



Common Issues + Solutions

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*Fluxergy's products comply with DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices. The devices are not endorsed or approved outside of the European Economic Area.

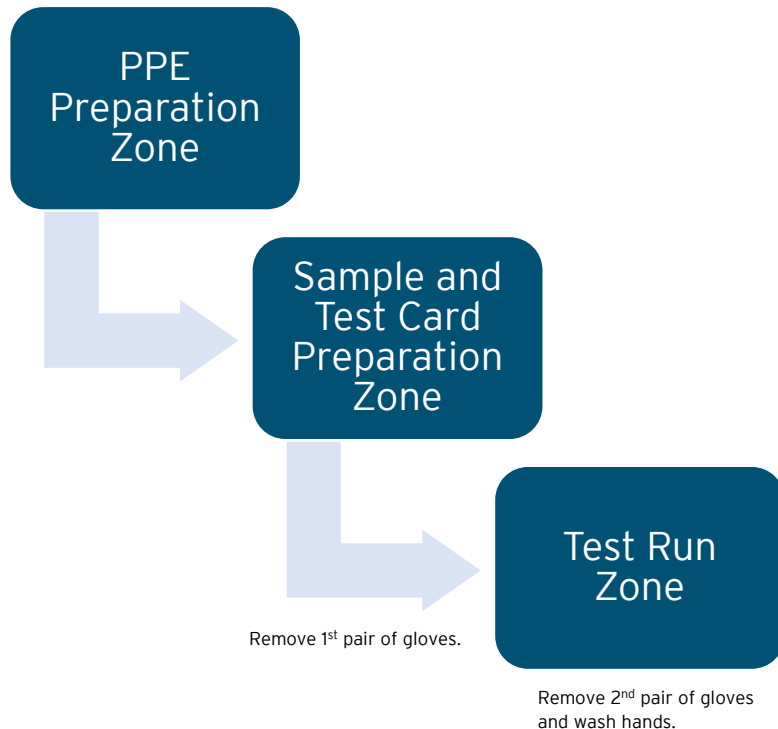
Fluxergy Analyzer



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Reducing Contamination Risk

Unidirectional Workflow



- The regular disinfection of your laboratory workspace is recommended to reduce the risk of contamination. The outside of the Fluxergy Analyzer can be gently wiped down with 70% isopropyl alcohol.
- Make sure to wipe down your workspace before starting the test and after the test set-up is completed. PCR only functions to detect nucleic acid from both non-viable and viable viral particles, so it is critical to routinely disinfect the testing area. However, do not spray solutions inside of the Analyzer. This will impact the sensors inside of the Analyzer.
- Your workspace should be cleaned with a 10% sodium hypochlorite (followed by sterile water to remove residual bleach), 70% ethanol, or irradiation with UV (using proper precautions for technician safety).

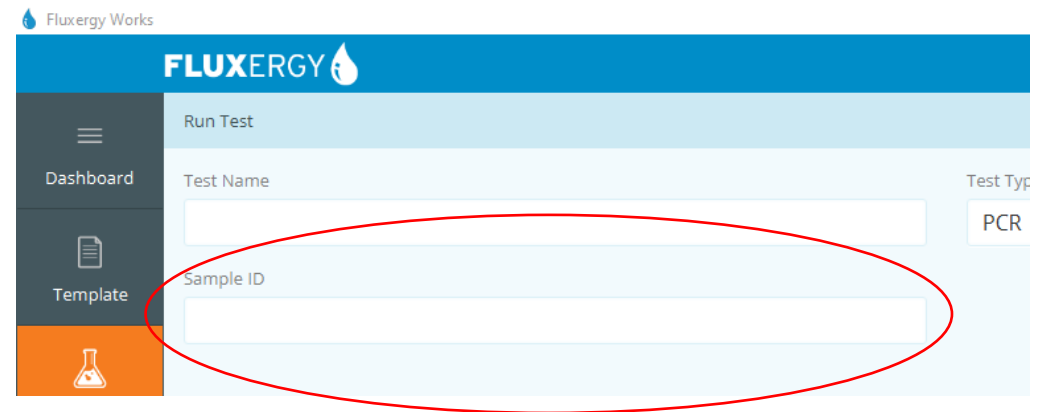
Labeling your Analyzers



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Naming Tests + PHI

- When naming a test, each test name and test card barcode must be unique when running a test in Fluxergy Works.
- If rerunning a sample, it is recommended to label as `TestName_RERUN`.
- If entering private or confidential information, place this information in the *Sample ID* field. This information will not be transferred into the encrypted data file after each test.



