FORENSIC TOXICOLOGY LABORATORY OFFICE OF CHIEF MEDICAL EXAMINER CITY OF NEW YORK

PREPARATION OF QUALITY CONTROL FOR HPLC ASSAYS

Calf blood, brain and liver are used as negative matrices for respective specimens. Deionized water is used as negative matrix for urine and gastric contents specimens. Validation of negative matrixes, calibrators and controls is entered into the QC/QA database by the QC/QA officer.

CERTIFIED NEGATIVE BLOOD

- 1. Each batch of purchased calf blood (or equivalent) is validated in triplicate (twice by adding the appropriate internal standard and once without the internal standard).
- 2. Refer to the appropriate section of the SOP for the extraction procedures for specific analytes.
- 3. Blood is certified as negative if there are no interfering peaks in the area of targeted analytes. If there are any interfering peaks, blood is extracted again. If interfering peaks still occur, blood is immediately discarded and fresh blood is obtained and validated. Lot numbers are assigned to batch of matrix after the validation is completed.

CERTIFIED NEGATIVE BRAIN

- 4. Label plastic specimen containers. Include sample type, date of preparation, initials.
- 5. Weigh 20 g of tissue and add 40 mL of deionized water. This will make a 1:3 dilution.
- 6. Carefully homogenize the specimen.
- 7. Validate each matrix in triplicate (twice by adding the appropriate internal standard and once without the internal standard.)
- 8. Refer to the appropriate section of the SOP for the extraction procedures for specific analytes. Brain homogenates are certified as negative if there are no interfering peaks in the area of targeted analytes. If there are any interfering peaks, brain and/or liver are extracted again. If interfering peaks still occur, matrix is immediately discarded and fresh brain and/or liver is obtained and validated. Lot numbers are assigned to batch of matrix after the validation

CERTIFIED NEGATIVE LIVER

- 1. Label plastic specimen containers. Include sample type, date of preparation, initials.
- 2. Weigh 15 g of tissue and add 60 mL of deionized water. This will make a 1:5 dilution.
- 3. Carefully homogenize the specimen.
- 4. Validate each matrix in triplicate (twice by adding the appropriate internal standard and once without the internal standard.)
- 5. Refer to the appropriate section of the SOP for the extraction procedures for specific analytes.

6. Liver homogenates are certified as negative if there are no interfering peaks in the area of targeted analytes. If there are any interfering peaks, brain and/or liver are extracted again. If interfering peaks still occur, matrix is immediately discarded and fresh brain and/or liver is obtained and validated. Lot numbers are assigned to batch of matrix after the validation is completed.

VALIDATION OF CALIBRATOR AND CONTROL STOCK SOLUTIONS

- 1. Remove calibrator and control stock solutions from refrigerator and let come to room temperature.
- 2. Once the solutions equilibrate to room temperature, follow the extraction procedure for the appropriate analytes (refer to SOP for extraction.)
- 3. Validate new calibrator and control solutions by analyzing in triplicate in a batch which includes previously validated calibrators and controls.

ACCEPTANCE CRITERIA

- 1. Retention time of the peak(s) of interest must match the retention time of analytes in the calibrator(s) ± 2 %.
- 2. UV spectra of the analytes in question must have the same absorbance curve as the corresponding analytes in the calibrator(s).
- 3. There must be no interfering peaks in the area of target analytes.
- 4. The concentration of the target analytes must be within \pm 20% of the weighed in target.

RECORDING QC VALIDATION RESULTS

- 1. All validation results are submitted to the QC/QA supervisor.
- 2. Concentrations for all analytes in the low and high controls are entered on a Levy-Jennings chart.

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