MEDICA EASYQC DRUGS OF ABUSE   [IVD] CE

REF 14780   1 X 5 ML BOTTLE, LEVEL A

BENZODIAZEPINE (BZO) NEGATIVE QC MATERIAL LEVEL A

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

INTENDED USE

The Medica Benzodiazepine Negative Level A Control is intended for in-vitro diagnostic use for the quality control testing in the benzodiazepine assay, which is used on the EasyRA for the qualitative determination of benzodiazepine 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 quality control material 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 $2^o – 8^oC$. The QC should not be frozen or exposed to temperatures above 32^oC.

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 Benzodiazepine Negative Level A Control:

Lot No. XXXXX   Expires: XXXX-XX-XX

Analyte:	Assigned Value	Units
Benzodiazepine	100 (- Neg)	ng/mL

Manufactured for:

Medica Corporation, 5 Oak Park Drive
Bedford, MA 01730-1413 USA

EC | REP Emergo Europe, Prinsessegracht 20
2514 AP The Hague, The Netherlands

008922-901 R0