DAT Oral Fluid Amphetamine (OFAMP)

In vitro diagnostic test for the qualitative and semiquantitative detection of amphetamine in human oral fluid, exclusively collected with the Intercept® collection device

Indication
Amphetamine is a central nervous system stimulant occasionally prescribed for the treatment of attention-deficit hyperactivity disorder and narcolepsy, but which is also widely abused. The drug is usually administered orally or intravenously, and passes from the blood into the salivary glands shortly before becoming detectable in oral fluid. The detection time varies depending on the dose, method of administration, and salivary pH, but is typically in the order of 20–50 hours. Oral fluid concentrations of amphetamine often exceed those in plasma by as much as 3-fold, which affirms saliva as a favorable medium for monitoring amphetamine abuse.

Reporting test results
To correlate a semiquantitative Intercept result from the assay or the associated LC/MS/MS confirmation result to a neat oral fluid value, the result from the Intercept sample should be multiplied by a factor of 3. For example, an amphetamine concentration of 43 ng/mL measured by the oral fluid assay is determined to be positive as the neat oral fluid cutoff for a sample collected by an oral fluid device pad is at 120 ng/mL (120 divided by 3 equals a cutoff of 40 ng/mL).

Assay technology: Kinetic interaction of microparticles in solution (KIMS)

- In the absence of amphetamine, the antibody-conjugated microparticles bind to the drug conjugate supplied with the assay and form particle aggregates.
- The light absorbance of the solution increases as the aggregation reaction proceeds in the absence of amphetamine.
- The presence of amphetamine inhibits particle aggregation by competing with the drug conjugate for binding to the antibody-conjugated microparticles.
- The increased absorbance of the solution is diminished in proportion to the amount of amphetamine within the sample and therefore the concentration of amphetamine can be determined.
**DAT Oral Fluid Amphetamine test characteristics**

**Analyzer compatibility**

MODULAR ANALYTICS P module, MODULAR ANALYTICS DAT (USA only), Roche/Hitachi 917, cobas c 311 analyzer, cobas c 501/502 modules, Olympus AU5400

**Assay technology**

Kinetic interaction of microparticles in solution (KIMS)

**Traceability**

Standardized against a primary reference method (LC/MS/MS)

**Calibration**

Full (semi-quantitative) or blank (qualitative) calibration after reagent lot change, and as required by quality control procedures

**On-board stability (refrigerated)**

8 weeks

**Sample material**

Neat oral fluid collected with the Intercept® Oral Specimen Collection Device, diluted in preservative Intercept® buffer

**Sample volume**

5 µl (cobas c 311 analyzer), cobas c 501/502 modules

8 µl (Roche/Hitachi 917, MODULAR ANALYTICS, Olympus AU5400)

**Reaction time**

10 min

**Cutoff concentration in neat oral fluid**

120 ng/mL (cutoff is at 40 ng/mL for a processed Intercept collection device sample)

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### Order information

<table>
<thead>
<tr>
<th>Parameter (incl. volume)</th>
<th>Catalogue-no.</th>
<th>Kit size R1</th>
<th>Kit size R2</th>
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<tbody>
<tr>
<td>DAT Oral Fluid AMP 70 mL</td>
<td>05388449 190</td>
<td>1 x 64 mL</td>
<td>1 x 33 mL</td>
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<td>1 x 978 mL</td>
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**References**