LABORATORY TECHNICAL SPECIFICATIONS MANUAL

Produced by
SYNLAB Laboratory Services

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Controlled Document – ID 103.0025
September 2020 – Version 25

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PURPOSE OF PROCEDURE

This document is effective from September 2020. This document is updated periodically in line laboratory quality reviews and method updates. If your results precede this date and you would like the document that was live at the time your result were provided, please contact customer services.

This document outlines the technical specifications to which this laboratory works. Should you require any services listed within this document that you have not been previously quoted for or have recently requested, please contact customer services prior to sending a sample in.

Laboratory procedures are designed to comply with the current recommendations of the United Kingdom Laboratory Guidelines for Legally Defensible Workplace Drug Testing (2001) and subsequent amendments and the European Laboratory Guidelines for Legally Defensible Workplace Drug Testing (2002). Onsite testing by breathalyser or Near Donor kit is not included in these guidelines but follows best practice. Breathalyser testing and results are designed to be legally defensible.

The laboratory holds UKAS accreditation to ISO/IEC 17025:2017 for most laboratory aspects of toxicology and for the collection of back to laboratory saliva and urine samples on client sites. These techniques may be amended from time to time for process improvement and method development, and all modified methods will be submitted for validation by UKAS. Customers will be notified of any significant changes to testing platforms and methodologies. Non-ISO/IEC 17025:2017 (UKAS) accredited tests are highlighted with a '†' beside the test. The Near Donor kits and breathalyser testing are not currently with the scope of the UKAS accreditation held by SYNLAB Laboratory Services. A copy of our current schedule of accreditation can be accessed from the UKAS website and can be found by searching for our UKAS number 2144.

COLLECTION SERVICE

SAMPLE COLLECTION

Samples are collected for either urine or saliva by SYNLAB Laboratory Services' (SYNLAB) Collection Technicians according to the UK and European guidelines. The Collection Service booking line is available 24 hours a day, 365 days of the year. SYNLAB has a network of approximately 100 Collection Technicians located throughout the UK and aim to arrive for "For Cause" testing at the client's site within 2 hours of the booking call.

SYNLAB has strict step by step checklists and documentation to ensure that these samples are collected to a legally defensible standard. SYNLAB request that a site representative is present during the sample collection process. This is to safeguard both the donor and the Collection Technician throughout the process.

BOOKING A DRUG AND ALCOHOL TEST

Drug and Alcohol tests can be booked through the Duty Manager, manned 24 hours a day for urgent calls, with an answerphone for messages when the Duty Manager is on another call. Drug and Alcohol tests can be booked through our dedicated booking line or by emailing collection.enquiries@synlab.co.uk.

When contacting the SYNLAB team to request a collection, customers must have their unique account PIN available, as well as the full collection address and any relevant special instruction.

After a Collection Technician is assigned the call, the customer will be telephoned with the name and estimated arrival time of the Collection Technician. If there is any significant delay, this will be communicated to the site contact.

Once a Collection Technician has been despatched, cancellation of the call will incur the full charge of the collection.

LOCATION OF TEST SITE

Sample collections can be made virtually anywhere in the UK, as long as there are suitable facilities as described below. On arrival at your worksite / premises, our collector will contact your nominated representative. Please note that the 2 hour response time does not apply to all areas.

ONSITE FACILITIES

It is essential that collection sites are suitable and secure. For urine collections lockable storage should be provided for the donor to hold valuables / pockets contents whilst the collection takes place. The facilities should afford visual and aural privacy for the donor and allow access only to authorised persons. For urine collections, there must be a toilet and wash basin for the exclusive use of the donor(s).

SYNLAB's collector will advise your on-site representative about the fine detail and take precautions in accordance with best practice. For example, he / she will add a coloured dye to the toilet cistern and bowl and tape up any taps so that the urine sample cannot be diluted. They will also remove any potential adulterants such as bleach and cleaning fluids. Access to the site will be secured using signs.

Finally, a quiet area will be required so that the documentation, including details of medication taken, can be completed in private. This could be a small office, the most important factor here is ensuring visual and aural privacy for the donor.

It usually takes about 20 minutes to collect one sample from one donor; therefore, a combination of tests (e.g. urine and breath test) will take about 30 minutes to complete so you should arrange for donors to arrive for testing at these intervals. A suitable waiting area should be provided for them.

Sometimes, a donor will have a 'shy bladder' i.e. they will be unable to provide a sufficient sample. In this case, the donor will be asked to go to the waiting area and drink sufficient fluid to enable them to provide enough urine, i.e. up to 250mls of water every 20 minutes with a maximum consumption of one litre. During the waiting period a member of your staff should remain with the donor.

COMPLIANCE WITH YOUR WORKING PRACTISES

In addition to complying with SYNLAB's own policies and procedures, we require our collectors to comply with your rules and regulations, so far as they are known, including:

- Health and Safety
- Smoking at work – no smoking
- Self-identification (photo ID badge)
- Booking in and out on your premises
- Parking on site
- Equal opportunities in service delivery

If you have any other special requirements that have not been addressed, please advise us as soon as possible.

DONOR IDENTIFICATION

Before our collector takes a sample, he / she will seek positive identification from the donor to ensure that they are whom they say they are, and that someone else is not giving the sample for them to 'beat the test'. Photo identification is preferred (e.g. Passport or Driving License) though a visual ID by a manager is accepted'.

Donors will also need to have with them details of any medication they have taken within the last 14 days.

Network Rail workers will also need to have with them their National Insurance number or Sentinel number.

COMPUTERISED RANDOM SELECTION OF DONORS

If required SYNLAB can provide **free of charge** a computerised selection of employees for 'random' testing. Most organisations that incorporate random testing into their programme take advantage of our expertise, thus removing most of the administrative burden and enabling them to be free of allegations of bias during selection.

SERVICES SPECIFICATION

The service provided will comprise, as appropriate:

- ***Collection and on-the-spot analysis of breath sample*** to measure blood alcohol level using Drager 6810 or Drager 6820 Breath Alcohol Monitor supplied by SYNLAB.

Our collector will take one breath sample from the donor. **If the reading on the monitor is zero, there will be no further testing.**

However, if the reading is **other than zero,** a **second** sample will be collected approximately 15-20 minutes later. This will determine whether the donor's blood alcohol level is rising or falling, and your on-site representative will be able to make an informed decision about the donor's suitability to return to work, and the nature of the duties that the donor can safely undertake.

Some policies allow for a third sample to be taken a further 15-20 minutes later if the second reading is higher than the first.

A new mouthpiece will be used for each breath sample, even for the same donor.

The breath test will measure the amount of alcohol in the donor's breath. For reporting purposes, this will be converted to an equivalent blood alcohol level, there being a direct relationship between alcohol in breath and in blood.

The result on the Drager instrument supplied by SYNLAB will be expressed in 'promille' units (‰). The England and Wales drink drive limit is **80 milligrams per 100 millilitres (80mg/100mL)**. On a Drager unit this would be equivalent to a reading of '0.80 promille' (0.80‰). The drink drive limit in Scotland is lower at **50mg/100mL or 0.50‰.**

Some Drug & Alcohol policies and breathalysers refer to the Breath Alcohol Concentration (BrAC) rather than the Blood Alcohol Concentration and SYNLAB report BrAC results in mg/L. The England and Wales drink drive limit is 35µg/100mL. On a Drager unit this would be equivalent to a reading of '0.35 mg/L'. The drink drive limit in Scotland is lower at **22µg/100mL or 0.22mg/L**

If a result is needed as a Breath Alcohol reading, please contact the laboratory where we can give the equivalent result.

Other cut-offs can also be requested on the client registration form and are as follows:

	Blood ‰	Breath mg/L	Urine mg/100mL
England & Wales Drink Drive Limit (default)	0.80	0.35	107
Scotland Drink Drive Limit / Maritime	0.50	0.22	67
England and Wales Warning Level (if used)	0.50	0.22	107 / 67
Network Rail	0.29	0.13	39
Aviation	0.20	0.10	27
Any Alcohol Present (Medical screening)	0.15	0.10	15

All samples for laboratory analysis will be sent by first class letter post unless we are instructed otherwise, or you may make other arrangements to send the samples to the laboratory.

FULL CHAIN OF CUSTODY TESTING

The sample collection processes carried out by SYNLAB's Collection Technicians for full laboratory analysis, whether urine or saliva are accredited by UKAS under ISO/IEC 17025:2017. For details of accredited laboratory tests following collection refer to Laboratory Testing section.

NEAR DONOR TESTING

SYNLAB's Collection Technicians carry a range of Near Donor Testing kits for both urine and saliva which allow for instant screening results to be obtained onsite, with the ability for any 'non-negative' samples to be sent back to the laboratory for confirmation (LC-MS/MS) analysis. It should be noted that the saliva test for Cannabis is at a much higher level than the laboratory cut-off of 10ng/ml and therefore the detection time for cannabis in saliva using these Near Donor Testing kits could be less than 4 hours.

The following range of NDT tests are available for Urine and Saliva:

Urine NDT Tests Available		
Drug Group	**Calibrated Against**	**Cut-Offs Available**
Amphetamines	Amphetamine	1000
Methamphetamine	Methamphetamine	1000
Opiates	Morphine	300, 2000
Cannabis	11-nor-∆9-THCC	50
Cocaine	Benzoylecgonine	300
Benzodiazepines	Oxazepam	300
Barbiturates	Secobarbital	300
Ketamine	Ketamine	1000
Phencyclidine	Phencyclidine	25
Methadone	Methadone	300
EDDP	EDDP	100
Buprenorphine	Buprenorphine	10
Propoxyphene	Propoxyphene	300

Saliva NDT Tests Available		
Drug Group	**Calibrated Against**	**Cut-Offs Available**
Amphetamines	Amphetamine	25/50
Methamphetamine	Methamphetamine	25/50
Opiates	Morphine	10/40
Cannabis	∆9-THC	40/100
Cocaine	Benzoylecgonine	20
Benzodiazepines	Oxazepam	5/20

LABORATORY TESTING

TRANSPORT OF SAMPLES

From 7th August 2020 SYNLAB have been instructed by the Royal Mail that all samples received in the laboratory are sent using the Track24 system, although we also accept deliveries from major delivery companies. Samples should be packaged to either the IATA PI650 guidelines, labelled “Biological Substance – Category B” with the UN3373 diamond or packaged to prevent damage or leaks and labelled “Fragile – Exempt Human Specimen”. Inadequately packaged and labelled samples may be rejected by Royal Mail or the courier company.

