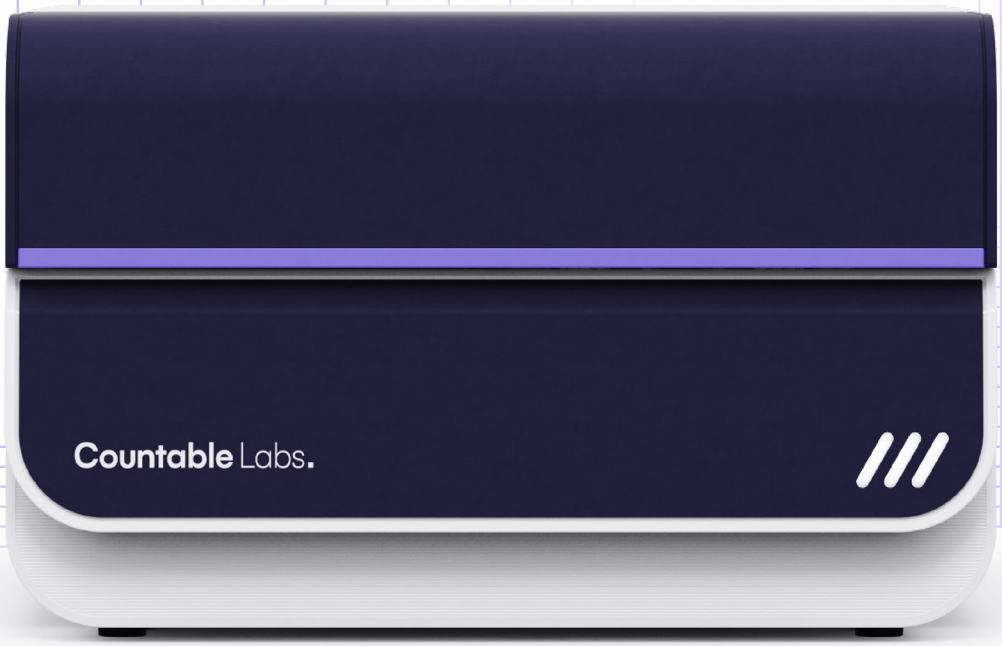
Countable Labs.



Countable System

Instructions for Use

For Research use only. Not for use in diagnostic procedures.

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USA
countablelabs.com

Notices

This document is intended for the use of the Countable System. All products, including instruments, consumables, accessories, reagents, and services described herein are intended molecular biology applications and are FOR RESEARCH USE ONLY. They are NOT FOR USE IN DIAGNOSTIC PROCEDURES, or for the prevention and/or treatment of a disease.

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Technical support

Your success is our success, so we are committed to supporting you at all times. Our Customer Success Team is made-up of scientists that are molecular biologists and Countable Labs product experts that are ready to answer any of your questions or help with any issue you may run into.

Contact us at success@countablelabs.com

Policy statement

We're always working to take our products to the next level so you'll have the best. Specification may be updated from time to time to reflect system improvements, but we'll keep you informed along the way. We also welcome your feedback on our guides so we can keep improving your experience.

Revision history

Document Revision	Revision Date	Description
IFU003 Rev 1.0	June 2025	Initial release

Table of contents

CHAPTER 1

Introducing, the Countable System!

Welcome

Congratulations on bringing the Countable System to your lab! We're excited to welcome you to the next advancement of PCR technology, where enhanced precision and efficiency await you. To help you get the most out of your Countable System, we recommend taking a quick look at this Instructions For Use guide for system setup, operation, and maintenance information. For details on sample prep or assay-specific workflows, check out Countable PCR Reaction Preparation User Guide.

Conventions

Note	**Note** highlights handy tips to help you use your Countable System.
Warning 	**Warning** calls your attention to situations where using the Countable System the wrong way could hurt you or someone else.
Caution 	**Caution** alerts you to situations that might damage the Countable System or other equipment.

Intended use of the Countable System

The Countable System is intended for the absolute counting of target nucleic acids and genomic biomarkers. It is intended to be used by research and commercial laboratories to support their activities in research, development, and manufacturing. Applications included, but are not limited to, pathogen detection, targeted mutation detection, molecular residual disease testing, genotyping, copy number analysis, gene integration characterization, viral titration determination, methylation analysis, and treatment or therapy selection.

The Countable System is intended for Research Use Only (RUO).

The Countable approach

The Countable System is a high-resolution imaging and analysis platform that performs 3D light sheet fluorescence image of the Countable Matrix. It gives you precise spatial detection and counting of discrete fluorescent signals across the full reaction volume, making it the perfect solution for workflows that rely on single-molecule or compartmentalized fluorescence detection.

How does it work? Fluorescently-labeled molecules in your sample are immobilized in the Countable Matrix, a structured gel that forms in the Matrix Tube Strip. The Countable System images the tubes in the Matrix Tube Strip without any hands-on steps—giving you a no-transfer workflow from signal generation to image capture and analysis.

When your sample is imaged, the system collects a full-volume fluorescence map of each tube in the strip by scanning multiple focal plans. The Countable Control Software automatically generates signal detection, thresholding, and spatial compartment data, giving you high-resolution quantitative results.

Countable users

Task	Personnel	Required training and experience
Delivery	No special requirements	No special requirements
Installation and commissioning	Countable Labs service personnel	Trained Countable Labs personnel
Routine use (*e.g.* running protocols)	Laboratory technicians or equivalent	Personnel who are appropriately trained, or experienced and familiar with the use of computers and automation systems
Assay design and validation	Scientist or equivalent	Personnel who are appropriately trained or experienced and familiar with molecular biology techniques.
Cleaning and preventative maintenance	Laboratory technicians or equivalent	Personnel who are appropriately trained or experienced and familiar with the use of computers and automation systems
Service	Countable Labs service personnel	Trained and authorized Countable Labs personnel

CHAPTER 2

Preparing your lab

Overview

For a smooth and stress-free installation, review this chapter so your lab will be ready when a Countable Labs representative arrives to install your instrument. You should not try to install or move the instrument yourself.

Warning/ Caution

Risk of personal injury and the Countable System damage

- Do NOT unpack the Countable System before the Countable Labs representative arrives to install your instrument.
- Do NOT try to install the Countable System yourself. It should ONLY be installed by a Countable Labs representative.
- Do NOT move the Countable Instrument yourself, either before or after installation. The instrument should ONLY be moved by a Countable Labs representative.

Space requirement

Caution

Risk of personal injury and the Countable System damage

- For proper ventilation, maintain a minimum clearance of 4 in (10.2 cm) on the sides and rear of the Countable System.
- Don't cover any slits or openings that are essential for ventilation.

Instrument dimensions

Component	Length/Depth	Width	Height	Weight
Countable Instrument	24.8 in (63.0 cm)	19.7 in (50.1 cm)	13.6 in (34.5 cm) 22.8 in (57.9 cm) w/ door open	75.0 lbs (31.8 kg)
Desktop computer	16.5 in (42.0 cm)	6.8 in (17.3 cm)	14.5 in (36.9 cm)	18.7 lbs (8.5 kg)
Computer monitor	6.0 in (15.2 cm)	21.2 in (53.8 cm)	16.3 in (41.4 cm	7.3 lbs (3.3 kg)
Keyboard and mouse	7.4 in (18.8 cm)	17.6 in (44.7 cm)	0.8 in (2.0 cm)	1.1 lbs (0.5 kg)

Lab bench requirements

The recommended lab workbench is at least 30 x 72 (L" x W"), and the minimum table size is 30 x 60 (L" x W"). The lab workbench must be able to support 110 lbs (50 kg) to accommodate the weight of the Instrument and computer set up.

The imaging process in your Countable Instrument is sensitive to mechanical vibrations. It is very critical that your instrument is installed on a sturdy, wobble-free, vibration-free lab workbench for optimal image quality.

If you have control over the workbench being used, we recommend a Bench-Tek model # BT40CR-3072BS-PS, However, any existing lab workbench with similar footprint, quality, and sturdiness will also work just fine.

Instrument positioning requirements

You'll want to leave enough space around the side of your Countable Instrument for proper ventilation and so service personnel can access the instrument when needed. Minimum clearance requirements are shown below.

Side of instrument	Minimum clearance
Left side	At least **6.0 in (15.2 cm)** clearance from the wall is required on the left side of the instrument, where the fan is mounted, for proper ventilation.
Right side and back side	**4.0 in (10.2 cm)** clearance is recommended for the right and back side of the instrument.
Top side	Shelves should be at least **27.0 in (68.9 cm)** from bench surface.

Electrical requirements

Plug your Countable Instrument into a dedicated, grounded circuit capable of delivering 100—240 VAC, 50/60 Hz, 5 As.

Environmental operating conditions

Condition	Acceptable range
Installation site	For indoor laboratory use only.
Operating temperature	19—25 °C (66—77 °F).
Operating humidity	20—80% RH (non-condensing).
Altitude	<2000 m (6500 ft).
Air quality	Pollution Degree II or better.
Vibration	Don't place the instrument adjacent to strong vibration sources (*e.g.*, centrifuges). Excessive vibration can negatively affect instrument performance.
Heat sources or direct sunlight	Don't place the instrument adjacent to heat sources or under direct sunlight. Temperature elevation inside the instrument due to heat sources or direct sunlight can negatively affect instrument performance.

CHAPTER 3

Safety and regulatory compliance

Before using your Countable System, review the following instructions and safety guidelines to avoid hurting yourself or damaging your instrument. The information in this chapter supplements, but does not replace, the safety requirements of your laboratory and/or institute.

Proper use

Warning/ Caution

Risk of personal injury and the Countable System damage

- You should only operate the system after you've been trained.
- Only Countable Labs personnel should perform instrument service and maintenance.
- Do NOT attempt to lift the Countable System yourself. The instrument should only be moved by Countable Labs personnel.
- Do NOT attempt to move the Countable System during sample imaging and analysis.

Caution

Risk of the Countable System damage

- Take care not to spill and liquid of any kind onto the Countable System. Damage caused by spills will void your warranty. In an emergency, turn off the instrument and unplug the power cord from the outlet.
- Only use Countable Labs validated consumables, accessories, and reagents with your Countable System. Damage caused by using other consumables may void your warranty.
- Don't put objects other than designated Matrix Tube Strips into the Countable System carousel.
- Don't stack or place objects on top of the Countable Instrument.

Electrical safety

General guidelines

- Connect the power cord to an outlet with proper grounding.
- Don't adjust and/or replace internal parts of the instrument yourself.
- **NEVER** operate the instrument with any covers or parts removed.
- If the instrument becomes electrically unsafe, stop others from using it and contact Countable Labs Support at success@countablelabs.com.

Don't operate the Countable System if:

- The instrument or power cord is or appears to be damaged.
- It has been stored in unfavorable conditions for a long time.
- Liquids have come into contact with electrical components on the instrument.

Warning

Risk of the Countable System damage

- Before powering on the Countable System for the first time, make sure you're using the correct supply voltage to avoid damaging the instrument electronics.
- Always connect the equipment to a grounded power outlet with the appropriate voltage and current rating.

Warning

Risk of the Countable System damage: Electrical hazard

- There are lethal voltages inside the instrument. When the instrument is connected to power, internal terminals could be live.
- Don't open covers and/or remove internal instrument parts when the instrument is connected to power, as this could expose you to live components.

Warning/ Caution

Risk of personal injury and the Countable System damage: Electrocution

- Don't open any panels on the Countable Instrument.
- You should only perform the maintenance steps described in this guide. Any other maintenance and/or repairs should only be carried out by Countable Labs personnel.

Mechanical safety

Warning/ Caution

Risk of personal injury and the Countable System damage

- Don't open any panels on the Countable Instrument when you're operating it.
- You should only perform the maintenance steps described in this guide. Any other maintenance and/or repairs should only be carried out by Countable Labs personnel.

Instrument dimensions

Safety standards

- The Countable Instrument has been tested to IEC 60825-1:2024 & EN 60825-1:204/A11:2021.

