



G-6-PDH

DETERMINATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE (EC 1.1.1.49) IN ERYTHROCYTES HAEMOLYSATE

Enzymatic method

Suitable for all analyzers – 300 tests

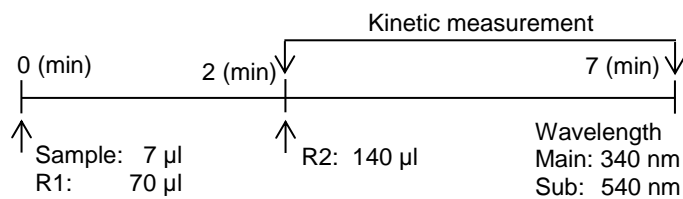
Product insert with instructions for automated and manual procedures

Stability reagents > 8 years after production

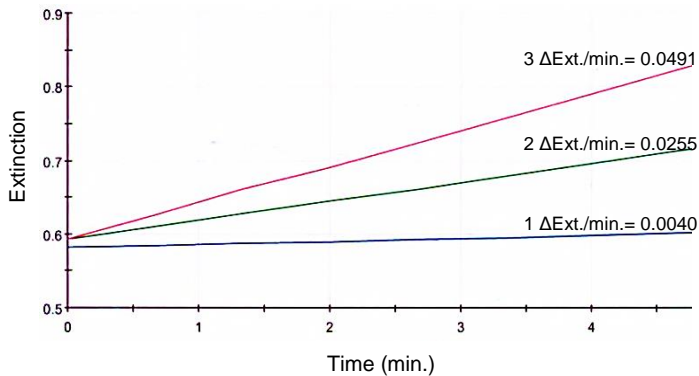
G-6-PDH controls available

**G-6PDH & PK in 1 sample
Haemolysate 8 hours stable**

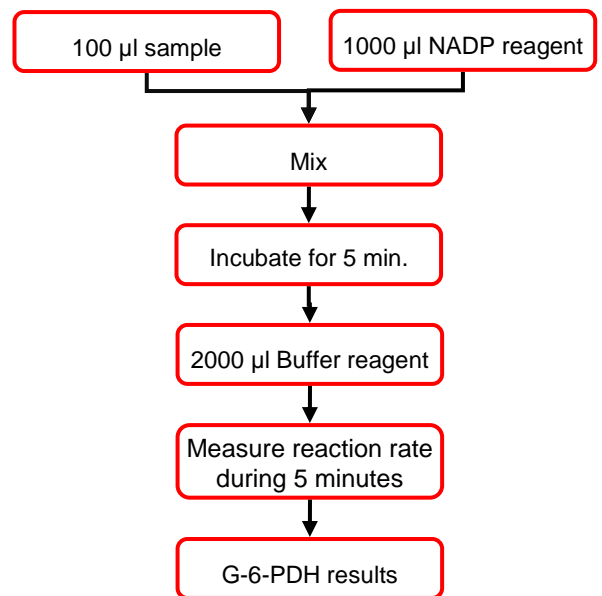
Settings for automatic analyzers



G-6-PDH kinetic measurements



Manual procedure



Linearity: 4500 U/l

Mean CV's: 2.28%

Mean recovery: 99.6%

Correlation compared to other manufacturers: 0.991

Product name	Product no.	Quantity
G-6-PDH Reagent Set	2958	25 -300 tests
PK/G-6-PDH Calibrator	2971	1 x 500 µl
G-6-PDH Control Deficient Level	2961	1 x 500 µl
G-6-PDH Control Normal Level	2963	1 x 500 µl
G-6-PDH Control High Level	2962	1 x 500 µl
PK/G-6-PDH Digitonin Hemolyzing Reagent	3028	1 x 60 ml





G-6-PDH

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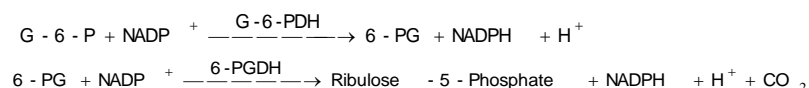
- Enzymatic method
- Suitable for all analyzers – 300 tests
- Product insert with instructions for automated and manual procedures
- Stability reagents > 8 years after production
- G-6-PDH controls available
- Wavelength 340, 334, 365 nm
- After preparing Haemolysate determine:
G-6-PDH and PK in one sample



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G-6-PDH Reagent Set	2958	25 - 300 tests
PK / G-6-PDH Calibrator	2971	1 x 500 µl
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SUMMARY

ASSAY PRINCIPLE



SAMPLE MATERIAL

Whole Blood, collected with EDTA, heparine or CPD (HAEMOLYSATE METHOD)

LINEARITY

Up to 4500 Units/liter.

