DAT Oral Fluid Methamphetamine (OFMA)

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

**Indication**

Methamphetamine is a potent, highly addictive synthetic stimulant with hallucinogenic effects. The d-isomer is prescribed for treatment of attention deficit disorder and for short-term treatment of obesity, and is considerably more potent than the l-isomer, which is sold over-the-counter as a nasal decongestant. Methamphetamine can be easily and cheaply manufactured in illicit laboratories and is abused worldwide. The drug is readily absorbed irrespective of the route of administration and rapidly appears in oral fluid due to its basicity, lipophilicity, and low degree of plasma protein binding. Ion trapping of methamphetamine results in salivary concentrations exceeding those in plasma, which affirms saliva as a favorable medium for monitoring methamphetamine 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, a methamphetamine concentration of 89 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 methamphetamine, 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 methamphetamine.
- The presence of methamphetamine 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 methamphetamine within the sample and therefore the concentration of methamphetamine can be determined.
DAT Oral Fluid Methamphetamine 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
8.1 µl (cobas c 311 analyzer, cobas c 501/502 modules)
13 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)

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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<td>DAT Oral Fluid MAMP 70 mL</td>
<td>05388481 190</td>
<td>1 x 64 mL</td>
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<td>ZRO, POS, NEG, 2 x 10 mL</td>
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References