BREATHSPEC®

A rapid, non-invasive, cost-effective, analytical device for bacterial or viral infection diagnosis through ultra-high sensitivity breath analysis

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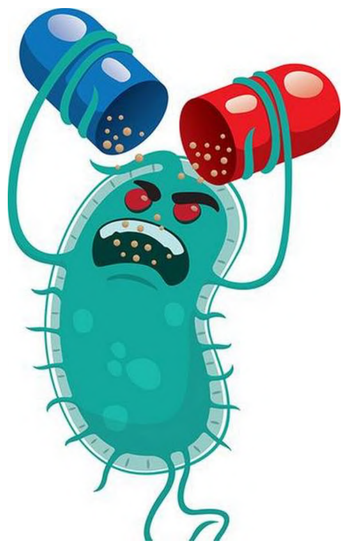
For more information, please visit: https://breathspec.com

PROJECT AIM

To measure the **Volatile Organic Compounds (VOC)** in present in breath, to distinguish patients with bacterial respiratory tract infections from those who have no infection or are virally infected. This hypothesis was explored through a large cohort study, in both primary and secondary care, to investigate the efficacy of breath analysis by **Gas Chromatography-on Mobility Spectrometry (GC-IMS).**

INTRODUCTION

- **Antimicrobial resistance (AMR)** is a continuous challenge for society and is defined as the ability of a microbe to resist the effects of medication.
- In the next 30 years, it is predicted that **2.4 million people in Europe**, North America and Australia will dies from infections caused by resistant microorganisms.
- Improved diagnosis of **respiratory tract infections (RTI)** in primary and secondary care is required to improve patient outcomes.
- Thus, there is an urgent need to develop a rapid, low-cost, point-of-care tests for diagnosing whether an **infection is bacterial or viral**, and then prescribing as appropriate.



RECRUITMENT

- **1,229 patients** were recruited from **2 primary** (397 patients) and **7 secondary** (832 patients) care sites across the UK.
- **Those presenting with symptoms of an RTI were included**, whilst those with pre-existing chest infections, on antimicrobials for longer than 18 hours or those who had lung cancer were excluded.
- X-rays, bacterial cultures and polymerase chain reaction (PRC) analysis of nose swabs were used to facilitate diagnosis and for identifying specific viruses and bacteria. **The clinical lead at each site determined final diagnosis.**

INSTRUMENTATION

- The **BreathSpec** (G.A.S, Dortmund, Germany) was used in this project (Fig. 1). It consists of a gas chromatograph and an ion mobility spectrometer, collectively known as **GC-IMS** (Fig. 2).
- The instrument has been optimised for **sensitive detection** of VOCs in human breath.
- Sampling is **rapid, easy to use and suitable for vulnerable subjects.** Only 4 seconds of exhaled breath is required.
- Measurement results are available in **less than 10 minutes.**

Figure 1. A patient using the BreathSpec

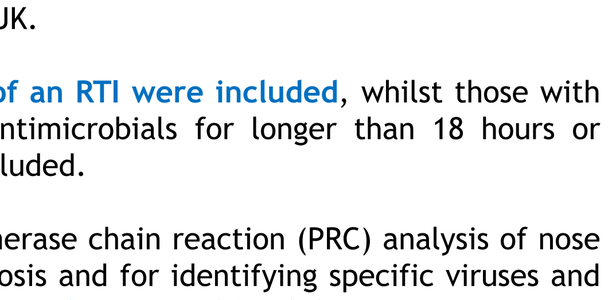


Figure 2. Diagrammatic representation of GC-IMS

DATA ANALYSIS

- A typical output plot from the **BreathSpec** instrument is shown below with common chemicals labelled. This breath sample is from a **confirmed RTI patient**.
- Data analysis was conducted using **5 classification algorithms**. The pipeline is displayed in Fig. 4.
- **Several performance metrics were generated** for each model, including Area Under the Curve (AUC), sensitivity and specificity.

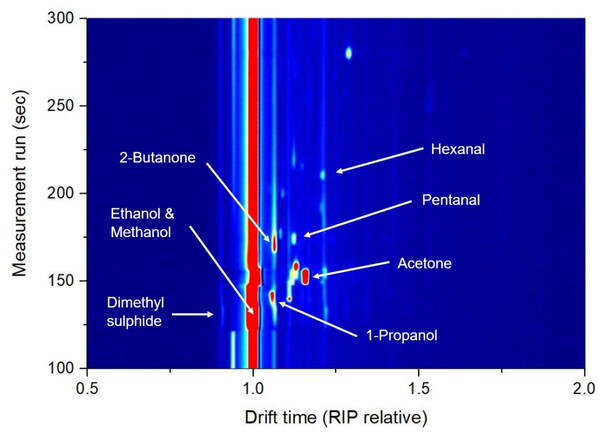


Figure 3. Typical BreathSpec GC-IMS output highlighting important VOCs

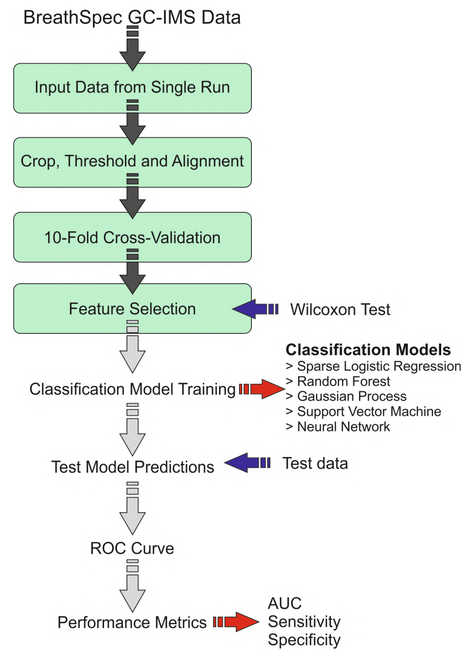


Figure 4. Data analysis pipeline used in the study

RESULTS

- This project has shown **there is potential to decrease prescribing rates** of antimicrobials, via breath analysis using the BreathSpec. Table 1 displays projected figures from our work.

Table 1. The potential increases or decreases in prescribing rates based upon the sensitivity and specificity of of the BreathSpec.

Sensitivity/specificity of breath test	40% prescribing rate	65% prescribing rate	90% prescribing rate
60%	+ 26.2	- 26.2	- 46.7
75%	+ 18.0	- 31.0	- 50.2
90%	+ 9.9	- 35.8	- 53.6

- It is thought that current antimicrobial prescribing rate in the UK is around 65%, meaning the **use of the BreathSpec can reduce prescribing rates by 31%**.
- VOC analysis indicates that **certain compounds play a crucial role** in distinguishing between diagnostic groups.
- Analysis of possible confounding factors indicate that gender, age and smoking habits have **insignificant influence on breath content**.

CONCLUSIONS

- Breath analysis has **great potential** as a point-of-care test for diagnosing RTI and **may help to reduce anti-microbial resistance**.
- Early results indicate that **there are some differences between probable and non-probable bacteria**.