STABILITY OF DRUGS IN SAMPLES

SYNLAB have determined urine samples are valid for analysis for up to 14 days at room temperature (i.e. in the post) and 30 days if refrigerated. Whilst drugs in urine are generally quite stable, this is the timeframe determined in which samples should be received and analysed to ensure the result is valid. Particularly, samples with a result near the cut off may be affected by a delay of greater than 14 days.

Samples received after 14 days can still be processed however a comment may be made on the report to state the sample was received and analysed after 14 days. This will be discussed with the customer prior to analysis.

Saliva samples may degrade if not received in the laboratory promptly and will be rejected if more than 7 days old.

All samples are kept for a minimum of 5 working days with samples that require confirmation being kept for a minimum of a year. After this time samples are disposed of using the laboratory’s waste management policy.

MINIMUM LABELLING CRITERIA

All samples must be labelled so that there is an unequivocal match between the sample and the request form, normally through the use of a unique Chain of Custody number. The request form must also contain (as a minimum) the name of the requesting company, identification of the collector and the donor and the donor’s consent to test.

Where samples do not require Chain of Custody, i.e. clinical samples, three points of identification are required.

CHAIN OF CUSTODY CHECKS

Samples received in the laboratory will be checked to ensure that the Chain of Custody is intact and that there are no errors or signs of tampering.

Tamper evident bags will be opened and the samples inside compared with the paperwork to ensure consistency. The paperwork will be checked to ensure correct completion before the sample will be logged in to the computer system.

If there is no donor consent to test, SYNLAB’s staff will contact the customer to request the original signature of the donor before completing analysis. In all other cases where there is a flaw in the Chain of

Custody, the customer will be contacted for further instruction. In these cases, the flaw in the paperwork may not prevent analysis but could make the results open to challenge. Where there is an error in the Chain of Custody, the normal turnaround time may be extended if there is a delay in authorising analysis.

If there is evidence of deliberate tampering of the sample, it will not be opened to preserve the evidence of tampering.

ADULTERATION CHECKS

A series of adulteration checks may be performed on the sample to identify attempts to affect the process. This will include a combination of creatinine and pH (for urine samples), CEDIA sample check (for urine and saliva tests), chromates, nitrites and oxidants and other tests as required to guarantee the authenticity of the sample as far as is possible in the laboratory. These will be reported as part of the 'Test for Adulterants.' Where a urine sample is reported as dilute, and a result is above 50% of the cut-off, a repeat sample may be suggested without a reason being given.

Where a sample is suspected on site to be adulterated or substituted the sample is packaged under Chain of Custody conditions and returned to the laboratory for adulteration tests. The sample is not tested for drugs as it may not be a true sample however if it is the dilution check that has failed, upon request, the laboratory can conduct a drug screen.

As part of this process a second set of samples is also collected.

DECISION RULES

The laboratory transitioned to ISO/IEC 17025:2017 from ISO/IEC17025:2005 in February 2020. A requirement of ISO/IEC 17025:2017 is for the laboratory to provide Decision Rules. These are the levels at which a result is determined to be either Positive or Negative.

Throughout this document the laboratory refers to Decisions Rules as Functional Cut Off Levels. These are the Cut Off Levels provided by the UK Workplace Testing Guidelines with the uncertainty of measurement applied.

UNCERTAINTY OF MEASUREMENT

The laboratory uses appropriate uncertainty of measurement based on the assay. This information and the calculated functional cut offs can be found in more detail in the individual assay sections below.

PRIMARY SCREENS

Screening tests are available in drugs panels to suit different testing requirements.

Urine

The primary screen is performed using CEDIA, DRI and ELISA immunoassay reagents. Each assay is calibrated weekly or after a QC failure, with a minimum of 5% of the samples run each day being QCs.

The standard cut-offs used for each drug group are specified below. Please contact the laboratory for the functional cut off if non-standard cut-offs are being used.

Drug Group	Calibrated Against	SOP Ref. No.	Method	Cut-Off ng/mL (unless stated)	Functional Cut off ng/mL (unless stated)	On UKAS Schedule Y/N
Amphetamines	Methamphetamine	9.01577	CEDIA	300	234	Y
Barbiturates	Secobarbital	9.01577	CEDIA	200	177	Y
Benzodiazepines	Nitrazepam	9.01577	CEDIA	200	177	Y
Buprenorphine	Buprenorphine	9.01577	CEDIA	5	4.3	Y
Cannabis	11-nor-Δ9-THCC	9.01577	CEDIA	50	43	Y
Cocaine	Benzoylecgonine	9.01577	CEDIA	300	258	Y
Ethyl Glucuronide*	Ethyl Glucuronide	9.01577	DRI	500	n/a	Y
Ketamine	Ketamine	9.01577	DRI	500	401	Y
Methadone	Methadone	9.01577	CEDIA	300	282	Y
Methaqualone	Methaqualone	9.01577	CEDIA	300	269	Y
Opiates	Morphine	9.01577	CEDIA	300	274	Y
6-Monoacetylmorphine	6-Monoacetylmorphine	9.01577	CEDIA	10	9.2	Y
Phencyclidine (PCP)	Phencyclidine	9.01577	CEDIA	25	22.2	Y
Propoxyphene	Propoxyphene	9.01577	CEDIA	300	263	Y
Tramadol	Tramadol	9.01577	ELISA	200	173	Y
Alcohol	Ethanol	9.0108	DRI	10mg/dL	10	Y
Creatinine	Creatinine	9.0117	DRI	<1.77mmol/L	1.9	Y
pH	pH	9.0116	DRI	Range 3-11	n/a	Y
Specific gravity	NaCl standard	9.0119	DRI	1.0003-1.0035g/L	n/a	Y
Oxidants	Pyridinium Chlorochromate	9.0119	Axiom	200mg/L	n/a	Y
Nitrite	Sodium Nitrite	9.0119	Axiom	500mg/L	n/a	Y
Chromate	Pyridinium Chlorochromate	9.0119	Axiom	200mg/L	n/a	Y

