MEDICA EASYQC DRUGS OF ABUSE

IVD CE

REF 14762 1 X 5 ML BOTTLE, LEVEL A

BUPRENORPHINE (BUP) NEGATIVE QC MATERIAL LEVEL A

The bottle contains 5.0 mL human urine based ready-to-use liquid spiked with a known concentration of norbuprenorphine.

INTENDED USE

The Medica Buprenorphine Negative Level A Control is intended for in-vitro diagnostic use for the quality control testing in the buprenorphine assay, which is used on the EasyRA for the qualitative determination of buprenorphine in urine.

SAFETY PRECAUTIONS AND WARNINGS

1. The human based material from which this product has been derived has not been tested for the presence of antibodies to HIV, the hepatitis antigens, or anti-hepatitis antibodies. This material and all patient samples should be handled and disposed of as though they are capable of transmitting infectious diseases.

2. The Buprenorphine Negative Level A Control contains sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing, always flush with copious volumes of water to prevent azide build-up

3. Do not use the QC beyond the expiration date.

4. The bottle containing this QC should be tightly capped and refrigerated when not in use to prevent evaporation.

INSTRUCTIONS FOR HANDLING, STORAGE AND STABILITY

The QC material is stable until the expiration date on the label if stored at 2^{o} – 8^{o}C. The QC should not be frozen or exposed to temperatures above 32^{o}C.

INSTRUCTIONS FOR USE

The QC material is ready-to-use. Remove bottle cap. Dispense six drops of material into a sample cup and proceed with instructions in the EasyRA Operator's Manual.

VALUE ASSIGNMENT

The table below contains the assigned values for the Buprenorphine Negative Level A Control:

Lot No. XXXXX Expires: XXXX-XX-XX

Analyte:	Assigned Value	Units
Buprenorphine	7 (- Neg)	ng/mL

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