Warning/ Caution

Class 1 Laser Product

Risk of personal injury

- Caution — Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
- You should only operate the system after you've been trained.
- The Countable Instrument is a CLASS 1 LASER PRODUCT. Never operate your Countable System with any cover panels removed and/or the system cover open.
- If the laser appears damaged or unsafe, turn off the instrument immediately and contact Countable Labs support.

Biological safety

Any specimens and reagents that you obtained from humans should be treated as potentially infectious. You should follow the standard laboratory practices for your institute and wear appropriate personal protective equipment when handling biological samples, as outlined in the CDC Biosafety in Microbiological and Biomedical Laboratories Manual (www.cdc.gov/labs/bmbl/index.html).

Samples

Warning

Risk of personal injury: Samples containing infectious agents

- Samples used with the Countable System may contain infectious agents. Handle all samples with caution and follow the required safety regulations.
- Always wear safety glasses, gloves, and a lab coat.
- You should only operate the system after you've been trained.
- Refer to relevant Material Safety Data Sheets to avoid being exposed to hazardous levels of infectious agents.

Personal Protective Equipment (PPE)

Warning/ Caution

Risk of personal injury

- When operating the Countable System and/or handling Countable Fluid and Matrix Tube Strips, always wear the appropriate personal protective equipment (PPE) to protect against potential hazards. This includes safety glasses, gloves, and a lab coat.
- Ensure that all your PPE is in good condition and properly fitted before use.
- Discard gloves that have impaired protective ability.
- Before reusing gloves exposed to chemicals, consider factors like chemical toxicity, storage conditions, exposure time, and temperature.
- The Code of Federal Regulations (CFR) outlines OSHA requirements for PPE at: 29 CFR 1910.132 (General requirements), 29 CFR 1910.138 (Hand protection), and 29 CFR 1926.95.

Chemicals

Warning

Risk of personal injury: Hazardous chemicals

- Some Countable Consumables used with the Countable System may be hazardous.
- Handle reagents and chemicals according to their Safety Data Sheets. SDS' can be found on the Countable Labs website.
- Always wear safety glasses, gloves, and a lab coat.

Maintenance safety

Warning

Risk of personal injury and the Countable System damage

- The only maintenance you'll need to perform is described in this guide
  → See "Chapter 6: Maintenance" on page 58 for more information.
- Additional maintenance should only be performed by a Countable Labs personnel.

Warning

Risk of the Countable System damage

- Don't use bleach, solvents, reagents with acids, alkalies, abrasives, alcohol, or disinfectants to clean the Countable System unless otherwise instructed.

Countable System compliance

The Countable System is certified to the following standards:

- EN 61010-1:2010/A1:2019 (Edition 3.1), IEC 61010-1:2010/AMD1:2016/COR1:2019, IEC 61010-2-081:2019, CSA C22.2 No. 61010-2-081:19

CHAPTER 4

General system description

System and workflow overview

Your Countable System includes the Countable Instrument, the Countable Computer, a monitor, a mouse and a keyboard. The Countable Computer comes ready to go with Windows 11 and the Countable Control Software already installed. You can tap into Countable technology by using your Countable System with Countable consumables, accessories, and reagents. Check out the Countable PCR Reaction Preparation User Guide for more information on using Countable consumables and reagents.

The Countable Instrument

Your Countable Instrument is a walk-away analytical instrument that takes care of the post-amplification steps for you—automatically detecting and measuring target molecules in your molecular biology assay so you can focus on the bigger picture. Matrix Tube Strips in the Countable System are imaged with lightsheet microscopy to give you high-resolution, 3D imaging in up to four channels of your choosing. This leads to rapid detection of single-molecule signaling across the entire 50 µL reaction.

Caution

Risk of error

- Avoid bumping or causing vibration to your Countable System or the bench it is placed on, as it may interfere with system performance.

Labels on the Countable Instrument

Label description	Label image
Countable Fluid (lower): located on the work surface in front of Countable Fluid bottle position.	COUNTABLE FLUID
Countable Fluid (upper): located on the vertical surface behind Countable Fluid bottle position.	COUNTABLE FLUID
Countable Fluid (bottle and tubing connector): located on the cap of the Countable Fluid bottle and tubing connector on the instrument.	
Waste (lower): located on the work surface in front of the waste bottle position.	⚠ WASTE
Waste (upper): located on the vertical surface behind the waste bottle position.	⚠ WASTE
Waste (bottle and tubing connector): located on the cap of the waste bottle and tubing connector on the instrument.	⚠

The Countable Computer

The computer that comes as part of your Countable System includes a desktop computer, monitor, keyboard, and mouse. The desktop computer comes ready to go with Windows 11 and the Countable Control Software already installed. Specifications for the Countable Computer are listed below:

Item	Description
Operating system	Windows 11
Processor	Intel i7
Memory	128 RAM
Storage	512 GB OS 2 x 4 TB SSD 22 TB HHD

A recommended layout for the computer is shown below:

The Countable Software

The Countable Control Software helps you operate the Countable System and set up experimental runs. The Countable Control Software also:

- Analyzes images and reports molecule counts.
- Measures the connectivity of targets across channels when the optional linkage analysis feature is enabled.
- Provides sample quality metrics and molecule counts in molecules per 50 µL.

Countable consumables, accessories, and reagents

You'll need Countable Fluid (KT0007) to operate the Countable System. Six (6) bottles of 500 mL Countable Fluid is included when you receive your Countable System. To purchase more, contact us at success@countablelabs.com.

The following Countable consumables and reagents will also be required to operate and analyze samples on your Countable System. Check out the Countable PCR Reaction Preparation User Guide for more information on using Countable consumables, accessories, and reagents.

Note	You should only use Countable consumables, accessories, and reagents to operate the Countable System. If other products are used, you'll need to validate their performance for your application.

Cat#	Name	Description
KT0001	Countable Matrix Consumables Kit	Single-use consumables for matrix formation. Supports 192 reactions per kit and includes: ■ Matrix Column Strips and Strip Seals ■ Matrix Tube Strips and Strip Caps
KT0002	Countable Swing Bucket Kit	Swing bucket inserts compatible with Eppendorf 5430/5430R centrifuge fitted with S-24-11-AT swing bucket rotor. Each spin holds 48 samples (8 samples × 6 buckets).

Cat#	Name	Description
KT0003	Countable Matrix Kit	Reagents for Countable Matrix formation. Includes MR01, MR02, MR03. Supports 192 reactions per kit.
KT0004	4X Countable PCR Mix Kit	Amplification mix for 50 µL reactions. Compatible with hydrolysis probes and Universal Multiplex chemistry. Supports 192 reactions per kit.
KT0005	Universal Multiplex Set A Kit	4-plex multiplexing chemistry using standard primers—no custom probes required. Designed for compatibility with 4X Countable PCR Mix. Supports 192 reactions per kit.
KT0007	Countable Fluid Kit	Maintenance fluid for routine use with the Countable System. One pack supports up to 1 month of operation.
KT0009	Countable Control Assay Kit	Positive control assay kit for Countable PCR. Required for new user training or routine QC testing.

CHAPTER 5

Operating the Countable System

Turning on your Countable System

01 Turn on the Countable Computer by pushing the computer power button.

02 Log into the computer using your user credentials.

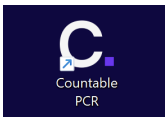
03 Power on your Countable Instrument by pressing the power button found on the right side of the instrument.

A LED indicator light at the bottom, right side of the front panel reflects the status of your instrument.

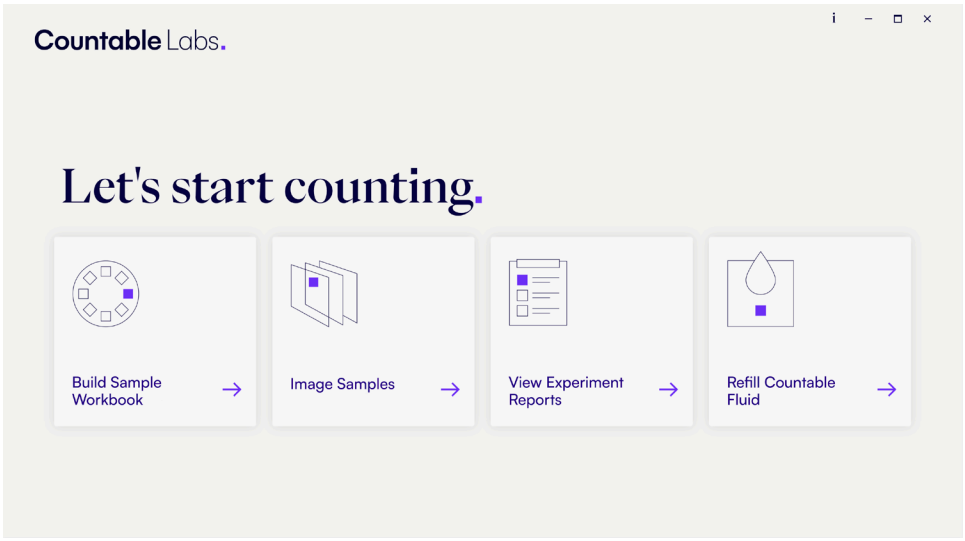
The table below summarizes different states for your Countable System.

Countable System status	LED status
Power off	No lights
Power on/idle	Left light white
Running	All lights white
Error	Left light white, center and right light red

04 Double-click on the Countable Control Software icon on your desktop to launch the application.

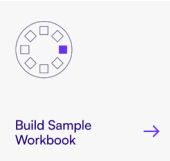
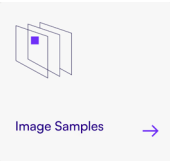
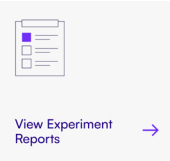
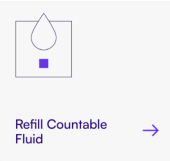


05 The Countable Control Software Main Menu will open.



Countable Control Software overview

The Countable Control Software Main Menu is used to operate and maintain your Countable System. It is a central hub to access the following core features of the system: Workbook maker, Image analysis, View results, Countable Fluid refill.

Tile	Function
	**Build a Sample Workbook** opens the **Sample Workbook Maker** that helps you create, organize, or import workbooks.
	**Image Samples** starts imaging and analyzing your samples based on the experimental parameters defined in your workbook(s).
	**View Experiment Reports** gives you access to the results of your analyses for your review. Processed data and outcomes are also stored here for easy access.
	**Refill Countable Fluid** manages liquid levels for the on-board Countable Fluid bottle and waste bottles.

Building a Sample Workbook

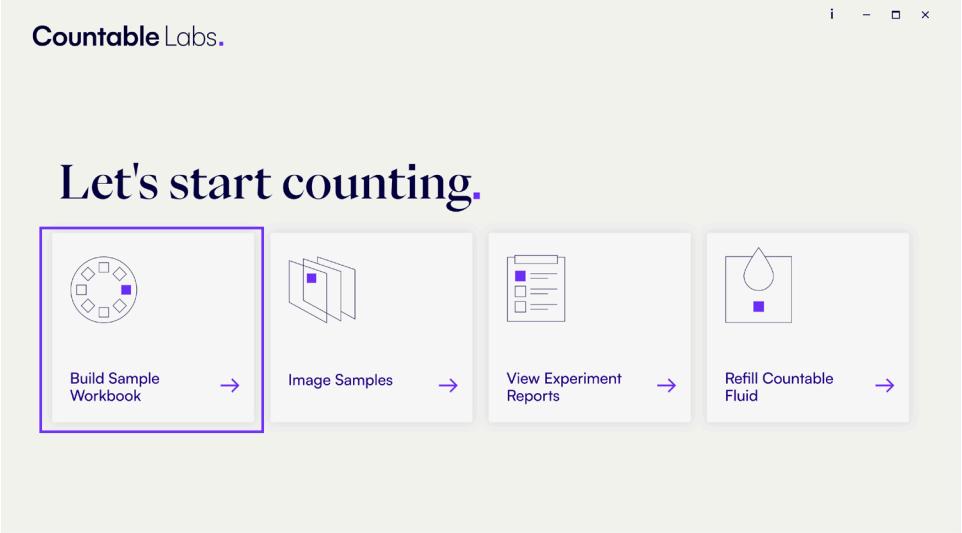
A Sample Workbook is created using the Countable Control Software and defines imaging and analysis parameters. A Sample Workbook must be created with each imaging and analysis run.

