BIOPORTO® Diagnostics

The NGAL Test™ Application Note for Roche Modular P

NGAL — **Code (ACN)** xxx

ANALYZE	Ser/Pl			Sample type			
Assay/Time/Point	2-Point-End	10	18	34			
Wave (2nd/Primary)	800	570					

Sample Volume			
Normal	3,0	0,0	0
Decrease	15,0	3,0	105
Increase	6,0	0,0	0

Reagent Vol.		Diluent	BCN	OBS	Timing
R1	150	0	xxx		
R2					T2
R3	50	0	xxx		T3
R4					

Diluent
- ○ Water
- ● Diluent

Code: (Saline) — OBS:

		Increase/Decrease				Upper/Lower
Abs. Limit	32000	Increase				
Prozone Limit	0	0	0	0	0	Lower
Cell Detergent	Detergent 1					
Twin Test						

Reagent Bottle Size

A		D	
B		E	
C			

CALIBRATION

Calibration Type	SPLINE		
Point	6		
Span	6		
Weight	0		
Update Type	none		
Isozyme Q Channel			
SD Limit	999		
Duplicate Limit	99	%	32000 Abs
Sensitivity Limit	-99999		99999
S1-Abs Limit	-32000		32000

Auto Calibration

Timeout

☐ Blank	
☐ Span	
☐ 2Point	
☐ Full	

Change Over

☐ Module	
■ Lot	full
☐ Bottle	

RANGE

App Code	xxx			Factor
Unit	ng/mL	**Unit 2**		
		Unit 3		
Report Name	NGAL			
Data Mode	Active			
Technical Limit	25		5000	
Repeat Limit	-99999		999999	
☐ **Control Interval Time**			0,0	

Qualitative

(1)	0	--
(2)	0	-
(3)	0	+/-
(4)	0	++
(5)	0	+++
(6)		++++

Expected Ranges

Male

#	Years	#	#
#	Years	#	#
		#	#

Female

#	Years	#	#
#	Years	#	#
		#	#

Default

Sex: ● Male | Female

Range: Range 1 ◯ Range 2 ◯ Range 3

OTHERS

Std

	(1)	(2)	(3)	(4)	(5)	(6)
Calib. Code	501	xxx	xxx	xxx	xxx	xxx
Concentration	0,00	150	600	1500	3000	5000
Position						
Conversion Factor						
Sample Volume	3,0	3,0	3,0	3,0	3,0	3,0
Diluent S. Volume	0,0	0,0	0,0	0,0	0,0	0,0
Diluent Volume	0	0	0	0	0	0

xxx: To be defined by operator.

BioPorto Diagnostics A/S

The Application Note applies to the quantitative determination of NGAL in human urine and EDTA plasma. The performance data shown were obtained by the manufacturer. Each individual laboratory should validate its test system.

