Genpax IDEM

Next Generation Infection Surveillance

IDEM Instructions for Use

IDEM Insight Series: Document 6 of 6 - Advancing Infection Prevention and AMR Surveillance

Version: v1.0
Date: March 2025
Contact: support@genpax.co

About This Document

This is Document 6 of 6 in the IDEM Insight Series, designed to guide you from understanding the power of Whole Genome Sequencing (WGS) in infection prevention and control through to the benefits, performance, and practical use of IDEM.

The full IDEM Insight Series includes:

1. **The Power of WGS –** Transforming Infection Control and Public Health.
2. **IDEM Introduction –** Next-Generation Genomic Surveillance.
3. **IDEM Performance Overview –** How Accuracy, Resolution, and Connectivity Drive Results.
4. **IDEM Technical Validation Guide –** In-Depth Data and System Design.
5. **Health Economic Impact –** How Proactive WGS Saves Lives and Costs.
6. **IDEM Instructions for Use (IFU).**

For more information, visit www.genpax.co or contact support@genpax.co.

Insight Series Progress

[■] 1. The Power of WGS → [■] 2. IDEM Intro → [■] 3. Why IDEM Works→ [■] 4. Technical Guide → [■] 5. Health Economics → [■] 6. IFU

Instructions for Use (IFU) – IDEM

Quick Start Videos

Before you begin, you can watch these short videos for a guided walkthrough of IDEM's features and workflows:

- ▶ Laboratory Module Overview
- ▶ IPC Module Overview

userguide | Genpax

These videos cover the full process from data upload through to analysis and interpreting results, helping you get started quickly and confidently.

1. Intended Use

IDEM is a cloud-based whole genome sequencing (WGS) surveillance platform designed for infection prevention and control (IPC) teams and microbiology laboratories. It enables the rapid analysis of bacterial and fungal pathogen genome sequences to detect outbreaks, antimicrobial resistance (AMR) genes, and transmission dynamics.

Important: IDEM is a **surveillance tool and not a diagnostic device**. It is not intended for individual patient diagnosis or treatment decision-making.

2. System Overview

IDEM is a **SaaS (Software as a Service)** platform that allows users to:

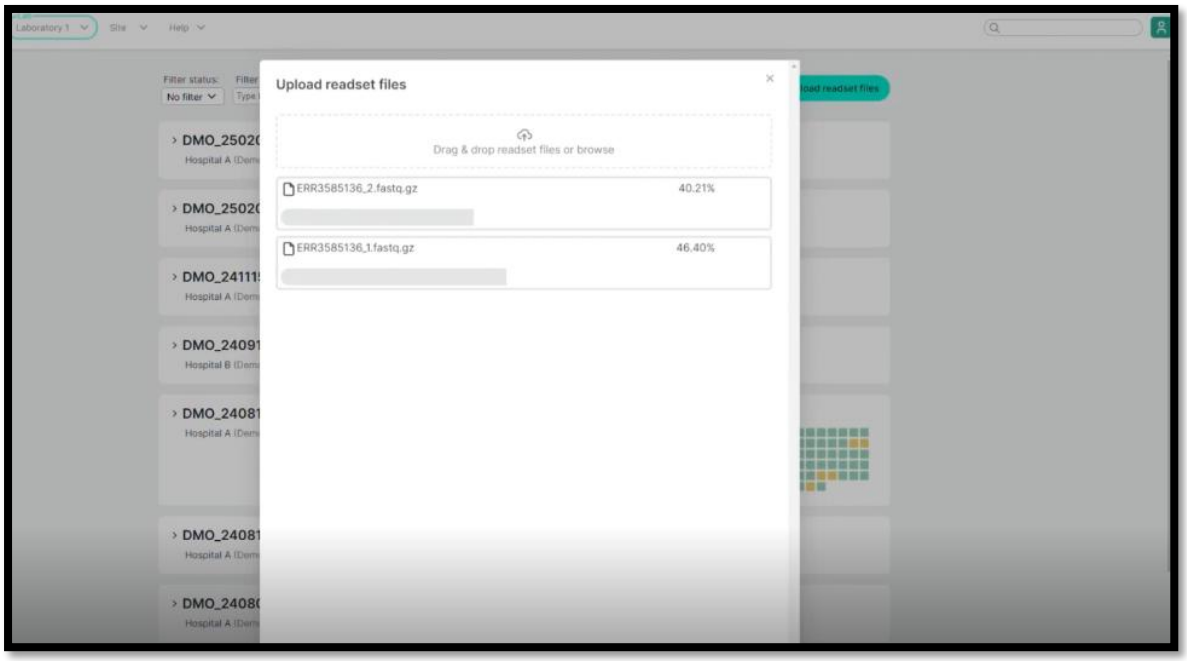
- Upload sequencing data in FASTQ format.
- Run automated quality control (QC) checks to ensure sequencing reliability.
- Perform high-resolution, naturally reference-free outbreak detection.
- Identify AMR and virulence genes.
- Track transmission dynamics across hospitals and regions.