* Screening for Ethyl Glucuronide (to confirm ethanol and not as a marker for alcohol abuse).

The laboratory is moving to an LC-TOF-MS screening system where each drug is individually calibrated (SOP 9.01574). Standard cut-off values in use are displayed below:

Analyte	Cut-Off (ng/mL)	Functional Cut off ng/mL (unless stated)	On UKAS Schedule Y/N
Amphetamines			
Amphetamine	300	227	Y
Methamphetamine	300	253	Y
MDMA	300	211	Y
MDEA	300	216	Y
Opiates			
Morphine	300	234	Y
Codeine	300	200	Y
DHC	300	193	Y
6-MAM	10	5.6	Y
Cocainics			
Cocaine	300	206	Y
Benzoylecgonine	300	208	Y
Cocaethylene	300	191	Y
Cannabinoids			
THCC	50	30	Y
THC	50	28	Y
Cannabinol	50	31	Y
Benzodiazepines			
Oxazepam	200	165	Y
Nordiazepam	200	151	Y
Temazepam	200	138	Y
Lorazepam	200	171	Y
Flunitrazepam	50	34	Y
Aminonitrazepam	200	158	Y
Aminoflunitrazepam	50	37	Y
Hydroxyalprazolam	200	157	Y
Phenazepam	200	147	Y
Opioids			
Methadone	250	161	Y
EDDP	100	213	Y
Buprenorphine	5	4.2	Y
Tramadol	200	163	Y
desmethyltramadol	200	151	Y

Analyte	Cut-Off (ng/mL)	Functional Cut off ng/mL (unless stated)	On UKAS Schedule Y/N
Opioids cont.			
Propoxyphene	300	218	Y
Norpropoxyphene	300	228	Y
Fentanyl	5	2.7	Y
Barbiturates			
Secobarbital	200	125	Y
Phenobarbital	200	87	Y
Psychoactives			
PCP	25	18	Y
Methaqualone	300	245	Y
Ketamine	500	332	Y
Norketamine	500	330	Y
Quetiapine	300	208	Y
Pregabalin	500	319	Y
Gabapentin	1000	698	Y
Mirtazapine	300	206	Y
Amitriptyline	500	337	Y
Nortriptyline	500	383	Y
Cathinones			
Mephedrone	300	235	Y

Saliva

The primary screen is performed using CEDIA immunoassay reagents. Each assay is calibrated weekly or after a QC failure, with a minimum of 5% of the samples run each day being QCs.

The standard cut-offs used for each drug group are specified below:

Drug Group	Calibrated Against	SOP Reference No.	Method	Cut-Off ng/ml	Functional Cut off ng/mL	On UKAS Schedule Y/N
Amphetamines	Methamphetamine	9.01576	CEDIA	40	32	Y
Methamphetamine	Methamphetamine	9.01576	CEDIA	40	24	Y
Benzodiazepines	Nitrazepam	9.01576	CEDIA	10	8.8	Y
Cannabis	THC	9.01576	CEDIA	4	3.6	Y
Cocaine	Benzoylecgonine	9.01576	CEDIA	20	19.0	Y
Methadone	Methadone	9.01576	CEDIA	20	14.7	Y
Opiates	Morphine	9.01576	CEDIA	40	37.4	Y

MEASUREMENT UNCERTAINTY FOR PRIMARY SCREENING

Primary screen analysis by immunoassay has a different response for different drugs within a class, such that the measured value may differ from the calibrated value by a small percentage. The drug giving 100% response is listed in the table above, and the relative responses of metabolites and other drugs in each class are available on request.

The primary screening methods are quantitative or semi-quantitative and the laboratory is aware of (but does not report) the relative concentrations of drugs in a sample, although the response is only approximately linear in the range of the cut-off values.

The UN Office on Drugs and Crime (UNODC) specifies that screening assays should never have a false negative rate greater than 5%. To guarantee this the laboratory applies a Functional Cut Off (Expanded Uncertainty k=2) such that 95% of samples at the Cut Off will proceed to confirmation. Samples that are below the functional Cut Off will be reported as Negative. This decision rule ensures that the risk of any false negative results is minimised.

The functional cut off for a primary screen is calculated to be the cut off provided in the workplace testing guidelines with the measurement of uncertainty subtracted from that value.

CONFIRMATORY TESTING

URINE

The standard turnaround time for in house confirmatory testing is 3 working days for samples received by 12:00 midday, unless waiting for authority to proceed. Referred tests may take up to 7 working days. For an additional fee, samples for in house tests may be Fast Tracked to enable results to be reported by 5:00pm on the next working day after receipt.

