

# ARCHITECT

SYSTEM



# en

Urine NGAL

**REF** 1P37

34-5491/R2

**B1P370**

# Urine NGAL

### Customer Service:

Contact your local representative or find country specific contact information on [www.abbottdiagnostics.com](http://www.abbottdiagnostics.com)

This package insert must be read carefully before product use. Package insert instructions must be followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

### Key to symbols used

<b>REF</b>	List Number	<b>REACTION VESSELS</b>	Reaction Vessels
<b>IVD</b>	<i>In Vitro</i> Diagnostic Medical Device	<b>SAMPLE CUPS</b>	Sample Cups
<b>LOT</b>	Lot Number	<b>REPLACEMENT CAPS</b>	Replacement Caps
	Expiration Date	<b>REAGENT LOT</b>	Reagent Lot
<b>SN</b>	Serial Number	<b>CONTROL NO.</b>	Control Number
	Store at 2-8°C	<b>SEPTUMS</b>	Septums
	Consult instructions for use	<b>WARNING: SENSITIZER</b>	Warning: Sensitizer
	Manufacturer		

See **REAGENTS** section for a full explanation of symbols used in reagent component naming.



## NAME

ARCHITECT Urine NGAL

## INTENDED USE

The ARCHITECT Urine NGAL assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of neutrophil gelatinase-associated lipocalin (NGAL) in human urine. NGAL quantitation may be used for the *in vitro* determination of human NGAL in urine as an indication of kidney injury.

## SUMMARY AND EXPLANATION OF TEST

The ARCHITECT Urine NGAL assay utilizes microparticles coated with monoclonal antibody for the detection of NGAL. Studies have shown that urinary NGAL is an early marker of Acute Kidney Injury (AKI) in a wide variety of settings.<sup>1-4</sup> NGAL is one of the earliest proteins induced in the kidney after ischemic or nephrotoxic insult; studies have demonstrated elevated urine NGAL levels within two hours of insult.<sup>5</sup> Early detection of NGAL may be used as an aid in the diagnosis of AKI and patient management.<sup>5</sup>

## BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT Urine NGAL assay is a two-step immunoassay for the quantitative detection of NGAL in human urine using CMIA technology with flexible assay protocols, referred to as Chemiflex.

In the first step, sample and wash buffer are combined to create a 1:10 sample dilution. An aliquot of the pre-diluted sample, wash buffer, and anti-NGAL coated paramagnetic microparticles are combined. NGAL present in the sample binds to anti-NGAL coated microparticles and the reaction mixture is washed. In the second step, anti-NGAL acridinium-labeled conjugate is added. Following another wash cycle, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). A relationship exists between the amount of NGAL in the sample and the RLUs detected by the ARCHITECT *i* System optics.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

## REAGENTS

### Reagent Kit, 100 Tests/500 Tests

Note: Some kit sizes are not available in all countries or for use on all ARCHITECT *i* Systems. Please contact your local distributor.

#### ARCHITECT Urine NGAL Reagent Kit (1P37)

- **MICROPARTICLES** 1 Bottle (6.6 mL/27.0 mL each) Anti-NGAL (mouse, monoclonal) coated microparticles in BIS-TRIS buffer with protein (bovine) stabilizer and detergent. Minimum concentration: 0.08% solids. Preservative: ProClin 300.
- **CONJUGATE** 1 Bottle (5.9 mL/26.3 mL each) Anti-NGAL (mouse, monoclonal) acridinium-labeled conjugate in MES buffer with protein (bovine) stabilizer and detergent. Minimum concentration: 200.0 ng/mL. Preservative: ProClin 300.

### Other Reagents

#### ARCHITECT *i* Pre-Trigger Solution

- **PRE-TRIGGER SOLUTION** Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.

#### ARCHITECT *i* Trigger Solution

- **TRIGGER SOLUTION** Trigger Solution containing 0.35 N sodium hydroxide.

#### ARCHITECT *i* Wash Buffer

- **WASH BUFFER** Wash Buffer containing phosphate buffered saline solution. Preservative: antimicrobial agents.

## WARNINGS AND PRECAUTIONS

### Safety Precautions

- **IVD**
- For *In Vitro* Diagnostic Use.
- **CAUTION: This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens<sup>6</sup>. Biosafety Level 2<sup>7</sup> or other appropriate biosafety practices<sup>8,9</sup> should be used for materials that contain or are suspected of containing infectious agents.**
- All components contain methylisothiazolones, which are components of ProClin, and are classified per applicable European Community (EC) Directives as: Irritant (Xi). The following are the appropriate Risk (R) and Safety (S) phrases.



- R43 May cause sensitization by skin contact.
- S24 Avoid contact with skin.
- S35 This material and its container must be disposed of in a safe way.
- S37 Wear suitable gloves.
- S46 If swallowed, seek medical advice immediately and show this container or label.

- For product not classified as dangerous per European Directive 1999/45/EC as amended - Safety data sheet available for professional user on request.
- For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

### Handling Precautions

- Do not use reagent kits beyond the expiration date.
- **Do not pool reagents within a kit or between reagent kits.**
- Before loading the ARCHITECT Urine NGAL Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may have settled during shipment. For microparticle mixing instructions, refer to the **PROCEDURE, Assay Procedure** section of this package insert.
- **Septums MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septums are not used according to the instructions in this package insert.**
- **To avoid contamination, wear clean gloves when placing a septum on an uncapped reagent bottle.**
  - Once a septum has been placed on the reagent bottle, **do not invert the bottle** as this will result in reagent leakage and may compromise assay results.
  - Over time, residual liquids may dry on the septum surface. These are typically dried salts, and have no effect on assay efficacy.
- For a detailed discussion of handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

### Storage Instructions

-  The ARCHITECT Urine NGAL Reagent Kit must be stored at 2-8°C in an upright position and may be used immediately after removal from 2-8°C storage.
- When stored and handled as directed, the reagents are stable until the expiration date.
- The ARCHITECT Urine NGAL Reagent Kit may be stored on board the ARCHITECT *i* System for a maximum of 30 days. After 30 days, the reagent kit must be discarded. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.
- Reagents may be stored on or off the ARCHITECT *i* System. If reagents are removed from the system, store them at 2-8°C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright. **If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded.** For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

### Indications of Reagent Deterioration

When a control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. Associated test results are invalid and samples must be retested. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

### INSTRUMENT PROCEDURE

- The ARCHITECT Urine NGAL assay file must be installed on the ARCHITECT *i* System from the ARCHITECT *i* System Assay CD-ROM - WW (excluding US), version 31.0 or higher, or the ARCHITECT *i* 1000<sub>SR</sub> System Assay CD-ROM - WW (excluding US), version 6.0 or higher, before performing the assay. For detailed information on assay file installation and viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.
- For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.
- For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.

## SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

### Specimen Types

- The specimen type used for the ARCHITECT Urine NGAL assay is human urine only.
- The ARCHITECT *i* System does not provide the capability to verify specimen type. It is the responsibility of the operator to verify that the correct specimen type is used in the ARCHITECT Urine NGAL assay.

### Specimen Conditions

- Do not use specimens with the following conditions:
  - pooled
  - obvious microbial contamination
  - fungal growth
- Performance has not been established for the use of cadaveric specimens or body fluids other than human urine.
- Use caution when handling patient specimens to prevent cross contamination. Use of disposable pipettes or pipette tips is recommended.

### Preparation for Analysis

- **As soon as possible but within 24 hours of collection, specimens must be transferred to a centrifuge tube and centrifuged at  $\geq 400$  RCF (Relative Centrifugal Force) for a minimum of five minutes.<sup>10</sup>**
- Transfer clarified specimen to a sample cup or secondary tube for testing and/or storage.
- If specimens were stored (refer to the **Storage** section below), mix all specimens thoroughly by low speed vortexing or by inverting 10 times. Visually inspect the specimens. If layering or stratification is observed, continue mixing until specimens are visibly homogeneous. Centrifuge as instructed above prior to testing.
- **Use good sample handling technique when preparing specimens for analysis as outlined in the ARCHITECT System Operations Manual, Section 5, such as inspecting all sample cups for bubbles, specimen droplets, and tilted cups. Straighten all tilted cups prior to testing. Remove bubbles and push down specimen droplets with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination. Specimen droplets can be minimized by touching the transfer pipette tip to the side of the sample cup when dispensing the sample.**

### Storage

- Specimens may be stored for
  - up to 24 hours at room temperature (22-30°C) or
  - for up to 7 days at 2-8°C.
  - If testing will be delayed more than 24 hours at room temperature or more than 7 days at 2-8°C, store specimens at -70°C or colder.
- Avoid more than three freeze/thaw cycles.

