

Fluxergy PCR Tests

Error(626) Result

What is an Error(626) Result?

This error occurs when there is not enough detectable reaction occurring in the test card.

Reasons for occurrence:

- The sample has high inhibition. See [What are PCR Inhibitors?](#)
- The user did not transfer the complete listed volume into the Fluxergy test card.
- Physical contaminants in the sample (lint, dust, etc.).
- Issues with performance of the Fluxergy Card or Reaction Mixture.
Contact customersupport@fluxergy.com.

How to Fix this Error

1. **Consider test workflow:**
 - Was your specimen collected with the right media or buffer?
 - Is your specimen listed as a sample according to the test kit Instructions for Use.
 - If you did not test immediately after sample collection, was the sample stored correctly?
 - Was your reaction mixture left at room temperature for over 30 minutes?
 - Were all workflow steps performed according to the test kit Instructions for Use?
 - Were all correct volumes used according to the test kit Instructions for Use?
 - Are any of your reagents expired?
2. **If the sample is suspected to have high inhibition**, suggested retesting dilution of sample is 1:1 volume of Prepared Sample and Diluent.

What are PCR Inhibitors?

PCR inhibitors are naturally found inorganic and organic compounds that reduce the efficacy of the PCR reaction. An example of an inorganic PCR inhibitor is calcium. Stool samples can contain many organic PCR inhibitors including bile and lipids.

Inhibitors reduce PCR reaction efficacy by

- Modifying or damaging DNA
- Modifying or destroying PCR enzymes
- Competitive binding to PCR enzymes

If the sample is suspected to have high inhibition, suggested retesting dilution of sample is 1:1 volume of Prepared Sample and Diluent. Dilution of the sample can reduce the effects of PCR inhibitors.

Remedying Error(626) Results

POSSIBLE CAUSES

SOLUTION

Not enough total volume of sample and reagent were dispensed into the test card.

Check your pipettor to confirm they are calibrated. Review your pipetting procedure to confirm that accurate volumes can be collected. Retest.

There is an issue with your sample collection procedure.

Refer to your assay's Instructions for Use. Retest.

- Samples for Fluxergy PCR testing should not be collected with cotton tipped swabs.
- Samples for Fluxergy PCR testing should not be collected in media not listed in the Instructions for Use.
- Samples should be processed immediately after collection.

The incorrect diluent buffer or media was used for sample processing.

Refer to your assay's Instructions for Use and determine if the correct sample type was collected in the correct media. Retest.

Review the instructions for your buffer or media if the collected sample was not immediately tested with your Fluxergy Test Kit. Retest.

The reagents are impaired or expired.

Check the expiration date for any reagents, buffer, and media that were used with Fluxergy test cards and your sample.

Confirm that all reagents, buffers and media were stored according to the Instructions for Use.

Faulty test card

Rerun the test with a new test card

There may be PCR inhibitors in your sample. PCR inhibitors can be found in diluents outside of Fluxergy validated materials. PCR inhibitors can also be found naturally in certain samples.

Refer to your assay's IFU and determine if the correct sample type was collected in the correct buffer or media. Retest.

If all Fluxergy workflow steps had been followed accurately, please perform a retest after diluting sample:

Mix equal part volume of your prepared sample and new, fresh diluent in a separate sterile container. Draw 14 uL of this further diluted sample and retest with new test card and reaction mixture.

If you continue to receive an Error(626) result after retesting, please contact Fluxergy Customer Support at customersupport@fluxergy.com.

*Only Fluxergy Test Kit COVID-19 has been approved for CE-IVD and is available for any markets that accept CE marking as the valid regulatory approval. All other products or any other markets are For Research Use Only (RUO) and are not for use in diagnostic procedures.