All confirmatory assays are performed by liquid chromatography coupled to a tandem mass spectrometer for detection after solid phase extraction and using deuterated / isotopically labelled internal standards.

Every sample is analysed with a set of 6 calibration standards, traceable to international reference materials, a blank sample and at least one quality control sample.

Tests are only accepted if a calibration containing at least 4 calibrators and a calibration coefficient of >0.990 is obtained. Additionally, the QC sample must pass a set of rules for accepting QC samples.

When a batch is accepted, individual analytes must have a retention time of ±2.5 percent of the deuterated internal standard, and the ion intensity ratio of the primary (quantification) ion to the secondary (qualifier) ion must be within a defined percentage of the ratio of the nearest standard value, following European guidelines on ion intensity ratios.

Drug Group	Cut-Off ng/ml	SOP Reference No.	Expanded Uncertainty at cut-off 99.7% CI (%)	Functional Cut off ng/mL	On UKAS Schedule Y/N
Opiates Group					
Morphine	300	12.0262	26.1	378	Y
Codeine	300	12.0262	19.7	359	Y
Dihydrocodeine	300	12.0262	26.7	380	Y
6 Mam	10	12.0264	30	13	Y
*Papaverine	5	12.0262	49.4	7.5	Y
*Noscapine	5	12.0262	63.2	8.2	Y
*Thebaine	5	12.0262	59.2	8	Y
*Desmethyl papaverine	5	12.0262	35.4	6.8	Y
*Dihydromorphine	100	12.0262	31.6	132	Y
*Hydrocodone	500	12.0262	32.8	664	Y
*Pholcodine	100	12.0262	55.2	155	Y
Cannabis					
THCC	15	12.0261	22	20.6	Y
Cocaine					
Benzoylecgonine	150	12.0263	19	194	Y
Amphetamines					
Amphetamine	200	12.0263	18	255	Y
Methamphetamine	200	12.0263	21	263	Y
MDA	200	12.0263	14	244	Y
MDMA	200	12.0263	21	264	Y
MDEA	200	12.0263	21	265	Y

Benzodiazepines					
Diazepam	10	12.0265	12	12	Y
Temazepam	100	12.0265	13	120	Y
Oxazepam	100	12.0265	15	123	Y
Desmethyl Diazepam	100	12.0265	11	117	Y
Flunitrazepam	10	12.0265	15	12	Y
Aminoflunitrazepam	10	12.0265	29	14	Y
Aminonitrazepam	100	12.0265	34	153	Y
Methadone					
Methadone	250	12.0263	29	289	Y
EDDP	250	12.0263	27	308	Y
Ketamine					
Ketamine	200	12.0269	8	255	Y
Nor Ketamine	200	12.0269	11	234	Y
Propoxyphene					
Propoxyphene	250	12.0267	25	376	N
Nor propoxyphene	250	12.0267	32	396	N
Mephedrone					
4-methylmethcathinone	200	12.0274	30	285	N
Buprenorphine					
Buprenorphine	5	12.027	32	6.7	Y
Nor Buprenorphine	5	12.027	46.8	6.8	Y
Barbiturates					
Referred Test	150	This assay is referred to one of our trusted partner labs			
Tramadol					
Tramadol	300	12.0266	20	361	N
O-desmethyltramadol	300	12.0266	22	367	N

*Used to assist in the interpretation of results and not normally reported

As for screening tests, non-standard cut-offs should only be used where sufficient justification has been made for the use of other reference values.

Results will normally be reported as either Positive for a named drug or drugs, or Negative for all drugs tested using the cut-off level stated and allowing a coverage factor of 3 standard deviations above the cut-off before reporting a result as positive, this ensures that positive results have at least a 99.7% degree of certainty.

An appropriate comment will be added to assist in the interpretation of results obtained and the medication declared. For accredited analytes, this interpretation relating to consistency of results with medication is

covered by ISO/IEC 17025:2017 accreditation. Opinion and interpretations outside of this are not covered by the ISO/IEC 17025:2017 accreditation. Customers may receive the numerical results of positive drug tests to support disciplinary and appeal procedures.

SALIVA

The standard turnaround time for confirmatory testing is 3-5 working days for samples received by 12:00 midday, unless waiting for authority to proceed. All confirmatory assays are performed by liquid chromatography coupled to a tandem mass spectrometer and using deuterated / isotopically labelled internal standards.

Every sample is analysed with a set of 6 calibration standards, traceable to international reference materials, a blank sample and at least one quality control sample.

Tests are only accepted if a calibration containing at least 4 calibrators and a calibration coefficient of >0.990 is obtained. Additionally, the QC sample must pass a set of rules for accepting QC samples.

When a batch is accepted, individual analytes must have a retention time of ±2.5 percent of the deuterated internal standard, and the ion intensity ratio of the primary (quantification) ion to the secondary (qualifier) ion must be within a defined percentage of the ratio of the nearest standard value, following European guidelines on ion intensity ratios.

As part of the validation process samples collected by our UKAS accredited collection service were compared with samples collected by non SYNLAB collectors and this data has been incorporated into the expanded uncertainty and tabulated as SYNLAB collectors and non SYNLAB collectors.