### Shipping

- When shipping specimens, package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.
- Specimens may be shipped ambient, at 2-8°C (wet ice), or frozen (dry ice). Do not exceed the storage time limitations listed above.

## PROCEDURE

### Materials Provided

- 1P37 ARCHITECT Urine NGAL Reagent Kit

### Materials Required but not Provided

- ARCHITECT *i* System
- 6E59 ARCHITECT *i* System Assay CD-ROM - WW (excluding US), version 31.0 or higher
- 1P61 ARCHITECT *i* 1000<sub>SR</sub> System Assay CD-ROM - WW (excluding US), version 6.0 or higher
- 1P37-01 ARCHITECT Urine NGAL Calibrators
- 1P37-10 ARCHITECT Urine NGAL Controls or other control material
- ARCHITECT *i* **PRE-TRIGGER SOLUTION**
- ARCHITECT *i* **TRIGGER SOLUTION**
- ARCHITECT *i* **WASH BUFFER**
- ARCHITECT *i* **REACTION VESSELS**
- ARCHITECT *i* **SAMPLE CUPS**
- ARCHITECT *i* **SEPTUM**
- ARCHITECT *i* **REPLACEMENT CAPS**
- Pipettes or pipette tips (optional) to deliver the volumes specified on the patient or control order screen.

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

### Assay Procedure

- Before loading the ARCHITECT Urine NGAL Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may have settled during shipment. After the first time the microparticles have been loaded, no further mixing is required.
  - **Invert the microparticle bottle 30 times.**
  - Visually inspect the bottle to ensure microparticles are resuspended. If microparticles are still adhered to the bottle, continue to invert the bottle until the microparticles have been completely resuspended.
  - **If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott representative.**
  - Once the microparticles have been resuspended, place a septum on the bottle. For instructions about placing septums on bottles, refer to the **Handling Precautions** section of this package insert.
- Load the ARCHITECT Urine NGAL Reagent Kit on the ARCHITECT *i* System.
  - Verify that all necessary reagents are present.
  - Ensure that septums are present on all reagent bottles.
- Order calibration, if necessary.
  - For information on ordering calibrations, refer to the ARCHITECT System Operations Manual, Section 6.
- Order tests.
  - For information on ordering patient specimens and controls and for general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
  - To troubleshoot control values that fall outside the control range, refer to the ARCHITECT System Operations Manual, Section 10.
- The minimum sample cup volume is calculated by the system and is printed on the Orderlist report. No more than 10 replicates may be sampled from the same sample cup. To minimize the effects of evaporation, verify adequate sample cup volume is present before running the test.
  - Priority: 70  $\mu$ L for the first ARCHITECT Urine NGAL test plus 20  $\mu$ L for each additional Urine NGAL test from the same sample cup.
  - $\leq 3$  hours on-board: 150  $\mu$ L for the first ARCHITECT Urine NGAL test plus 20  $\mu$ L for each additional Urine NGAL test from the same sample cup.
  - $> 3$  hours on-board: replace with a fresh sample (patient specimens, controls, and calibrators).
  - If using primary or aliquot tubes, use the sample gauge to ensure sufficient patient specimen is present.
- Prepare calibrators and controls.
  - Mix the ARCHITECT Urine NGAL Calibrators and Controls by gentle inversion before use.
  - To obtain the recommended volume requirements for the ARCHITECT Urine NGAL Calibrators and Controls, hold the bottles **vertically** and dispense 5 drops of each calibrator or 5 drops of each control into each respective sample cup.
- Load samples
  - For information on loading samples, refer to the ARCHITECT System Operations Manual, Section 5.
- Press RUN.
- For additional information on principles of operation, refer to the ARCHITECT System Operations Manual, Section 3.
- For optimal performance, it is important to perform routine maintenance as described in the ARCHITECT System Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

### Specimen Dilution Procedures

- Specimens with an ARCHITECT Urine NGAL value exceeding 1500.0 ng/mL are flagged with the code ">1500.0 ng/mL" and may be diluted with the Automated Dilution Protocol.
- Specimens with an ARCHITECT Urine NGAL value exceeding 6000.0 ng/mL are flagged with the code ">6000.0 ng/mL" when tested using the Automated Dilution Protocol.

