



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

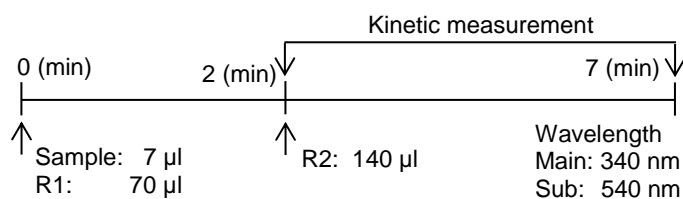
Product insert with instructions for automated and manual procedures

Stability reagents > 8 years after production

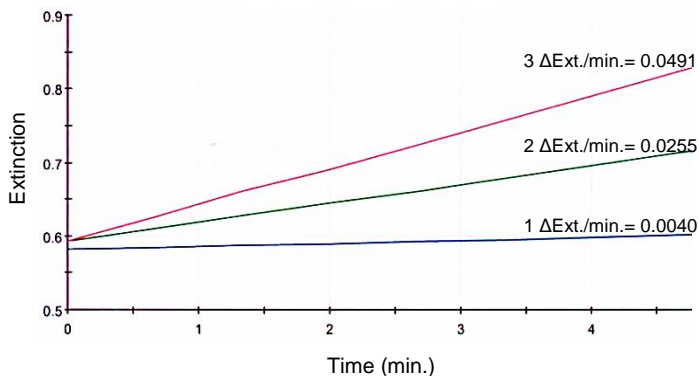
PK / G-6-PDH controls available

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

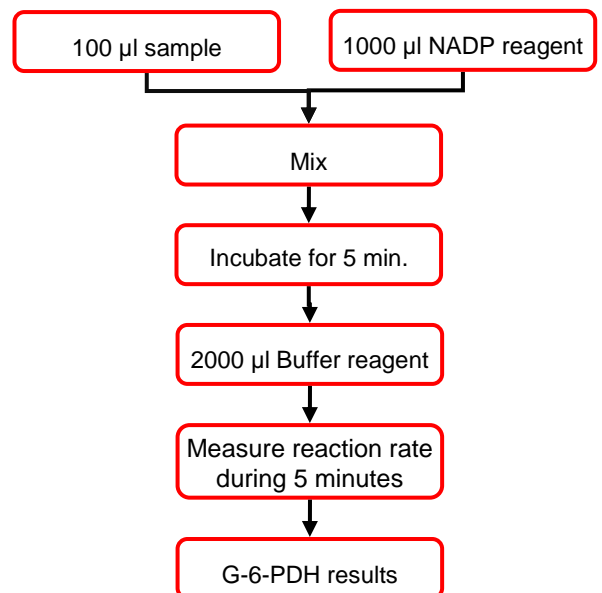
Settings for automatic analyzers



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
PK / G-6-PDH Control Deficient Level	3141	1 x 500 µl
PK/ G-6-PDH Control Normal Level	3142	1 x 500 µl
PK / G-6-PDH Control High Level	3143	1 x 500 µl
PK / G-6-PDH Digitonin Hemolyzing Reagent	3028	1 x 60 ml





G-6-PDH

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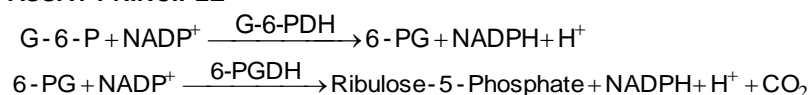
- Enzymatic method
- Suitable for all analyzers – 300 tests
- Product insert with instructions for automated and manual procedures
- Stability reagents > 8 years after production
- PK / G-6-PDH controls available
- Wavelength 340, 334, 365 nm
- After preparing Haemolysate determine:
G-6-PDH and PK in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



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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
PK / G-6-PDH Control Deficient Level	3141	1 x 500 µl
PK / G-6-PDH Control Normal Level	3142	1 x 500 µl
PK / G-6-PDH Control High Level	3143	1 x 500 µl

QUANTITY OF DETERMINATIONS

Procedure

- Manual : 25 tests
- Automated : 300 tests

NOTES

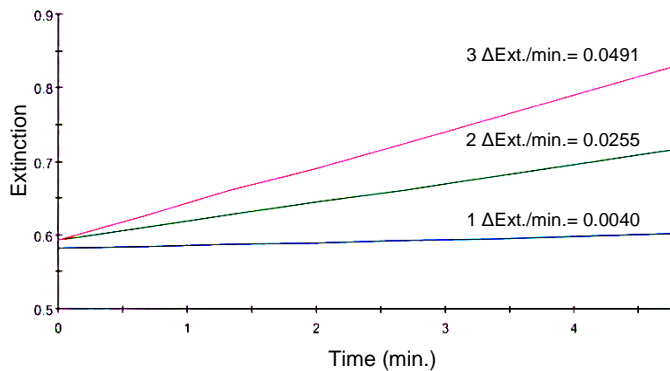
1. For in vitro diagnostic use only.
2. For professional use only.
3. Contact INstru**chemie** for the complete validation report and the latest edition product insert.



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

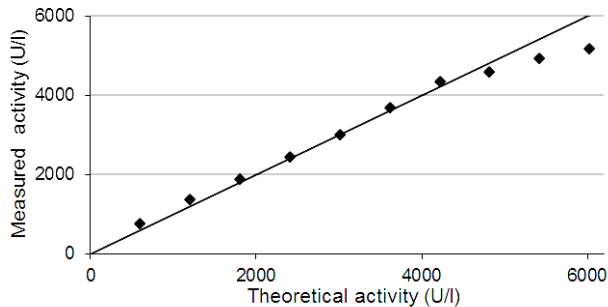
The sensitivity (limit of detection) was determined by measuring human control material (G6PDH activity = 0 U/l) 20 times.

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.

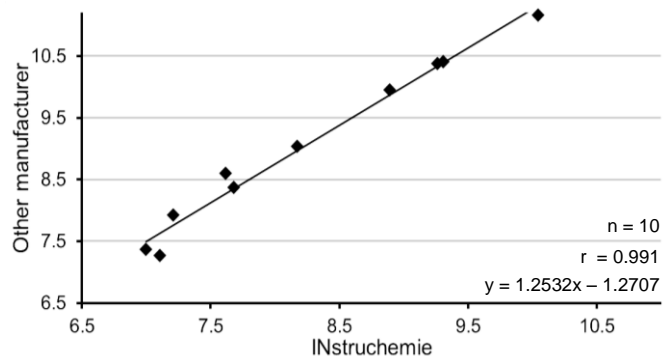
Repeatability:		
	Sample (U/g Hb)	Control (U/l)
Mean	6.4	1169
Standard deviation	0.10	25.6
Variation coefficient	1.6	2.2

Reproducibility:		
	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 INstru**chemie** and reagent from another manufacturer.

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





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