Quality assurance in forensic Laboratory

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Introduction

The analytical laboratory provides qualitative and quantitative data for use in decision-making. To be valuable, the data must accurately describe the characteristics and concentrations of constituents in the samples submitted to the laboratory, to avoid false positive and false negative.
Laboratories must guarantee that analyses are carried out with state-of-the-art analytical techniques. Methods of analysis should be laid down in Standard Operating Procedures (SOPs). In principle, the laboratory may choose the methods to be applied. Depending on the problem, targeted or non-targeted methods may be used, but it must be guaranteed that the result is reliable.
Laboratory Techniques

- In a forensic-toxicological laboratory appliances must be available which enable an unambiguous identification of individual substances as well as the exact determination of their concentration (qualitative and quantitative analysis).
- Apart from the basic equipment, the presently required appliances in an analytic laboratory generally consist of:
  - Gas chromatography with special detectors such as a nitrogen-specific detector, electron capture and flame ionization detectors or a mass spectrometer,
  - high performance liquid chromatography with special detectors such as a diode array detector, UV-and fluorescence detectors or a mass spectrometer
  - immunochemical and photometric analyses.
- Other procedures or equipment which deliver equivalent results may be applied.
Types of Analysis in forensic laboratory

- Headspace analysis
  - Ethanol and volatiles
- Immunoassays
  - Classes of drugs
- Solvent extractions (GCMS)
  - Alkaline drugs
- Solid phase extractions (GCMS)
  - Acid/Neutral drugs
Instruments:

**Gas chromatography – Mass Spectrum (Triple Quadrupole)**

GC-MS-MS

THERMO
Instruments:

GC-MS Agilent 5975 C
Liquid chromatography – Mass Spectrum
LC-MS-MS
TSQ – VANTAGE
THERMO
Liquid chromatography – Mass Spectrum
LC-MS-MS, TSQ – Quantum, THERMO
Liquid chromatography – Mass Spectrum
LC-MS-MS, ZEVO - TQ, WATERS
Alcohol Analysis

Equipment: Headspace GC-MS

- BLOOD ALCOHOL
- URINE ALCOHOL
Common Alcohols

Carbon-containing compounds with an oxygen-hydrogen (-OH) bond, including:

Methanol : (Toxic)

Ethanol : (Prohibited alcoholic beverages)

Isopropanol : (rubbing alcohol)
Alcohols

* Onset of Effects: Depends on absorption status
  (15 to 90 minutes)

* Duration of Effects: 0.015 gm/100mL on average cleared per hour

* Detectable in Blood: 2-14 hours

* Detectable in Urine: variable (may be >24 hours)
Drug Analysis

Samples are analyzed by two different techniques:

**Screening Test (ELISA)**
- Detects classes of drugs
- Distinguishes negative from presumptive positive samples

**Confirmatory Tests (GC/MS)**
- **Sensitive:** detects very small amounts of drug in a sample
- **Specific:** distinguishes individual drugs
- **State of the art, standard for forensic laboratories**
Eight ELISA Drug Screen Panels

- **PCP**
  - Phencyclidine

- **Opiates**
  - Hydrocodone
  - Codeine
  - Oxycodone

- **Benzoylcegonine**
  - Cocaine/Benzoylcegonine

- **Phenethylamines**
  - Methamphetamine/MDMA

- **Cannabinoids**
  - THC
  - THCA

- **Benzodiazepines**
  - Alprazolam
  - Diazepam
  - Temazepine

- **Barbituates**
  - Phenobarbital
  - Secobarbital
  - Butalbital

- **Carisoprodol**
Drugs Detected in an Alkaline Screen

- Methamphetamine
- Cocaine
- Carisoprodol
- Diazepam
- Alprazolam
- PCP
- Codeine
- Hydrocodone
- Fluoxetine
- Zolpidem
- Trazodone
- Methadone
- Oxycodone
- Citalopram
- MDMA
- Tramadol
- Diphehydramine
- Caffeine
Drugs Detected in an Acid/Neutral Screen

- Butalbital
- Secobarbital
- Pentobarbital
- Carisoprodol
- Meprobamate
DIAZEPAM

- Sedative /Anti-anxiety (CNS Depressant).
- Treatment for Anxiety, Muscle Spasm.
- Possible Effects: Drowsiness, Dizziness, Confusion, Slowed Reaction Time.
- Half-life 29 hours
ZOLPIDEM

- Sedative-Hypnotic (CNS Depressant).
- Short Term Treatment of Insomnia.
- Possible Effects Drowsiness, Dizziness, Fatigue, Confusion.
- Half-life 3 hours
METHAMPHETAMINE

- Sympathomimetic Amine (CNS Stimulant)
- Treatment: Narcolepsy, ADD, Appetite Suppressant.
- Possible Effects: Restlessness, Insomnia, Hyperactivity, Dizziness, Euphoria.
- Half-life 10 hours
Cannabinoids

- Delta-9-tetrahydrocannabinol (Delta-9-THC) Parent compound, main psychoactive component. Detectable in blood from 2 to 4 hours.

