



General Practices and Guidelines for PCR Test Kits

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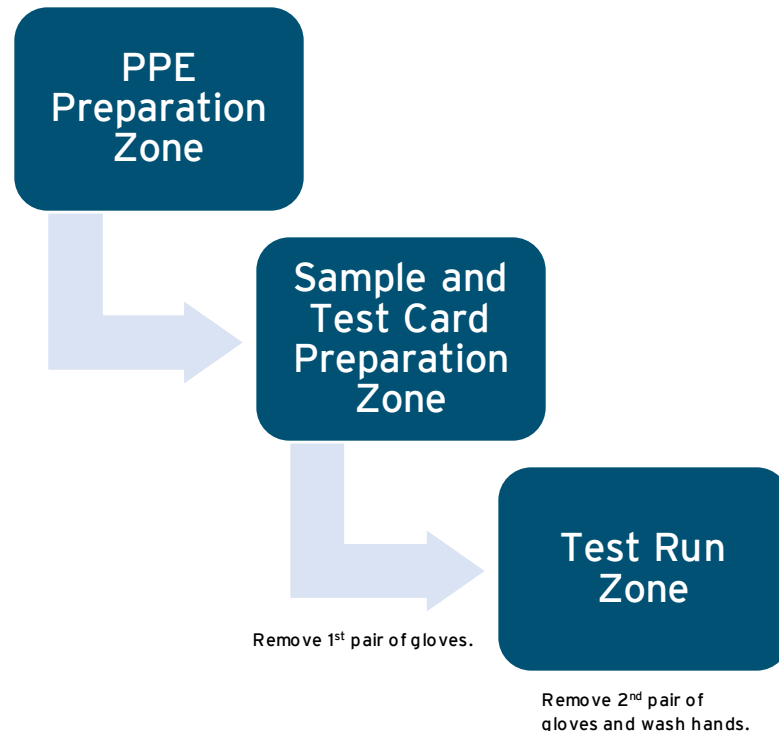
Handling Reagents

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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 percent sodium hypochlorite (followed by sterile water to remove residual bleach), 70% ethanol, or irradiation with UV (using proper precautions for technician safety).

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Labeling your Analyzers

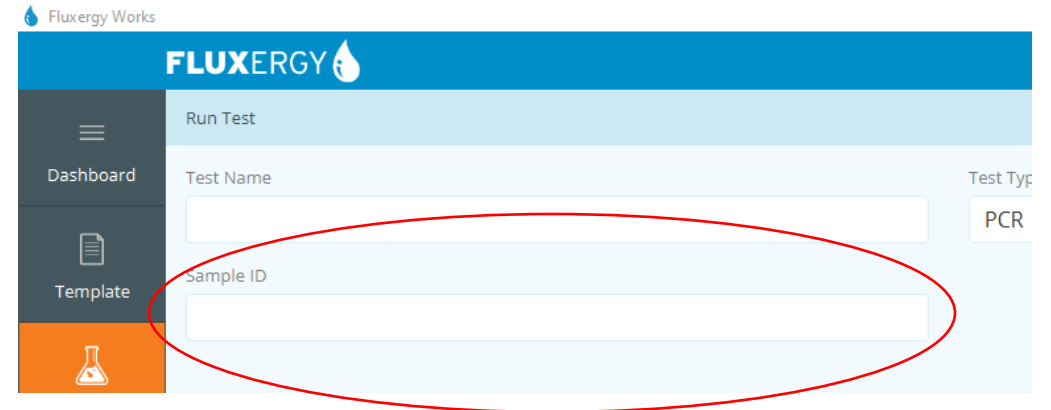


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Naming Tests

- 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.



