

## The NGAL Test™ Application Note for Abbott Architect c8000

### General parameters

Name: NGAL	Assay type: Photometric
Assay number: *1	Assay availability: Enabled
Assay version: 1	Cal version: 1

### Reaction definition

Reaction mode: End Up	Main read time: 27 - 28
Primary wavelength: 572	
Secondary wavelength:	Color correction read time: 0 - 0
Last read required: 33	Blank read time: 19 - 20
Absorbance range: 0.0000 - 0.0000	
Sample blank type: Self blank	
Blank assay:	

### Reagent/Sample

Reagent: NGAL	
R1 reagent volume: 120	R2 reagent volume: 40
R1 water volume: 0	R2 water volume: 0
R1 dispense mode: Type 0	R2 dispense mode: Type 0
Diluent name: Saline	Diluent dispense mode: Type 0

Dilution name	Sample volume	Diluted sample volume	Diluent volume	Water volume	Dilution factor
Normal	2,4				1 : 1,00
Rerun 1	15,0	2,4	105,0		1 : 8,00
Rerun 2	6,0				1 : 1,00

### Validity checks

Reaction check type: Rate RATIO	
Read time A range: 32 - 33	Read time B range: 19 - 20
Calculation limit: 0,1 - 9,9	Minimum absorbance: 0,0150
	Rate linearity %: 0
Maximum absorbance variation:	

\*1: To be defined by operator.

### Calibration parameters

Calibration method: Spline  
 Use cal factor from: Factor:  
 Full interval hours: 0 Adjustment interval hours: 0  
 Adjustment type: None Adjustment level:  
 Expected cal factor: 0,00 Default ordering type: Full  
 Expected factor tolerance %: 0,0 Blank absorbance range: 0.0000 - 0.0000  
 Span: Span absorbance range: 0,00 - 0,00  
 Maximum curve fit: 0,00  
 Calibrator set name: \*1 Replicates: 3

Cal level	Concentration	Sample volume	Diluted sample volume	Diluent volume	Water volume
Blank	0	2,4			
Cal.1	150	2,4			
Cal.2	600	2,4			
Cal.3	1500	2,4			
Cal.4	3000	2,4			
Cal.5	5000	2,4			

### Smart wash

Cal level	Reagent/Assay	Wash	Volume	Replicates	Wash protocol

### Results parameters

Linearity range: 25 - 5000

Flag range specification:

Gender	Age	Normal range	Extreme range
		-	-

### Interpretation parameters

### Result units

Result concentration unit: ng/mL Correlation factor: 1,0000  
 Result decimal places: 0 Intercept: 0,0000

\*1: To be defined by operator.

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.