You can choose between two modes when building a Sample Workbook:

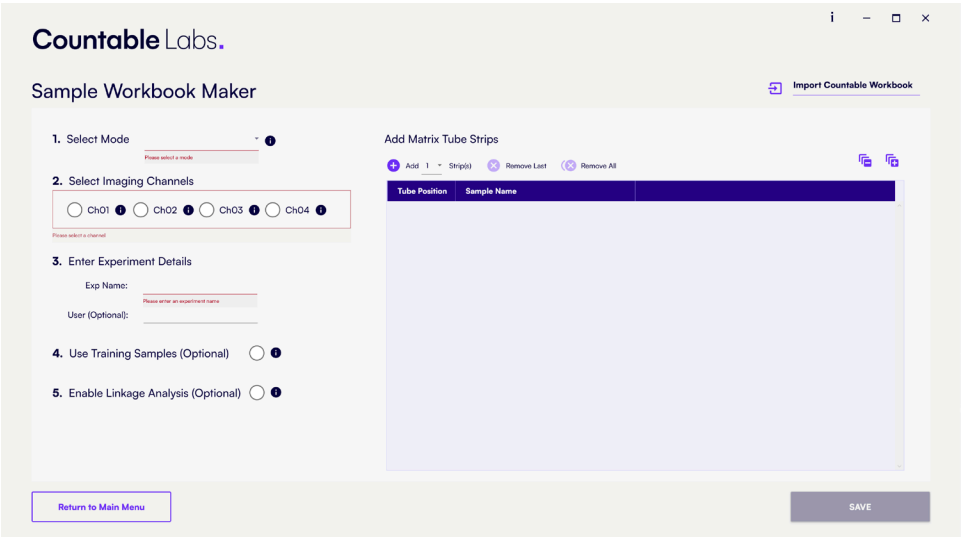
- **Position Mode**: The position of the Matrix Tube Strip in the carousel is fixed. You'll need to enter sample information based on the position of the Matrix Tube Strip in the carousel.
- **Barcode Mode**: The position of the Matrix Tube Strip in the carousel is flexible. You'll need to enter sample information and the corresponding barcode on the Matrix Tube Strip.

To build a Sample Workbook:

01 Click on the **Build Sample Workbook** tile on the Countable Control Software Main Menu.



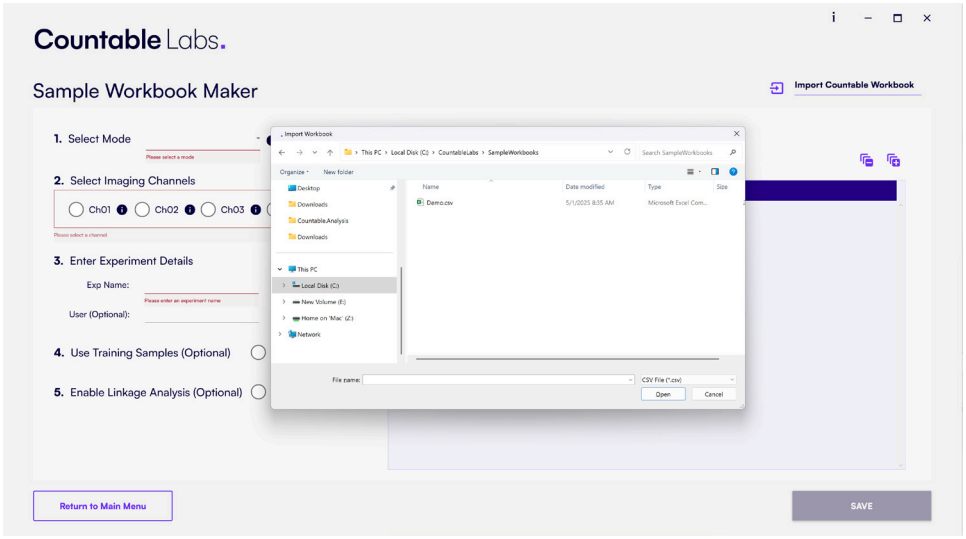
02 The Sample Workbook Maker Screen will open. If at any point you want to return to the Main Menu, click **Return to Main Menu**.



03 If you are creating a new Sample Workbook, skip to → Defining Sample Workbook experimental parameters

If you are importing a workbook that was created previously, select **Import Sample Workbook**.

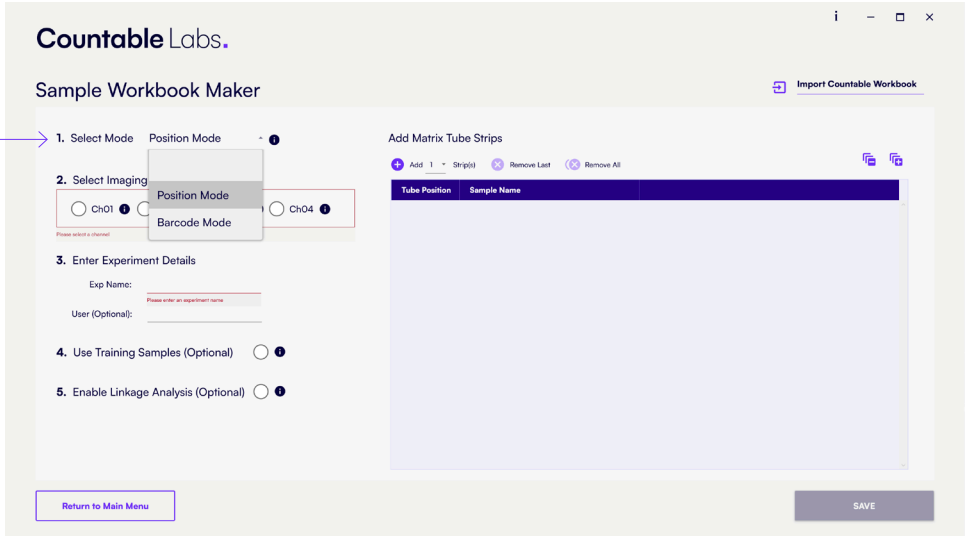
04 Select the Sample Workbook you want to run in the dialog box that appears.



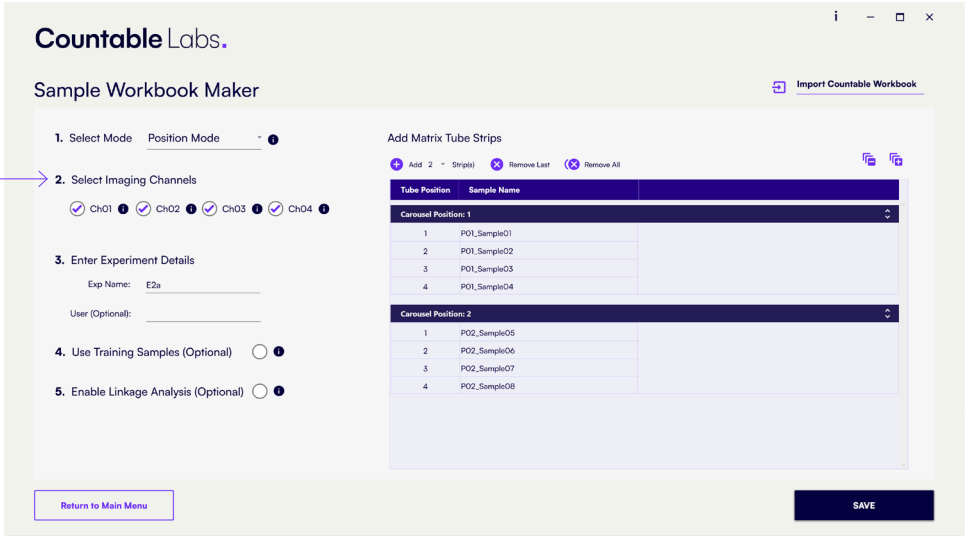
05 Click **Open**.

Defining Sample Workbook experimental parameters

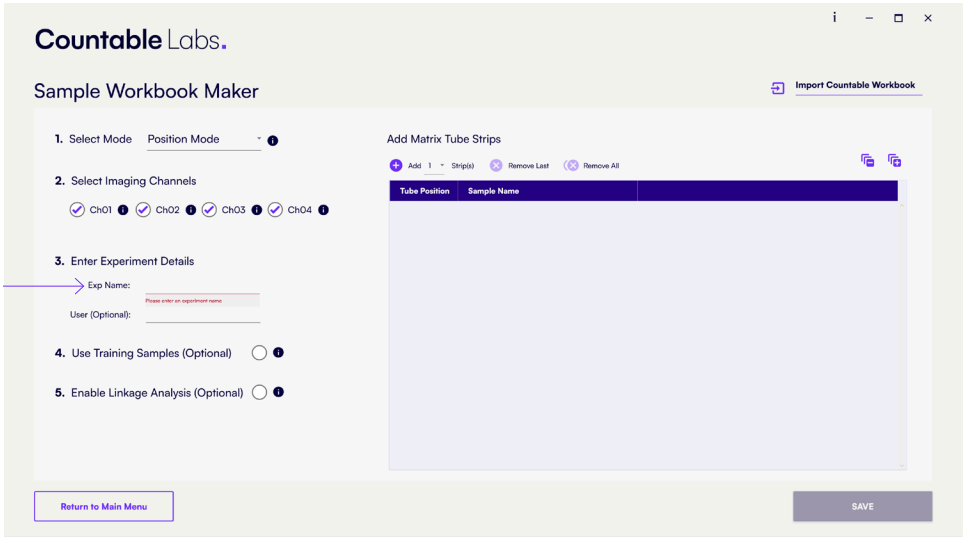
01 Select **Position Mode** or **Barcode Mode** in the pull-down menu.



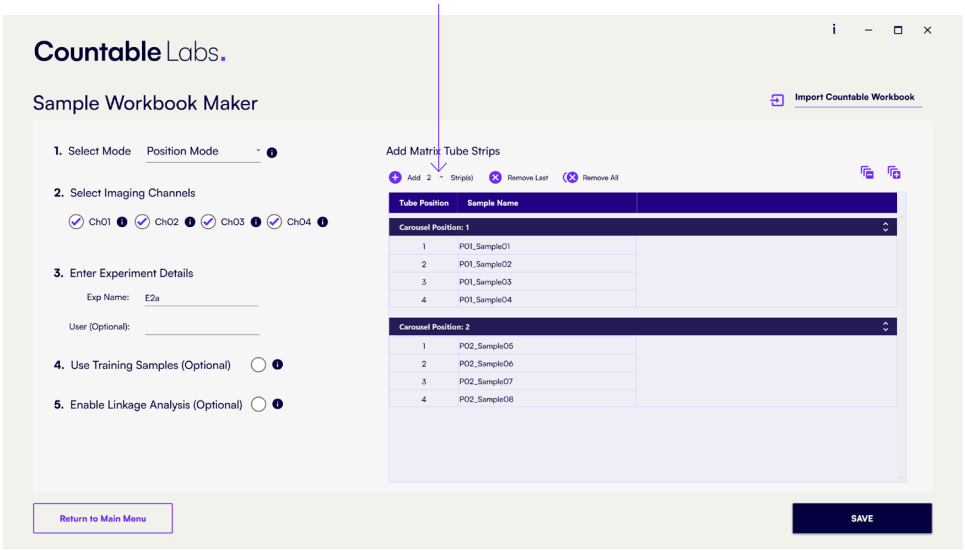
02 Select the imaging channels to use for imaging and analysis.