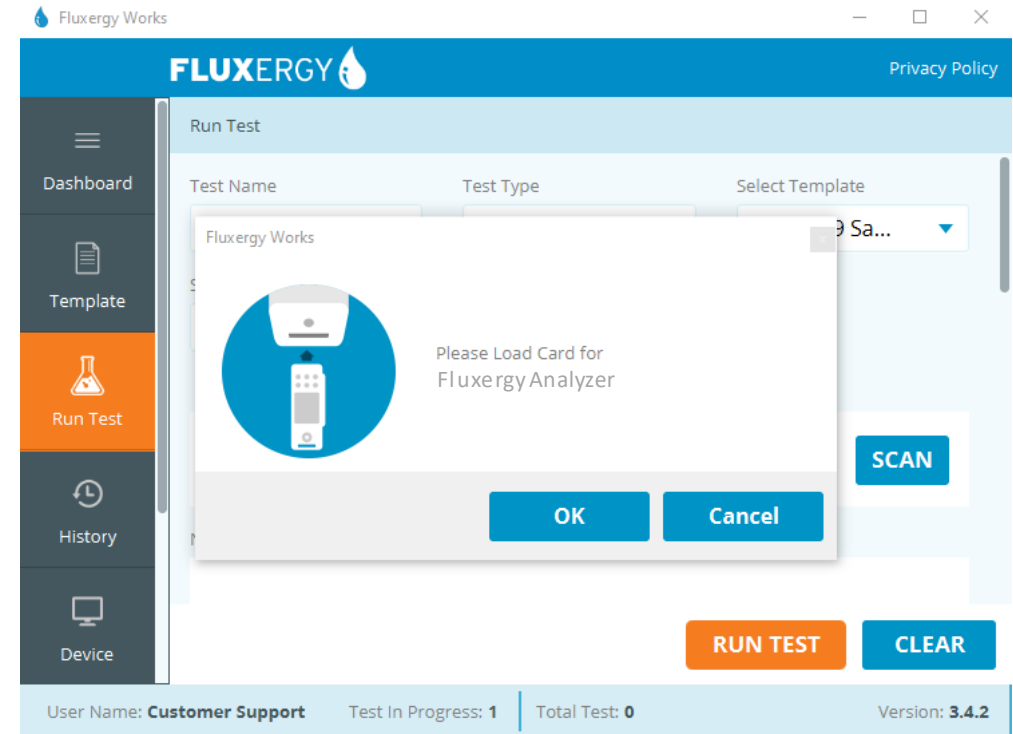
The screenshot shows the 'Run Test' interface in Fluxergy Works. It features a sidebar with 'Dashboard' and 'Template' options, and a main form area. The form includes a 'Test Name' field, a 'Sample ID' field (circled in red), and a 'Test Type' dropdown menu set to 'PCR'.

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Test Set-up Time Limit

- 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.



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Pipetting Techniques + Issues

- Use aerosol barrier pipette tips for preventing carryover contamination
- Look at angle and depth of immersion. Keep pipette at a 90° angle to the liquid surface when aspirating and dispensing
- Use the smallest tip possible (if using your own calibrated pipettes)
- Pipetting slowly and carefully
- Make sure to aspirate all instructed volumes from Reaction Mixture and sample tube
- Avoiding pipetting air bubbles into test card
- Only use pipette tips once

**Eject Pipette Tip into
Biohazard Bin after each use**



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Pipetting Technique Guide



Starting Position

Make sure that your pipette is set to the correct volume.



Set-up Pipette To Aspirate

Push piston until you feel a slight resistance. This is the 1st stop of the pipettor. You want to hold the pipettor at the 1st stop before aspirating fluid.



Starting Position

While holding at 1st stop, insert the pipette tip of the pipettor into your collection fluid, just above the bottom of its container. To aspirate, slowly remove pressure from the 1st stop until the piston is back at starting position.



Dispense

While at starting position, place your pipette with tip just above the bottom of the destination of the fluid. To dispense, slowly push the piston all the way down, past the 1st stop. This is the 2nd stop of the pipettor.