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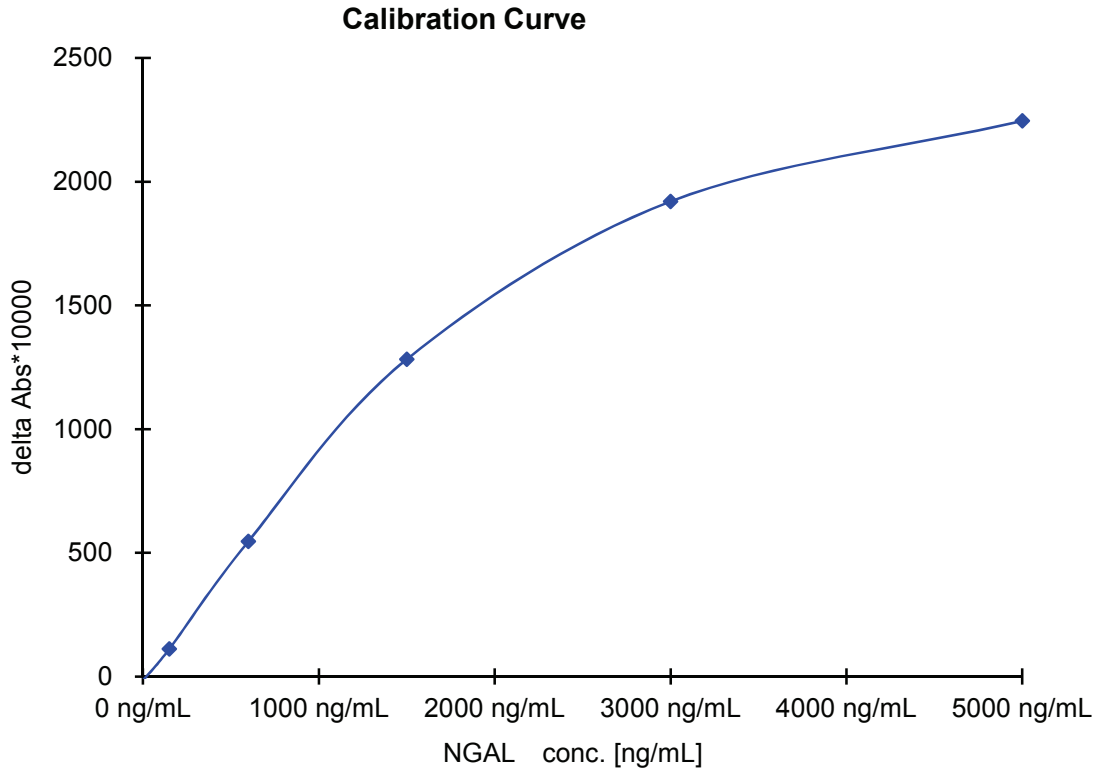
The NGAL Test™ Performance on Roche Modular-P

Sensitivity

Reagent	The NGAL Test™ Lot.RD23
calibrator	Master Calibrator
instrument	**Roche Modular-P**
parameter	3/150/50 P18-34 570/800nm Spline

	0 ng/mL	150 ng/mL	600 ng/mL	1500 ng/mL	3000 ng/mL	5000 ng/mL
Lot. RD23	-15,5	111,0	546,5	1282,0	1920,0	2245,5

Unit:delta Abs*10000



0 ng/mL	0,0
150 ng/mL	146,0
600 ng/mL	601,5
1500 ng/mL	1539,5
3000 ng/mL	3023,5
5000 ng/mL	4870,5

Unit:ng/mL

Recovery	
0 ng/mL	*-*
150 ng/mL	*97%*
600 ng/mL	*100%*
1500 ng/mL	*103%*
3000 ng/mL	*101%*
5000 ng/mL	*97%*

Re-run	
Normal	4923,0
Re-run	5031,0
Recovery	*102%*

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Within Run Imprecision / Specificity

Sample	QC fluid -25ng/mL / Control Low,High / QC Panel Low,
Reagent	The NGAL Test™ Lot.RD23
Calibrator	Master Calibrator
Instrument	**Roche Modular-P**
Parameter	3/150/50 P18-34 570/800nm Spline

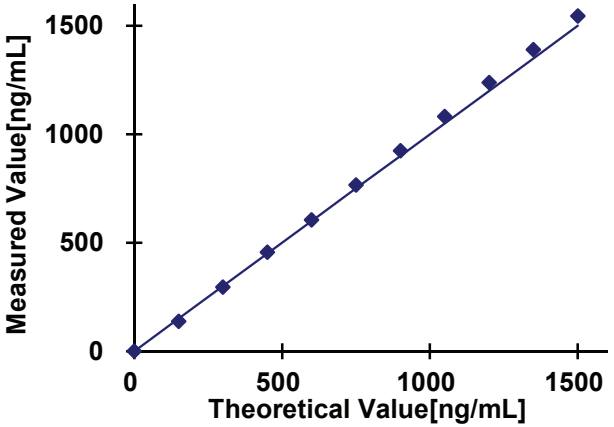
	QC Fluid 25ng/mL	Control Low Lot.100831	Control High Lot.100831
1	24	195	498
2	20	201	500
3	26	194	492
4	24	194	490
5	19	195	505
6	24	195	492
7	23	192	489
8	24	198	487
9	15	195	495
10	23	214	491
11	24	-	-
12	26	-	-
13	18	-	-
14	26	-	-
15	19	-	-
16	25	-	-
17	18	-	-
18	18	-	-
19	24	-	-
20	20	-	-
N	20	10	10
Mean	22,0	197,3	493,9
Max	26,0	214,0	505,0
Min	15,0	192,0	487,0
SD	3,2927	6,3605	5,5867
CV%	***14,97%***	***3,22%***	***1,13%***
			Unit:ng/mL