**Automated Dilution Protocol**

- If using the Automated Dilution Protocol, the system performs a 1:4 dilution of the specimen and automatically calculates the concentration of the specimen before dilution and reports the results.

**Calibration**

- To perform an ARCHITECT Urine NGAL calibration, test the calibrators in duplicate. The calibrators should be priority loaded.
- A single replicate of each control level must be tested to evaluate the assay calibration.
  - Order controls as described in the **Assay Procedure** section.
  - Ensure that assay control values are within the concentration ranges specified in the control package insert.
- Calibration Range: 0.0 ng/mL - 1500.0 ng/mL.
- Once an ARCHITECT Urine NGAL calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:
  - A reagent kit with a new lot number is used.
  - Controls are out of range.
- For detailed information on how to perform an assay calibration, refer to the ARCHITECT System Operations Manual, Section 6.

**QUALITY CONTROL PROCEDURES**

The recommended control requirement for the ARCHITECT Urine NGAL assay is that a single sample of each control be tested once every 24 hours each day of use. If your laboratory quality control procedures require more frequent use of controls to verify test results, follow those procedures. Additional controls may be tested in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory's quality control policy.

The control values must be within the acceptable ranges specified in the control package insert. If a control is out of its specified range, the associated test results are invalid and must be retested. Recalibration may be indicated.

**Verification of Assay Claims**

For protocols to verify package insert claims, refer to the ARCHITECT System Operations Manual, Appendix B. The ARCHITECT Urine NGAL assay belongs to method group 1.

**RESULTS**

The ARCHITECT Urine NGAL assay uses a 4 Parameter Logistic Curve fit (4PLC, Y-weighted) data reduction method to generate a calibration curve.

**Flags**

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the ARCHITECT System Operations Manual, Section 5.

**Measuring Interval (Reportable Range)**

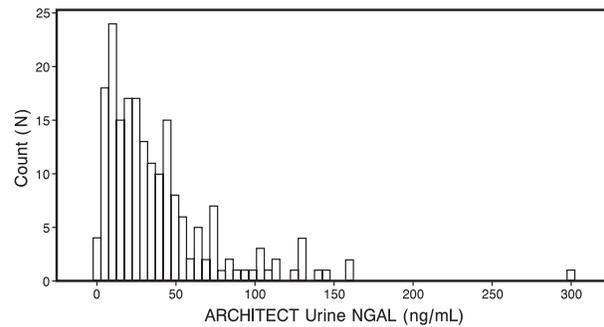
The measuring interval of the ARCHITECT Urine NGAL assay is 10.0 ng/mL to 1500.0 ng/mL. When using the automated dilution procedure, the assay can report values up to 6000.0 ng/mL.

**LIMITATIONS OF THE PROCEDURE**

- If the NGAL results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- For diagnostic purposes, results should be used in conjunction with other data; e.g., symptoms, results of other tests, clinical impressions, etc.
- Refer to the **SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS** section of this package insert for specimen limitations.

**EXPECTED VALUES**

The expected range for the ARCHITECT Urine NGAL assay was determined by testing specimens from 196 non-hospitalized donors that had blood creatinine values within 0.7 and 1.5 mg/dL and urine protein/urine creatinine ratios less than or equal to 200 mg/g. The expected range was determined to be less than or equal to 131.7 ng/mL (95<sup>th</sup> percentile). The data are summarized in the following graph.\*



\* Representative data; results in individual laboratories may vary from these data.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

**Precision**

The ARCHITECT Urine NGAL assay is designed to have an imprecision of ≤ 10% total CV.