3. Workflow & User Instructions

3.1 Uploading Samples

- Users can drag and drop FASTQ files for upload or automatically upload through BaseSpace.
- CSV files with sample metadata can be drag and dropped directly into IDEM
- IDEM will automatically verify the file formats and integrity, matching metadata with FASTQ data.

Simple Drag & Drop File Upload – Automated Workflows Also Available

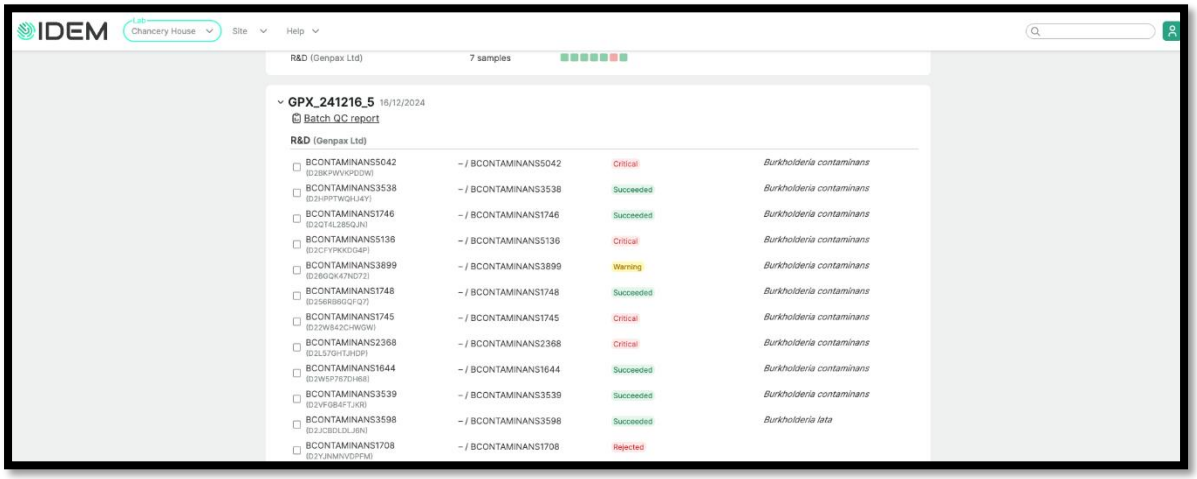


3.2 Quality Control (QC) Checks

IDEM performs QC to ensure only high-quality sequencing data is analysed.

QC indicators:

✅ **Pass:** Data meets quality thresholds for accuracy and coverage.
⚠️ **Warning:** Possible issues detected – review required.
❌ **Critical:** Sample does not meet the quality standard; resubmission advised.

