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Issue No.	Revision Details	Effective Date
1.01	Original	25/10/12
1.02	Addition of reference range/ cut off sources to all tests as per ISO 15189:2012. Removal of Sample check assay. Reason for rejection of samples/non reporting of tests	01/05/14
1.03	Named consultant. Update TAT to 48 hours.	12/02/16
2.01	Rebranded to Eurofins Biomnis; Removed Oral Fluid Methamphetamine and Urine Methadone.	24/05/17
2.02	- Kit insert references updated to Abbott - SOP Numbers updated - Amp/Ecstasy changed to Amp/Methamphetamines - Removed OFT	28/09/18
2.03	Ecstasy not detected by Amp/Meth assay	23/10/18
2.04	Comment added: the Drugs Of Abuse assays (with the exception of ALC and UCRD) are screening tests which provide preliminary positive or negative results. If clinically indicated, confirmation by GCMS is available on request. 21 days stability changed to 5 days stability as stated in DFU.	28/05/19

Electronic copies are available to all staff on Q-Pulse and on the Eurofins Biomnis website.

Additional copies of this SOP must not be made without prior approval and documentation. Refer to SOP G94.

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REASONS FOR REJECTION OF SAMPLES/NON-REPORTING OF TESTS

1. Samples received beyond the stability limits.
2. Samples received in the incorrect tube.
3. Samples received without the necessary patient identifiers. For more details, see [here](#).
4. No documentation received with the specimens.
5. Leaking specimen received.
6. For workplace Chain of Custody specimens the following criteria also apply:
 - No seals on either specimen
 - Seal on A container broken or tampered with
 - Seal on B container broken or tampered with
 - Only one specimen received
 - Insufficient specimen for complete analysis (IA & GC-MS)

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AMPHETAMINES / METHAMPHETAMINES

Minor hallucinogens which can induce psychic dependence. Administered orally or by the inhalation of smoke. Appears in the urine 24 to 48 hours after administration.
 NOTE: The presence of MDMA (Ecstasy) is not detected by this assay.

Preparation of patient: There is no physical preparation for the amphetamine/methamphetamine test.

Precautions: Prescriptions drugs to be listed in case of interferences with the result.

Accredited	Yes
Method	Drugs of Abuse – Enzyme-immunoassay SOP: CC162
Sample Requirements	Tube Type: Urine (clean glass or plastic containers) Temperature: + 4°C Miscellaneous: Non fasting
Turn Around Time	48h
Stability	5 days @ + 4°C
Units - Reference Ranges	ng/ml Positivity Cut-Off: 1000 Source: Abbott Amphetamine/Methamphetamines assay Kit Insert; Ref:3L37-20, November 2017. The Drugs Of Abuse assays (with the exception of ALC and UCRD) are screening tests which provide preliminary positive or negative results. If clinically indicated, confirmation by GCMS is available on request.

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BARBITURATES

Barbiturates are prescribed as anticonvulsants, sedatives and hypnotics. Detection of these compounds in the serum, urine or gastric juice for toxicological purposes is based on a qualitative immunoassay. The antibody used was actually raised against secobarbital but it recognizes all barbiturates (with varying affinity) without interference from corresponding hydroxylated derivatives. In order to interpret the results, the class of barbiturate concerned must be taken into account. Barbiturates with a short half-life induce far fewer side effects than longer-acting members of the class like phenobarbital. Acute over dosage could result in drowsiness followed by deep coma with respiratory depression, hypothermia, hypotension and anuria.

Preparation of patient: There is no physical preparation for the barbiturates test.

Precautions: Prescriptions drugs to be listed in case of interferences with the result.

Accredited	No
Method	Drugs of Abuse – Enzyme Immunoassay SOP: CC172
Sample Requirements	Tube Type: Urine (clean glass or plastic containers) Temperature: + 4°C Miscellaneous: Non fasting
Stability	5 days @ + 4°C
Units - Reference Ranges	ng/ml Positivity Cut-Off: 200 The Drugs Of Abuse assays (with the exception of ALC and UCRD) are screening tests which provide preliminary positive or negative results. If clinically indicated, confirmation by GCMS is available on request.

BENZODIAZEPINES

Benzodiazepines are prescribed as sedatives, anxiolytics and antiepileptics. Poisoning may be either accidental or deliberate. Detection of these compounds in the serum, urine or gastric juice for toxicological purposes is based on a qualitative immunoassay. The antibody used was actually raised against nordiazepam but it cross reacts with a wide range of different benzodiazepines and their metabolites. Distinguishing between different benzodiazepines or metabolites and quantitative determination depends on GC/MS.

