This saliva test is based on a specific antigen antibody reaction and it is a competitive immunochromatographic test. Each test contains the colour-marked specific antibody against the drug to be detected (gold linked, monoclonal mouse antibody), the membrane-bound control antigen (drug to be detected) and membrane-bound antibodies for test control (polyclonal anti-mouse IgG antibodies).

### Required materials that are not in scope of delivery:
- Work instruction
- Swap for saliva sampling
- Blue buffer container with 400 µl solution
- Test cartridge
- One-way pipette

### Optionally available materials:
- Gloves
- Result protocols for documentation

### Important notes:
1. Please observe hygienic instructions when handling quick tests. We can provide you with a leaflet for more information regarding disposal.
2. Use package content only for in vitro diagnostics.
4. Avoid direct contact of sample materials and test reagents with skin and mucous membranes.
5. All urine samples are potentially infectious. Have disinfectants ready.
6. Do not use the test after the expiry date printed on it.
7. Used tests and test utilities are waste class B and therefore can be disposed together with household waste. Please refer to our leaflet for more information regarding disposal.

### Test principle:
This saliva test is based on a specific antigen antibody reaction and it is a competitive immunochromatographic test. Each test contains the colour-marked specific antibody against the drug to be detected (gold linked, monoclonal mouse antibody), the membrane-bound control antigen (Crea-BSA) and a second membrane-bound antibody for test control (polyclonal anti-mouse IgG antibodies). After the sample has been pipetted into the sample opening the antibodies bound control antigen (Crea-BSA) and a second membrane-bound antibody for test control (polyclonal anti-mouse IgG antibodies). The drug molecules contained in the saliva are mobilised through the absorbed fluids and flow along the membrane together with the sample fluid. The drug molecules contained in the saliva sample compete with the drug molecules fixed on the test membrane for a limited number of specific binding sites at colour-marked antibodies. There is no test line, when the antibodies are saturated with drug molecules. The sample fluid contains the colour-marked specific antibody against the drug to be detected (gold linked, monoclonal mouse antibody), the membrane-bound control antigen (Crea-BSA) and a second membrane-bound antibody for test control (polyclonal anti-mouse IgG antibodies).
Usage information

Sample collection:
Sample collection should be executed with the supplied collection device. Please observe the detailed work instruction below. For this test no other collection containers shall be used. Collection of saliva is not subject to a specific time during the day for this test.

Storage of tests and samples:
Store test only in original packaging and at room temperature or cooled (59°F to 86°F; 2 to 30°C). Avoid direct sunlight. Do not freeze the tests! Samples can be preserved up to 48 hours at room temperature or up to 72 hours in the refrigerator (35°F to 46°F; 2°C to 8°C) or in the freezer (-4°F; -20°C). After defrosting bring the samples to room temperature and mix well.

Test execution:

1. Take required test out of the packaging immediately prior to executing the test. Document the test person’s identity (ID) on the test.
2. Release seal of the collection device (swap). Take swap out of the tube. Swipe over the mucous membranes and salivary glands under the tongue with the sponge (fig. 1, arrow) until the sponge is soaked. (fig. 1)
3. Put swap into the enclosed blue buffer tube and keep it moving in there for 30 seconds. Press out the swap well at the edge of the buffer tube that the fluid can flow back into the tube. Take out the swap, put it back into the package tube and dispose. (fig. 2)
4. Close buffer tube and shake well. Pull up the fluid from the buffer tube with the enclosed precision one-way pipette until at least one of the chambers overflow. (fig. 3, arrows, important!). Pipette complete content of the pipette into the left window (fig. 4, arrows) of the test. Repeat procedure for the right side of the test.
5. Wait until coloured lines appear. Read results after 10 minutes. Don’t evaluate results after more than 20 minutes. (fig. 4)

All reagents are included in the test ready for use. To execute the test only the sample to be tested is required. Test handling temperature: 59°F to 86°F (+15°C to 30°C).

Interpreting the results:

NEGATIVE = 2 lines

Two lines appear in the display window (for T = Test line and for C = Control line). A slightly rose colour is also to be considered a negative result.

The corresponding drug accordingly named next to the display window is not present or its concentration is lower than the given cut-off value.

POSITIVE = 1 line in C-area

One line appears in the display window for C = Control line and no line for T = Test line. Test is positive for the drug named above the display window.

Drug concentration is equal or higher than the shown cut-off value. (=set limit value)

Invalid = no line in C-area (=customer service)

If no line appears for C (=control line), the test is invalid in any case, even in case there is a test line. Repeat the detection with a new test – also then, if the control line is only missing for one of the parameters.

Send the invalid test together with the packaging back to us and receive replacement for free.

Restrictions:

Despite the very specific detection possibilities via monoclonal and polyclonal antibodies for each immunological method cross reactivities can appear caused by metabolites from the organism or reactions with chemically related medications and other substances!

Evaluation of a positive result of immunological tests must therefore always be executed very carefully. Before legally grave measures are taken, conclusive confirmation analyses are required by all means. These can be mediated through us, if required (results are usually available within 4-5 days). The evidence of a drug does not provide any information about its origin and amount.

A negative result doesn’t necessarily show a drug free sample. The drug concentration can be present below the cut-off value of the test.

Screening test specifications:

Due to their scope we have only summarised in these work instructions the information that are required for a safe test execution.

Further information regarding correctness, precision etc. can be obtained from our advice service or from our website at any time.

Literature: