

# DRI® Fentanyl Assay Calibrators and Controls

For In Vitro Diagnostic Use

**REF** 1388, DRI® Negative calibrator (25 mL)  
10016485, DRI® Fentanyl 2 ng/mL calibrator (10 mL)  
10016484, DRI® Fentanyl 1 ng/mL control (25 mL)  
10016486, DRI® Fentanyl 3 ng/mL control (25 mL)

## Intended Use

The DRI® Fentanyl calibrators are intended for the calibration of the DRI® Fentanyl Assay. The DRI® Fentanyl controls are used to validate the DRI® Fentanyl Assay calibration.

## Description of DRI® Fentanyl calibrators and controls

The DRI® Fentanyl calibrators and controls are liquid ready-to-use. They are prepared by spiking known quantities of fentanyl into negative human urine matrix.

The calibrators and controls are sold separately. Each laboratory should establish its own acceptable control ranges.

## Precautions and Warning

The DRI® Fentanyl calibrators and controls are for in vitro diagnostic use only. They are harmful if swallowed. The calibrators and controls contain  $\leq 0.09\%$  sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up. The calibrators and controls are prepared from non-sterile human urine. **Handle the calibrators and controls as if they were potentially infectious.**

**DANGER:** DRI Fentanyl Calibrators and Controls contain  $\leq 0.3\%$  bovine serum albumin (BSA).

H317 - May cause allergic skin reaction.

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Avoid breathing mist or vapor. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. If on skin: Wash with plenty of soap and water. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If skin irritation or rash occurs: Get medical advice/attention. If experiencing respiratory symptoms: call a POISON CENTER or doctor/physician. Wash contaminated clothing before reuse. Dispose of contents/container to location in accordance with local/regional/national/international regulations.

Do not use the calibrators and controls beyond their expiration dates printed on their respective labels.

## Storage

The calibrators and controls should be stored refrigerated at 2° to 8°C when not in use. They are stable until the expiration date indicated on the box label.

## Assay Procedure

For instructions, refer to the instrument specific application sheets for the DRI® Fentanyl Assay.

## Results and Expected Values

The DRI Fentanyl assay is for qualitative use only. The 2 ng/mL calibrator is used as a cutoff reference for distinguishing "positive" from "negative" samples. A sample that exhibits a change in absorbance value ( $\Delta A$ ) equal to or greater than that obtained with the cutoff calibrator is considered positive. A sample that exhibits a change in absorbance value ( $\Delta A$ ) lower than that obtained with the cutoff calibrator is considered negative. The controls should be used in parallel to validate the calibration. The results of the controls should be within the range established by each laboratory.

## Quality Control

All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

## Limitations

The DRI® Fentanyl calibrators and controls are designed for use with the DRI® Fentanyl Assay for the detection of fentanyl in human urine.

## Bibliography

DRI® Fentanyl Assay Package Insert.

**REF** Catalog Number

**Cont.** Contents


 Manufacturer

 Temperature Limitation

 Caution

**LOT** Lot Number

**EC REP** Authorized Representative In The European Community

 Consult Instructions for Use

 Use By

**CALIBRATOR** Calibrator

**CONTROL** Control

**IVD** For In Vitro Diagnostic Use

 CE Marking of Conformity

  
Microgenics Corporation  
46500 Kato Road  
Fremont, CA 94538 USA  
US Customer and  
Technical Support:  
1-800-232-3342



**EC REP**  
B-R-A-H-M-S GmbH  
Neuendorfstrasse 25  
16761 Hennigsdorf, Germany

## Other countries:

Please contact your local Thermo Fisher Scientific representative.