Service Specification - Toxicology

1. Background

1.1 Haringey Council (the Council) is the lead Authority for the London North Coroners' Jurisdiction, which covers the population of Barnet, Brent, Enfield, Haringey and Harrow. The Council is responsible for meeting all the costs of the service and for arranging a toxicology service to support the needs of the Senior Coroner (the Coroner).

1.2 The Coroner is required in some circumstances to establish the cause of a person's death. The Coroner will ask a pathologist to conduct an examination to establish the cause of death, as part of that examination the pathologist may request that samples taken at examination are submitted for toxicological analysis.

1.3 Toxicological analysis involves the detection, identification and quantification of toxicologically relevant substances and the interpretation of the results, to assist with determining the cause of death.

1.4 The provision of an effective toxicology service supports the Coroner's compliance with the Coroners and Justice Act 2009 (the 2009 Act), the Coroners (Investigation) Regulations 2013 and the Coroners (Inquest Rules) 2013 and the Council's continual commitment to bereaved families.

1.5 The service provider will be responsible for providing appropriate laboratory services on behalf of the Coroner and will be expected to operate to the highest professional standards, maintaining the integrity of test results, reports and comprehensive analysis.

2. Defining the need

2.1 The Service Provider will provide all year-round toxicology analysis and reports service.

2.2 1,739 post mortem examinations (PME's) were carried out in 2023 within the jurisdiction, with approximately 22% having toxicology analysis carried out which includes general screens together with a varying number of specific screens.

2.3 The Coroner also has a responsibility to act in incidents resulting in mass fatalities. In such cases the service provider must be able to respond and support high volume processing in emergency situations. The service provider shall support any out of hours processing in urgent situations.

3. Specification

The Service Provider will:

3.1 Be required to analyse tissue and body fluids obtained during PME for the detection of substances, and assist the Coroner to investigate sudden unexpected deaths in accordance with the 2009 Act.

3.2 Engage in an iterative process with the Coroner and his officers, staff and pathologists as the investigation progresses in order to make the most effective use of samples and resources in order to establish cause of death.

3.3 Supply suitable securable containers, that include the appropriate chemicals, and arrange for the safe and secure collection and transportation of samples from Haringey Public Mortuary, Church Lane, N17 7AA and Brent, Harrow and Barnet mortuary based at Northwick Park Hospital, Watford Road, Wembley, Harrow HA1 3UJ to the laboratory for analysis. The courier must have specific expertise in the transportation of pathology and toxicology samples.

3.4 Provide protective packaging that is appropriate to the sample being collected, prevents contamination of the sample, and ensures no breakages during transportation at no extra cost to the council.

3.5 Ensure all samples are always kept at the appropriate temperature, including both in transit and at the laboratory.

3.6 Ensure the courier presents a form of identification to the mortuary at the time of the sample collection, confirming that they are providing a service on behalf of the Coroner.

3.7 Ensure the courier service obtains verification, in writing or by way of signature from the mortuaries that the samples are complete and intact at the point of collection.

3.8 Ensure the courier checks that all samples are adequately labelled with appropriate details before removal from the mortuary.

3.9 As part of the audit trail send an email to the mortuary and the coroner's office to confirm that the samples have arrived at the service providers Laboratory. The coroner's office will provide a direct dial telephone number (07795 983 701) and an email address (enquiries.northlondon@coronerservice.haringey.gov.uk) for the service provider to raise any queries with regards to samples that need to be clarified before the testing begins, in order to avoid any delays to the test results being notified to the Coroner. Any significant communication on a query should be followed up in writing by the service provider.

3.10 Note that whilst not common, there may be times when a PME is carried out at other mortuaries outside the coroner area, and therefore collection may be required from such mortuaries. This might include but is not exclusive to St Thomas's, Great Ormond Street, Royal London, Kings College, St Marys, Whittington and UCH. The collection procedures that apply to Haringey and Brent, Harrow and Barnet mortuaries will apply to collections from mortuaries outside the coroner area.

3.11 Collect samples when required between the hours of 09:00 to 16:00 for Haringey mortuary and between the hours of 09:00 to 15:00 for Brent, Harrow and Barnet mortuary. The Mortuary will notify the service provider if there are no samples to collect on the usual collection day(s).

3.12 Analyse samples in accordance with the U.K.I.A.F guidelines.

3.13 Ensure that all samples must have a proper and agreed audit trail to a forensic standard from the point of collection, to the laboratory and within the laboratory to ensure security, and traceability (continuity of evidence).

3.14 Provide a full written report within calendar 21 days of the receipt of the sample at the laboratory, findings to include but not limited to: nature and results of any drug or substances found, the acceptable therapeutic, toxic and potential lethal concentrations, the testing methodology employed, the results of any assay tests, any other relevant matters, and interpretation and comment on the findings. In addition, where applicable the actual concentrations found for each drug or alcohol. Should a longer period for analysis be required, any extension must be agreed with the coroner's office within 10 calendar days of receipt of the sample at the laboratory.

