

FebriDx® Pediatric Validation Study

NCT07211997

Status	RECRUITING
Sponsor	Lumos Diagnostics
Enrollment	800 participants

Key Eligibility Criteria

Inclusion (3)

- Signed informed consent by parent/guardian and Assent for ages 7-11 years
- Exhibit or report of a new onset measured temperature (oral or tympanic) of greater than or equal to 100.4°F/38°C within 3 days (72 hours) of enrollment
- Clinical suspicion for Acute Respiratory Infection beginning within 7 days before enrollment AND presents with at least one of the following new onset of symptoms: runny nose, nasal congestion, sore throat, cough, hoarse voice, shortness of breath / difficulty breathing

Exclusion (6)

- Unwilling to participate in 7-day follow-up or sign HIPAA waiver to obtain medical record if hospitalized
- Immunocompromised state or taking immunosuppressive or chemotherapeutic medications in the last 30 days (e.g. oral / inhaled steroids, Methotrexate, Cyclosporine, Chemotherapy, interferon therapy)
- Taking antibiotics or antiviral therapy in the last 14 days
- Received a live viral immunization in the last 14 days
- Clinical diagnosis of otitis media or recognizable viral syndrome (i.e., croup, varicella, stomatitis) at the time of enrollment
- ... and 1 more (see full listing online)

Locations (10 total)

Avacare, Colton, California, United States
PAS Research- Myrtle Avenue Pediatrics, Inc, Clearwater, Florida, United States
PAS Research- Sandhill Pediatrics PA, Lutz, Florida, United States
... and 7 more locations