# Saliva Multi-Drug of Abuse Test

## Cross Reactivity

The cross reactivity of the test was evaluated by spiking drug free samples with structurally similar compounds. Compounds producing positive responses are listed below:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMP</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>AMP</td>
<td>100 ng/mL</td>
</tr>
<tr>
<td>AMP</td>
<td>500 ng/mL</td>
</tr>
<tr>
<td>AMP</td>
<td>10,000 ng/mL</td>
</tr>
<tr>
<td>AMP</td>
<td>30,000 ng/mL</td>
</tr>
<tr>
<td>AMP</td>
<td>100,000 ng/mL</td>
</tr>
<tr>
<td>d-AMP</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>d-AMP</td>
<td>100 ng/mL</td>
</tr>
<tr>
<td>d-AMP</td>
<td>500 ng/mL</td>
</tr>
<tr>
<td>d-AMP</td>
<td>10,000 ng/mL</td>
</tr>
<tr>
<td>d-AMP</td>
<td>30,000 ng/mL</td>
</tr>
<tr>
<td>d-AMP</td>
<td>100,000 ng/mL</td>
</tr>
</tbody>
</table>

## References


## INTENDED USE

The ORAL-VIEW™ Saliva Multi-Drug of Abuse Test is a one-step rapid qualitative immunoassay for screening potential abuse of one or more drugs in human oral fluid.

### Abbreviation Test

<table>
<thead>
<tr>
<th>Substance</th>
<th>Cutoff</th>
<th>Detection Time</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>Cutoff</th>
<th>Detection Time</th>
</tr>
</thead>
</table>

### Assay Procedure

1. **One Step Assay**
   - Take the kit out of the refrigerator and let it sit at room temperature for 10–20 minutes before use.
   - The following table lists the concentrations at which the analytes do not cross-react with the antibodies.

### Principle of the Procedure

The ORAL-VIEW™ Saliva Multi-Drug of Abuse Test is a one-step lateral flow drug test using a chromatographic immunoassay based on the principle of competition between limited antibody binding sites and the drug in the sample and a drug-protein conjugate immobilized on a porous membrane support. The drug sample, or oral fluid, migrates to the test area of the membrane by capillary action, displacing the colloidal gold conjugate. The antibody conjugate will only bind to the limited antibody binding sites in the test area. The absence of drug in the sample results in the gold conjugate migrating across the membrane to the control line (C line), while the presence of drug in the sample results in the gold conjugate migrating to the test line (T line). The combined concentration of the drug and conjugate at the test line (T line) is detected by a visual result. The following reagents are supplied with the test kit:

### REAGENTS AND MATERIALS SUPPLIED

- **Technical Information**
  - Manual
  - Technical Data Sheet (TDS)

### REAGENTS AND MATERIALS NOT PROVIDED

- **Technical Information**
  - Drug Reference Chart

### Instructions for Use

1. **Test Preparation**
   - **CALIBRATION**
     - **CALIBRATION**
   - **STORAGE**
     - **STORAGE**
   - **TROUBLESHOOTING**
     - **TROUBLESHOOTING**

### Catalog Number

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Catalog Number</th>
</tr>
</thead>
</table>

### Manufacturer

[Manufacturer Name] - SAN DIEGO, CA 92121 – USA

**Powered by YYYY00**

This test provides only a preliminary result. A more specific alternate confirmatory method should be applied to any drug that test result, particularly when preliminary positive results are obtained.

### Laboratory Details

- **Temperature Limit:** Use by YYYY00

- **Expiration Date:**

### Notes

- **Manufactured for:**
  - [Manufacturer Name]

### Material Safety Data Sheet

- **MATERIALS REQUIRED BUT NOT PROVIDED**
  - **MATERIALS REQUIRED BUT NOT PROVIDED**

### Summary

- **Amphetamine (AMP)**
  - Amphetamines are central nervous system stimulants that may lead to pupil dilation, increased heart rate, and reduction of overall performance.
  - A more specific alternate confirmatory method should be applied to any drug result, particularly when preliminary positive results are obtained.

### Meeting the Challenge

- **Meeting the Challenge**
  - **Meeting the Challenge**

### Override

- **Override**
  - **Override**

### Conclusion

- **Conclusion**
  - **Conclusion**

### Literature Cited

- **References**
  - **References**

### Acknowledgments

- **Acknowledgments**
  - **Acknowledgments**
**PERFORMANCE CHARACTERISTICS**

This test is capable of detecting specific drugs and/or drug metabolites in human oral fluid at or above the cutoff concentrations indicated in the Intended Use section.

**EXPECTED VALUES**

Three hundred (300) spiked saliva samples were blind labeled and tested for each analyte (drug or drug metabolite). Each sample was tested with one test device. The test results were grouped into: below 50% cutoff (Negative), between 50% cutoff and cutoff, between cutoff and 150% cutoff, and above 150% cutoff (Positive). Twenty-six (26) discrepancies were observed at the cutoff to 150% cutoff level. Twenty (20) discrepancies were observed at all cutoffs.

The test results are tabulated as follows:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Cutoff (ng/ml)</th>
<th>Concentration range</th>
<th>Below 50%</th>
<th>Between 50% and Cutoff</th>
<th>Between Cutoff and 150%</th>
<th>Above 150%</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMP</td>
<td>12</td>
<td>0</td>
<td>20</td>
<td>100</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>BZD</td>
<td>5</td>
<td>0</td>
<td>5</td>
<td>100</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>THC</td>
<td>5</td>
<td>0</td>
<td>5</td>
<td>100</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>PCP</td>
<td>5</td>
<td>0</td>
<td>5</td>
<td>100</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**LIMITATIONS**

- This product is for forensic or investigational use only.
- This product is for testing human oral fluid only.
- Results obtained by this device provide only a preliminary, qualitative analytical test result. A more specific determinate oral fluid drug assay should be used to obtain a confirmed analytical result.
- A negative result may not necessarily indicate a drug-free specimen. Drugs may be present in the specimen below the cutoff levels of the test.