Drug	Cut-Off ng/ml	SOP Reference No.	95% CI (%) with SYNLAB Collector at Cut-Off	95% CI (%) with non SYNLAB Collector at Cut-Off	Functional Cut off ng/mL – SYNLAB Collections	On UKAS Schedule *Y/N
Opiates Group						
Morphine	40	12.0271	42.7%	54.1%	57.1	Y
Codeine	40	12.0271	46.8%	57.4%	58.7	Y
Dihydrocodeine	40	12.0271	45.3%	56.2%	58.1	Y
6 Mam	4	12.0271	33.4%	47%	5.3	Y
Heroin	22	12.0271	99.8%	105.2%	26.0	N
Acetyl codeine	13	12.0271	97.2%	102.7%	16.9	N
Cocainoics						
Cocaine	23	12.0271	43.3%	54.6%	26.5	Y
Benzoylecgonine	8	12.0271	42.4%	53.8%	11.4	Y
Norcocaine	8	12.0271	96.7%	102.3%	15.7	N
Cocaethylene	8	12.0271	48.9%	59.1%	11.9	Y

Ketamine						
Ketamine	30	12.0271	42%	53.5%	42.6	Y
Nor Ketamine	30	12.0271	48.6%	58.8%	44.6	Y
Mephedrone						
Mephedrone	30	12.0271	47.8%	58.2%	44.3	Y
Amphetamines						
Amphetamine	30	12.0271	29.7%	44.6%	38.9	Y
Methamphetamine	30	12.0271	43%	54.3%	42.9	Y
MDA	30	12.0271	135.2%	139.2%	36.3	N
MDMA	30	12.0271	21.1%	39.3%	70.6	Y
MDEA	30	12.0271	22.5%	40.1%	36.8	Y
Cannabis						
THC	1	12.0272	n/a	n/a	1.3	N
Tramadol						
Tramadol	40	12.0271	38.2%	50.6%	55.3	Y
Methadone						
Methadone	20	12.0271	49.1%	59.3%	29.8	Y
EDDP	20	12.0271	47.1%	57.6%	29.4	Y
Benzodiazepines						
Diazepam	10	12.0271	36.2%	49.1%	13.6	Y
Temazepam	10	12.0271	42.6%	54%	14.3	Y
Oxazepam	10	12.0271	47.4%	57.9%	14.7	Y
Desmethyl Diazepam	10	12.0271	35.7%	48.8%	13.6	Y
Nitrazepam	10	12.0271	194%	196.8%	29.4	N
Alprazolam	10	12.0271	37.3%	49.9%	13.7	Y
Lorazepam	10	12.0271	42.8%	54.2%	14.3	Y

* Accreditation only applies when samples are collected by SYNLAB.

Collection Technicians when working to the accredited saliva collection procedure, use the Quantisal saliva collection device.

As for screening tests, non-standard cut-offs should only be used where sufficient justification has been made for the use of other reference values.

Results will normally be reported as either Positive for a named drug or drugs, or Negative for all drugs tested using the cut-off level stated and allowing a coverage factor of 2 standard deviations above the cut-off before reporting a result as positive, this ensures that positive results have at least a 95% degree of certainty.

An appropriate comment will be added to assist in the interpretation of results obtained and the medication declared. For accredited analytes, this interpretation relating to consistency of results with medication is

covered by ISO/IEC 17025:2017 accreditation (when collected with Quantisal saliva collection device). Opinion and interpretation outside of this are not covered by the ISO/IEC 17025:2017 accreditation. Customers may receive the numerical results of positive drug tests to support disciplinary and appeal procedures.

MEASUREMENT UNCERTAINTY FOR CONFIRMATION TESTING

There is always a degree of variation in any analytical method, and the laboratory takes steps to minimise this variation. Typically, the urine results reported have an Uncertainty of Measurement at the 99.7% confidence interval at the cut-off value and with saliva testing these are typically reported at 95%. Due to the higher uncertainties associated with saliva testing a different coverage factor is used. Results may also be truncated to integers and/or 2 significant figures for ease of reading.

Results will normally be reported as either Positive for a named drug or drugs, or Negative for all drugs tested using the cut-off level stated and allowing a coverage factor before reporting a result as positive.

Addition of the coverage factor to the cut off level provided in the workplace testing guidelines, and that which is reported on the COA, provides the functional cut off. Results equal to or greater than the functional cut off are reported as Positive. Results less than the functional cut off or where the analyte has not been detected are reported as Negative. Use of this coverage factor to provide the functional cut off ensures:

- **Urine:** Coverage factor of 3 standard deviations, this ensures that positive results have at least a 99.7% degree of certainty that the result is greater than the cut off.
- **Saliva:** Coverage factor of 2 standard deviations, this ensures that positive results have at least a 95% degree of certainty that the result is greater than the cut off.

MEASUREMENT UNCERTAINTY FOR CLINICAL TOXICOLOGY

SPMA (ISO/IEC 17025:2017 accredited) – the Uncertainty of Measurement at the 95% confidence interval for 12µmol/mol creatinine is ±2.9µmol/mol creatinine.

DRUGS IN BLOOD ANALYSIS

Preserved or non-preserved whole blood samples can be analysed for clinical purposes. For non-preserved blood samples analysis of cocaine or heroin is not possible and would be rejected. Samples will be tested using the methodology used for Criminal Justice samples. Please refer to Criminal Justice section for more details.