Preparation of patient: There is no physical preparation for the benzodiazepines test.

Precautions: Prescriptions drugs to be listed in case of interferences with the result.

Accredited	Yes
Method	Drugs of Abuse – Enzyme-immunoassay SOP: CC163
Sample Requirements	Tube Type: Urine (clean glass or plastic containers) Temperature: + 4°C Miscellaneous: Non fasting
Turn Around Time	48h
Stability	5 days @ + 4°C
Units - Reference Ranges	ng/ml Positivity Cut-Off: 200 Source: Abbott Benzodiazepines assay kit insert; Ref:3L39-20, March 2018 The Drugs Of Abuse assays (with the exception of ALC and UCRD) are screening tests which provide preliminary positive or negative results. If clinically indicated, confirmation by GCMS is available on request.

CANNABIS METABOLITES

Cannabis is a derivative of a plant which originates in Asia (*Cannabis sativa*). The active substance is delta-9-tetra-hydrocannabinol. It is presented in the form of leaves, a resin or an oil and can be smoked on its own or mixed with tobacco. Low doses lead to mild intoxication and higher doses can induce sensory hallucination. Dependence is largely psychological. It can be detected for 7 days in the urine of light users (1 to 2 cigarettes per week) and for 21 days in that of regular users (5 cigarettes per day). Abuse is signalled by the presence of metabolites in the urine. Passive inhalation and former use can be distinguished from current, active use on the basis of the level of tetra-hydro-cannabinol.

Preparation of patient: There is no physical preparation for the cannabis metabolites test.

Precautions: Prescriptions drugs to be listed in case of interferences with the result.

Accredited	Yes
Method	Drugs of Abuse – Enzyme-immunoassay SOP: CC164
Sample Requirements	Tube Type: Urine (clean glass or plastic containers) Temperature: + 4°C Miscellaneous: Non fasting
Turn Around Time	48h
Stability	5 days @ + 4°C
Units - Reference Ranges	ng/ml Positivity Cut-Off: 50 Source: Abbott Cannabinoids assay Kit Insert; Ref: 3L41-20, August 2016 The Drugs Of Abuse assays (with the exception of ALC and UCRD) are screening tests which provide preliminary positive or negative results. If clinically indicated, confirmation by GCMS is available on request.

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COCAINE METABOLITE

Cocaine is a narcotic drug derived from the leaves of the Erythroxylon coca bush. It is usually used as cocaine hydrochloride. The drug can be administered via the following routes (the most common first): intranasal, pulmonary (inhalation of the fumes), intravenous and oral. Its main psychiatric effect is stimulation (intellectual hyperactivity and euphoria) and the most obvious of its somatic effects are cardiovascular (tachycardia and high blood pressure). Abuse leads to strong psychoactive dependence. It takes 2 to 4 days before it can be detected in the urine following administration. Cocaine use is detected by assaying benzoylecgonine.

Preparation of patient: There is no physical preparation for the cocaine test.

Precautions: Prescriptions drugs to be listed in case of interferences with the result.

Accredited	Yes
Method	Drugs of Abuse – Enzyme-immunoassay SOP: CC161
Sample Requirements	Tube Type: Urine (clean glass or plastic containers) Temperature: + 4°C Miscellaneous: Non fasting
Turn Around Time	48h
Stability	5 days @ + 4°C
Units - Reference Ranges	ng/ml Positivity Cut-Off: 300 Source: Abbott Cocaine assay kit insert; Ref: 3L40-20, November 2017. The Drugs Of Abuse assays (with the exception of ALC and UCRD) are screening tests which provide preliminary positive or negative results. If clinically indicated, confirmation by GCMS is available on request.

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ECSTASY

Minor hallucinogens which can induce psychic dependence. Administered orally or by the inhalation of smoke. Appears in the urine 24 to 48 hours after administration.

Preparation of patient: There is no physical preparation for the amphetamine/ecstasy test.

Precautions: Prescriptions drugs to be listed in case of interferences with the result.

Accredited	No
Method	Drugs of Abuse – Enzyme Immunoassay SOP: CC173
Sample Requirements	Tube Type: Urine (clean glass or plastic containers) Temperature: + 4°C Miscellaneous: Non fasting
Turn Around Time	48h
Stability	5 days @ + 4°C
Units - Reference Ranges	ng/ml Positivity Cut-Off: 500 Source: Abbott Ecstasy assay Kit Insert 3L42-20 The Drugs Of Abuse assays (with the exception of ALC and UCRD) are screening tests which provide preliminary positive or negative results. If clinically indicated, confirmation by GCMS is available on request.