3.15 Ensure the interpretation of the findings is of sufficient detail and opinion to assist the pathologist in helping determine the cause of death.

3.16 Ensure that the toxicologist who prepared the report is able to attend court in person (or virtually) when required by the Coroner as a professional witness to present the report findings. Payment for such attendance will be as a professional witness in line with the Coroners Allowances, Fees and Expenses Regulations 2013. The Coroner will provide a minimum of 4 weeks' notice that attendance is required.

3.17 Dispose of the samples post analysis, in line with industry standards and guidelines. This disposal must follow guidance as detailed to comply with the Human Tissue Act. However residual samples should be stored for at least 6 months or until the completion of the inquest by the Coroner to enable re-analysis should this be required for the conclusion of a legal case.

3.18 Respect at all times the confidentiality of the deceased personal data, specimen samples and results of analysis in line with the Data Protection Act and associated legislation and good practice.

3.19 Ensure that no research, teaching or audit will be completed on any Coroners samples without the express written consent of the Coroner and family/next of kin. A clear understanding of the scope/parameters of the research will be required before the Coroner provides consent to research. Where this consent is given, research/case studies must protect the confidentiality of the deceased and their family. In the case of research, the protocol must be approved by a Research Ethics Committee.

4. Toxicology and associated laboratory testing requirements

4.1 The toxicological analysis should include all relevant tests required for the substance under review. To include (but not limited to) ability to sample/screen, blood, urine, stomach, hair and vitreous fluid.

4.2 Tests in blood, urine, liver, muscle, cavity fluid, bile. Samples of blood, urine, vitreous humour and stomach contents are submitted as routine. Samples of cavity blood, liver, muscle and/or bile are submitted when blood, urine and vitreous cannot be obtained. These tests are considered part of a 'routine' full general PME toxicology screen and may be requested either individually or as a complete 'Drugs of Misuse' panel. The constitution of a screening panel may vary with the circumstances of a particular case and be not limited to:

- Ethanol (in blood, vitreous, urine, stomach contents, cavity fluid)
- Methanol, acetone, isopropanol (in blood, urine and vitreous)
- Beta-hydroxybutyrate (in blood/vitreous if acetone raised)
- Glucose (in vitreous and urine)
- Paracetamol
- Salicylates
- Barbiturates
- Benzodiazepines and metabolites
- Cannabinoids and metabolites
- Cocaine and metabolites
- Opiates, opioids (including methadone) and their metabolites
- Phenethylamine groups
- Piperazines, cathinones, tryptamines and indanes
- Nitazines

4.3 Tests in blood, urine, stomach contents, vitreous humour, liver, muscle, cavity fluids, bile that may be requested in addition to a 'Drugs of Misuse' panel. Therapeutic drugs, including but not limited to:

- Antidepressants
- Anticonvulsants
- Antihypertensives
- Antipsychotics
- Anxiolytics
- Insulin and C-Peptide
- Non-opioid analgesics

- The capability to differentiate chiral forms of drugs where necessary, for example *d* & *l* amphetamine

4.4 New Psychoactive Substances (so-called 'Legal Highs'). A wide test range is essential, including but not limited to:

- Mephedrone
- Cannabinoid receptor agonists (such as 'Clockwork orange', 'Exodus') in biological fluids and where necessary in other exhibits.
- Cathinones
- Phenethylamines.
- Ketamine
- Nicotine in biological fluids and, if necessary, in material such as e-cigarette fluid
- Caffeine

4.5 Other poisons but not limited to:

- Organophosphates (e.g. malathion, parathion) (including cholinesterase activity estimations on blood where appropriate)
- Paraquat (N,N'-dimethyl-4,4'-bipyridinium dichloride)
- Ethylene glycol and related compounds and metabolites.

4.6 Tests in blood and/or cavity blood that do not form part of the standard 'Drugs of Misuse' screen but not limited to:

- Carboxyhaemoglobin
- Steroids (both corticosteroids and anabolic steroids, as well as an endogenous "steroid profile" if clinically indicated). A "Urinary Free Cortisol" assay should be part of the laboratory's repertoire in this context.
- Lysergic acid diethylamide (LSD)
- Phencyclidine (PCP)
- Gamma-hydroxybutyric acid (GHB) and related compounds
- Lithium
- Arsenic and other toxic metallic poisons

4.7 Tests in blood and/or lung tissue that do not form part of the standard 'drugs of misuse' screen but not limited to:

- Butane and other volatiles (including fuel gases, glues and solvents)
- Alkyl nitrites ('Poppers' – butyl nitrite, isopropyl nitrite, isobutyl nitrite, amyl nitrite)

4.8 Vitreous biochemistry, but not limited to:

- Urea
- Creatinine

- Glucose
- Beta hydroxybutyate
- Ethanol

4.9 Tests in urine that do not form part of the standard 'drugs of misuse' screen, but not limited to:

- Urinary catecholamines/metanephrines
- Free cortisol

4.10 The service provider must provide a list of what it can and cannot test about illicit drugs.

5. Laboratory facilities

5.1 Access to the laboratory should be limited to authorised persons.

5.2 The laboratory must be equipped with the appropriate calibrated instruments to carry out all the relevant tests/analysis and work to an acceptable scientific standard.