NETWORK RAIL CERTIFICATES / SENTINEL UPLOAD

Network Rail samples collected by SYNLAB's Collection Technicians that are negative for all drugs will be reported as a "PASS" and will be uploaded to sentinel within 24 hours of the final report. Samples that require review by a Medical Review Officer (MRO) may take additional time. Positive results will be uploaded to Sentinel following MRO review. Where the MRO results in a "FAIL", SYNLAB will ensure the result is uploaded within 24 hours.

Requests for Sentinel Uploads should be made to the Duty Manager when booking the collection. The donor telephone number should be provided to the Collection Technician when conducting the collection in order for the MRO to contact them should this be required.

National Insurance numbers are required to be collected during the collection process to enable the result to be uploaded into the Sentinel Database.

MEDICAL REVIEW OFFICER

No interpretation of results in relation to fitness to practice will be made by laboratory staff. A company doctor or MRO may discuss a case to ascertain fitness to practice, and SYNLAB can supply MRO services if required. The MRO may need to discuss the results confidentially with the donor, in which case contact details will be requested along with the company's Drug and Alcohol Policy.

REPORT FORMAT

Test reports comply with the simplified test report format option allowed by ISO/IEC 17025:2017. This simplified report does not include all of the information on the report by ISO/IEC 17025:2017 but as stated in the standard this data is held by the laboratory and available if requested.

WITNESS STATEMENTS / TRIBUNAL / COURT ATTENDANCE

If required, a witness statement can be prepared that can be submitted to tribunals or other proceedings. Witness statements will give more detail and background to the testing and interpretation and can include answers to specific questions and statements that a tribunal might need. Please note that there will be a charge for all witness statements that are written, even if they are no longer required.

Our expert witnesses are also able to give evidence via video link, attendance at tribunals or other proceedings is available upon request. SYNLAB can also provide independent expert witness statements relating to all aspects of drugs of abuse testing.

UNKNOWN SUBSTANCES

Drug paraphernalia, tablets and powders found on site can also be sent to the laboratory for drugs of abuse. The laboratory must be contacted before these samples are sent to determine what analysis can be done and the cost involved as this will vary depending on what has been found. All samples must be safely and securely packaged before sending to the laboratory. Items are not returned as standard and in line with our drugs licence and waste policy illicit substances are destroyed once analysed.

Analysis is conducted by one of our trusted partner laboratories.

Syringes sent with a needle attached may not be accepted for analysis if the needle cannot be removed safely. Unsheathed needles will be rejected and placed into a sharp's container immediately.

RECORD RETENTION AND STORAGE

Samples that are negative for all drugs during primary screening are disposed of 5 working days from receipt. During this period, it may be possible to request additional testing. Samples will be discarded without further notice.

All other samples are stored frozen for 1 year from the date of receipt, with the unopened ‘B’ sample stored with the ‘A’ sample so that they may be re-analysed if there is a challenge to the results.

Quality records and Chain of Custody forms are stored for 8 years after analysis and procedures and training records are stored for a minimum of 30 years.

CHALLENGES TO THE ANALYTICAL PROCESS

If a donor wishes to challenge an analytical result, they should make arrangements through an alternative laboratory accredited to ISO/IEC 17025:2017. Where the testing has been conducted for Network Rail, the chosen laboratory must be a RISQS approved laboratory.

When requested by the referral laboratory, the ‘B’ sample will be released to that laboratory after authorisation has been received from both the donor (or donor’s representative) and a company representative. Customer services can provide a booklet with advice on this process.

REFERRAL TO OTHER LABORATORIES

There may be occasions where samples are sub-contracted to other laboratories to complement the range of analytes offered by SYNLAB. Samples will be referred to laboratories accredited to ISO/IEC 17025:2017 or to other appropriate providers. Customers will be informed of this and consent from the customer is given by signing the Customer Service Level Agreement when setting up or reviewing an account. Customer services should be contacted should this need to be discussed further.

Referral laboratories will be assessed for the suitability of testing, and a full Chain of Custody will be maintained where appropriate. Where a referral laboratory is used, this will be made clear on the Certificate of Analysis.

CRIMINAL JUSTICE TESTING

Testing will be available in relation to section 4 and 5a of the Road Traffic Act (1988) and The Drug Driving (Specified Limits) (England and Wales) Regulations 2014, The Drug Driving (Specified Limits) (England and Wales) (Amendment) Regulations 2015 and The Drug Driving (Specified Limits) (Scotland) Regulations 2019. The laboratory holds accreditation to the Forensic Regulators Codes of Practice and Conduct and ILAC_G19.

SAMPLE TYPE

Samples should be collected into fluoride oxalate bottles as used for alcohol testing. A minimum of 3mL is required, although a full (5mL) bottle is preferred. Samples must be placed in Chain of Custody (evidence) bags and sent to the laboratory as soon as possible. If not sent immediately, samples may be placed in a fridge for up to 4 days before sending or a freezer for longer delays.

Samples should come with a request form (MG DD/E or equivalent) detailing the donor details and case reference number and the requesting officer and force (or solicitor for defence testing).

TRANSPORT OF SAMPLES

Samples are received in the laboratory from couriers or authorised police delivery methods. Samples should be packaged to either the IATA PI650 guidelines, labelled “Biological Substance - Category B” with the UN3373 diamond or packaged to prevent damage or leaks and labelled “Fragile - Exempt Human Specimen”.

