

# Mynarix

PRESCRIBING INFORMATION

## HbA1c Immunoassay Control

Diagnostics | Control | Rx only

A bi-level quality control material for monitoring precision and accuracy of HbA1c immunoassay systems.

### 1. Composition

Analyte: Hemoglobin A1c

Levels: Normal and elevated

Presentation: 6 x 1.0 mL lyophilized

Storage: 2-8 deg C

### 2. Indications

Assayed quality control to verify HbA1c immunoassay performance. Not a calibrator or for treatment decisions.

### 3. Dosage and Administration

Reconstitute with the specified volume of deionized water, mix gently and equilibrate before use.

### 4. Mechanism of Action

Assigned values are traceable to recognised reference measurement procedures with lot-specific value sheets.

### 5. Warnings and Precautions

- For in-vitro diagnostic use by trained personnel only.
- Handle per standard laboratory biosafety practice.
- Do not use beyond stated open-vial or expiry stability.

### 6. Storage

Store lyophilized product at 2-8 deg C. Reconstituted control is stable per the value sheet when capped at 2-8 deg C.

### 7. Manufacturer

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For informational purposes only and not a substitute for professional medical advice. Approved indications and formulations vary by market.