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EDDP

EDDP is the primary metabolite of methadone. Methadone is a synthetic diphenylheptane-derivative opiate agonist that is often used in detoxification programs as an oral substitute for heroin or other morphine-like drugs to suppress withdrawal symptoms and/or to maintain chronic relapsing heroin addicts. Methadone is classified as a Schedule II drug under the Federal Controlled Substances Act of 1970 and is subject to U.S. Food and Drug Administration regulations for drugs that special studies, records, and reports when used for detoxification and maintenance of opiate dependence. EDDP results from the N-demethylation and cyclization of methadone, and is excreted in the urine and the bile along with unchanged drug and another metabolite, 2-ethyl-5-methyl-3,3-diphenylpyrrolidine (EMDP). In patients on methadone maintenance, unchanged methadone may account for 5-50% of the dose and EDDP 3-25% of the dose in urinary excretion during the first 24 hours. Commonly, detection of urinary methadone is used to assess compliance in methadone programs. However, measurement of urinary EDDP has two benefits over tests directed at methadone. One benefit is that the individuals in methadone maintenance programs sometimes divert (sell) their methadone into the illicit drug market and then spike their urine sample with a small quantity of methadone to cover the diversion. Their urine sample may test positive for methadone but would not test positive for EDDP, since the drug was not ingested and therefore never metabolised. Secondly, renal clearance of methadone is affected by urinary pH. At a low pH (pH<6.0), nearly a three-fold increase in renal clearance of methadone has been seen. Conversely, at a high urinary pH (pH>7.7) renal clearance of unchanged methadone may be too low to give a positive result (>300 ng/ml) on a urine screening test. The negative test result, therefore is not necessarily due to non-compliance. Renal clearance of EDDP, however, is not affected by urinary pH.

Preparation of patient: There is no physical preparation for the EDDP test.

Precautions: Prescription drugs to be listed in case of interferences with the result.

Accredited	Yes
Method	Drugs of Abuse – CEDIA-immunoassay SOP: CC167
Sample Requirements	Tube Type: Urine (clean glass or plastic containers) Temperature: + 4°C Miscellaneous: Non fasting
Turn Around Time	48h
Stability	5 days @ + 4°C
Units - Reference Ranges	g/ml Positivity Cut-Off: 100 Source: CEDIA Methadone metabolite (EDDP) Assay Kit Insert 10006492 2002-08. The Drugs Of Abuse assays (with the exception of ALC and UCRD) are screening tests which provide preliminary positive or negative results. If clinically indicated, confirmation by GCMS is available on request.

ETHANOL (ALCOHOL)

Ethanol (ethyl alcohol) can cause both acute and chronic poisoning. Symptoms depend on the amount ingested, age, concomitant drugs, the subject's general state of health and individual sensitivity :- between 50 and 100 mg/dl: mild intoxication, mental confusion;- between 100 and 300 mg/dl: intoxication, hypoglycemia, convulsions, encephalopathy, delirium tremens;- over 300 mg/dl: coma, anoxia, alveolar hyperventilation, respiratory acidosis, metabolic acidosis

Preparation of patient: There is no physical preparation for the ethanol test.

Precautions: Prescriptions drugs to be listed in case of interferences with the result.

Accredited	Yes
Method	Drugs of Abuse – Alcohol Dehydrogenase SOP: CC165
Sample Requirements	Tube Type: Urine (clean glass or plastic containers) Temperature: + 4°C Miscellaneous: Non fasting
Turn Around Time	48h
Stability	21days @ + 4°C
Units - Reference Ranges	mg/dl Results below 10 mg/dl are considered not detected. Source: Abbott Ethanol Assay Kit insert; Ref: 3L36-20, February 2017.

METHADONE

A narcotic analgesic which is used in the treatment of major opiate dependence.

Preparation of patient: There is no physical preparation for the methadone test.

Precautions: Prescriptions drugs to be listed in case of interferences with the result.

Accredited	No
Method	Drugs of Abuse –Enzyme Immunoassay SOP: CC171
Sample Requirements	Tube Type: Urine (clean glass or plastic containers) Temperature: + 4°C Miscellaneous: Non fasting
Turn Around Time	48h
Stability	5 days @ + 4°C
Units - Reference Ranges	ng/ml Positivity Cut-Off: 300 Source: Abbott Methadone Assay Kit Insert 3L35-20 - July 2016 The Drugs Of Abuse assays (with the exception of ALC and UCRD) are screening tests which provide preliminary positive or negative results. If clinically indicated, confirmation by GCMS is available on request.