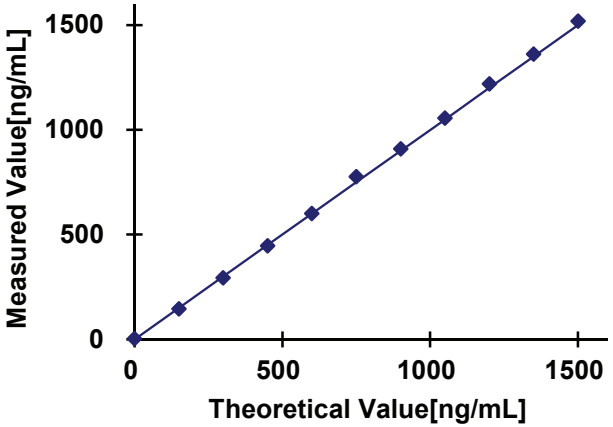
Specificity

	H917	Roche Modular-P	Recovery
Control Low	194,9	197,3	*101%*
Control High	485,2	493,9	*102%*
Panel Low	110,2	113,3	*103%*
Panel Medium	313,4	321,4	*103%*
Panel High	873,2	909,4	*104%*

Linearity ~ 1500ng/mL

Sample	Calibrator
Dilution	Saline, Calibrator diluent
Calibrator	Master Calibrator
Instrument	**Roche Modular-P**
Parameter	3/150/50 P18-34 570/800nm Spline





Dil.levels		Theoretical	Measured	*Recovery*
1500ng/mL - Saline				
10,0	0,0	0,0	0,0	
9,0	1,0	150,0	137,5	***92%***
8,0	2,0	300,0	295,0	***98%***
7,0	3,0	450,0	456,0	***101%***
6,0	4,0	600,0	605,0	***101%***
5,0	5,0	750,0	766,0	***102%***
4,0	6,0	900,0	924,5	***103%***
3,0	7,0	1050,0	1081,5	***103%***
2,0	8,0	1200,0	1238,5	***103%***
1,0	9,0	1350,0	1390,5	***103%***
0,0	10,0	1500,0	1545,5	***103%***

Unit:ng/mL

Dil.levels		Theoretical	Measured	*Recovery*
1500ng/mL - Calibrator diluent				
10,0	0,0	0,0	4,0	
9,0	1,0	150,0	146,0	***97%***
8,0	2,0	300,0	293,0	***98%***
7,0	3,0	450,0	447,0	***99%***
6,0	4,0	600,0	601,5	***100%***
5,0	5,0	750,0	777,0	***104%***
4,0	6,0	900,0	909,0	***101%***
3,0	7,0	1050,0	1055,5	***101%***
2,0	8,0	1200,0	1220,0	***102%***
1,0	9,0	1350,0	1361,5	***101%***
0,0	10,0	1500,0	1518,5	***101%***

