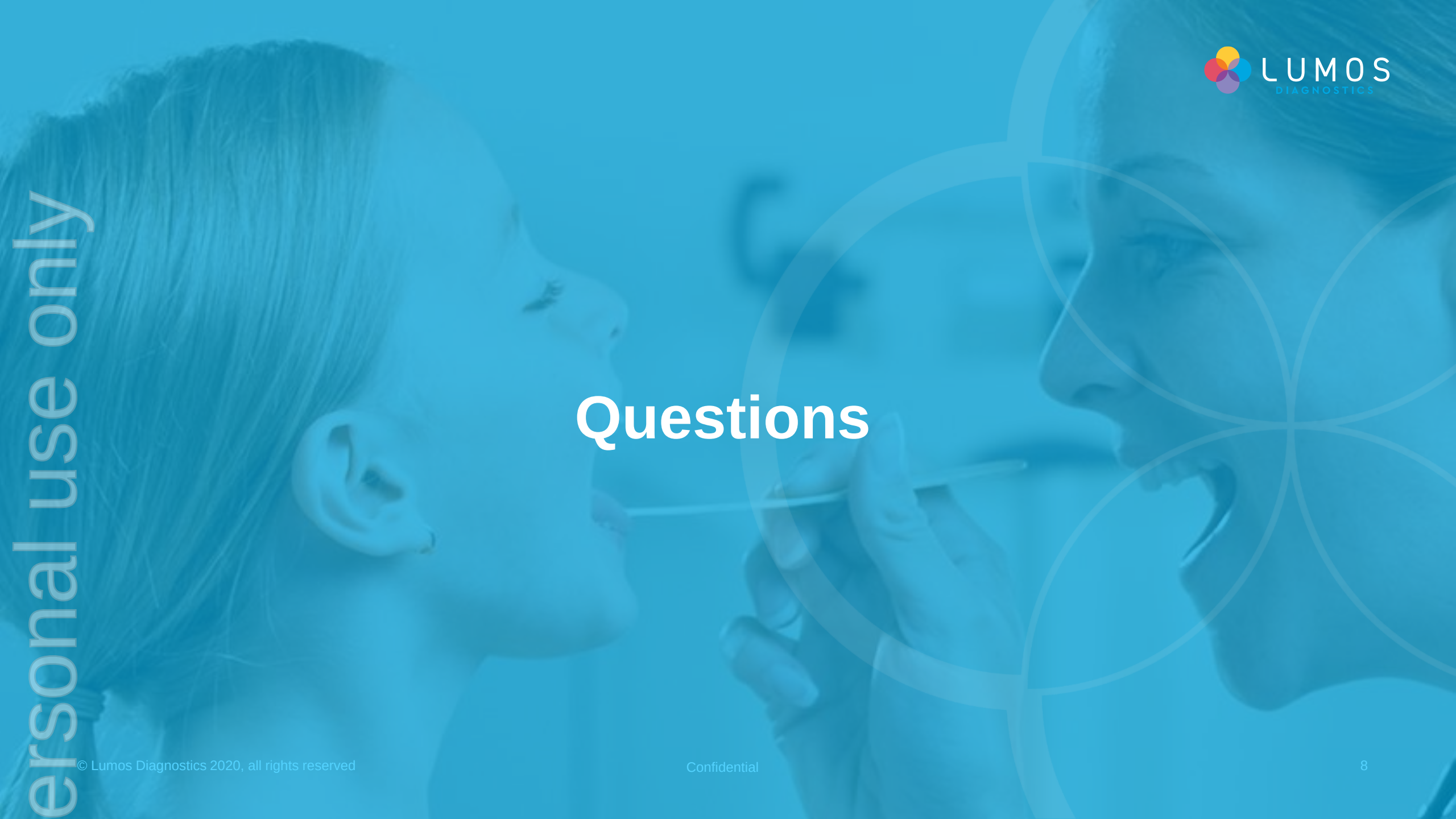
- Success Criteria: FDA criteria for obtaining CLIA waiver is very high (small number of errors).
- Timeline: low prevalence of bacterial infection in the respiratory season could result in the need to sign on additional sites to enroll or could lead to a longer than expected enrollment timeline.

[1]These timelines are indicative only and subject to change without notice.

Lumos and BARDA to Partner to Support FebriDx® bacterial/non-bacterial point-of-care test CLIA Waiver Study and Application

Key highlights

- BARDA has awarded Lumos with US$2.984m in non-dilutive funding to support the CLIA waiver study and US FDA application
    - Payment over the next 12 months based on milestone achievements
    - The partnership aims to expand authorized testing to CLIA-waived, point-of-care settings, including U.S. physician offices, urgent care clinics, or other outpatient clinics, where empiric antibiotic prescription is common practice
    - BARDA will support the CLIA waiver study, comparing test usage among untrained users in a CLIA-waived setting to trained users and provide regulatory expertise and support for the application to obtain a CLIA-waiver from the FDA
- Total contract value, if all contract options are exercised, is US$8.258m
    - Option value of US$5.274m is to support FebriDx expanded claim for patients under 12 years of age
    - Assuming option is exercised (anticipated mid-calendar 2025), payment to be over 12-18 months based on milestone achievement



Questions

LUMOS
DIAGNOSTICS

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