EXPECTED VALUES

4.2 – 6.9 Units/gram Hb (30 °C)

6.4 – 10.4 Units/gram Hb (37 °C)

QUALITY CONTROL

Products	Product no.	Quantity
G-6-PDH Control Deficient Level	2961	1 x 500 µl
G-6-PDH Control Normal Level	2963	1 x 500 µl
G-6-PDH Control High Level	2962	1 x 500 µl

QUANTITY OF DETERMINATIONS

Procedure

- Manual : 25 tests
- Automated : 300 tests

NOTES

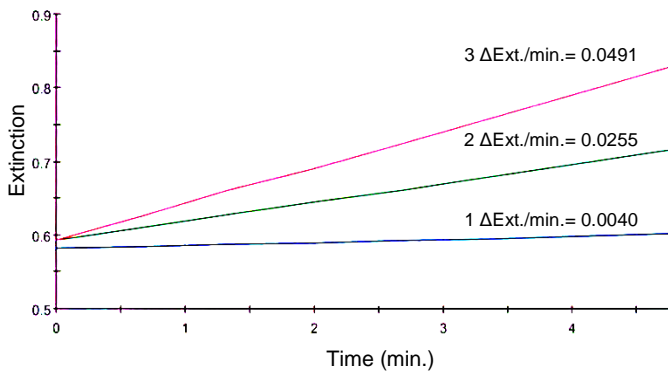
1. For in vitro diagnostic use only.
2. For professional use only.
3. Contact INstru**chemie** for the complete validation report and the latest edition product insert.



ACTIVITY MEASUREMENT

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

G6PDH 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 : Haemolysate

SENSITIVITY

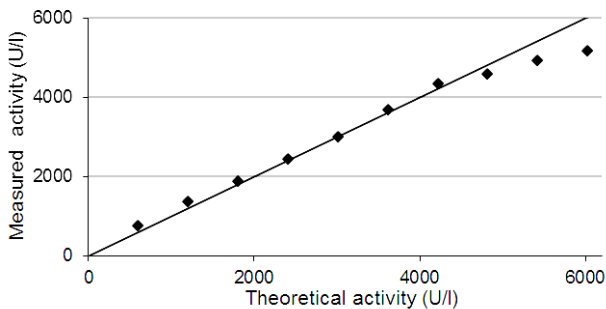
The sensitivity (limit of detection) was determined by measuring human control material (G6PDH activity = 0 U/l) 20 times.

Sensitivity = 3 x standard deviation = 3 x 9 = 27 U/l

LINEARITY

The G6PDH assay is linear up to 4500 U/l.

G6PDH linearity measurements with an automatic analyzer



RECOVERY

The recovery is determined by measuring the G6PDH activity in spiked human hemolysates 10 times using an automatic analyzer.

Recovery:

Added G6PDH (U/l)	Measured (U/l)	Recovery (%)
551	562	102.0
1309	1295	98.9
2067	2026	98.0

PRECISION

The precision is determined by measuring a human haemolysate and G6PDH Control Normal Level 10 times a day (repeatability) for 5 consecutive days (reproducibility), using an automatic analyzer.

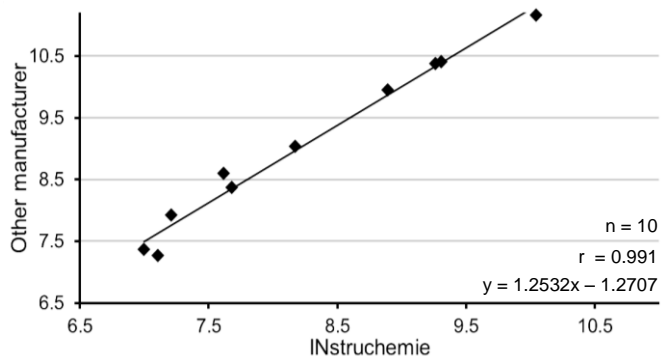
<i>Repeatability:</i>		
	Sample (U/g Hb)	Control (U/l)
Mean	6.4	1169
Standard deviation	0.10	25.6
Variation coefficient	1.6	2.2

<i>Reproducibility:</i>		
	Sample (U/g Hb)	Control (U/l)
Mean	6.4	1115
Standard deviation	0.15	33.0
Variation coefficient	2.3	3.0

CORRELATION

Pearsons' correlation is determined by measuring the G6PDH activity in multiple human haemolysates with reagent of INstruChemie and reagent from another manufacturer.

Correlation measured with an automatic analyzer (U/g Hb)





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