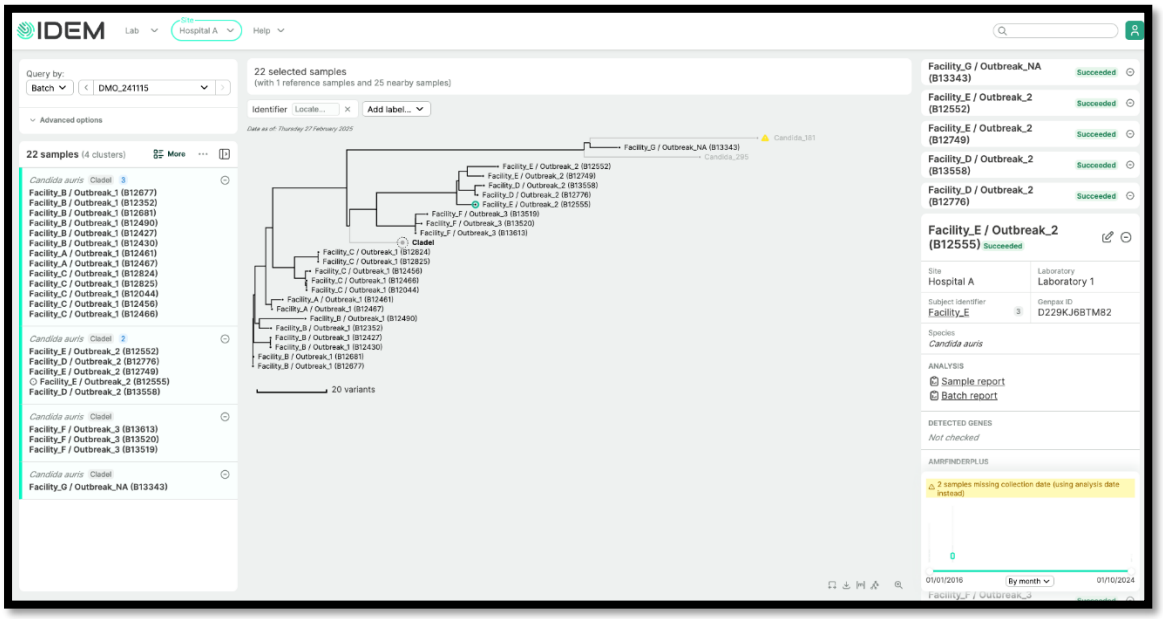


3.3. Species identification

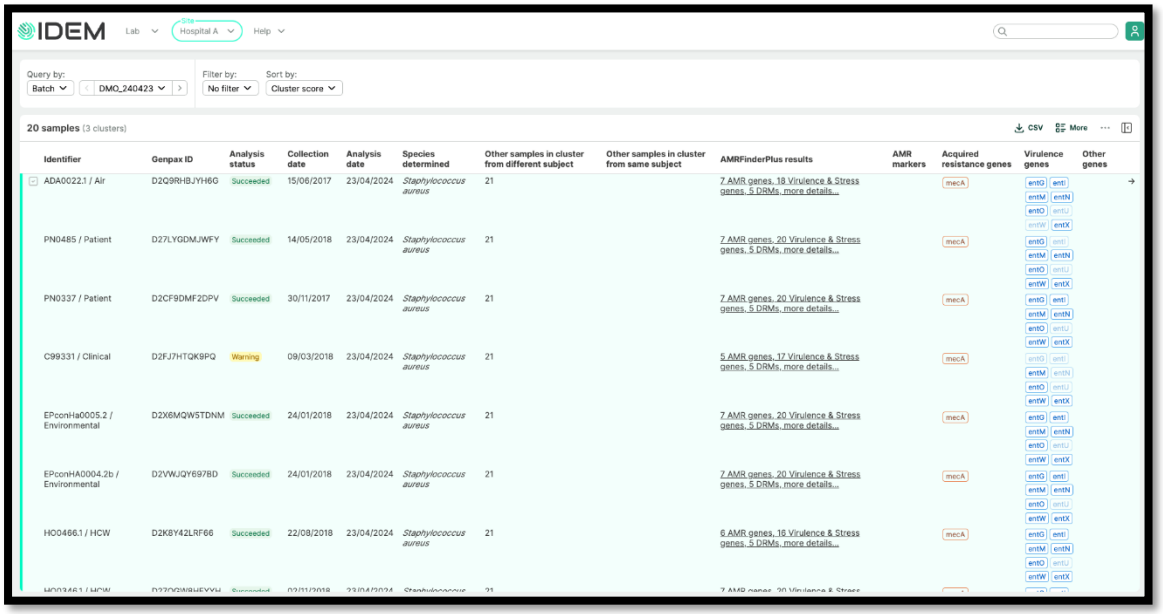
- IDEM supports the analysis of over 100 different microbial pathogens.
- The species to which a sample belongs is detected automatically. IDEM then selects the appropriate analyses to perform.
- The expected species can optionally be uploaded as part of the sample metadata. IDEM will provide a QC warning if this does not match the species detected.