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OPIATES

Opium is obtained from the opium poppy (*papaver soniferum*) by scraping the unripe seed capsule and then collecting and drying the rubbery exudates. The name opium comes from the Greek opion, or poppy juice. It is an important painkilling drug and the source of other analgesics such as morphine and the narcotic heroin. Screening is for the presence of compounds with the typical opiate morphinane group; buprenorphine has a different structure and is missed in this screen. It takes about 2 days for these substances to become detectable in the urine.

Preparation of patient: There is no physical preparation for the opiates test.

Precautions: Prescriptions drugs to be listed in case of interferences with the result.

Accredited	Yes
Method	Drugs of Abuse – Enzyme-immunoassay SOP: CC166
Sample Requirements	Tube Type: Urine (clean glass or plastic containers) Temperature: + 4°C Miscellaneous: Non fasting
Turn Around Time	48h
Stability	5 days @ + 4°C
Units - Reference Ranges	ng/ml Positivity Cut-Off: 300 Source: Abbott Opiate Assay Kit Insert; Ref: 3L34-20, September 2016 The Drugs Of Abuse assays (with the exception of ALC and UCRD) are screening tests which provide preliminary positive or negative results. If clinically indicated, confirmation by GCMS is available on request.

6-MONOACETYL MORPHINE (6-AM)

6-MONOACETYL MORPHINE is the primary metabolite of heroin. Its presence in biological samples is more indicative of heroin use than standard opiate screens as there are no cross-reactivity issues with medicinal opiate derivatives e.g. codeine.

Preparation of patient: There is no physical preparation for the 6-AM test.

Precautions: Prescriptions drugs to be listed in case of interferences with the result.

Accredited	Yes
Method	Drugs of Abuse – CEDIA-immunoassay SOP: CC168
Sample Requirements	Tube Type: Urine (clean glass or plastic containers) Temperature: + 4°C Miscellaneous: Non fasting
Turn Around Time	48h
Stability	5 days @ + 4°C
Units - Reference Ranges	ng/ml Positivity Cut-Off: 10 Source: CEDIA Heroin Metabolite (6MAM) Assay Kit Insert 10006723-1 2003-07 The Drugs Of Abuse assays (with the exception of ALC and UCRD) are screening tests which provide preliminary positive or negative results. If clinically indicated, confirmation by GCMS is available on request.

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URINE PH

A urine drug of abuse testing program involves specimen collection, initial screening with an immunoassay, followed by a confirmation test. Many drug users will attempt to evade detection by adulterating the specimen in order to produce false negative results during the initial immunoassay screening. Adulteration methods include dilution with water, substitution with a drug free liquid, addition of readily available household materials (e.g., vinegar baking soda, liquid drano, detergent, etc.) or tampering with certain chemicals.

Several methods have been used to detect urine adulteration. These methods include measuring the temperature, pH, specific gravity and creatinine concentration of the sample. Normal urine should have the following typical characteristics: temperature between 32.5-37.7°C or 90.5-99.8°F, pH within 4.7-7.8, specific gravity within a range of 1.003-1.035 and creatinine concentration of 0.8-2.0mg/ml. If any of the urine parameters is outside the specified range, there should be reason to believe that the urine sample has been adulterated.

Preparation of patient: There is no physical preparation for the urine pH test.

Precautions: Prescriptions drugs to be listed in case of interferences with the result.

Accredited	Yes
Method	Drugs of Abuse – Spectrophotometry SOP: CC169
Sample Requirements	Tube Type: Urine (clean glass or plastic containers) Temperature: + 4°C Miscellaneous: Non fasting
Turn Around Time	48h
Stability	5 days @ + 4°C
Units - Reference Ranges	Normal Range: 4.7-7.8 Source: DRI pH-Detect test Kit Insert 10009578-0 08-2005

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URINE CREATININE

Creatinine is used in the area of drug abuse, as a urine test to evaluate sample integrity. As can frequently happen, urine samples for drug testing can be diluted to mask the presence and levels of various drugs. By measuring Creatinine levels in urine this acts as an aid to verify the integrity of the urine sample.

Preparation of patient: There is no physical preparation for the urine creatinine test.

Precautions: Prescriptions drugs to be listed in case of interferences with the result.

Accredited	Yes
Method	Drugs of Abuse – Spectrophotometry SOP: CC12
Sample Requirements	Tube Type: Urine (clean glass or plastic containers) Temperature: + 4°C Miscellaneous: Non fasting
Turn Around Time	48h
Stability	5 days @ + 4°C
Units - Reference Ranges	>2.0 mmol/l: Compatible with normally concentrated urine. 0.5-2.0 mmol/l: Dilute sample. <0.5 mmol/l: Sample integrity questionable. Source - EWDTS guidelines 2004