Fluxergy Works

FLUXERGY

Run Test

Dashboard

Test Name

Test Type

PCR

Template

Sample ID

Using Validated UTM + VTM

Transport Media Name	Catalog Number	Media Compatible with Reaction Mixture and Test Card	Sold in 3mL	Glass Beads Present	Includes Stability Agents for Viral Storage
Copan UTM 3mL™		✓	✓	✓	✓
Puritan UT-300™	UT-300	✓	✓	✓	✓
BD UVT 3 mL™	220527, 220528, 220529, 220531	✓	✓	✓	✓
Remel MicroTest™ M4RT™	R12552	✓	✓	✓	✓
Citoswab VTM™	780028	✓	✓		✓
Medschenker STM™	STM 30-A	✓	✓		✓
Avantik VTM™	GL4692	✓	✓		✓
Hardy	3C036NHL, 3C037NHL, 3C038NHL	TBD	✓		✓
CDC	SOP# DSR-052-05	TBD	✓		✓
PBS without Magnesium or Calcium		TBD	✓		

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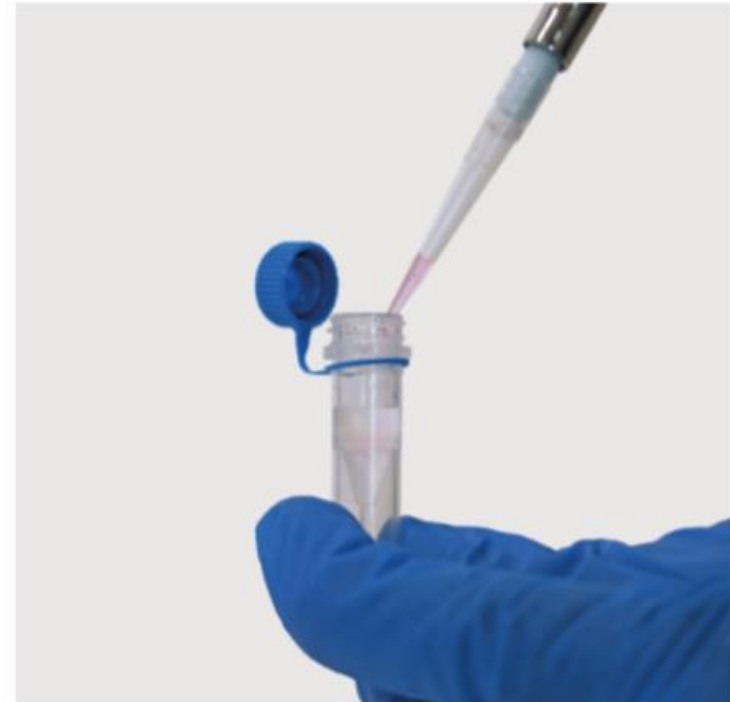
Using Validated Sample Types

Sample Types	Performance Validated	Compatible	Regulatory Status
Nasopharyngeal Swab	✓	✓	CE
Nasal/ Mid Turbinate Swab		✓	
Saliva with 8% Alcohol Scope		✓	
Oropharyngeal Swab			

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Handling + Storage of Materials

- Fluxergy's COVID-19 Test Kit Reaction Mixtures must always be stored at -20° C freezer.
- If the Reaction Mixtures undergo freeze thaw cycles after shipment, then results and performance will be adversely impacted. Before running a test, a Reaction Mixture can be taken from the freezer to thaw.
 - The thawing process takes 2-4 minutes depending on ambient temperature.
 - Once thawed the Reaction Mixture should be used within 30 minutes.
 - Do not vortex Reaction Mixture as it may adversely affect enzyme performance



Thoroughly Vortexing the Sample

- It is crucial to sufficiently vortex the NPS in UTM for 90 seconds prior to taking your sample and dispensing into the Reaction Mixture.
- It is beneficial to agitate the swab sufficiently to dislodge any genetic material from the swab.
- Ensure that the UTM vial has glass beads inside to disrupt the swab.



Pipetting Techniques + Issues

- The use of pipette tips with the aerosol barrier is recommended for preventing carryover contamination
- Look at angle and depth of immersion
- Use the smallest tip possible (if using your own calibrated pipettes).
- Only use tips once
- Keep pipette 90° from liquid when filling
- Pipetting slowly and carefully
- Make sure to aspirate all 130µL from Reaction Mixture and sample tube
- Avoiding pipetting air bubbles into test card as they may adversely affect performance of microfluidics.

Volume	Immersion Depth (MM)
0.1 - 1 µL	1
1 - 100 µL	2 - 3
101 - 1000 µL	2 - 4
1001 µL - 10 mL	3 - 6

Fluxergy Works Log Offs


- When setting up a test, Fluxergy Works will allow 4 minutes and 30 seconds for the user to load the Fluxergy Card before timing out after the test has been initiated.
 - Once Fluxergy Works has timed out, the test card serial number and Fluxergy Card that were entered are no longer usable.
- Fluxergy Works will log the user out after 5 minutes of inactivity.
 - Tests will still be in progress no matter what user account is accessed on the control computer.

FLUXERGY 

LOGIN

User ID

Password

 **SUBMIT**

Most Common Error Codes

Error Code	Why This Occurs	How to Fix This Error
Error 626	This error occurs when there is no amplification seen in either the internal control or target channels during the RT-PCR reaction. The sample has high inhibition. The user did not transfer the total Reaction Mixture and sample volume into the test card. Issues with performance of the Fluxergy Card or Reaction Mixture.	Dilute the sample in UTM and retest
Error 604	This error occurs when the test card cannot reach temperature to run a PCR. This is usually a test card issue.	Rerun the sample using a new Test Card and Reaction Mixture
Error 618	This occurs when there is a software error.	Retest the original sample using a new Test Card and Reaction Mixture

Questions?

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