3.4 Data Analysis & Reporting

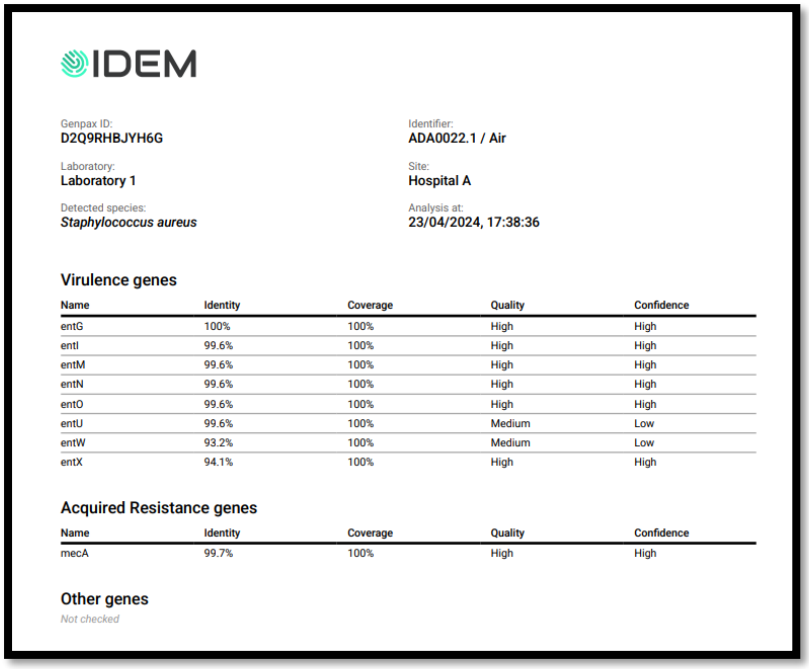
- **Cluster Analysis:** Identifies closely related samples grouping them into clusters.



- **AMR & Virulence Gene Detection:** Highlights genes associated with antimicrobial resistance and pathogen virulence.



- **Transmission Tracking:** Connects samples across space and time, allowing IPC teams to assess ongoing outbreaks.
- **Report Download:** Users can generate PDF, CSV, or image reports for documentation and decision-making.



IDEM

Genpax ID:
D2Q9RHBJYH6G

Identifier:
ADA0022.1 / Air

Laboratory:
Laboratory 1

Site:
Hospital A

Detected species:
Staphylococcus aureus

Analysis at:
23/04/2024, 17:38:36

Virulence genes

Name	Identity	Coverage	Quality	Confidence
entG	100%	100%	High	High
entI	99.6%	100%	High	High
entM	99.6%	100%	High	High
entN	99.6%	100%	High	High
entO	99.6%	100%	High	High
entU	99.6%	100%	Medium	Low
entW	93.2%	100%	Medium	Low
entX	94.1%	100%	High	High

Acquired Resistance genes

Name	Identity	Coverage	Quality	Confidence
mecA	99.7%	100%	High	High

Other genes

Not checked

Example Sample report

3.4 Integration with Laboratory Workflows

- IDEM is compatible with major sequencing workflows, including BaseSpace, direct FASTQ uploads, and manual input methods.
- Results are provided within 2 hours of data submission.
- For a full demonstration of the laboratory module, please refer to the video links provided on page 2.

4. Data Interpretation Guidelines

- Clusters are defined based on genetic distance thresholds (e.g., 15 SNPs).
- AMR gene detection includes known resistance markers but does not replace traditional phenotypic susceptibility testing.
- Users should cross-check IDEM reports with local epidemiological data and patient information to support transmission and source analysis.
- For a full demonstration of the IPC module, please refer to the video links provided on page 2.

5. Support & Troubleshooting

For technical support, contact support@genpax.com.

Intended Use Statement: IDEM is a surveillance tool and not a diagnostic device. It is not intended for individual patient diagnosis or treatment decision-making.

Next in the IDEM Document Series:

➡️ *(End of series)*

Previous in the IDEM Document Series:

⬅️ *Health Economic Impact – How Proactive WGS Saves Lives and Costs*

Genpax IDEM

Next Generation Infection Surveillance

Disclaimer:
This IFU provides guidance for the correct use of the IDEM platform. It is intended for use by trained professionals, following all applicable local, national, and international regulations.

Genpax Ltd accepts no responsibility or liability for outcomes arising from use of this document or the IDEM platform, including misuse, modification, or failure to follow procedures.

Users are responsible for ensuring compliance with local governance, regulatory requirements, and best practices.