**System Reproducibility**

A five-day precision study was performed for the ARCHITECT Urine NGAL assay based on guidance from the Clinical and Laboratory Standards Institute (CLSI) Document EP15-A2.<sup>11</sup> Testing was conducted at one clinical site using three lots each of ARCHITECT Urine NGAL Reagents, Calibrators, and Controls. Three levels of controls and panels were assayed in replicates of four at two separate times per day for 5 days. The data are summarized in the following tables.\*

Sample	n	Mean (ng/mL)	Within-Run		Between-Run		Between-Day	
			SD	%CV	SD	%CV	SD	%CV
Low Control	120	20.2	0.88	4.4	0.40	2.0	0.42	2.1
Medium Control	120	196.7	5.96	3.0	0.67	0.3	3.44	1.7
High Control	120	1174.4	26.40	2.2	0.00	0.0	16.16	1.4
Panel 1	120	20.0	0.74	3.7	0.00	0.0	0.32	1.6
Panel 2	120	150.7	4.05	2.7	2.23	1.5	3.19	2.1
Panel 3	120	237.3	7.33	3.1	6.14	2.6	4.66	2.0

Sample	n	Mean (ng/mL)	Total		Between-Lot		Overall	
			SD	%CV	SD	%CV	SD	%CV
Low Control	120	20.2	1.05	5.2	0.86	4.3	1.36	6.7
Medium Control	120	196.7	6.92	3.5	5.67	2.9	8.95	4.5
High Control	120	1174.4	30.96	2.6	23.04	2.0	38.59	3.3
Panel 1	120	20.0	0.81	4.0	0.92	4.6	1.23	6.1
Panel 2	120	150.7	5.62	3.7	4.01	2.7	6.90	4.6
Panel 3	120	237.3	10.64	4.5	4.45	1.9	11.53	4.9

\* Representative data; results in individual laboratories may vary from these data.

**Within-Laboratory Precision**

A study was performed based on guidance from the National Committee for Clinical Laboratory Standards (NCCLS) Document EP5-A2.<sup>12</sup> Testing was conducted at Abbott Laboratories using three ARCHITECT Urine NGAL reagent lots, three calibrator lots, one control lot, and three instruments. Three levels of controls and panels were assayed in replicates of three (to obtain a minimum of two replicates) at two separate times per day for 20 different days. Each reagent lot used a single calibration curve throughout the study. The data are summarized in the following table.\*

Sample	Instrument	n	Mean (ng/mL)	Within Run		Total	
				SD	%CV	SD	%CV
Low Control	1	358	20.6	0.70	3.4	0.89	4.3
	2	359	20.7	0.74	3.6	0.83	4.0
	3	359	20.1	1.39	6.9	1.42	7.0 <sup>a</sup>
Medium Control	1	359	199.6	5.37	2.7	6.77	3.4
	2	360	196.2	5.06	2.6	5.63	2.9
	3	359	199.3	4.17	2.1	4.71	2.4
High Control	1	359	1213.8	25.60	2.1	32.48	2.7
	2	359	1210.6	24.94	2.1	27.99	2.3
	3	360	1228.6	22.37	1.8	23.84	1.9
Panel 1	1	357	21.3	0.68	3.2	0.88	4.1
	2	360	21.4	0.72	3.3	0.76	3.6
	3	359	20.6	0.61	3.0	0.69	3.3
Panel 2	1	358	256.8	6.46	2.5	8.49	3.3
	2	360	251.7	6.34	2.5	7.32	2.9
	3	360	256.3	5.14	2.0	5.93	2.3
Panel 3	1	358	155.9	3.65	2.3	4.85	3.1
	2	360	153.7	3.68	2.4	4.29	2.8
	3	360	155.2	3.23	2.1	3.32	2.1

<sup>a</sup> One aberrant result was observed and the total %CV was 3.1 with this replicate excluded.

\* Representative data; results in individual laboratories may vary from these data.

#### Recovery

The ARCHITECT Urine NGAL assay is designed to have a mean recovery of 100 ± 15% for samples with NGAL concentrations ranging from 20.0 ng/mL to 200.0 ng/mL.