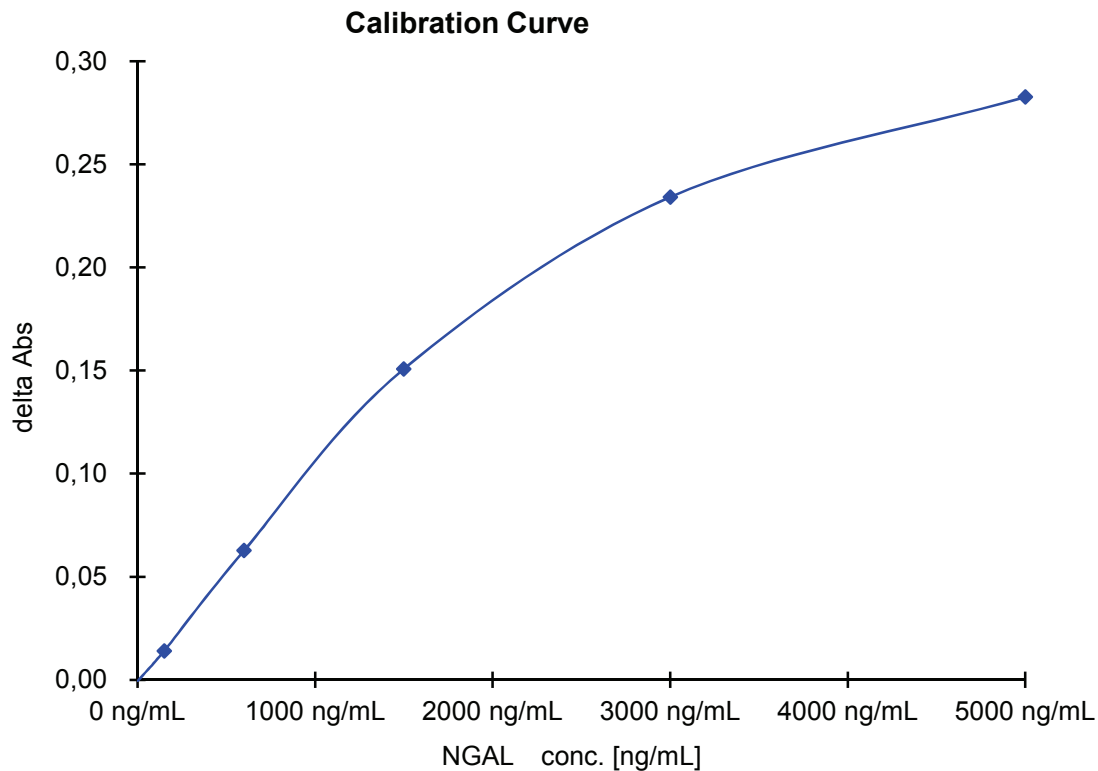
## Performance for NGAL Test™ Reagent Kit

### Sensitivity

Reagent	The NGAL Test™ Lot.RD23
calibrator	Master Calibrator
instrument	<b>Abbott Architect c8000</b>
parameter	2.4/120/40 P19-20/27-28 572nm Spline

	0 ng/mL	150 ng/mL	600 ng/mL	1500 ng/mL	3000 ng/mL	5000 ng/mL
Lot. RD23	-0,0006	0,0141	0,0627	0,1508	0,2341	0,2826

Unit:delta Abs



0 ng/mL	-0,3
150 ng/mL	151,0
600 ng/mL	606,7
1500 ng/mL	1515,3
3000 ng/mL	3034,7
5000 ng/mL	5000,0
	Unit:ng/mL

<i>Recovery</i>	
0 ng/mL	-
150 ng/mL	101%
600 ng/mL	101%
1500 ng/mL	101%
3000 ng/mL	101%
5000 ng/mL	100%

<b>Re-run</b>	
Normal	4773,0
Re-run	4130,5 (Saline)
<i>Recovery</i>	87%
Re-run-2	4556,5 (Calibrator diluent)
<i>Recovery</i>	95%

## 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	<b>Abbott Architect c8000</b>
Parameter	2.4/120/40 P19-20/27-28 572nm Spline

	QC Fluid 25ng/mL	Control Low Lot.100831	Control High Lot.100831
1	18	202	520
2	26	220	500
3	22	210	501
4	24	209	509
5	30	219	508
6	28	208	511
7	26	202	509
8	30	210	519
9	24	204	505
10	26	210	509
11	23	-	-
12	25	-	-
13	29	-	-
14	27	-	-
15	24	-	-
16	26	-	-
17	23	-	-
18	26	-	-
19	29	-	-
20	18	-	-
N	20	10	10
Mean	25,2	209,4	509,1
Max	30,0	220,0	520,0
Min	18,0	202,0	500,0
SD	3,3811	6,2039	6,5566
<b>CV%</b>	<b>13,42%</b>	<b>2,96%</b>	<b>1,29%</b>

