



BIOMÉRIEUX EPISEQ[®] CS

for clinical pathogen outbreak monitoring

QUICK START GUIDE



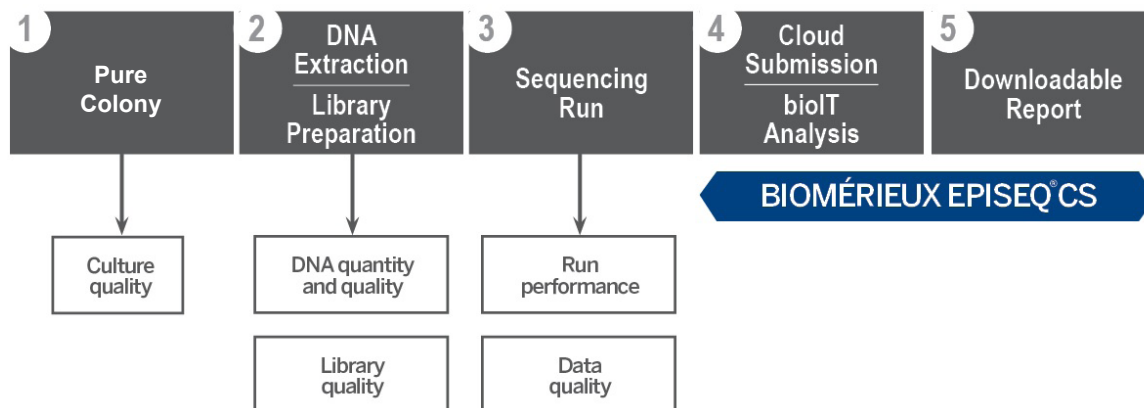
051408-02-en - 2019-11

NOT FOR DIAGNOSTIC USE

WORKFLOW AT A GLANCE



Before using the application, you must select a clone of the isolate(s) of interest, and extract, purify and sequence the DNA. These steps are represented in the figure below, where the user's interaction with the application begins after ensuring that the sequencing data meet the quality criteria shown in Sequencing Prerequisites, page 5.



1. Upload your samples:

- Select your FASTQ or FASTA files for each sample.
- Enter metadata for each sample using the sample sheet or fill-in fields.
- Optional: Add panel name and description to worklist.
 - Select upload to start the data processing.

2. Wait for the **analysis** to be processed.

3. View results:

- A warning, if samples are genetically related with strains in the system.
 - QC warnings and QC report.
 - The resistome and virulome*.
 - The epidemiological tree.

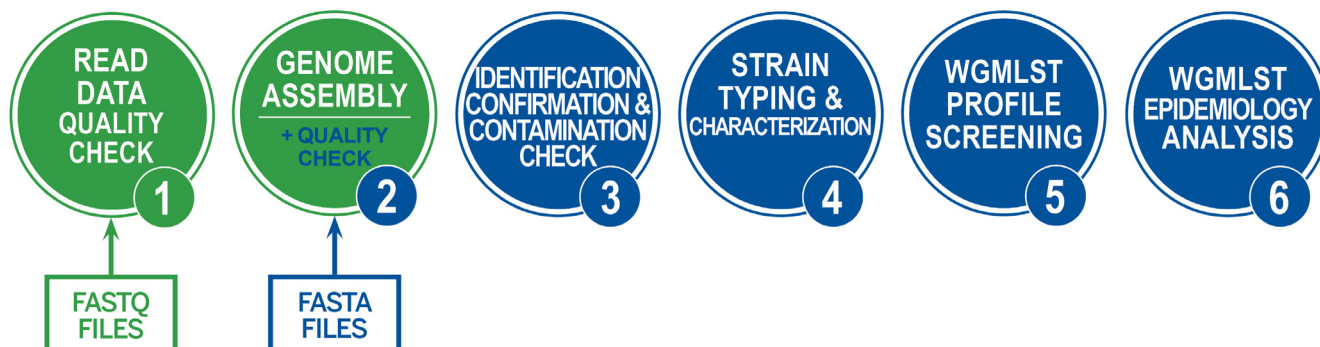
* The virulome is available only for *C. difficile*, *E. coli* / *Shigella* spp. and *S. aureus*

Additionally, you can create a custom analysis or export a PDF report.

