

The NGAL Test™ Reagent Kit

| REF/Cat.No. | ST001CA | | ST002CA | ST003CA |
|--------------|----------------------------|----------|--------------------------------|----------------------------|
| Product name | The NGAL Test™ Reagent Kit | | The NGAL Test™ Calibrator Kit | The NGAL Test™ Control Kit |
| | R1 | R2 | 50, 150, 600, 1500, 3000 ng/mL | Low and High |
| | 1 x 35 mL | 1 x 7 mL | 5 x 1 mL | 3 x 1 mL x 2 levels |

Number of determinations: 1 mL of immunoparticle suspension **R2** provides 20 cuvette readings with the provided settings in this application. The dead volume of the analyzer and reagent container should be added when calculating the required amount of reagent.

PERFORMANCE DATA

The performance data shown were obtained by the manufacturer for this particular analyzer model. For additional performance data and product application, please read the instructions for use accompanying the product carefully. Each individual laboratory should validate the use of The NGAL Test™ on its system.



LIMIT OF DETECTION (LoD)

Not tested on this analyzer model. The limit of detection was estimated as 7.3 ng/mL on a Roche Hitachi 917 which belongs to the same family of analyzers and uses the same application settings as the Modular® P.

RANGE

The measuring range of The NGAL Test™ is 25 - 3000 ng/mL on the Roche Modular® P analyzer.

SECURITY RANGE

Not tested on this analyzer model. However, The NGAL Test™ showed no effect of antigen excess for NGAL concentrations below 40,000 ng/mL (the highest concentration tested) on a Roche Hitachi 917 which belongs to the same family of analyzers and uses the same application settings as the Modular® P. The user should consider the requirement for entering prozone check settings.

LIMIT OF QUANTIFICATION (LoQ)

The LoQ was determined to be <25 ng/mL on this analyzer model. Observed results:

| Sample | Mean (ng/mL) | SD | CV % | n |
|----------|--------------|-----|------|----|
| 22 ng/mL | 24.2 | 3.5 | 14.4 | 20 |

PRECISION

| REF | Mean (ng/mL) | SD | CV% | n |
|--------------|--------------|-----|-----|----|
| ST003CA Low | 192.0 | 6.0 | 3.2 | 10 |
| ST003CA High | 512.7 | 6.2 | 1.2 | 10 |

METHOD COMPARISON

NGAL measurements have been compared to measurements on a Hitachi 917. Data is available on request.

CALIBRATION STABILITY

It is recommended to recalibrate every 4 weeks, when reagent lots change or quality control results fall outside the range as established by the individual laboratory.

TROUBLE SHOOTING

If performance is unacceptable, try to recalibrate. Check reagents and procedure. If the problem persists, please contact instrument supplier or reagent supplier.

INTERFERENCE

Not tested on this analyzer model. However, no interference was detected with hemoglobin up to 5 g/L, conjugated bilirubin up to 300 mg/L, free bilirubin up to 300 mg/L, and up to 5% v/v of a 10% v/v lipid emulsion (corresponding to 5 g/L) on a Roche Hitachi 917 analyzer which belongs to the same family of analyzers and uses the same application settings as the Modular® P

¹ Modular® P is a registered trademark of Roche Diagnostics GmbH, Mannheim, Germany.

For your clinical chemistry analyzer

APPLICATION PARAMETERS

| | | | | | | | |
|-----------------------|----------------------------------|------------------------------------------|---------------------------------------|----------------------------------|--------------------------------|--------------------------------|------------------------------------|
| Assay/Time/Point | 2-Point-End | <input type="text" value="10"/> | <input type="text" value="18"/> | <input type="text" value="34"/> | <input type="text" value="0"/> | <input type="text" value="0"/> | |
| Wave (2nd/Primary) | <input type="text" value="800"/> | <input type="text" value="570"/> | | | | | |
| Sample Volume | | <input type="text" value="3.0"/> | <input type="text" value="0.0"/> | <input type="text" value="0"/> | | | |
| Normal | | <input type="text" value="15.0"/> | <input type="text" value="3.0"/> | <input type="text" value="105"/> | | | |
| Increase | | <input type="text" value="6.0"/> | <input type="text" value="0.0"/> | <input type="text" value="0"/> | | | |
| Diluent | | | | | | | |
| ○ Water | | | | | | | |
| ● Diluent | | <input type="text" value="314"/> | <input type="text" value="0"/> | | | | |
| Abs. Limit | | <input type="text" value="32000"/> | <input type="text" value="Increase"/> | | | | |
| Prozone Limit | | <input type="text" value="0"/> | <input type="text" value="0"/> | <input type="text" value="0"/> | <input type="text" value="0"/> | <input type="text" value="0"/> | <input type="text" value="Lower"/> |
| Cell Detergent | | <input type="text" value="Detergent 1"/> | | | | | |
| Twin Test | | <input type="text" value="Cancel"/> | | | | | |
| Reagent Vol. | | | | | | | |
| R1 | <input type="text" value="150"/> | <input type="text" value="0"/> | <input type="text" value="xxx"/> | <input type="text" value="0"/> | Timing | | |
| R2 | <input type="text" value="0"/> | <input type="text" value="0"/> | <input type="text" value="xxx"/> | <input type="text" value="0"/> | T2 | | |
| R3 | <input type="text" value="50"/> | <input type="text" value="0"/> | <input type="text" value="xxx"/> | <input type="text" value="0"/> | T3 | | |
| R4 | <input type="text" value="0"/> | <input type="text" value="0"/> | <input type="text" value="xxx"/> | <input type="text" value="0"/> | | | |