- 11-nor Delta-9-THC Metabolite of Delta-9-THC Non psychoactive compound, detectable in blood for several days.
AB Slim

Not suitable for human consumption due to contamination with high level of Toxic heavy metal (Arsenic) and Sibutramine
Example:

Liquid Sample
Contains 2000 ppb of Diazinon
Royal Honey
Containing Synthetic drug Tadalafil
Tadalafil is sexual stimulant (Commericially Cialis)
Quality control – Quality assurance

- **Quality Control (QC):** refers to the measures that must be included during each assay run to verify that the test is working properly.

- **Quality Assurance (QA):** is defined as the overall program that ensures that the final results reported by the laboratory are correct. Quality assurance is about doing the right things in the right way to get the right results.

- “The aim of quality control is simply to ensure that the results generated by the test are correct. However, quality assurance is concerned with much more: that the right test is carried out on the right specimen, and that the right result and right interpretation is delivered to the right person at the right time.”
Quality Assurance

Quality Control
- Certification of Analyst Competence
- Recovery of Known Additions
- Analysis of Standards
- Analysis of Reagent Blanks
- Calibration with Standards
- Analysis of Duplicates
- Maintenance of Control Charts

Quality Assessment
- Evaluation Samples
- Audits and inspections
How is quality achieved?

- Using validated methods.
- Having the necessary equipment and materials and the appropriate
- Employing competent and motivated people who continue their skills during their work.
- Participating in interlaboratory exercises that provide for an external mechanism
- of assessing the performance of a laboratory.
Variables that affect the quality of results

- The educational background and training of the laboratory personnel
- The condition of the specimens (Sampling)
- The controls used in the test runs
- Reagents
- Equipment
- The interpretation of the results
- The reporting of results
Proficiency Test

- **Quality Assessment** - quality assessment (also known as proficiency testing) is a means to determine the quality of the results generated by the laboratory. Quality assessment is a challenge to the effectiveness of the QA and QC programs.
Quality control (QC) samples

- Quality control samples should monitor and document the quality of measurements over the complete measurement series. Combined, they monitor the bias as well as precision.
Liquid chromatography – Mass Spectrum
LC-MS-MS, ZEVO - TQ, WATERS
Quality Control Measures

- Quality control chart (QC Chart)
- Standards and Calibration
- Blanks
- Recovery Studies
- Precision and Accuracy Studies
- Method Detection Limits
Accuracy

- Accuracy is the nearness of a test result to the true value (How well a measurement agrees with an accepted value).
Precision

- Precision is how closely repeated measurements agree with each other.

  (How well a series of measurements agree with each other)
Imprecise and inaccurate

Accurate but imprecise

Precise but inaccurate

Precise and accurate
Analysis of Duplicates

- Assesses precision
Method Detection Limit

“The minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero”
Control Chart ( QC Chart )

- Quality control (QC) measuring device that visually represents the QC data
- Information in a control chart can aid in determining:
  Probable source of measurement variability
  Whether or not a process is in statistical control
Normal Distribution

(Standard Deviation around the Mean)
Confidence Limits

68%
Confidence Limits

-3s  -2s  -1s  10.00  +1s  +2s  +3s

95%
Control Chart

Upper Control Limit
Mean
Lower Control Limit

+3σ
+2σ
+1σ
-1σ
-2σ
-3σ
Quality Control Chart
(Example)
Uncertainty

Uncertainty of a measured value is an interval around that value such that any repetition of the measurement will produce a new result that lies within this interval. This uncertainty interval is assigned by the experimenter following established principles of uncertainty estimation.
Specifity

- The ability of a method to measure solely the component of interest.

- A lack of specificity will affect accuracy
Sensitivity

- The ability to detect small quantities of a measured component.

- Measurements of trace amount and residues.
According to ISO 17025, at least the dates and times of sample collection and sample receipt as well as the period of analysis (beginning and end of analysis) must be given as header data in the results report. If known, the time of the incident must be included. The name of the person responsible for the analysis and external representation must be indicated.
Documentation

- The head of the laboratory is responsible for the written documentation of all methodological instructions used by the laboratory, such as standard operation procedures (SOPs) and procedures for all important operations in the laboratory, as part of the quality management handbook. The instructions should comply with approved quality criteria and must be audited, e.g. within the framework of an accreditation. Methods and procedures must be set up and described in such a way that technical personnel is able to attend to these after adequate training. Any change of regulations should be documented. It must be ensured that the work is carried out exactly according to the actual directives. Methods must be validated. The result of the validation should be documented with the instructions.
summary

- A laboratory is a complex system and all aspects must function properly to achieve quality.
- Start with the easiest, implement in stepwise process.
- Legal limits maybe vary from country to country.
- Forensic examination results play an increasingly important role in bringing many criminal investigations to a successful conclusion. Therefore it is essential to ensure and maintain the highest standards of accuracy in forensic science. In recent years, there has been increased awareness of importance of well documented Quality assurance (QA) programs in forensic laboratories. Quality assurance is about doing the right things in the right way to get the right results and provide reliable evidence for court proceedings.
References

- Scientific Committee Quality Control GTFCh (www.gtfch.org)
- UNODC (United Nations Office on Drugs and Crime)
- Quality assurance in the pathology laboratory, Edited by Maciej J. Bogusz
- Handbook of Analytical Separations, Volume 6, Forensic science, Edited by Maciej J. Bogusz