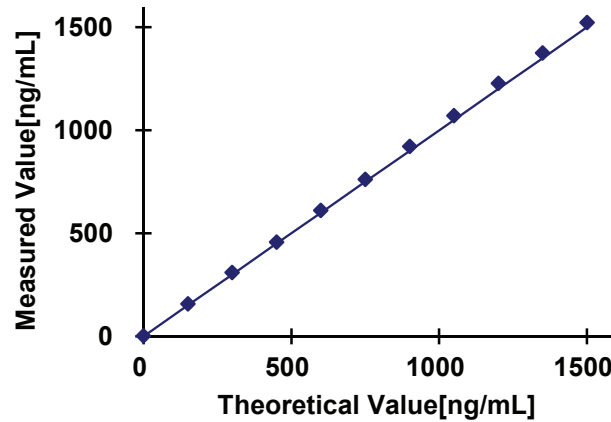
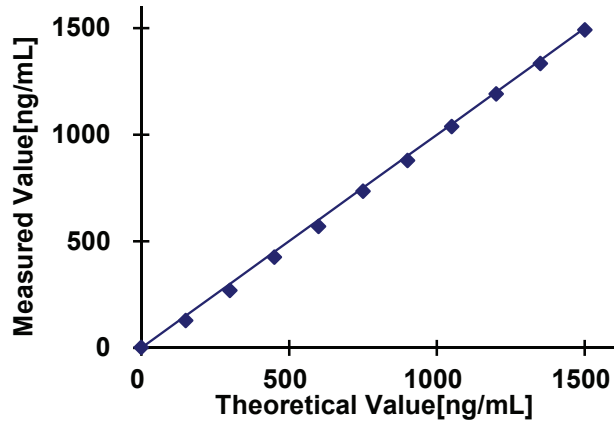
Unit:ng/mL

## Specificity

	H917	Architect c8000	Recovery
Control Low	194,9	209,4	107%
Control High	485,2	509,1	105%
Panel Low	110,2	121,9	111%
Panel Medium	313,4	341,7	109%
Panel High	873,2	951,9	109%

## Linearity ~ 1500ng/mL

Sample	Calibrator
Dilution	Saline, Calibrator diluent
Calibrator	Master Calibrator
Instrument	<b>Abbott Architect c8000</b>
Parameter	2.4/120/40 P19-20/27-28 572nm Spline



Dil.levels	Theoretical	Measured	Recovery
<b>1500ng/mL - Saline</b>			
10,0	0,0	0,0	2,0
9,0	1,0	150,0	128,0 <b>85%</b>
8,0	2,0	300,0	269,5 <b>90%</b>
7,0	3,0	450,0	426,0 <b>95%</b>
6,0	4,0	600,0	569,5 <b>95%</b>
5,0	5,0	750,0	735,0 <b>98%</b>
4,0	6,0	900,0	879,5 <b>98%</b>
3,0	7,0	1050,0	1038,0 <b>99%</b>
2,0	8,0	1200,0	1191,0 <b>99%</b>
1,0	9,0	1350,0	1334,0 <b>99%</b>
0,0	10,0	1500,0	1491,5 <b>99%</b>

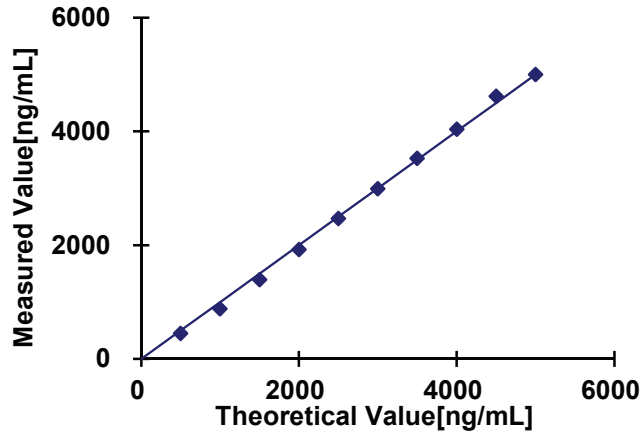
Unit:ng/mL

Dil.levels	Theoretical	Measured	Recovery
<b>1500ng/mL - Calibrator diluent</b>			
10,0	0,0	0,0	2,5
9,0	1,0	150,0	158,0 <b>105%</b>
8,0	2,0	300,0	309,5 <b>103%</b>
7,0	3,0	450,0	457,0 <b>102%</b>
6,0	4,0	600,0	611,5 <b>102%</b>
5,0	5,0	750,0	762,0 <b>102%</b>
4,0	6,0	900,0	922,0 <b>102%</b>
3,0	7,0	1050,0	1071,0 <b>102%</b>
2,0	8,0	1200,0	1227,5 <b>102%</b>
1,0	9,0	1350,0	1375,0 <b>102%</b>
0,0	10,0	1500,0	1523,5 <b>102%</b>

