

ALDOLASE LEVEL 2 CONTROL (ALS CONTROL 2)

CAT. NO. AD 5001 **LOT NO.** 513AD
SIZE: 3 x 1 ml **EXPIRY:** 2028-09-28
GTIN: 05055273200096

INTENDED USE

The Aldolase Level 2 Control Serum is intended for *in vitro* diagnostic use in the Quality Control of the Aldolase assay AD189.

DEVICE DESCRIPTION

The Aldolase Level 2 Control is composed of human serum. An assigned value and range is supplied for Aldolase.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Human source material from which this product has been derived has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY

Unopened: Store at +2°C to +8°C. Stable to expiration date printed on individual vials.

Opened: The control serum is stable for 5 days when reconstituted and stored at +2°C to +8°C.

PREPARATION FOR USE

The Aldolase Level 2 Control is supplied lyophilized.

1. Carefully reconstitute each vial of control serum with 1 ml of distilled water. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.
2. Refer to the control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

IMPORTANT NOTE

Stabilisation is not required.

MATERIALS PROVIDED

Aldolase Level 2 Control 3 x 1 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric Pipette

ASSIGNED VALUES

Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

Values are assigned from Internal testing at Randox Laboratories Ltd. and compared to a master lot stored at -80°C.

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Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

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Method

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Method		Aldolase Level 2 Control (ALS CONTROL 2)					
Lot. No: 513AD Cat. No: AD5001 Expiry: 2028/09/28							
Size: 3 x 1 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Aldolase	U/l	8.39	6.29	10.5	1.06	2.11	Enzymatic UV method