Unit:ng/mL

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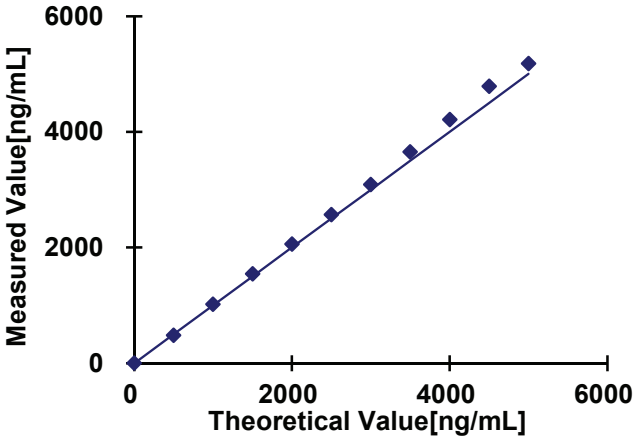
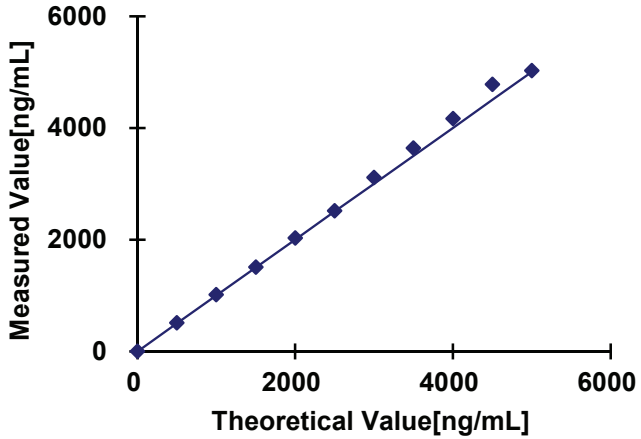
Linearity ~ 5000ng/mL & Prozone

Sample	Calibrator, QC fluid
Dilution	Saline, Calibrator diluent
Calibrator	Master Calibrator
Instrument	**Roche Modular-P**
Parameter	3/150/50 P18-34 570/800nm Spline



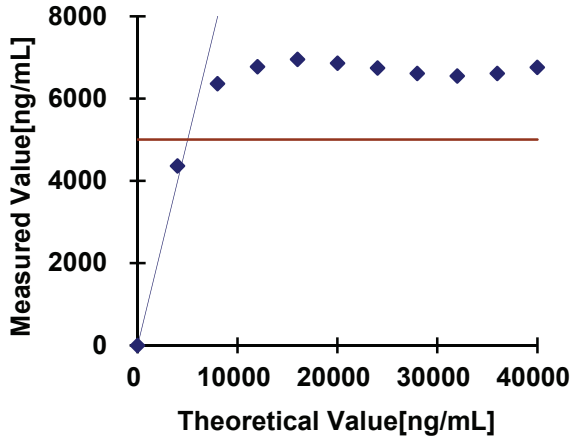
Dil.levels		Theoretical	Measured	*Recovery*
5000ng/mL - Saline				
10,0	0,0	0,0	0,0	
9,0	1,0	500,0	484,5	*97%*
8,0	2,0	1000,0	1018,0	*102%*
7,0	3,0	1500,0	1544,5	*103%*
6,0	4,0	2000,0	2061,5	*103%*
5,0	5,0	2500,0	2569,0	*103%*
4,0	6,0	3000,0	3090,5	*103%*
3,0	7,0	3500,0	3655,5	*104%*
2,0	8,0	4000,0	4210,5	*105%*
1,0	9,0	4500,0	4790,5	*106%*
0,0	10,0	5000,0	5182,5	*104%*

Unit:ng/mL



Dil.levels		Theoretical	Measured	*Recovery*
5000ng/mL - Calibrator diluent				
10,0	0,0	0,0	0,0	
9,0	1,0	500,0	510,0	*102%*
8,0	2,0	1000,0	1018,0	*102%*
7,0	3,0	1500,0	1510,5	*101%*
6,0	4,0	2000,0	2028,0	*101%*
5,0	5,0	2500,0	2518,5	*101%*
4,0	6,0	3000,0	3114,0	*104%*
3,0	7,0	3500,0	3641,5	*104%*
2,0	8,0	4000,0	4164,0	*104%*
1,0	9,0	4500,0	4777,0	*106%*
0,0	10,0	5000,0	5028,5	*101%*

