

ALDOLASE LEVEL 3 CONTROL (ALS CONTROL 3)

CAT. NO.	AD 5002	LOT NO.	516AD
SIZE:	3 x 1 ml	EXPIRY:	2029-01-28
GTIN:	05055273200102		

INTENDED USE

The Aldolase Control is intended for use with *in vitro* diagnostic assays for the quantitative determination of Aldolase. The device is assayed with target values and is suitable for use on clinical chemistry analysers.

Aldolase Control is for use by trained laboratory professionals and can be used in determining the precision of testing systems and in identifying sources of variation.

DEVICE DESCRIPTION

The Aldolase Control is supplied at 2 levels, level 2 and 3. Aldolase Control Level 3 is composed of human serum with added stabilisers and preservatives and is supplied lyophilised.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. For use only by trained personnel. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents. Wear PPE when handling this product. Any spillages must be treated immediately with a suitable disinfectant such as 1% Virkon solution. Exercise aerosol-minimizing techniques. Dispose of any discarded materials in accordance with the requirements of your local waste management authorities.

Other hazards:



Biohazard

Biological source material. Treat as potentially infectious.

Product contains material of human origin. This material has been tested for the HIV (Human Immunodeficiency Virus) Antibody, HBs Ag and HCV and found to be non-reactive. However as 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 disease and disposed of accordingly.

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher. This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Safety Data Sheets are available on request.

If there is damage to the material upon arrival, the appearance is not as expected or the material is not performing as it should please contact Randox Laboratories Technical Services, Northern Ireland, telephone +44 (0) 28 9445 1070 or email technical.services@randox.com.

STORAGE AND STABILITY

OPENED: Store refrigerated (+2°C to +8°C). The Aldolase Control is stable for 5 days at +2°C to +8°C, if capped in the original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

UNOPENED: Store refrigerated (+2°C to +8°C). The Aldolase Control is stable up to the expiration date printed on individual vials.

PREPARATION FOR USE

The Aldolase Control is supplied lyophilised.

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 3 Control 3 x 1 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette
Distilled Water

LIMITATIONS

1. This product is provided for quality assurance only and should not be used for calibration purposes.
2. This product should not be used beyond the expiration date.
3. This product should not be used in evidence of microbial contamination or high turbidity.

VALUE ASSIGNMENT

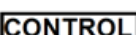
Values are assigned from internal testing conducted at Randox Laboratories Ltd. Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

TECHNICAL ASSISTANCE

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established. Contact Randox Laboratories Technical Services, Northern Ireland, telephone +44 (0) 28 9445 1070 or email technical.services@randox.com

SYMBOL GLOSSARY

Randox Laboratories uses the following symbols, which may appear on the product labelling.

Symbol	Description
	Catalogue number
	Batch code
	Control
	Use-by date
	Manufacturer
	Authorized representative in the European Community
	Consult IFU
	<i>In vitro</i> diagnostic medical device
	CE Marking
	CE Marking with Notified Body
RxOnly	Prescription device (US only)
	Temperature limit
	Do not re-use
YY/MM/DD	Date format (year/month/day)
	UK CA mark
	Keep away from sunlight
	Biological risks
	This way up
	Caution
	Do not use if package is damaged and consult instructions for use

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Method			Aldolase Level 3 Control (ALS CONTROL 3)				
Lot. No: 516AD Cat. No: AD5002 Expiry: 2029/01/28							
Size: 3 x 1 ml			Range				
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Aldolase	U/l	21.6	16.2	27.0	2.70	5.40	Enzymatic UV method