The laboratory is open Monday to Friday 08:30 - 17:00 for receipt of samples. Samples will be signed for on receipt and the Chain of Custody documentation completed as appropriate. Immediately on receipt, the sample will be transferred to a secure area so that the Chain of Custody is maintained.

MINIMUM LABELLING CRITERIA

All samples must be labelled so that there is an unequivocal match between the sample and the donor or case, normally through the use of a unique Chain of Custody number. The request form must also contain (as a minimum) the name of the requesting force or solicitor, identification of the donor and the case reference and Chain of Custody reference number

CHAIN OF CUSTODY CHECKS

Samples received in the laboratory are only opened by authorised NPPV3 vetted staff in the secure forensic area. Access to this area is recorded and is restricted to authorised staff.

An internal Chain of Custody file will be started, and all laboratory handling and paperwork recorded in this file.

The sample will be opened, and a laboratory reference number assigned to the sample and paperwork. This laboratory number will be the unique reference number identifying the sample throughout the time the sample is processed in this laboratory. The sample packaging will be retained, and the condition of the sample noted.

Any flaw in the Chain of Custody will be communicated to the requestor at the earliest opportunity.

TESTING PROCESS

The standard turnaround time for confirmatory testing is 10 working days for samples received by 12:00 midday, unless waiting for instructions.

All assays are performed by liquid chromatography coupled to a tandem mass spectrometer for detection after sample precipitation or liquid-liquid extraction and using deuterated / isotopically labelled internal standards. All samples will be analysed in duplicate in line with best practice.

The laboratory cannot accept samples that also require alcohol analysis.

Drug Group	Drug(s) Reported	Legal Limit µ/L	SOP Reference No.	FSR Expanded Uncertainty at S5a 99.7% CI (%)	Common Reporting Threshold µ/L	On UKAS Schedule Y/N
Cocaine	Cocaine	10	12.03200/ 12.0322	35	17	Y
	Benzoylecgonine	50	12.03200/ 12.0322	20	64	Y
Cannabis	Tetrahydrocannabinol	2	12.03210	30	3	Y
Opiates	Morphine	80	12.0322	20	108	Y
	6-monoacetylmorphine	5	12.0322	35	8	Y
Amphetamines	Amphetamine	250	12.0322	20	314	Y
	Methamphetamine	10	12.0322	40	19	Y
	MDMA	10	12.0322	25	15	Y
Benzodiazepines	Diazepam	550	12.0322	20	689	Y
	Nordiazepam	20*	12.0322	19.4	n/a	Y
	Flunitrazepam	300	12.0322	25	402	Y
	Temazepam	1000	12.0322	20	1252	Y
	Clonazepam	50	12.0322	20	64	Y
	Oxazepam	300	12.0322	20	377	Y
	Lorazepam	100	12.0322	25	135	Y
Opioids	Methadone	500	12.0322	25	668	Y
Ketamine	Ketamine	20	12.0322	20	27	Y
Norketamine	Norketamine	20*	12.0322	17.7	n/a	Y

*Nordiazepam and nor ketamine are metabolites of diazepam and ketamine respectively. The legal limit is not defined by legislation and the reporting threshold has been set by the laboratory.

MEASUREMENT UNCERTAINTY FOR CRIMINAL JUSTICE TESTING

There is always a degree of variation in any analytical method, and the laboratory takes steps to minimise this variation. The uncertainty values used have been defined by the Crown Prosecution Service and the Forensic Regulator (and endorsed by the Department for Transport) to give harmonised results across all laboratories and to ensure that there is at least 99% certainty that all results are greater than the limits defined by law. The uncertainty obtained in this laboratory is better than this harmonised value and can be made available on request.

REPORT FORMAT

Test reports comply with the simplified test report format option allowed by ISO/IEC 17025:2017. This simplified report does not include all of the information on the report by ISO/IEC 17025:2017 but as stated in the standard this data is held by the laboratory and available if requested.

Streamlined Forensic Reports MG22(b) meeting the guidelines of the CPS and current Criminal Procedure Rules and Practice Directions can be produced for prosecution samples, containing the quantity detected (for Positive results) or that a test is Negative.

EXPERT REPORTS / STREAMLINED FORENSIC REPORTING STAGE 2 / COURT ATTENDANCE

If required, an expert report or MG22(c) SFR2 report can be prepared that can be submitted to the court via the appropriate channels. Statements will give more detail and background to the testing and interpretation and can include answers to specific questions and statements that a court might need.

Attendance of an expert witness at court is also available upon request. This will be charged in line with the CPS guidelines on remuneration of experts, including travel time. SYNLAB can also provide independent expert reports relating to all aspects of drugs of abuse testing.

RECORD RETENTION AND STORAGE

All samples are stored frozen for 3 years from the date of receipt, with the unopened ‘B’ sample (if held by this laboratory) stored with the ‘A’ sample so that they may be re-analysed if there is a challenge to the results.

Quality records and Chain of Custody records are stored for 8 years after analysis and training records are stored for a minimum of 30 years.

CHALLENGES TO THE ANALYTICAL PROCESS

If a donor wishes to challenge an analytical result, they should make arrangements through an alternative laboratory accredited to ISO/IEC 17025:2017 and ILAC-G19/FSR Codes compliant.

When requested by the referral laboratory, the ‘B’ sample will be released to that laboratory after authorisation has been received. Full Chain of Custody will be maintained throughout.