03 Add a name for the experiment. You can also have the option to add user information.

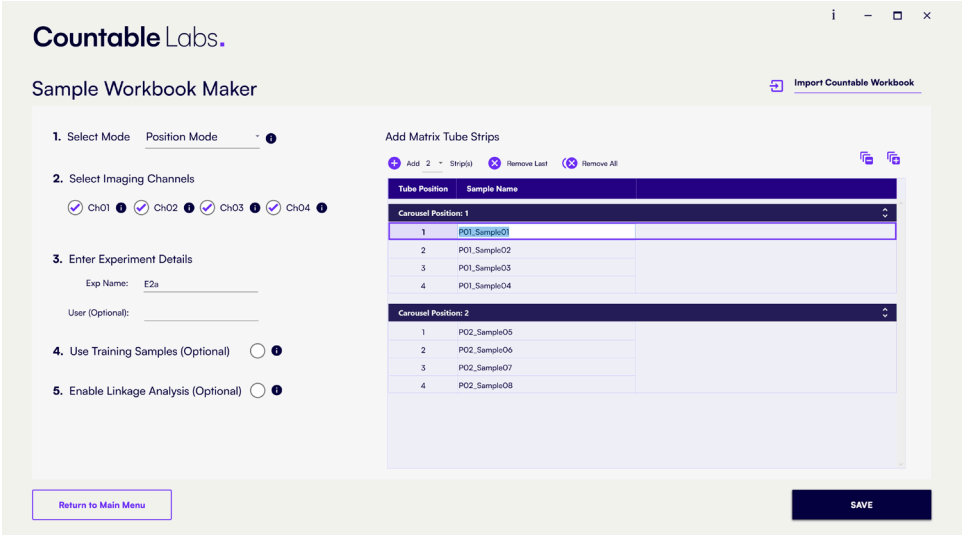


04 Add the number of Matrix Tube Strips using the pull-down next to the ⊕ icon.

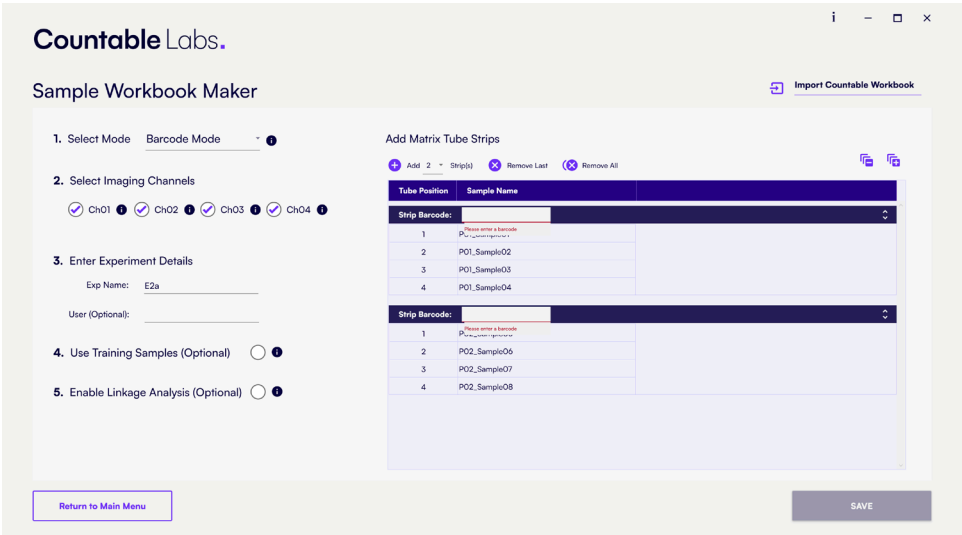


05 Start entering sample details.

a In **Position Mode**, you must input sample names that correspond to the Matrix Tube Strip placed in a specific carousel position. You can also use default sample names.



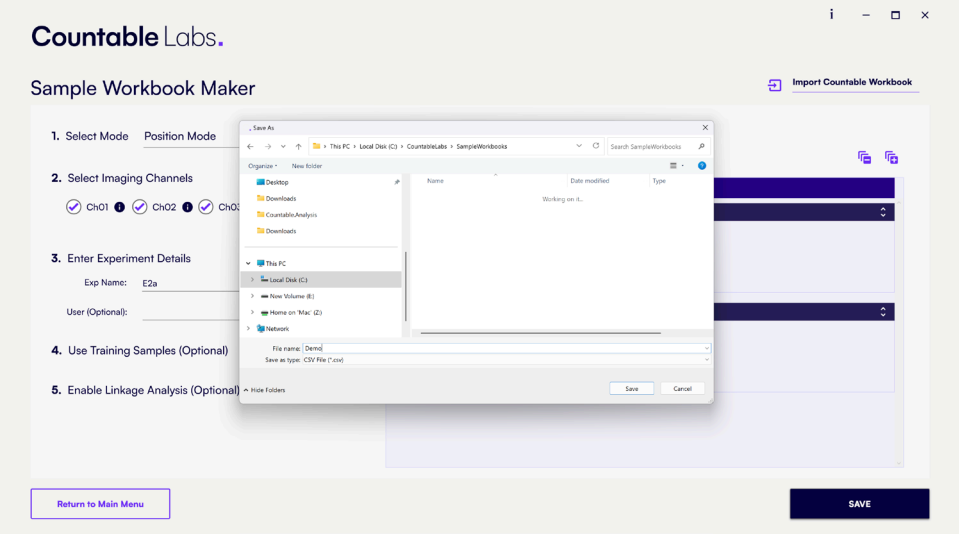
b In **Barcode Mode** you will input sample information and scan the corresponding Matrix Tube Strip barcode using a compatible USB barcode scanner. We recommend the Zebra Hand Held Barcode Reader (P/N LS2208).



06 Optional: Select **Using Training Samples** if you are including a training sample to improve rare molecule detection. Refer to the Countable PCR Reaction Preparation User Guide for information on how to prepare this sample.

07 Optional: Select **Enable linkage analysis** to determine if two or more targets are physically connected in a single molecule to enable applications like measuring DNA integrity and fragmentation in a sample.

08 Click **Save** to create your Sample Workbook. You will be asked to give the workbook a name before returning to the Countable Control Software Main Menu.

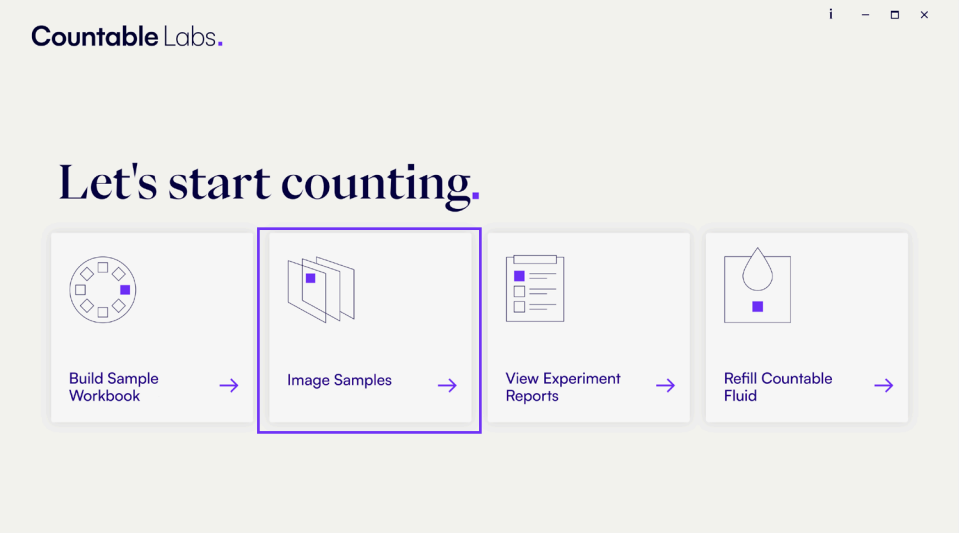


Sample imaging

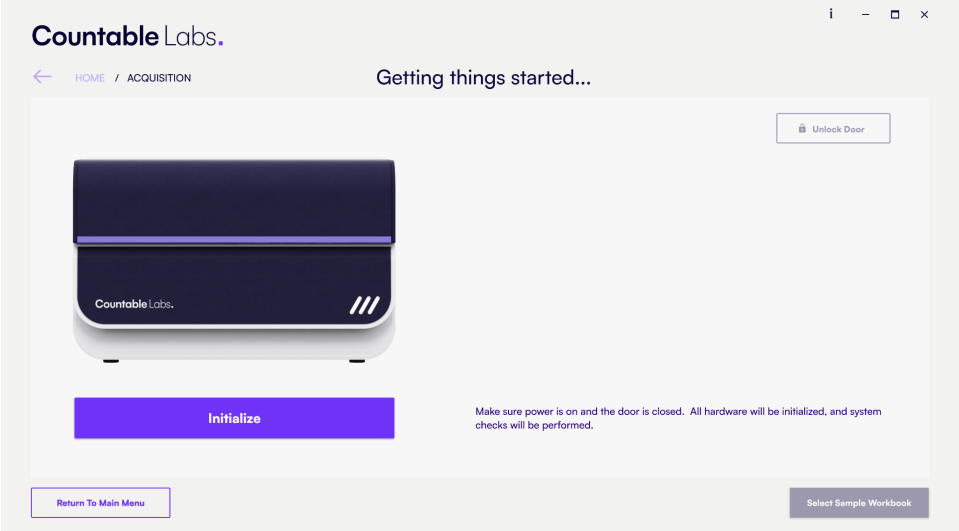
Starting sample imaging and analysis

To begin imaging and analyzing your sample:

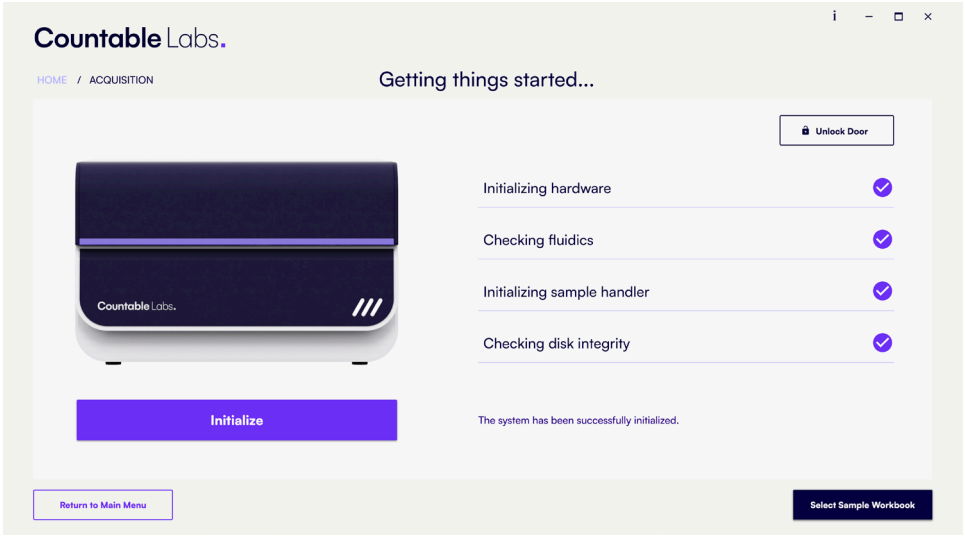
01 Click on the **Image sample**s tile on the Countable Control Software Main Menu.