Unit:ng/mL

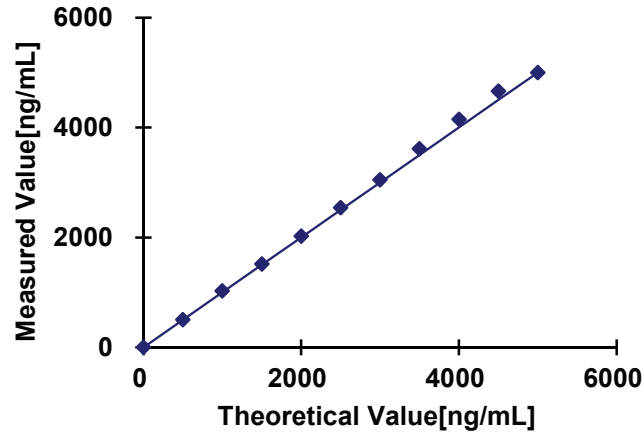
## Linearity ~ 5000ng/mL & Prozone

Sample	Calibrator, QC fluid
Dilution	Saline, Calibrator diluent
Calibrator	Master Calibrator
Instrument	<b>Abbott Architect c8000</b>
Parameter	2.4/120/40 P19-20/27-28 572nm Spline



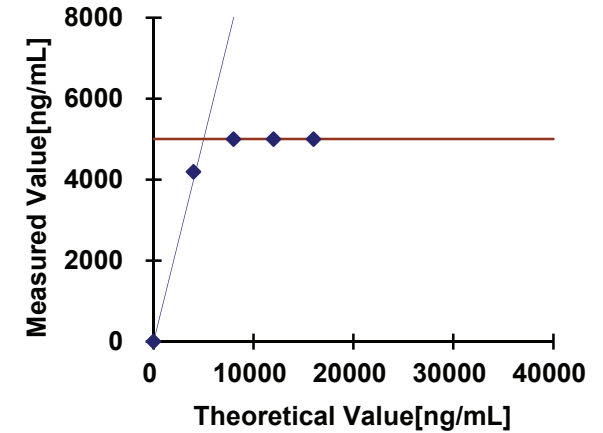
Dil.levels	Theoretical	Measured	Recovery
<b>5000ng/mL - Saline</b>			
10,0	0,0	0,0	-5,0
9,0	1,0	500,0	446,5 <b>89%</b>
8,0	2,0	1000,0	884,0 <b>88%</b>
7,0	3,0	1500,0	1395,5 <b>93%</b>
6,0	4,0	2000,0	1925,0 <b>96%</b>
5,0	5,0	2500,0	2468,0 <b>99%</b>
4,0	6,0	3000,0	2994,0 <b>100%</b>
3,0	7,0	3500,0	3525,0 <b>101%</b>
2,0	8,0	4000,0	4038,5 <b>101%</b>
1,0	9,0	4500,0	4618,0 <b>103%</b>
0,0	10,0	5000,0	4998,5 <b>100%</b>

Unit:ng/mL



Dil.levels	Theoretical	Measured	Recovery
<b>5000ng/mL - Calibrator diluent</b>			
10,0	0,0	0,0	5,0
9,0	1,0	500,0	505,5 <b>101%</b>
8,0	2,0	1000,0	1026,5 <b>103%</b>
7,0	3,0	1500,0	1518,5 <b>101%</b>
6,0	4,0	2000,0	2022,0 <b>101%</b>
5,0	5,0	2500,0	2541,5 <b>102%</b>
4,0	6,0	3000,0	3052,0 <b>102%</b>
3,0	7,0	3500,0	3617,0 <b>103%</b>
2,0	8,0	4000,0	4152,0 <b>104%</b>
1,0	9,0	4500,0	4661,5 <b>104%</b>
0,0	10,0	5000,0	5000,0 <b>100%</b>