| | | | |
|-------------------------------------|------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| CALIBRATION | | Auto Calibration | |
| Calibration Type | | Change Over | |
| <input type="text" value="SPLINE"/> | | <input type="text" value="Cancel"/> | |
| Point | <input type="text" value="6"/> | Modul | <input type="text" value="Cancel"/> |
| Span | <input type="text" value="6"/> | Lot | <input type="text" value="Cancel"/> |
| Weight | <input type="text" value="0"/> | Bottel | <input type="text" value="Cancel"/> |
| Update Type | <input type="text" value="none"/> | | |
| Isozyme Q Channel | <input type="text" value="Cancel"/> | | |
| SD Limit | | Timeout | |
| <input type="text" value="999"/> | | ● <input type="checkbox"/> Blank <input type="text" value="1"/> <input type="text" value="2 Point"/> <input type="text" value="1"/> | |
| Duplicate Limit | <input type="text" value="99"/> <input type="text" value="32000"/> | <input type="checkbox"/> Span <input type="text" value="1"/> <input type="text" value="Full"/> <input type="text" value="1"/> | |
| Sensitivity Limit | <input type="text" value="-99999"/> <input type="text" value="99999"/> | | |
| S1-Abs Limit | <input type="text" value="-32000"/> <input type="text" value="32000"/> | | |
| V Auto Masking | | QC Violation | |
| | | Method | <input type="text" value="Blank"/> <input type="text" value="Rule"/> <input type="text" value="1s"/> |
| | | Control | <input type="text" value="None"/> <input type="text" value="None"/> <input type="text" value="None"/> |

RANGE

Application Code xxx
 Unit ng/mL

Report Name NGAL
 Data Mode Active

V Automatic rerun

Technical Limit 25 3000
 Repeat Limit -99999 999999
 Control Interval Time 1

Qualitative Control Interval Time

| | | |
|-----|----------|-------------|
| (1) | <u>0</u> | <u>--</u> |
| (2) | <u>0</u> | <u>-</u> |
| (3) | <u>0</u> | <u>+/-</u> |
| (4) | <u>0</u> | <u>++</u> |
| (5) | <u>0</u> | <u>+++</u> |
| (6) | <u>0</u> | <u>++++</u> |

Expected Ranges

Male

| | | | |
|------------|-------------|---------------|--------------|
| <u>99</u> | <u>Year</u> | <u>-99999</u> | <u>99999</u> |
| <u>100</u> | <u>Year</u> | <u>-99999</u> | <u>99999</u> |
| | | <u>-99999</u> | <u>99999</u> |

Female

| | | | |
|------------|-------------|---------------|--------------|
| <u>99</u> | <u>Year</u> | <u>-99999</u> | <u>99999</u> |
| <u>100</u> | <u>Year</u> | <u>-99999</u> | <u>99999</u> |
| | | <u>-99999</u> | <u>99999</u> |

Default

Sex
 Male Female

Range
 Range 1 Range 2 Range 3

OTHERS

Standards

| | (1) | (2) | (3) | (4) | (5) | (6) |
|-------------------|--------------|---------------|---------------|---------------|---------------|---------------|
| Calibrator Code | <u>501</u> | <u>xxx</u> | <u>xxx</u> | <u>xxx</u> | <u>xxx</u> | <u>xxx</u> |
| Concentration | <u>0</u> | <u>50</u> | <u>150</u> | <u>600</u> | <u>1500</u> | <u>3000</u> |
| Rack No. – Pos. | <u>XXXXX</u> | <u>XXXXXX</u> | <u>XXXXXX</u> | <u>XXXXXX</u> | <u>XXXXXX</u> | <u>XXXXXX</u> |
| Sample Volume | <u>3.0</u> | <u>3.0</u> | <u>3.0</u> | <u>3.0</u> | <u>3.0</u> | <u>3.0</u> |
| Diluent S. Volume | <u>0.0</u> | <u>0.0</u> | <u>0.0</u> | <u>0.0</u> | <u>0.0</u> | <u>0.0</u> |
| Diluent Volume | <u>0</u> | <u>0</u> | <u>0</u> | <u>0</u> | <u>0</u> | <u>0</u> |

xxx: To be defined by operator.