Confirm species
if other than uploaded
is detected.

Please visit <http://www.biomerieux-episeq.com> for additional information on the workflow.

Once the sequencing data are uploaded, the application will automatically deliver results following this workflow:



HOW TO GET STARTED

1. Contact your local bioMérieux distributor

Contact the bioMérieux sales department to purchase one of the following credit plans:

- Pay-Per-Use: pay per sample submission and 15 days of data storage
- One year subscription: a fixed number of sample analyses and one year of data storage
- Yearly subscription: a fixed number of sample analyses, one year of data storage and storage of past analyses


Once the credits are purchased, bioMérieux will send you a voucher code.

This code will allow you to activate your credit plan.

2. Register to the bioMérieux Data Analytics Platform

1. On your PC, browse to <https://data-analytics.biomerieux.com>.
 - > The Sign-In screen appears.
 2. Click the **Register** link.
 - > The Register screen appears.
 3. Complete the information in the fields.
 4. Check the **Terms and conditions** box.
 5. Click the **Register** button.
 - > The bioMérieux Data Analytics Home page appears.
 6. Verify your email address by clicking on the hyperlink in the email sent by bioMérieux Data Analytics.
-

3. Create an organization in the bioMérieux Data Analytics Platform

1. On the Home page, click the **Settings** icon in the bar (), then click **Create organization**.
 - > The Create a new organization screen appears.
 2. Complete the **Name** field for your organization and click **Next**.

Now you can invite users to your organization (Step 3) or do it later, and continue to Step 4 of this section.
 3. Invite users by typing or pasting their email address and clicking the **+ Add** button.
 - > Edit or delete each email address, as needed.
 4. Scroll to the bottom of the page, click **Next**, then click **Finalize**.
-

4. Install the BIOMÉRIEUX EPISEQ® CS application in your organization portal

1. Click the **Application store** tab in the bar.
2. Click the BIOMÉRIEUX EPISEQ® CS **Install** button.
3. If useful, add a suffix to the application name by typing in the Suffix (optional) box.
4. Select the box to agree on the Terms and conditions, and click **Install**.
 - > The BIOMÉRIEUX EPISEQ® CS application appears in your organization portal.

By default, the administrator role is assigned to the creator of an organization. As the administrator, you can assign user roles (Laboratory manager, Hygienist and Laboratory Technician) which are associated with specific permissions to the invited users.

5. Enter the voucher code

1. Have your voucher code handy.
2. In the bioMérieux Data Analytics platform, click on the organization name.
 - > The BIOMÉRIEUX EPISEQ® CS application tile appears, displaying the application version number and a "Credit plan" button.
3. Click the "Credit plan" button in the BIOMÉRIEUX EPISEQ® CS application tile.
4. Enter your voucher code in the field and click the **Activate** button.
 - > The number of purchased credits appears.

If the voucher code is invalid, a message will appear inviting you to contact Customer Support.



CAUTION

This application has been designed and validated to work on FastQ files generated only on Illumina instruments and FastA files assembled from Illumina raw data, following the sequencing prerequisites described on page 5. BIOMÉRIEUX EPISEQ® CS will accept the uploading of FastA files assembled from other types of raw sequence data, but the relevance of the QC report and of the results in this situation is not guaranteed.

IMPORTANT: One credit is used for each uploaded sample.

1. Log in to the BIOMÉRIEUX EPISEQ® CS application.
2. Launch the application in your organization, click the **Upload** tab in the bar to open the Upload page.



3. The Upload page opens with the default panel name appearing in the **Panel title** field. Optionally, rename the panel and add a description.
4. Click the **Select sequence files** button to upload the FastA or FastQ files of the samples of interest.
5. Add the samples' metadata by clicking the **Select samplesheet** button or by manually filling-in the fields. Once all the mandatory data is filled in, the Upload button on the bottom will become active.
6. Click the **Upload** button.
The panel cards appear on the left side for each of the different organisms that were uploaded. Inside the panel cards, each of the sample cards are displayed.