Unit:ng/mL



Dil.levels		Theoretical	Measured	*Mark*
Prozone - Calibrator diluent				
10,0	0,0	0,0	0,5	
9,0	1,0	4000	4361,5	
8,0	2,0	8000	6360,0	*>5000*
7,0	3,0	12000	6768,5	*>5000*
6,0	4,0	16000	6953,0	*>5000*
5,0	5,0	20000	6855,5	*Error*
4,0	6,0	24000	6742,0	*Error*
3,0	7,0	28000	6612,0	*Error*
2,0	8,0	32000	6544,5	*Error*
1,0	9,0	36000	6605,5	*Error*
0,0	10,0	40000	6755,0	*Error*

Unit:ng/mL

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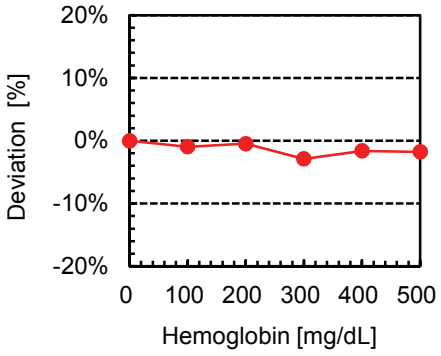
Interferences

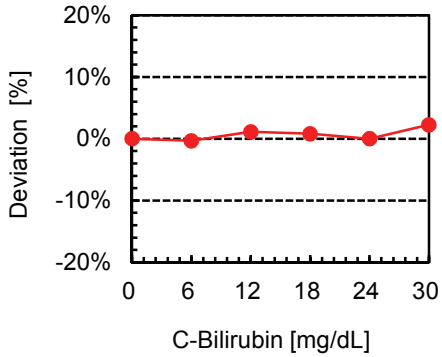
Sample	Hemoglobin, Bilirubin, Intrafat
Dilution	Calibrator diluent
Calibrator	Master Calibrator
Instrument	**Roche Modular-P**
Parameter	3/150/50 P18-34 570/800nm Spline

Hemoglobin :



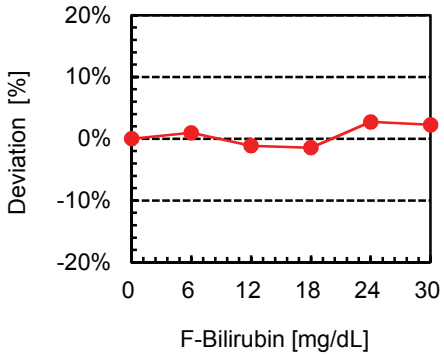
mg/dL	Deviation
0	*0,0%*
100	*-1,0%*
200	*-0,5%*
300	*-2,9%*
400	*-1,6%*
500	*-1,8%*

C-Bilirubin :



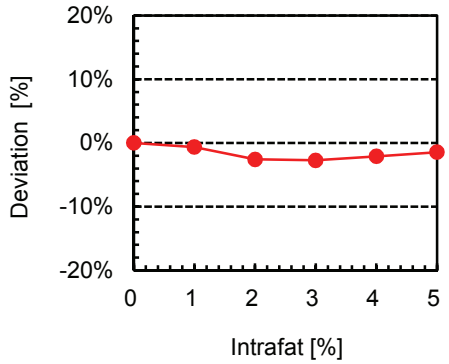
mg/dL	Deviation
0	*0,0%*
6	*-0,3%*
12	*1,1%*
18	*0,8%*
24	*0,0%*
30	*2,3%*

F-Bilirubin :



mg/dL	Deviation
0	*0,0%*
6	*1,0%*
12	*-1,1%*
18	*-1,4%*
24	*2,7%*
30	*2,3%*

Intrafat :



%	Deviation
0	*0,0%*
1	*-0,6%*
2	*-2,6%*
3	*-2,7%*
4	*-2,1%*
5	*-1,4%*