5.3 Laboratory facilities and procedures must allow for the safe handling of potentially infectious and/or toxic biological samples, in a secure environment. The coroners office will inform the service provider if it is believed that any samples might be infectious.

5.4 Laboratory procedures must allow satisfactory detection, identification, and quantification of individual substances.

5.5 All samples are to be stored securely and in a manner that minimises the risk of contamination and degradation and ensuring all samples and information remain confidential.

6. Personnel

6.1 The toxicology laboratory must be led by an appropriately qualified person who is able to act as an expert witness in relation to this field.

6.2 The Laboratory must ensure that all laboratory personnel/technicians are appropriately qualified and trained to carry out toxicological tests.

6.3 Ensure that all laboratory personnel maintain professional competency and skill by monitoring their performance, ensuring training is ongoing.

6.4 The toxicologists will need to ensure they maintain professional awareness and training in relation to emerging science e.g changing legislation and novel psychoactive agents/ Legal highs.

7. Reports

7.1 High quality and comprehensive reports are essential. The service provider must ensure that details of the author and their professional qualification are documented on all analysis reports.

7.2 A copy of each report must be sent to both the Pathologist and the coroner's office.

7.3 All reports must include an overall interpretation of all of the findings, with an explanation as to how they might affect the individual both medically and cognitively. The Council reserves the right to modify reporting requirements as necessary, upon 30 days' written notification to the service provider.

7.4 Clinical terminology should be explained so the coroner and properly interested parties can understand the content of the report.

7.5 All information and data on reports will remain the property of the coroner and shall not be released to other agencies or individuals without prior written consent of the Coroner.

8. Experience, Qualifications and Accreditation

8.1 Toxicologists should be appropriately qualified and certified for example: MSc (Med Sci/Forensic Sci), PhD, BSc, CChem, MRSC, DipMedTox, MRCP, PhD, MScForensic Science, FIBMS, FRCPath, EuSpLM, ERT (European Registered Toxicologist).

8.2 Supervisory staff and those reporting results should have at least 5 years of relevant experience. Their qualification should include relevant higher degrees, such as MSc or PhD in a relevant subject, and/or a basic medical qualification (MB, ChB) as well as a higher professional qualification such as FRCPath, as well as registration with a professional organisation which enforces professional and ethical standards, such as, but not limited to, the General Medical Council, The Royal Pharmaceutical Society or the Royal Society of Chemistry. They must be equipped with the Technical Resources, Ability and Quality Assurance to be able to provide clear and concise reports in a timely manner. They must have systems in place for auditable records of disposal of samples to comply with the Human Tissue Act 2004.

8.3 The laboratory tendering to provide these services should be accredited to ISO 17025 and/or ISO 15189 or an equivalent accreditation throughout the contract period. Exceptionally a laboratory service that can demonstrate compliance with the criteria for toxicology laboratories set out by the UK & Ireland Association of Forensic Toxicologists (UKIAFT) (See Science and Justice 50 (2010) 166–176) may also have their tender considered.

9. Performance management and reporting

9.1 The Councils Contract Manager will monitor the performance of the service provider against the specification to ensure the provision is consistent.

9.2 The service provider will nominate a Responsible Person (RP) to oversee the provision of the contract on its behalf.

9.3 The Councils Contract Manager and the RP will meet at 6 monthly intervals to discuss the service provision and KPI's.

9.4 The service provider will supply a monthly report by the 15th of each month for the preceding month which includes the following:

- Name of deceased/identifier of each sample
- Name of person within the coroner's office dealing with the case
- Date the report was submitted to the coroner
- Date of receipt of the sample at the laboratory
- Type of tests carried out and total cost for each case
- Number of days between sample arrival at the laboratory and the date the report was issued to the coroner.

9.5 A yearly summary of statistics for each type of test carried out by volume, volume of test per month and average timescales for toxicology turnaround.

9.6 If any failings are identified on the part of the service provider, the council or the Coroner, an action plan will be drawn up, discussed, agreed and implemented to improve performance. Deadlines will be agreed and set.

10. Key Performance Indicators

10.1 Quality

KPI	Measurement	Service Level target
Complaints	No of complaints based on service specification and service delivery requirements	100%
Toxicology Reports	Service provider to provide high quality and comprehensive legible reports	100%
Analysis data	Service provider to provide accurate data based on precise analysis and in a timely manner	100%

10.2 Service Delivery

KPI	Measurement	Service Level target
Sample collections	Weekly collection (Wednesday) between the hours of 9am-4pm	100%

Timescales	Contractor to meet the minimum standard timeframes as identified in the specification	100%
Vehicles	Contractor's vehicles must be appropriate to carry samples securely and free from the possibility of interference / contamination	100%
Condition and integrity	Contractor's courier should maintain the condition and integrity of samples during transportation	100%
Present invoice by due date	Invoices presented in a timely manner	100%

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