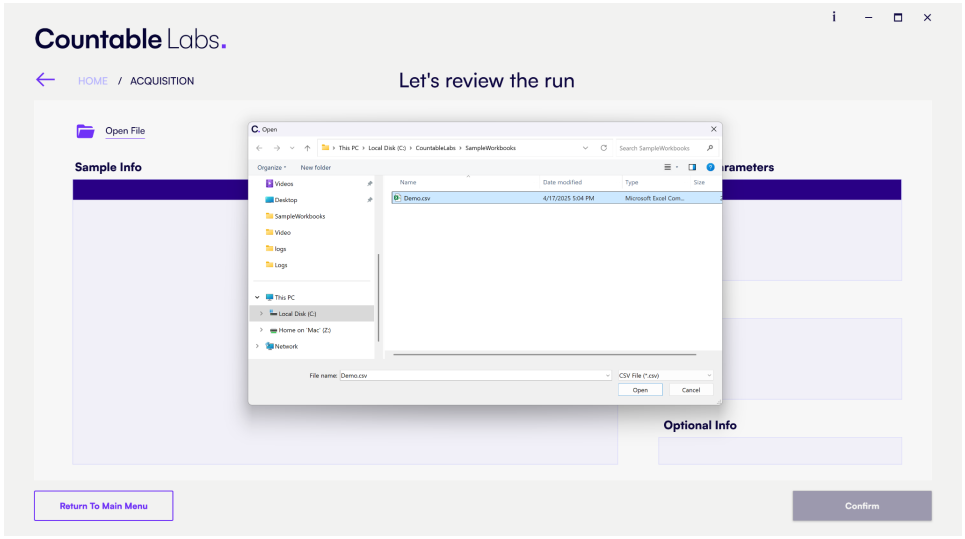
02 The Imaging and Analysis Menu will appear. If at any point you want to return to the Main Menu, select Return to Main Menu.



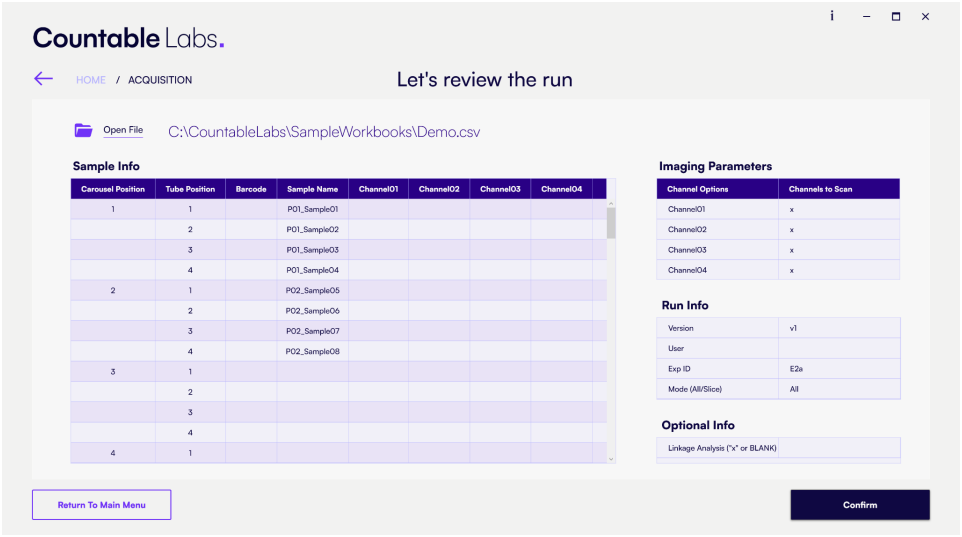
03 Click on the Initialize button to start the system initialization process. Confirmation will appear after the system has confirmed that the hardware is operating correctly, that there is enough Countable Fluid in the system, and that the Countable Computer has enough storage capacity to run your experiment.



04 Click **Select Sample Workbook** to choose and load the workbook you want to use for the imaging and analysis.



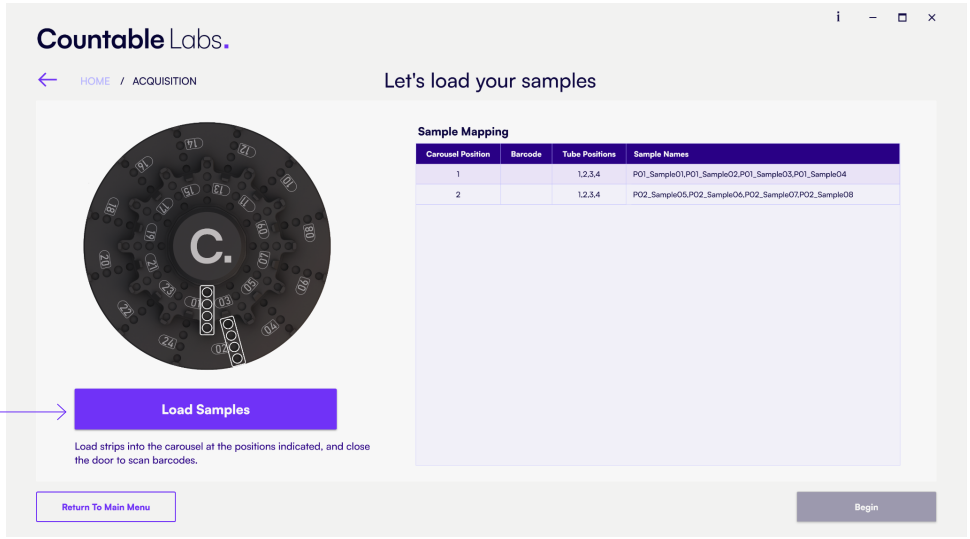
05 Review the Run info, Imaging parameters, and Sample info parameters for your experiment in the Acquisition menu.



a If all the parameters look good, click **Confirm** to start sample loading.

b If you want to edit some parameters, you'll need to go back to go back to the Workbook Maker, import the workbook, make the desired adjustments, and save the workbook.

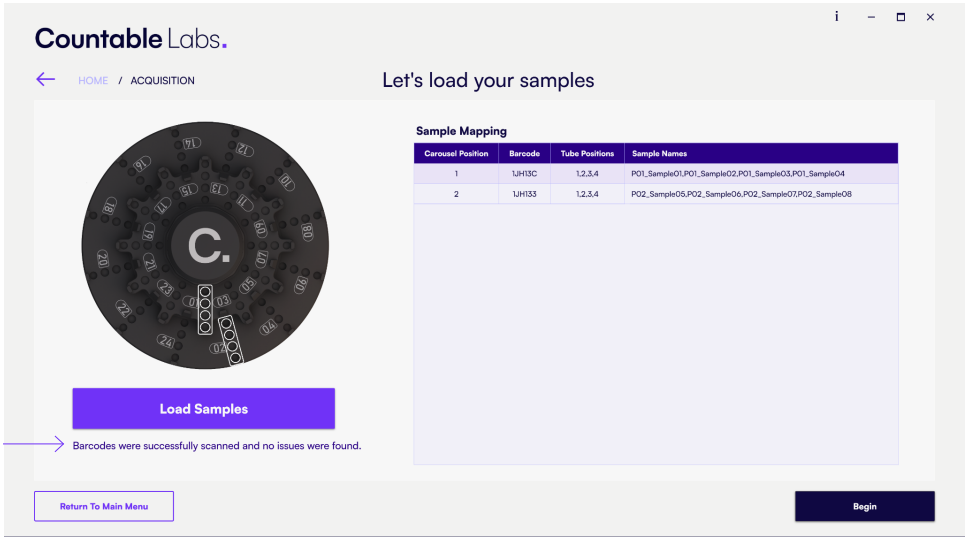
06 The Loading Samples screen will appear. Click **Load samples** to unlock the Countable Instrument door.



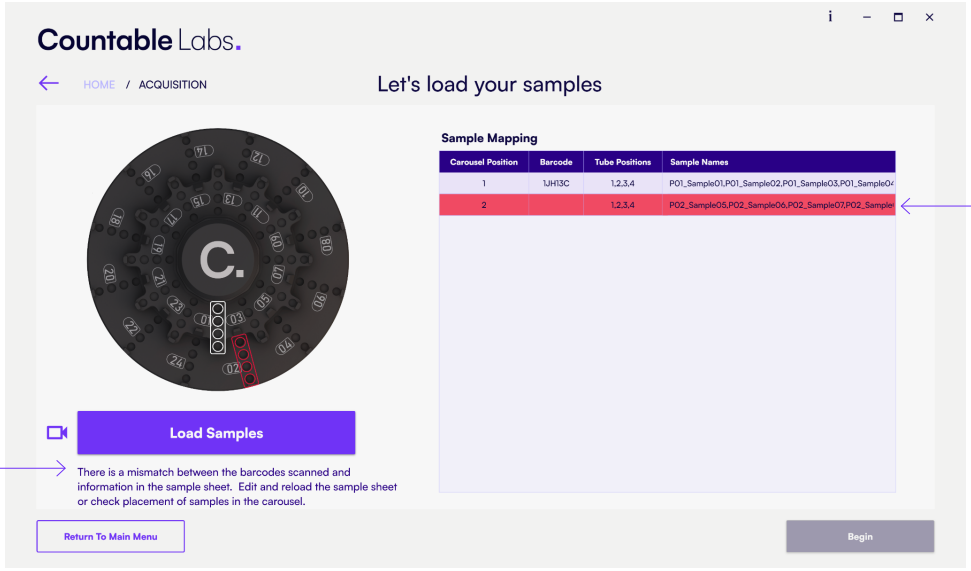
07 Open the Countable Instrument door and start loading your samples into the carousel, starting from position 01. If you have barcodes on your Matrix Tube Strips, make sure that they are facing left.

08 After all of your samples have been loaded, close the Countable Instrument door.

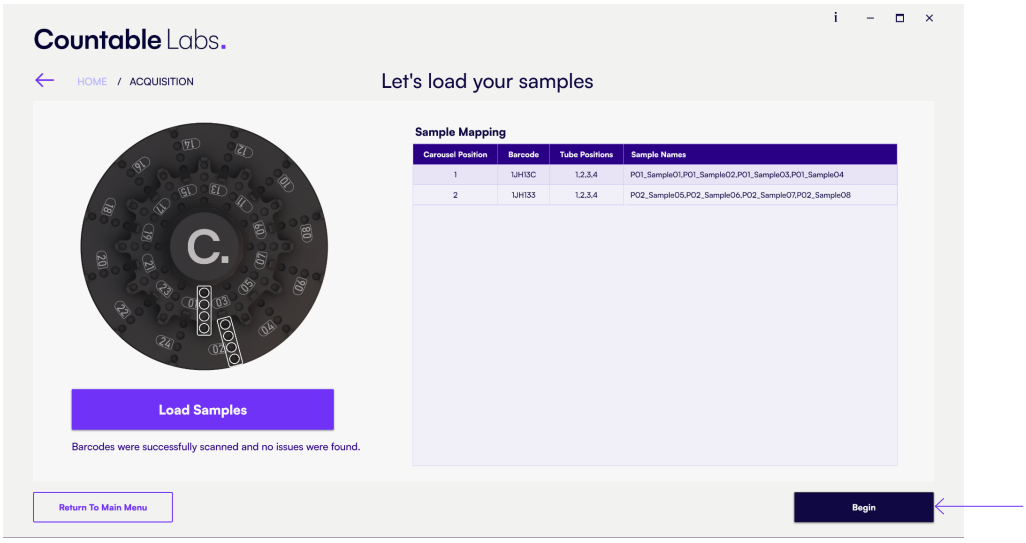
09 If you are operating in Barcode mode, the instrument will automatically start scanning the Matrix Tube Strip barcodes and will map the loaded strips. Confirmation that all barcodes were successfully scanned will appear.



10 If there are barcode scan errors the strip with the issue will be highlighted in the Sample Mapping table. You'll need to check the mismatched Matrix Tube Strip(s) before continuing.