SPECIFICATIONS AND DEFINITIONS

Computer Specifications

The workstation computer or laptop shall meet the following specifications:

- Microsoft Windows® 7 Operating System or higher
- Access to the Internet
- Access to e-mail
- Internet Explorer® version 11, Firefox® version 60
- Screen resolution of 1366 x 768 and screen size of 19 inches
- Optional: Access to a printer

For an improved software performance, we recommend using a 64-bit processor. Use of a 32-bit processor may result in a slower performance of the application.

While we strive to ensure the confidentiality and security of your data sent to and from our secured cloud, it is your responsibility to secure your network and ensure that this protection is appropriate and maintained. We recommend using all appropriate means (including antivirus software, security patches, and firewall) to protect your network from virus intrusion, unauthorized use, alteration, manipulation, and disclosure.

Sequencing Prerequisites

- **Mandatory use of an Illumina® sequencing instrument**
- An optimal average depth of 45x
- An optimal average insert size between 300 and 500 bp
- Paired end reads of at least 150b (2x150b)
- A sequence quality greater than 70% of bases with $\geq Q30$ Phred score

Recommendations for sequencing on an Illumina instrument are available on the Online Help with the search: Wet lab procedure.

.....

bioMérieux Data Analytics Platform

The bioMérieux Data Analytics Platform web portal hosts the BIOMÉRIEUX EPISEQ® CS application. It supports User management and Credit management functions for embedded applications.

User Management

BIOMÉRIEUX EPISEQ® CS supports user roles that determine the level of access to the application and underlying data. Organization administrators can manage users in their organization. They can also invite or remove users, and install, rename, and uninstall applications. User roles correspond to various privileges and can be associated with user groups.

By assigning users to user groups, administrators can determine user permissions, i.e., which actions a user can undertake in the bioMérieux Data Analytics platform or in its applications.

User Support

Contact customer support at episeq_support@biomerieux.com or by emailing from the application via the Help center.

User Documentation

In addition to this guide, instructions for use are available by clicking the Help center icon (?) on the navigation bar. The Help center is composed of the tabs Topics and Documentation, that contain information to guide you through the application.

Credit Plan and Data Retention Period

Currently, there are two credit plans available: Pay Per Use and Subscription. Please contact your sales representative for more information. Data will be stored 15 days if you choose the Pay-Per-Use plan, or for one year if you choose the subscription plan, and beyond if you opt for an extended storage plan of existing data.

Credits

Before using the application, you must purchase credits to use towards strain analyses, with one sample upload requiring one credit. After purchasing the credits, you will receive a voucher code to enter in the application.

Voucher Code

A voucher code is a string of characters required to activate the purchased credits (or credit plan) in the system. The voucher code will be communicated by your bioMérieux sales contact once the order has been confirmed.



LEGAL MENTIONS

LIMITED WARRANTY

Except as expressly set forth under BIOMÉRIEUX EPISEQ® CS Terms of Use, and to the maximum extent permitted by law, BIOMÉRIEUX makes no warranties, express, implied or statutory, with respect to BIOMÉRIEUX EPISEQ® CS Solution or any of the services provided via BIOMÉRIEUX EPISEQ® CS Solution, including without limitation any implied warranty of merchantability, fitness for a particular purpose, noninfringement, or arising from course of performance, dealing, usage or trade.

INTELLECTUAL PROPERTY

BIOMERIEUX, the BIOMERIEUX logo, APPLIED MATHS, and BIOMERIEUX EPISEQ are used, pending and/or registered trademarks belonging to bioMérieux, or one of its subsidiaries, or one of its companies. Any other name or trademark is the property of its respective owner.

INTENDED USE AND USERS

The BIOMÉRIEUX EPISEQ® CS software application enables the user to characterize an array of bacterial strains at the genomic level and study their epidemiological relevance.

The BIOMÉRIEUX EPISEQ® CS software application is intended to be used by laboratory professionals trained in microbiology and familiar with epidemiological analyses of bacterial strains, without concern for personal safety as it is web-based only.

LIMITATIONS OF USE

The BIOMÉRIEUX EPISEQ® CS software application is not for diagnostic use.