



Market Research Summary for Avisa Breath Test Indications

March 2018

Potential Indications for Avisa Breath Test

- Pneumonia in the Emergency Department
 - Immediate detection of urease pathogens to inform antimicrobial therapy, reduce unnecessary hospital admissions and support antimicrobial stewardship
- Ventilator associated infections
 - Monitoring of bacterial load to facilitate prevention of ventilator associated infections and effectiveness of antimicrobial therapy
- Chronic Obstructive Pulmonary Disease (COPD)
 - Periodic monitoring of COPD patients to prevent exacerbations
- Cystic Fibrosis (CF)
 - Periodic monitoring of CF patients to prevent exacerbations
- C. difficile
 - Monitoring of effectiveness of antibiotic therapy in hospitalized patients diagnosed with C. difficile infection

Overview of Market Size Research

- Indications for use tested in interviews with physicians, respiratory therapists, insurance plan chief medical officers and Avisa medical advisory board
- Calculated total addressable market (TAM) by region
- Disease prevalence estimates obtained from literature
- Nebulized administration of ^{13}C -urea for following indications:
 - Pneumonia in the Emergency Department
 - Ventilator Associate Infections
 - Chronic Obstructive Pulmonary Disease
 - Cystic Fibrosis
- Oral administration of ^{13}C -tyrosine for C. difficile indication

Pneumonia in the Emergency Department TAM

- Assumptions

- Administered once to all patients diagnosed with pneumonia in the emergency department
- Pneumonia cases are mix of community acquired and healthcare associated, prevalence of urease pathogens 5 to 15%

Market	Cases/Year	Tests/case	Total Tests
Japan	1,880,000	1	1,880,000
USA	2,305,675	1	2,305,675
EU	3,100,000	1	3,100,000
China	16,459,654	1	16,459,654

Ventilator Associated Infections TAM

- Assumptions

- Administered to mechanically ventilated patients 24 hours after start of ventilation (baseline) and then daily thereafter to monitor bacterial load for signs of infection
- Average length of mechanical ventilation in ICU = 5 days
- Urease pathogens cause >70% of ventilator associated infections

Market	Cases/Year	Tests/case	Total Tests
Japan	362,000	4	1,448,000
USA	1,653,000	4	6,612,000
EU	1,570,800	4	6,283,200
China	631,420	4	2,525,680

Chronic Obstructive Pulmonary Disease TAM

- Assumptions

- Administered to high risk COPD patients (~50%) during quarterly office visit to monitor bacterial load and assess risk of exacerbation
- Urease pathogens (H. influenza, P. aeruginosa) cause >30% of COPD related pneumonia exacerbations
- Prevalence estimates obtained from published literature

Market	Cases/Year	Tests/case	Total Tests
Japan	2,795,000	4	11,180,000
USA	6,000,000	4	24,000,000
EU	10,000,000	4	40,000,000
China	25,760,000	4	103,040,000

Cystic Fibrosis TAM

- Assumptions

- Administered to CF patients during quarterly office visit to monitor bacterial load and assess risk of exacerbation
- Urease pathogens (*S. aureus*, *P. aeruginosa*) cause >70% of CF-related pneumonia exacerbations
- CF is primarily found in patients of Caucasian descent

Market	Cases/Year	Tests/case	Total Tests
Japan	564	4	2,256
USA	30,000	4	120,000
EU	35,806	4	143,224
China	6,222	4	24,888

C. difficile TAM

- Assumptions
 - Administered to patients diagnosed with C. difficile in the hospital when diagnosed and then every two days thereafter to monitor effectiveness of antimicrobial therapy
 - Average length of antimicrobial administration for C. difficile is 10 days

Market	Cases/Year	Tests/case	Total Tests
Japan	47,655	5	238,275
USA	435,000	5	2,265,000
EU	123,997	5	619,985
China	59,497	5	297,485