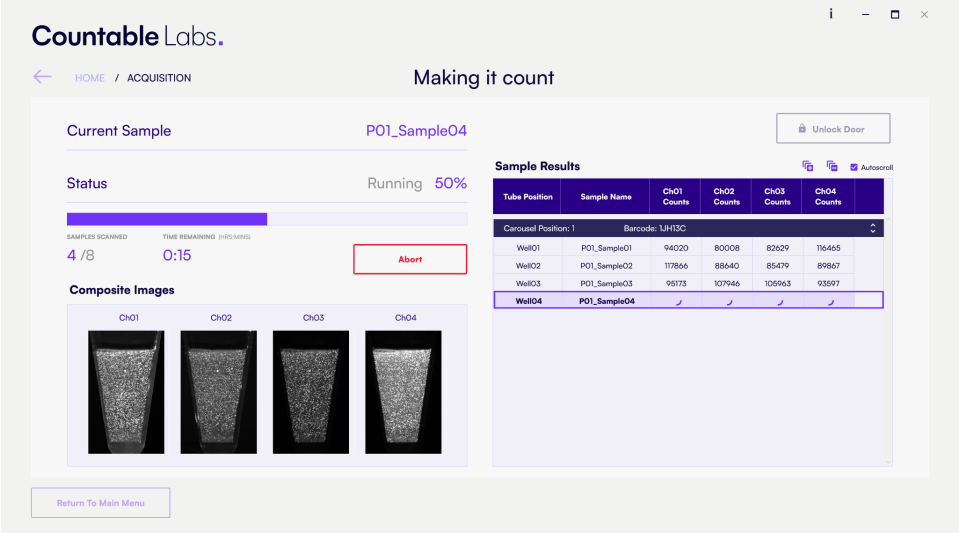
11 Click **Begin** to start the imaging and analysis process.



During sample imaging and analysis

The Countable Instrument door will remain locked while your samples are being imaged and analyzed.

01 The Acquisition Menu will show a progress bar with information about the status of your imaging and analysis, and provide a projection of when sample imaging will be completed.



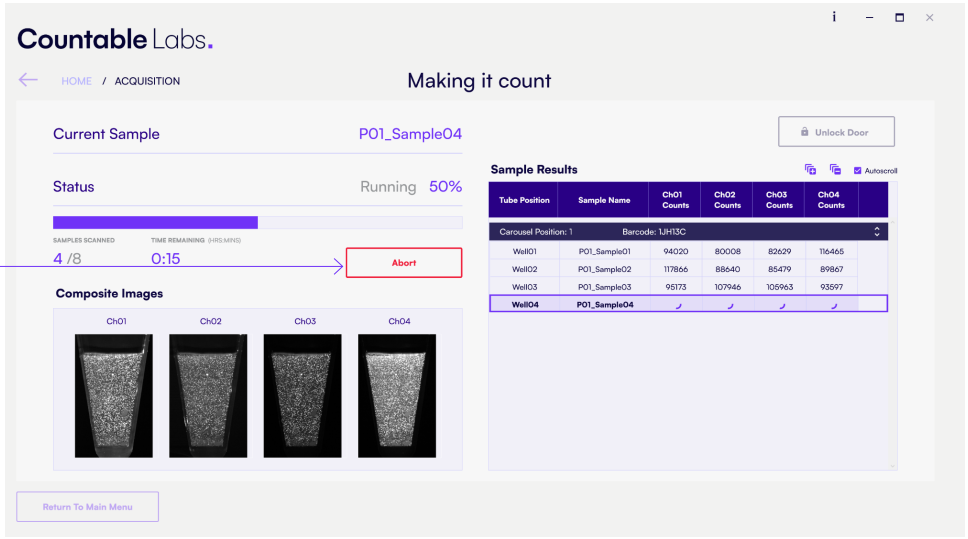
02 Snapshots of each sample will also appear for each of the previously selected channels.

03 The table below describes different fields that you'll see during the run.

Field	Description
Current sample	Indicates the sample that is currently being imaged.

Field	Description
Status	Indicates the status and percent completion of the analysis.
Samples scanned	Indicates the number of samples already scanned out of the total number of samples in the acquisition.
Time remaining	Estimates the remaining time of the imaging in (HRS:MIN).
Sample results	Displays the total counts per sample per 50 µL, for each channel selected.
Counts	Reports the total counts per 50 µL per channel for each sample.

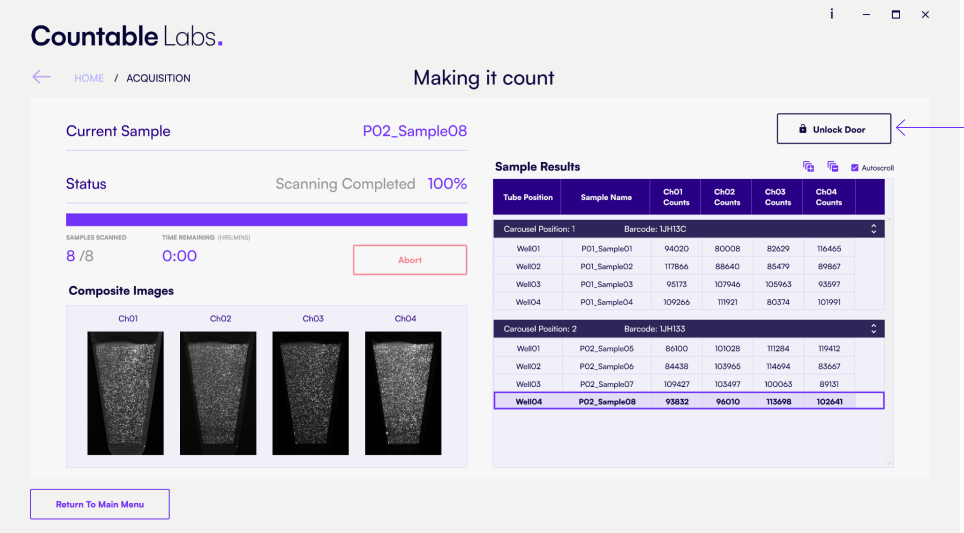
04 If you need to stop the imaging and analysis mid-run, click **Abort**, then select **Return to Main Menu.** You'll be able to start a new imaging run from here.



At the end of the run

01 When the Countable System is done imaging and analyzing your samples, you'll be able to open the Countable Instrument door.

02 Select **Unlock door** and open the door.



03 Remove the Matrix Tube Strips from the Countable Instrument carousel.

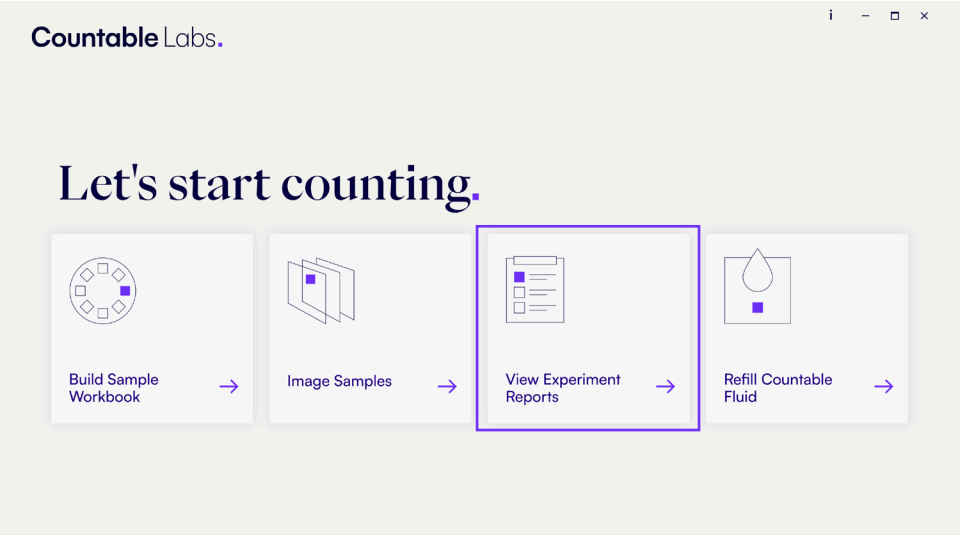
04 Close the Countable Instrument door and click **Return to Main Menu**.

Viewing experiment reports

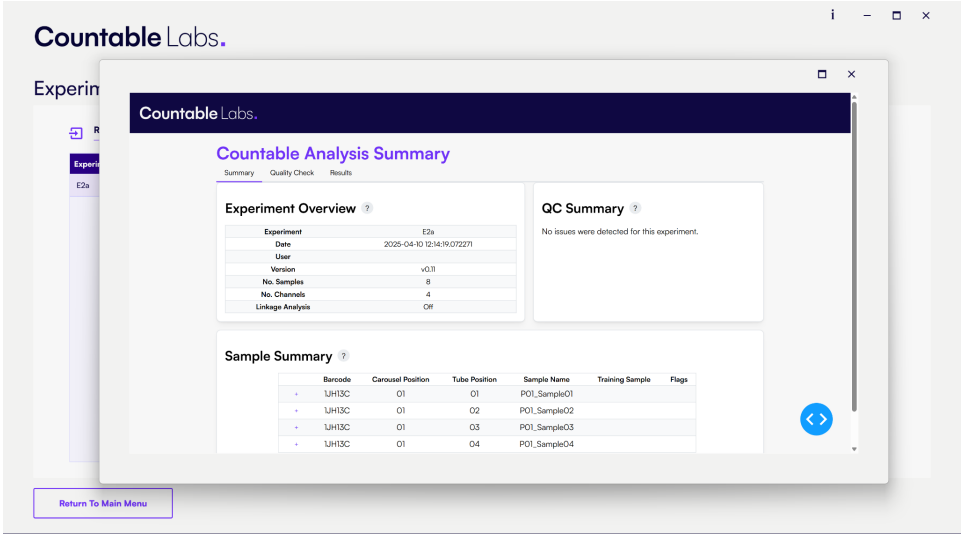
You can view a summary of the run and the data collected in the experiment report. The data can also be accessed as .html and .csv files. See → Output data files for information on accessing the files in the [CountableLabs] folder.

To view a report in the Countable Control Software:

01 Click on the **View experiment reports** tile in the Countable Control Software Main Menu.



02 Select the results you want to view in the selection screen.



03 Once you've finished viewing your report, close the report and click **Return to Main Menu**.

Countable Analysis Summary

The Countable Analysis Summary can be viewed in the Countable Control Software or as an .html file. The summary contains the following sections:

- Summary
- Quality check
- Results

Summary

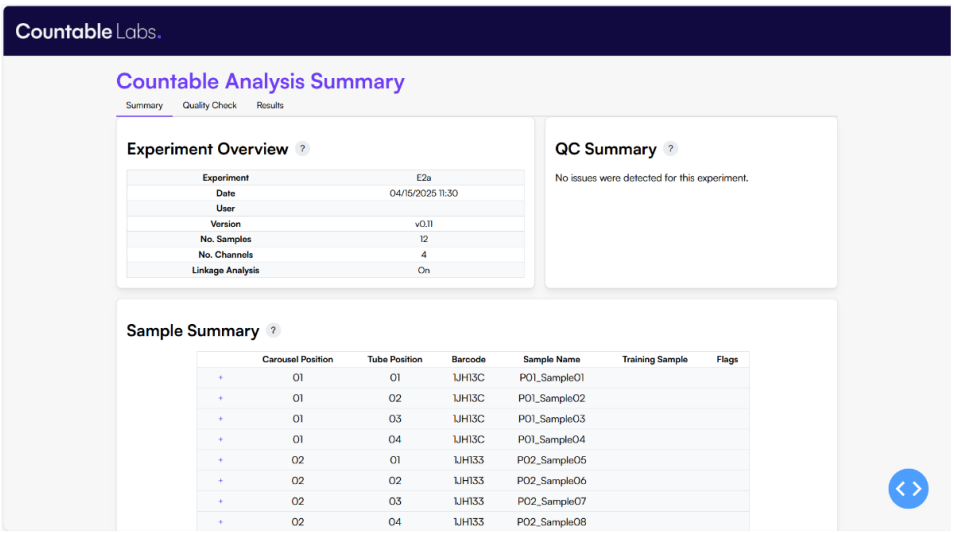
The Summary tab includes the following panels:

- **Experiment overview**: An overview of the analysis parameters, including the number of samples and channels imaged, and whether additional analysis like linkage analysis was turned on. Information in this section should match the Sample Workbook.
- **QC summary**: A list of any warnings that occurred during the run, and recommendations for how to address the warnings.
- **Sample summary**: A list of all the samples imaged. If Training Samples were included in the run, a colored square icon matching the channel selected will appear.

