

WORK INSTRUCTIONS

3.9.2 Quantitation of Strongly Basic 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 100.0 μ L each 1mg/mL Drug-of-Interest Stock Solution to \approx 9mL Methanol in a 10mL volumetric class A flask. QS to 10mL.

1ng/mL

Add 1.0mL 10ng/ μ L working solution to \approx 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/ μ L)	Volume to add (μ L)
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.

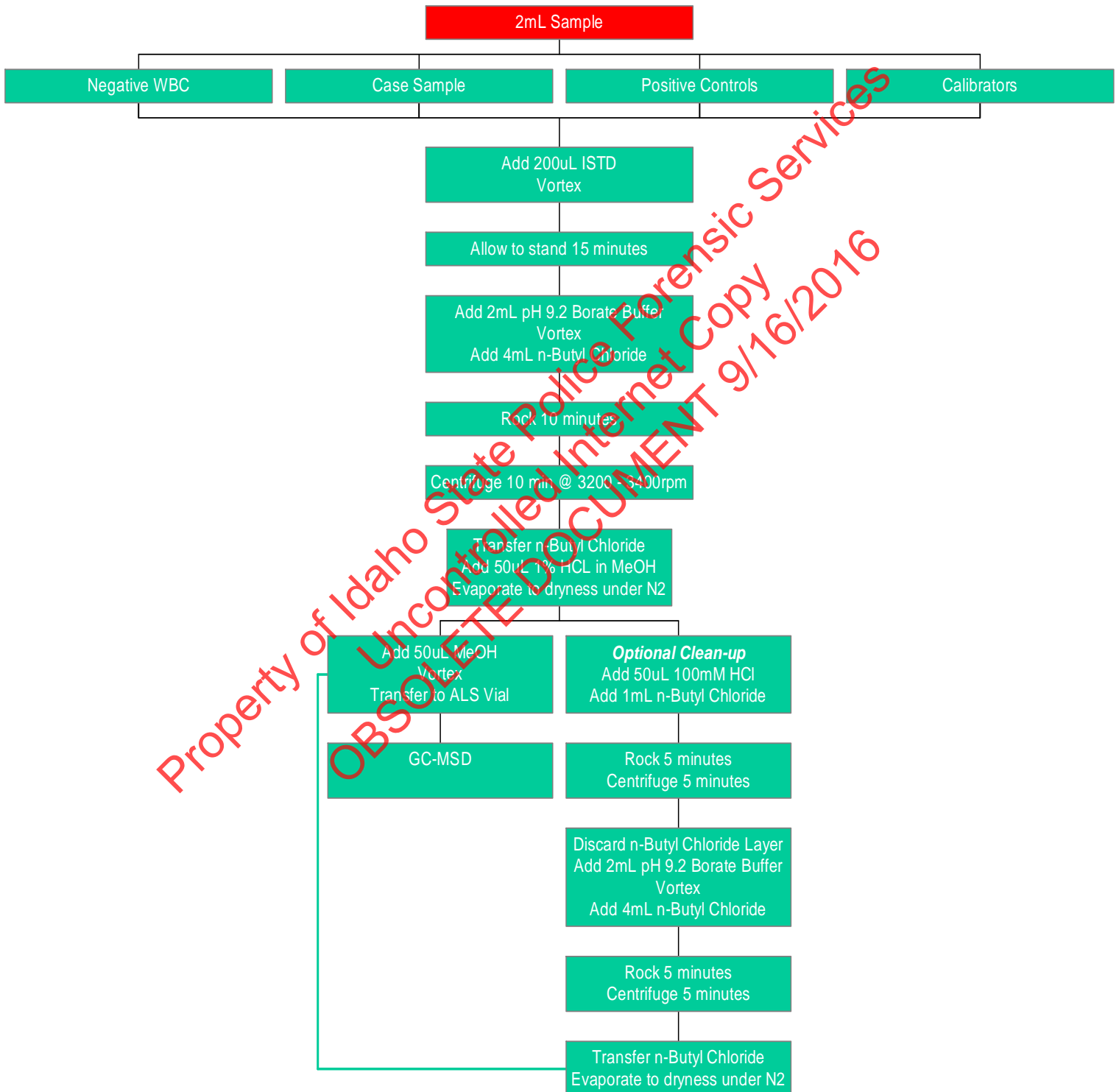
ng/mL	Working Solution (ng/ μ L)	Volume to add (μ L)
75	1	75
750	10	75

1.0ng/ μ L Working Internal Standard Solution

Add 10.0 μ L each 1mg/mL (1000ng/ μ L) or 100 μ L 100 μ g/mL (0.1 μ g/ μ L) Stock Solution to to \approx 9mL Methanol in a 10mL volumetric class A flask. QS to 10mL. Solution if stable for 6 months when stored at at 4°C.

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