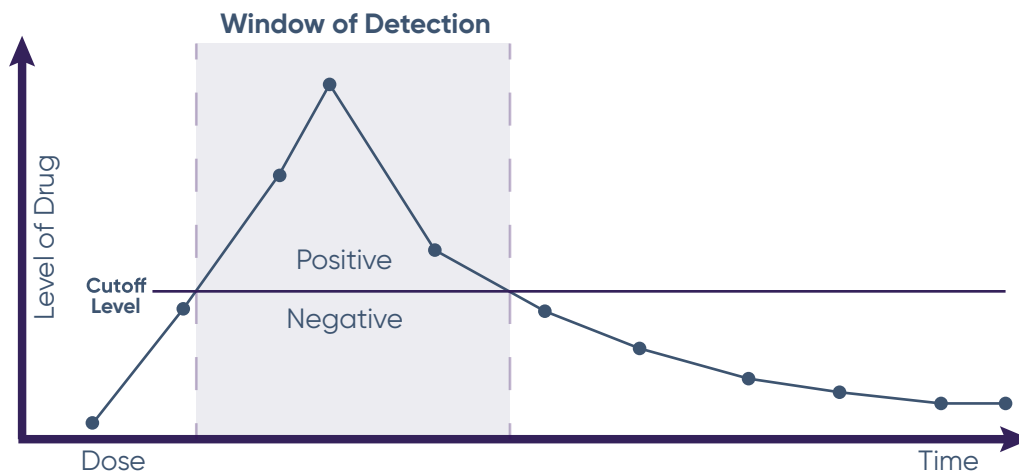




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## Technical Bulletin: +/-50% of Cutoff. What Does It Mean?

One of the key components of lateral flow or point-of-care rapid drug testing is the application of a cutoff level. This is the point at which a test result is determined as either a preliminary positive or negative. The image below shows how, following initial dose, the drug level changes over time and how it relates to the window of time in which the drug can be detected.



A cutoff level is chosen that will minimize the number of false positive or false negative results. Note that a negative result doesn't necessarily mean that a sample is completely drug free since there could be drug present at a level lower than the defined cutoff.

Cutoffs are determined following rigorous validation studies where test performance is assessed using the industry standard range of +50% of cutoff to -50% of cutoff. Some manufacturers will also include +/-25% data for reference.

### But what does this actually mean?

In the standard Package Insert (PI) or Instructions for Use (IFU) the Precision and Sensitivity section describes the validation testing carried out in order to launch the test. Samples with known drug concentrations ranging from drug free to +50% of cutoff level are tested using each lateral flow product format to assess how the test indicates positive or negative results against the drug concentration range.

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### Why is +/-50% used as the validation standard?

The data obtained from the +/- 50% studies is more reliable since the amount of drug present is more distinct from the cutoff concentration and less likely to give ambiguous results than other concentrations.

### Will all drug tests perform at cutoff level?

Manufacturers make every effort to develop drug tests that produce positive results as close to the cutoff level as possible but there can be some batch-to-batch variation due to differences in antibodies and reagents. If there is any doubt in the result, particularly when dealing with faint lines it is always advised to obtain a confirmation test. Laboratory testing is more sensitive, with generally lower cutoffs providing confirmation of the presence or absence of a drug.

### Will other drugs produce positive results?

It is possible for other drugs and non-drug substances to produce positive results on lateral flow tests due to cross reactivity or interference. This is particularly true of drugs within the same drug class – e.g. the opiates class contains heroin (illicit), morphine (prescription) and codeine (over the counter) and therefore any of these drugs may produce a positive result on an opiates test even if we are only trying to identify one of these drugs. It is important to refer to the Analytical Specificity section of the PI/IFU to determine at what concentration other drugs will be identified. During validation testing manufacturers will also perform interference/cross reactivity testing on a long list of substances to ensure they do not produce positive results. These are listed in the section Interfering Substances / Cross Reactivity.