WORK INSTRUCTIONS

3.9.3 Quantitation of Basic and Neutral Drug Compounds in Blood

QUALITY ASSURANCE MATERIAL

Working Drug Standard Solutions
Standards for the preparation calibrator and control must be obtained through different vendors. Working drug standard solutions are stable for 6 months when stored at 4°C.

10ng/mL
Add 100.0μL each 1mg/mL Drug-of-Interest Stock Solution to ≅9mL Methanol in a 10mL volumetric class A flask. QS to 10mL.

1ng/mL
Add 1.0mL 10ng/μL working solution to ≅5mL Methanol in a 10mL volumetric class A flask. QS to 10mL.

Calibrator Preparation
Add the volume of working standard to appropriate tube as indicated below.

Level	ng/mL	Working Solution (ng/μL)	Volume to add (μL)
1	25	1	25
2	50	1	50
3	100	1	100
4	250	10	25
5	500	10	50
6	1000	10	100

Spiked Positive Control Preparation
Add the volume of working standard to appropriate tube as indicated below.

ng/mL	Working Solution (ng/μL)	Volume to add (μL)
75	1	75
750	10	75

1.0ng/μL Working Internal Standard Solution
Add 10.0μL each 1mg/mL (1000ng/μL) or 100μL 100μg/mL (0.1μg/μL) Stock Solution to to ≅9mL Methanol in a 10mL volumetric class A flask . QS to 10mL. Solution if stable for 6 months when stored at at 4°C.

WORK INSTRUCTIONS

3.9.3 Quantitation of Basic and Neutral Drug Compounds in Blood