ALDOLASE

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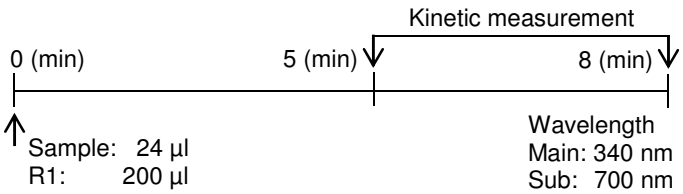
DETERMINATION OF FRUCTOSE-1.6-BISPHOSPHATE ALDOLASE (EC 4.1.2.13) IN SERUM OR PLASMA

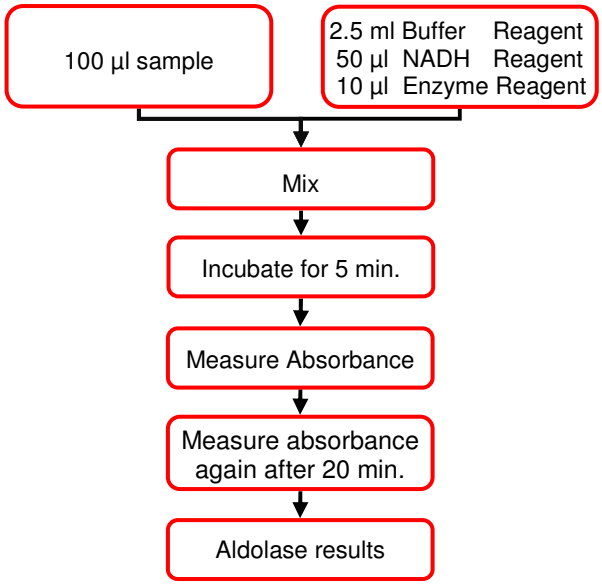
Enzymatic method
Suitable for all analyzers – 500 tests
Product insert with instructions for automated and manual procedures
Stability > 4 years after production
Aldolase controls available

Stability working solution:
4 weeks (2 – 6°C)
2 months (-20°C)

Settings for automatic analyzers



Manual procedure



Precision (inter/intra)

	Repeatability (Inter)	Reproducibility (Intra)
Mean	6.55 U/l	6.55 U/l
Standard deviation	0.18 U/l	0.12 U/l
Variation coefficient	2.75 %	1.83 %

Linearity: 45 U/l **Mean CV's: 1.77%** **Mean recovery: 98.1%**

Correlation compared to other manufacturers: 0.977

Product name	Product no.	Quantity
Aldolase Reagent Set	2904	40 -500 tests
Aldolase Calibrator	3008	1 x 1 ml
Aldolase Control Normal Level	2908	10 x 1 ml
Aldolase Control High Level	3007	10 x 1 ml

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- *Enzymatic Method*
- *Suitable for all analyzers – 500 tests*
- *Product insert with instructions for automated and manual procedures*
- *Stability > 4 years after production*
- *Aldolase controls available*
- *Wavelength 340, 334, 365 nm*

Products	Product no.	Quantity
Aldolase Reagent Set	2904	40 manual 500 automated
Aldolase Calibrator	3008	1 x 1 ml
Aldolase Control Normal Level	2908	10 x 1 ml
Aldolase Control High Level	3007	10 x 1 ml

SUMMARY

ASSAY PRINCIPLE

$$F-1.6-P2 \xrightarrow{\text{Aldolase}} GAP + DAP$$

$$GAP \xrightarrow{\text{TIM}} DAP$$

$$2\,DAP + 2\,NADH + 2\,H^{+} \xrightarrow{\text{GDH}} Glycerol\text{-}1\text{-}phosphate + 2\,NAD^{+}$$

SAMPLE MATERIAL
Serum, heparinized plasma or EDTA plasma

LINEARITY
Up to 45 U/l

NORMAL VALUE
Up to 7.6 U/l (37ºC)
Up to 3.1 U/l (25ºC)

QUALITY CONTROL

Products	Product no.	Quantity
Aldolase Control Normal Level	2908	10 x 1 ml
Aldolase Control High Level	3007	10 x 1 ml

QUANTITY OF DETERMINATIONS
According to product insert of Aldolase Reagent Set (2904):
Procedure
- Manual : 40 tests
- Automated : 500 tests

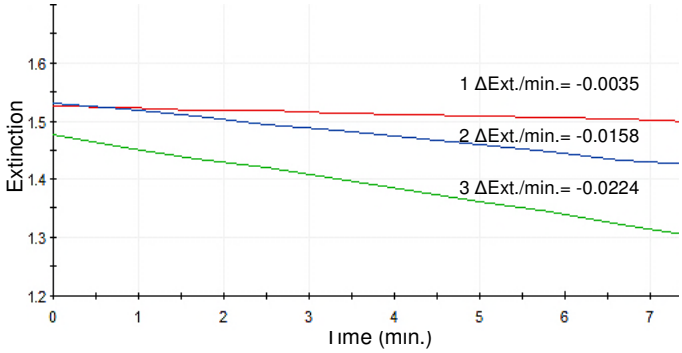
NOTES
1. For in vitro diagnostic use only.
2. For professional use only.
3. Always contact INstruchemie for the complete product insert and latest edition.

ALDOLASE

ACTIVITY MEASUREMENTS

The activities of a normal (1), high (2) and extra high (3) human serum were measured with a spectrophotometer.

Aldolase kinetic measurements



TEST CONDITIONS

All tests were conducted under the following conditions:

Temperature	:	37 °C
Wavelength	:	340 nm
Light path	:	Analyzer: 0.7 cm / Manual: 1.0 cm
Blank	:	Reagent blank
Sample	:	Serum

SENSITIVITY

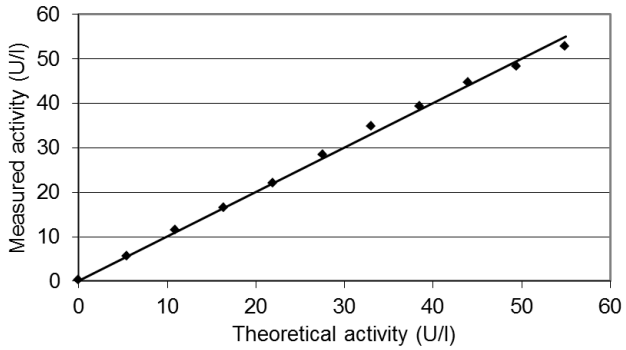
The sensitivity (limit of detection) was determined by measuring human control material (Aldolase activity = 0 U/l) 20 times.

Sensitivity = 3 x standard deviation = 3 x 0.17 = 0.51 U/l

LINEARITY

The Aldolase assay is linear up to 45 U/l.

Llinearity measurements with an automatic analyzer



RECOVERY

The recovery is determined by measuring the aldolase activity in spiked human sera 10 times using an automatic analyzer.

Recovery:

Added aldolase (U/l)	Measured (U/l)	Recovery (%)
4.12	4.05	98.3
10.41	10.20	98.0
25.94	25.39	97.9

PRECISION

The precision is determined by measuring a human serum and Aldolase Calibrator 10 times a day (repeatability) for 5 consecutive days (reproducibility), using an automatic analyzer.

Repeatability:

	Sample (U/l)	Calibrator (U/l)
Mean	6.55	12.47
Standard deviation	0.18	0.17
Variation coefficient	2.75	1.36

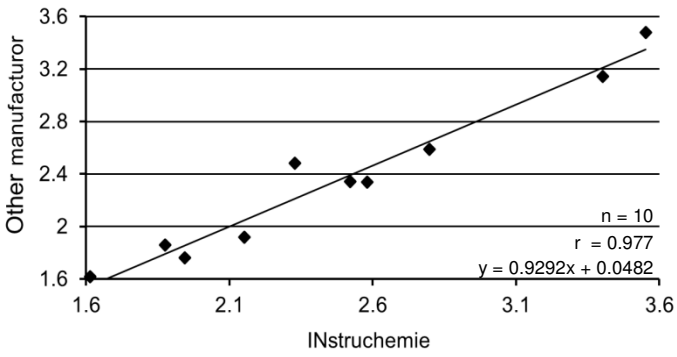
Reproducibility:

	Sample (U/l)	Calibrator (U/l)
Mean	6.55	12.48
Standard deviation	0.12	0.14
Variation coefficient	1.83	1.12

CORRELATION

Pearsons' correlation is determined by measuring the Aldolase activity in multiple human sera with reagent of INstruchemie and reagent from another manufacturer.

Correlation measured with an automatic analyzer (U/l)



Printed in the Netherlands, February 2015, Edition 4.0

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