  If a warning was flagged for a specific sample, the panel will default to an expanded view so you can get additional warning information. Warnings can be for an entire sample or can be channel specific.
  The following flags will also appear in the panel so you will know how to approach your results:

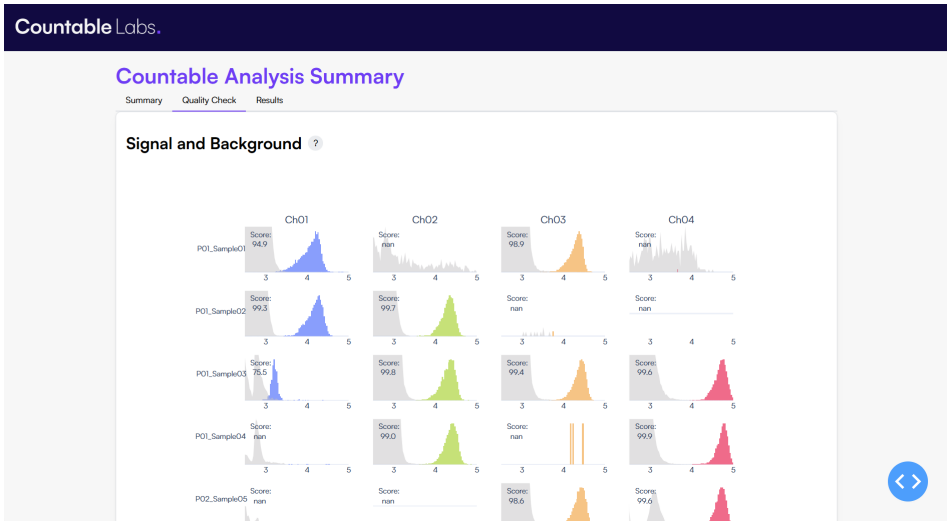
  Issues ⛔ : Reported counts for this sample/channel should not be used.

  Observations ⚠ : Additional investigation of sample/channel quality should be performed before the reported counts are used.



Quality Check

The Quality Check tab gives you fluorescent intensity of samples per channel in the Signal and Background panel. The panel displays histograms of the fluorescence intensity distribution of the target signal (colored) and background (grey), with the Intensity Distribution (ID) score appearing at the upper-left corner.



Here are some guidelines on using the histograms to evaluate the sample and assay quality:

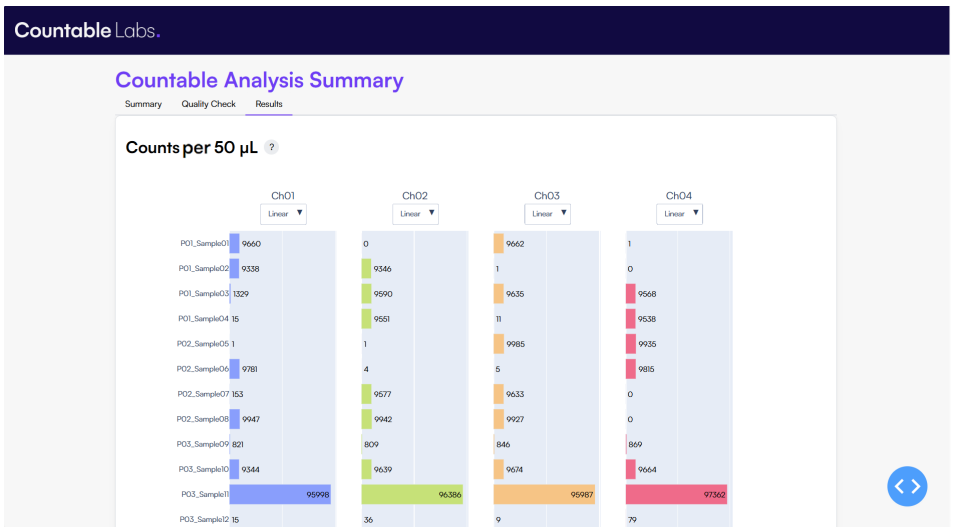
01 The signal and background distributions should be as distinct as possible.

02 Secondary peaks and shoulders between the signal and background intensities can indicate non-specific primer/probe interactions. Normal intensity units for the signal should be greater than 4.

03 A long intensity tail connecting the signal and background distribution may indicate spatial variations, such as PCR inhibition.

Results

The Results tab uses a bar chart to visualize the counts per 50 µL for each sample. You can toggle each channel between linear- and log-scale views depending on your preference.



Output data files

Several data files are generated when your analysis is done. Data files can be found in the [CountableLabs] folder, which contains subfolders organized by the Countable Control Software versions. Each version folder contains data and metadata folder which each contains folders that correspond to the unique experiment IDs you designated.

Folder	Description
Data	Contains results including the Countable Analysis Summary (.html), the Countable Data Report (.csv) and Snapshot folder. It also contains the Linkage Summary (.csv) if the linkage option was selected for the experiment.
Metadata	Contains folders (.zip) for each sample of the experiment. Each sample contains files generated during the analysis process. It also contains one folder (.zip) for experiment. These folders can be shared with Countable Labs if support and troubleshooting is needed.

Folder and file names for each experiment includes the Experiment ID, date, and time using the following format: ID_YYMMDD_HHmm. For example. “Exp1a_250409_1125” is experiment Exp1a that was run on April 9, 2025 at 11:25 am.

Countable Data Report

The Countable Data Report (.csv) contains the sample counts, in counts per 50 µL, in a format that can be opened in a spreadsheet software. The report can be accessed from the “View experiment results” tile of the Countable Control Software and in the [CountableLabs] folder.

Countable Data Report file names follow this format: ExperimentID_timeStamp_ CountableDataSummary.csv. Each line corresponds to one sample. An example of a Data Report is captured below.

CarouselPos	TubePosition	StripBarcode	SampleNam	SampleID	Ch01_Count	Ch02_Count	Ch03_Count	Ch04_Count	Ch01_IDscor	Ch02_IDscor	Ch03_IDscor	Ch04_IDscor	Ch01_Signal	Ch02_Signal	Ch03_Signal	Ch04_Signal	Ch01_Backg	Ch02_Backg	Ch03_Backg	Ch04_Backg
1	1	1JH13C	P01_Sample(	1JH13C_01	9619	0	9646	0	94.1	NA	99	NA	13213	0	20893	0	563	39	609	201
1	2	1JH13C	P01_Sample(	1JH13C_02	9346	9355	1	0	99.3	99.7	NA	NA	16376	21057	5764	0	352	336	3	3
1	3	1JH13C	P01_Sample(	1JH13C_03	1317	9577	9622	9555	NA	99.8	99.4	99.6	1653	21597	25509	52179	82	630	619	277
1	4	1JH13C	P01_Sample(	1JH13C_04	45	9547	5	9533	NA	99	NA	99.8	1757	24470	22902	57201	66	590	4	300
2	1	1JH133	P02_Sample(	1JH133_01	0	1	9982	9942	NA	NA	98.6	99.7	0	14570	24752	50309	47	31	603	203
2	2	1JH133	P02_Sample(	1JH133_02	9765	5	3	9808	91.6	NA	NA	99	20024	44762	17629	59716	624	32	4	319
2	3	1JH133	P02_Sample(	1JH133_03	614	9563	9618	0	NA	98.4	98.2	NA	1735	20548	23342	0	75	569	592	15

The table below summarizes the columns included in the Data Report.

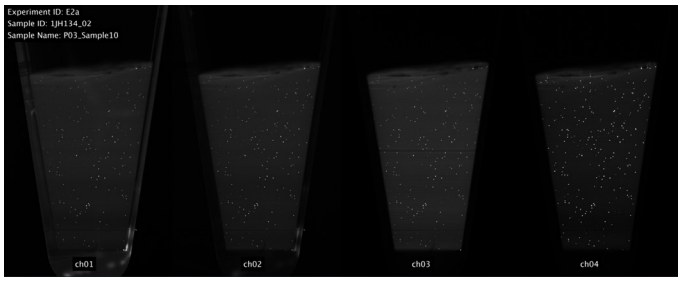
Field	Description
CarouselPosition	Position of the Matrix Tube Strip on the carousel.
TubePosition	Position of the sample within the Matrix Tube Strip.
StripBarcode	Strip Barcodes on Matrix Tube Strips.
SampleName	Name of the sample provided in the Sample Workbook.
SampleID	Unique sample identifier (StripBarcode_TubePosition).
CountsPer50µL	Number of targets per 50 µL detected in each channel.

Field	Description
IDscore	Intensity Distribution (ID) score: A unitless metric with a scale from 0—100 that describes the distribution of fluorescence intensity of the detected single molecules per channel. Reported for samples with >3000 and <1 M counts. The higher the metric, the better the signal distribution is from the background. The metric is influenced by a combination of assay and sample quality. The optimal score should be >90.
Signal	Median of fluorescence signal intensity from single molecules per channel.
Background	Average fluorescence intensity of the rest of the tube with no identified single molecule signals per channel.
Issues	Issue with a sample preventing the generation of reliable counts per channel.
Observations	Observed warning signs in a sample which may lower accuracy of the counts in specified channels.

Countable Snapshots

Countable Snapshots are images of the cross section at the center of the sample tube per selected channel, taken by the Countable Instrument during imaging and analysis. They can be used to visually inspect the sample tubes for troubleshooting purposes.

The Experiment ID, Sample ID, and Sample Name can be found on the top left corner of each snapshot image. You can also find the name of each channel at the bottom of the image. Countable Snapshot files can be found in the [CountableLabs] folder and can be accessed from the “View experiment reports” tile of the Countable Control Software Main Menu.



Linkage Summary

The Linkage Summary (.csv) is created when you enable the linkage analysis option when building a Sample Workbook. The file contains molecule counts per 50 µL for all possible channel configurations (i.e., all individual channels and their combinations) for each imaged sample. Linkage Summary files can be found in the [CountableLabs] folder and can be accessed from the "View experiment reports" tile of the Countable Control Software Main Menu.

Linkage Summary file names use the following format: ExperimentID_timeStamp_CountableLinkageSummary.csv.

The Linkage Summary contains the following information:

- **Sample information**: Carousel position, Matrix Tube Strip position, Sample Name, and Sample ID.
- **Molecular counts per 50 µL for all channel configurations**: For each sample, the listed counts relate to the corresponding configuration. For example:
  - Ch01_only: counts from Ch01 only (no linkage).
  - Ch01_02: counts from Ch01 and Ch02, only in this configuration.
  - The sum of counts in (Ch01_only, Ch01_02, Ch01_03, Ch01_04, Ch01_02_03, Ch01_02_04, Ch01_03_04, and Ch01_02_03_04): the total counts in Ch01.
  - The sum of counts from all configurations: the total count per sample.
- **Flags**: Warning that there was a failure in the linkage analysis process.

CarouselPos	TubePosition	StripBarcode	SampleName	SampleID	Ch01_only	Ch02_only	Ch03_only	Ch04_only	Ch01_02	Ch01_03	Ch01_04	Ch02_03	Ch02_04	Ch03_04	Ch01_02_03	Ch01_02_04	Ch01_03_04	Ch02_03_04	Ch01_02_03	Flags
1	2	1JH13C	P01_Sample(	1JH13C_02	28	37	0	0	9317	0	0	0	0	0	1	0	0	0	0	
1	3	1JH13C	P01_Sample(	1JH13C_03	30	72	89	37	8	3	8	74	57	87	7	4	7	8105	1250	
1	4	1JH13C	P01_Sample(	1JH13C_04	9	96	2	84	2	0	0	1	9413	1	0	34	0	1	0	
2	1	1JH133	P02_Sample(	1JH133_01	0	0	82	42	0	0	0	0	0	9899	0	0	0	1	0	
2	2	1JH133	P02_Sample(	1JH133_02	161	0	0	203	2	0	9602	0	0	0	0	0	0	3	0	
2	3	1JH133	P02_Sample(	1JH133_03	7	115	146	0	3	27	0	8868	0	0	577	0	0	0	0	
2	4	1JH133	P02_Sample(	1JH133_04	133	97	159	0	216	136	0	166	0	0	9466	0	0	0	0	
3	1	1JH134	P03_Sample(	1JH134_01	7	0	6	21	0	0	0	0	5	3	3	5	38	28	762	
3	2	1JH134	P03_Sample(	1JH134_02	102	32	63	76	42	20	9	12	19	24	47	34	52	411	9041	
3	3	1JH134	P03_Sample(	1JH134_03	485	477	400	1432	343	178	171	135	377	326	434	582	371	706	92872	

Metadata

During data processing, a metadata folder is automatically generated. This folder contains more information about the data processing for a specific scan and analysis. Share the contents of this folder with Countable Labs support when you need troubleshooting help.