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Incubation for Sample Enrichment

- Samples should be incubated within the time frame indicated by your test kit
- Samples should not be left in the incubator for more than 24 hours
- Samples should be tested within 48 hours of enrichment
- Ensure that your incubator is set to 37.5°C
 - Confirm the temperature of your incubator with a thermometer
- If not testing immediately after enrichment, store enriched sample at 4°C

Set to 37.5°C



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Using Validated Sample Types

- **Please refer to your Test Kit’s Instructions for Use (IFU) to find list of Validated Sample Types**
- **Sample types outside of Fluxergy’s intended usage have not been validated. Fluxergy is unable to provide instructions or guidelines for the use of the product that is not outlined in the Intended Use section of the Test Kit Instruction for Use.**

Sample Types	Performance Validated	Compatible
Sample Type listed in IFU	✓	✓
Compatible Sample A		✓
Other Sample B		

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Handling + Storage of Materials

Fluxergy Reaction Mixture

- Reaction Mixtures for Fluxergy RT-PCR Test Kits 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 min.
 - Do not vortex Reaction Mixture as it may adversely affect enzyme performance



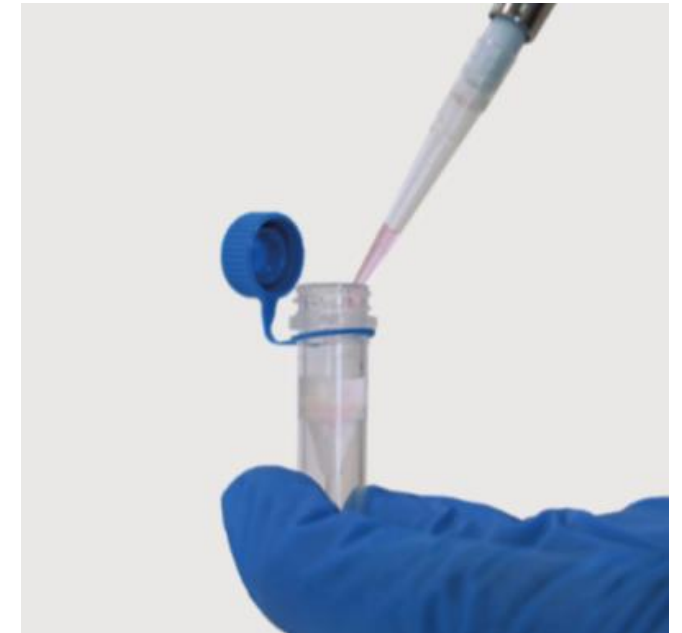
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Handling + Storage of Materials

Sample Collection Material

- Only use Fluxergy-validated media and buffers for performing any Fluxergy PCR test kits.
 - Refer to the SDS of each required material for Handling and Storage instructions
- Avoid collection of PCR inhibitors in your sample collection
 - Introduction of bleach can result in erroneous results



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Thoroughly Vortexing the Sample

- It is crucial to sufficiently vortex your prepared Sample for 90 seconds prior to dispensing into the thawed Reaction Mixture.
- Only vortex your sample. Do not vortex the Reaction Mixture in any part of the workflow.



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Most Common Error Codes

Error Code	Why This Occurs	How to Fix This Error
Error 626 (No Amplification)	This error occurs when there is no amplification seen in either the internal control or target channels during the RT-PCR reaction. Reasons for occurrence: <ul style="list-style-type: none"> • 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. 	Consider test workflow. If sample is suspected to have high inhibition, suggested retesting dilution of sample is 1:1 volume of Original Sample and Diluent.
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
Other Errors	These can occur because of multiple different reasons.	Please contact Fluxergy Customer Support

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Customer Support

For any issues, questions, or feedback:

Contact customersupport@fluxergy.com and CC: your Account Manager.

Please provide:

- Complete description of issue
- Exported .flx or .pdf test result labeled by Test Run Attempt #
- Test Card Lot #
- Reaction Mixture Lot #

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Questions?

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