A study was performed with 12 urine samples containing low levels of NGAL. The samples were spiked with additional NGAL to create five test samples with concentrations ranging from 20.0 ng/mL to 200.0 ng/mL and seven samples with concentrations ranging from 200.0 ng/mL to 6000.0 ng/mL. The samples were tested using the ARCHITECT Urine NGAL assay on two instruments and the resulting percent recovery was calculated. For the 12 samples, the individual percent recovery of the ARCHITECT Urine NGAL assay ranged from 89.6% to 107.8%. For the five samples with NGAL concentrations ranging from 20.0 ng/mL to 200.0 ng/mL, the individual percent recovery of the ARCHITECT Urine NGAL assay ranged from 89.6% to 105.1% and the mean percent recovery was 96.4% for one instrument and 97.9% for the other instrument.\*

\* Representative data; results in individual laboratories may vary from these data.

#### Sensitivity

##### Limit of Quantitation

The ARCHITECT Urine NGAL assay is designed to have a Limit of Quantitation (LoQ) of ≤ 10.0 ng/mL.

A study was performed with one zero-level urine sample, and seven low-level urine samples with NGAL concentrations of approximately 1.0, 1.5, 2.0, 3.0, 5.0, 7.0, and 10.0 ng/mL. These samples were tested in replicates of four in five separate runs over a minimum of 3 days using two reagent lots and two instruments per system (ARCHITECT *i* 2000, ARCHITECT *i* 2000<sub>SR</sub>, and ARCHITECT *i* 1000<sub>SR</sub>). The LoQ for the ARCHITECT Urine NGAL assay ranged from 1.5 ng/mL to 3.0 ng/mL by system.\*

\*Representative data; results in individual laboratories may vary from these data.

##### Limit of Blank and Limit of Detection

In the same study, the Limit of Blank (LoB) and Limit of Detection (LoD) were determined based on guidance from the NCCLS Document EP17-A.<sup>13</sup> The LoB ranged from 0.1 ng/mL to 0.6 ng/mL and the LoD ranged from 0.7 ng/mL to 1.0 ng/mL by system.\*

\*Representative data; results in individual laboratories may vary from these data.

#### Analytical Specificity

Urine specimens from individuals with other medical conditions were evaluated for the presence of NGAL using the ARCHITECT Urine NGAL assay. The data are summarized in the following table.\*

#### Concentration of ARCHITECT Urine NGAL in Individuals with Other Medical Conditions

Category <sup>a</sup>	n	Concentration Range (ng/mL)
Anti-Cytomegalovirus (anti-CMV positive)	10	0.3 - 44.0
Epstein-Barr Virus (anti-EBV positive)	10	4.7 - 61.9
Hepatitis A Virus (anti-HAV positive)	10	3.4 - 57.9
Herpes Simplex Virus (anti-HSV positive)	10	5.8 - 43.5
Multiple Myeloma	3	0.7 - 47.0
Rubella Virus (anti-Rubella positive)	10	2.2 - 64.1

<sup>a</sup> Urine specimens from patients with Urinary Tract Infection may yield elevated NGAL concentrations.

\* Representative data; results in individual laboratories may vary from these data.

#### Autodilution Verification

The ARCHITECT Urine NGAL automated dilution method is designed to have a mean concentration difference of ≤ 10% versus a manual dilution method when performed on samples with values > 1500 ng/mL.

The ARCHITECT Urine NGAL assay was evaluated with the 1:4 autodilution method versus a 1:4 manual dilution method using 12 human urine samples with NGAL levels ranging from 1500.0 to 6000.0 ng/mL. Three replicates each of the autodiluted and manually diluted samples were assayed on two instruments using the ARCHITECT Urine NGAL assay. The percent difference ranged from -1.5% to 13.3% across all samples. The percent difference results are summarized in the following table.\*