Refilling Countable Fluid

Matrix Tube Strips are immersed in Countable Fluid when they are imaged in the imaging chamber by the Countable Instrument. The Countable Control Software automatically tracks how much Countable Fluid you need for each experiment and will let you know if you need to replace the Countable Fluid bottle.

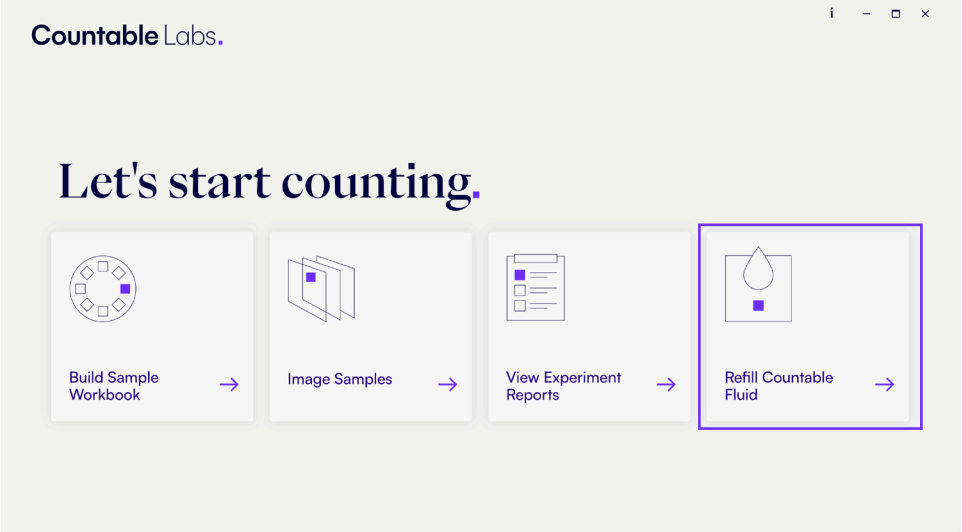
Caution

The Countable System damage

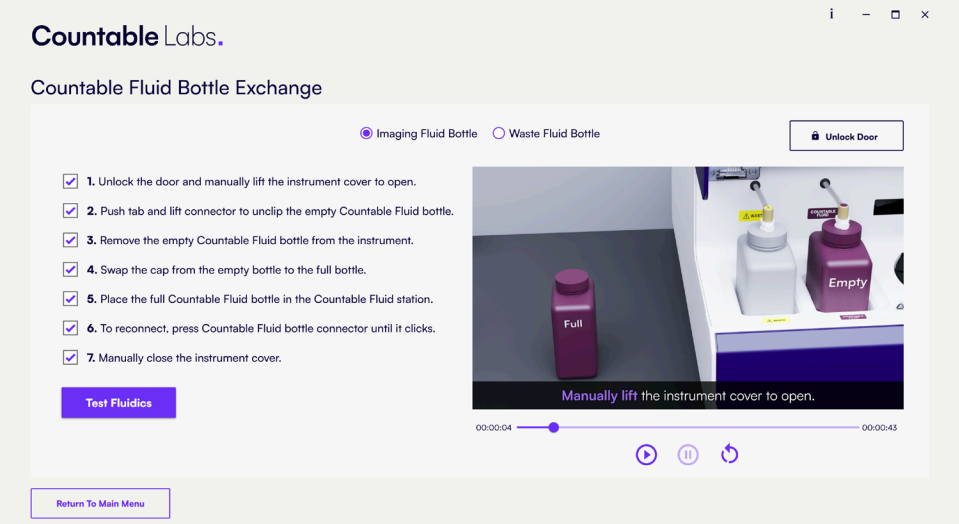
- The waste bottle must be emptied every time the Countable Fluid is refilled.

To Refill Countable Fluid:

01 Click on the **Refill Countable Fluid** tile in the Countable Control Software Main Menu.



02 A screen will appear with a video that will take you through the steps listed below on how to refill the Countable Fluid.



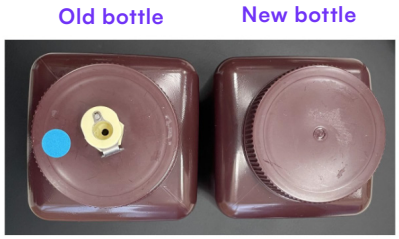
03 Open the Countable Instrument door to reveal the amber Countable Fluid bottle and white/clear waste bottle.

04 Press the silver notch on the Countable Fluid bottle to engage it. You will feel or hear a click.

05 Gently remove the male connector. There should be minimal pressure if the notch is correctly engaged.

06 Remove the empty bottle from the Countable Instrument.

07 Unscrew and remove the cap on a new bottle of the Countable Fluid (KT0007).



08 Unscrew and remove the cap from the empty Countable Fluid bottle. Watch out for any residual fluid on the internal tubing.

09 Transfer the cap from the empty Countable Fluid bottle to the new Countable Fluid bottle.

10 Place the new Countable Fluid bottle back onto the Countable Instrument in the correct bottle position.

11 While supporting the Countable Fluid bottle, connect the tubing connector on the instrument to the connector on the bottle cap. Listen or feel for a click to ensure the connectors are fully closed to prevent leaks.

12 Close the Countable Instrument door.

13 Click **Return To Main Menu**.

14 Cap the empty Countable Fluid bottle and properly dispose of it according to your lab protocols in the proper waste container.

Emptying the waste bottle

The waste bottle contains used Countable Fluid and is located next to the Countable Fluid bottle on the Countable Instrument.

Caution

Risk of Countable System damage

- The waste bottle must be emptied every time the Countable Fluid is refilled.

To empty the waste bottle:

01 Click on the **Refill Countable Fluid** tile in the Countable Control Software Main Menu.

02 Open the Countable Instrument door to reveal the amber Countable Fluid bottle and white/clear waste bottle.

03 Press the silver notch on the waste bottle to engage it. You will feel or hear a click.

04 Gently remove the male connector. There should be minimal pressure if the notch is correctly engaged.

05 Remove the waste bottle from the instrument.

06 Unscrew the cap and dispose of the used Countable Fluid. The Countable Fluid waste can be poured into a larger fluid waste container for chemical disposal according to your lab protocol and local guidelines.

07 Screw the cap onto the waste bottle.

08 Place the empty waste bottle with cap back onto the instrument in the correct bottle position.

09 While supporting the waste bottle, connect the tubing connector on the instrument to the connector on the bottle cap. Listen or feel for a click to ensure the connectors are fully closed to prevent leaks.

10 Close the Countable Instrument door.

11 Click **Return To Main Menu**.

CHAPTER 6

Maintenance

Cleaning the Countable System

Caution

Risk of personal injury and the Countable System damage

- Turn off the Countable Instrument and the Countable Computer before cleaning the instrument.

Once a month:

01 Apply 70% isopropyl alcohol to a lint-free wipe.

Caution

Risk of the Countable System damage

- Apply cleaning solution to the wipe and not directly to the instrument to avoid excess solution leaking into the instrument and damaging components.
- Do NOT use bleach to clean the Countable Instrument.

02 Wipe down the Countable covers and working surfaces.

Caution

Risk of personal injury and the Countable System damage

- Make sure that the Countable Instrument and the Countable Computer are both turned off before cleaning.

Cleaning carousel spills

Samples might contain Countable Fluid remnants when they are transferred from the imaging chamber to the carousel. The remnants may accumulate over time.

To clean the carousel:

01 Remove the carousel.

02 Clean it with 70% isopropyl alcohol on a lint-free wipe.

03 Replace the carousel in the instrument.

Caution

Risk of personal injury and the Countable System damage

- Apply cleaning solution to the wipe and not directly to the instrument to avoid excess solution leaking into the instrument and damaging components.
- Do NOT use bleach to clean the Countable System.

Removing equipment from use for repair or disposal

Only Countable Labs personnel should prepare the system for removal from use, transportation, or disposal. Reach out to Countable Labs for information on how to prepare for their visit.

CHAPTER 7

Troubleshooting

Every now and then, you may need to troubleshoot your Countable System. Some common fixes are listed in this chapter. If you still need help, contact Countable Labs support at success@countablelabs.com.

Sending data to Countable Labs for troubleshooting or support

If you're asked to send data files from your Countable Computer as part of the support process, send requested files to success@countablelabs.com. If requested, information about your instrument serial number can be found on a label at the back of the instrument.

System initialization errors

Error	User action
Software crashes or doesn't initialize	01 Restart the computer and try to initialize the system again. 02 If the issue persists, contact Countable Labs Technical support at success@countablelabs.com.
Unable to connect to the camera	01 Unplug and replug the blue USB connection from the desktop computer to check the camera USB connection. 02 Restart the Countable Control Software.

Error	User action
Unable to connect to barcode scanner	01 Unplug and replug the USB from the desktop computer to check the barcode scanner USB connection. 02 Restart the Countable Controls Software.
One or more lasers are not warmed up	01 Wait until the LED indicator lights are no longer flashing (~1 minute). 02 Try to initialize the system again.

Workbook is not accepted

Description	User action
A workbook is not accepted by the Countable Control Software	01 Make sure that the Matrix Tube Strips are placed in the appropriate position and orientation in the carousel. 02 Make sure that the samples listed in the workbook match the samples placed in the carousel.

Fluidics

The Countable System cannot start a new acquisition if the Countable Fluid bottle or waste bottle is not properly connected. The Countable Control Software will send an alert in the Countable Control Software if there is an issue.

Description	User action
The tubing connector have not properly engaged the caps of the Countable Fluid bottle and/or waste bottle	01 Remove and reattach connectors again. 02 You should feel or hear a small click when the connectors are engaged. 03 Rerun the instrument initialization.
The Countable Fluid bottle may not have enough fluid to fill the internal Imaging Chamber	01 Check if the Countable Refill bottle is near empty. 02 Refill the Countable Fluid bottle, following steps in Chapter 5. 03 Empty the waste bottle. 04 Rerun the instrument initialization.
Persistent error messages	Contact Countable Labs Technical Support at success@countablelabs.com if: 01 The system thinks the Countable Fluid or waste bottle is missing when they are both present. 02 The system thinks the Countable Fluid bottle is empty when they are full. 03 The system incorrectly flags a full waste bottle.

Countable Analysis Summary issues and observations

The tables below summarize issues and observations you may see in the Countable Analysis Summary (.html) file.

Reported issue	Description	User action
Analysis failed	The Countable System analysis did not run to completion.	Contact Countable Labs support to troubleshoot.
Low Intensity Distribution (ID) Score	Intensity Distribution Score is low.	Assay may require further optimization.

Reported observation	Description	User action
ChX high count accuracy alert (>1 M)	Detected counts are greater than 1 million and counting accuracy may be suboptimal.	Repeat experiment with less input DNA template to lower count.
The Countable Control Software doesn't detect the Training Sample or asks you to provide an appropriate Training Sample for ChX to increase counting accuracy	The count of molecules per 50 µL are less than 1000 counts and no training sample was provided OR the provided training sample had less than 1000 counts.	Repeat the experiment with a selected Training Sample included in the Sample Workbook. Refer to the Countable PCR Reaction Preparation User Guide for more details.
Low signal	Fluorescence intensity of target DNA is low.	Assay may require further optimization.
High background	Fluorescence intensity of matrix background is very high.	Assay may require further optimization.

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