Unit:ng/mL



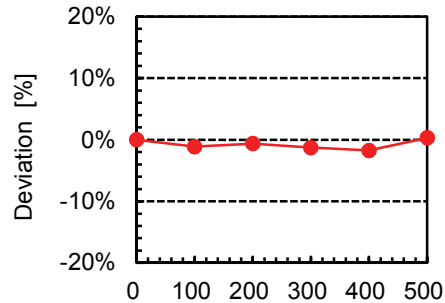
Dil.levels	Theoretical	Measured	Mark
<b>Prozone - Calibrator diluent</b>			
10,0	0,0	0,0	0,0
9,0	1,0	4000	4196,0
8,0	2,0	8000	5000,0 <b>&gt;5000</b>
7,0	3,0	12000	5000,0 <b>&gt;5000</b>
6,0	4,0	16000	5000,0 <b>&gt;5000</b>
5,0	5,0	20000	<b>Error</b>
4,0	6,0	24000	<b>Error</b>
3,0	7,0	28000	<b>Error</b>
2,0	8,0	32000	<b>Error</b>
1,0	9,0	36000	<b>Error</b>
0,0	10,0	40000	<b>Error</b>

Unit:ng/mL

## Interferences

Sample	Hemoglobin, Bilirubin, Intrafat
Dilution	Calibrator diluent
Calibrator	Master Calibrator
Instrument	<b>Abbott Architect c8000</b>
Parameter	2.4/120/40 P19-20/27-28 572nm Spline

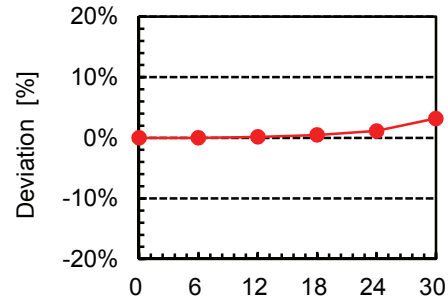
### Hemoglobin :



Hemoglobin [mg/dL]

mg/mL	Deviation
0	0,0%
100	-1,1%
200	-0,6%
300	-1,3%
400	-1,7%
500	0,3%

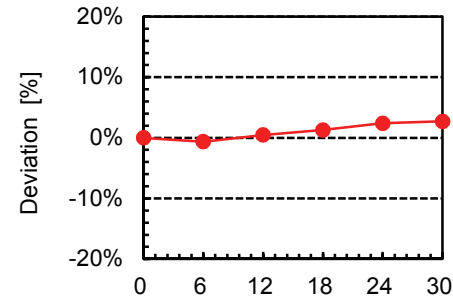
### C-Bilirubin :



C-Bilirubin [dg/mL]

mg/mL	Deviation
0	0,0%
6	0,0%
12	0,2%
18	0,5%
24	1,1%
30	3,2%

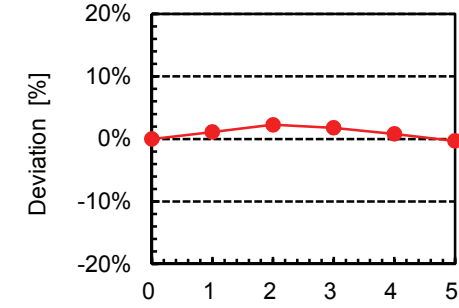
### F-Bilirubin :



F-Bilirubin [dg/mL]

mg/mL	Deviation
0	0,0%
6	-0,6%
12	0,5%
18	1,3%
24	2,4%
30	2,7%

### Intrafat :



Intrafat [%]

%	Deviation
0	0,0%
1	1,1%
2	2,3%
3	1,8%
4	0,8%
5	-0,3%