Sample	Instrument	Mean Automated Diluted Value (ng/mL)	Mean Manually Diluted Value (ng/mL)	% Difference <sup>a</sup>
1	1	2541.7	2394.0	6.2
	2	2516.5	2375.5	5.9
2	1	2256.4	2079.3	8.5
	2	2276.8	2114.9	7.7
3	1	2314.8	2163.3	7.0
	2	2346.4	2317.9	1.2
4	1	2133.6	2060.9	3.5
	2	2324.4	2197.3	5.8
5	1	3746.5	3562.5	5.2
	2	3797.5	3651.5	4.0
6	1	3789.5	3483.5	8.8
	2	3865.0	3411.1	13.3
7	1	3841.1	3707.5	3.6
	2	3901.6	3909.7	-0.2
8	1	3943.9	3858.5	2.2
	2	4041.0	3843.3	5.1
9	1	5789.7	5444.3	6.3
	2	5472.7	5389.7	1.5
10	1	5654.2	5424.7	4.2
	2	5495.4	5430.3	1.2
11	1	5599.4	5436.4	3.0
	2	5526.9	5391.5	2.5
12	1	5441.8	5523.2	-1.5
	2	5486.2	5386.8	1.8

$$^a \% \text{ Difference} = \frac{[\text{Mean Automated Diluted Value (ng/mL)} - \text{Mean Manually Diluted Value (ng/mL)}]}{\text{Mean Manually Diluted Value (ng/mL)}} \times 100$$

\* Representative data; results in individual laboratories may vary from these data.

### Interference

The ARCHITECT Urine NGAL assay is designed to have ≤ 10% interference from potentially interfering antibiotics, potential cross-reactants, potentially interfering endogenous substances, and potentially interfering conditions.

#### Potentially Interfering Antibiotics

Potentially interfering antibiotics were evaluated to determine whether NGAL concentrations were affected when using the ARCHITECT Urine NGAL assay. The antibiotics listed below were spiked into normal urine samples (control samples) and into two sample levels of NGAL (one level within the expected range and one level above the expected range [Refer to the **EXPECTED VALUES** section]). The samples were assayed and the NGAL concentrations of the spiked samples were compared to the control samples. The data are summarized in the following table.\*

Potentially Interfering Antibiotic	Interferent Concentration	% Difference	
		Within the Expected Range	Above the Expected Range
Amikacin	15 mg/dL	-1.9	-0.5
Amphotericin B	5.8 µg/mL	-1.1	-0.6
Cefdinir	100 µg/mL	-2.8	-1.7
Cefuroxime	100 µg/mL	-1.5	0.1
Cephadrine	100 µg/mL	-2.9	-2.1
Ciprofloxin	7.4 µg/mL	0.3	0.2
Gentamicin	12 mg/dL	-0.5	-0.6
Kanamycin A	6 mg/dL	0.1	-0.5
Kanamycin B	6 mg/dL	-0.3	1.1
Penicillian G	100 µg/mL	-0.8	-0.8
Rifampin	5 mg/dL	-1.5	-2.0
Spectinomycin	100 µg/mL	-1.7	-0.1
Tobramycin	2 mg/dL	-1.7	-0.0
Vancomycin	6 mg/dL	2.3	0.1

\* Representative data; results in individual laboratories may vary from these data.

#### Potential Cross-Reactants

Potential cross-reactants were evaluated to determine whether NGAL concentrations were affected when using the ARCHITECT Urine NGAL assay. The cross-reactants listed below were spiked into normal urine samples (control samples) and into two sample levels of NGAL (one level within the expected range and one level above the expected range [Refer to the **EXPECTED VALUES** section]). The samples were assayed and the NGAL concentrations of the spiked samples were compared to the control samples. The data are summarized in the following table.\*

Potential Cross-Reactants	Interferent Concentration	% Difference	
		Within the Expected Range	Above the Expected Range
Acid Glycoprotein	100 µg/mL	0.7	-0.3
Alpha-1-microglobulin	100 µg/mL	0.6	0.5
Hepatocyte Growth Factor	100 ng/mL	-2.2	-1.1
Matrix Metalloprotease 2	1000 ng/mL	-1.1	-1.9
Matrix Metalloprotease 8	200 ng/mL	-1.0	-1.1
Matrix Metalloprotease 9	1500 ng/mL	-2.5	-0.3

\* Representative data; results in individual laboratories may vary from these data.

#### Potentially Interfering Endogenous Substances

Potentially interfering endogenous substances were evaluated to determine whether NGAL concentrations were affected when using the ARCHITECT Urine NGAL assay. The endogenous substances listed below were spiked into normal urine samples (control samples) and into two sample levels of NGAL (one level within the expected range and one level above the expected range [Refer to the **EXPECTED VALUES** section]). The samples were assayed and the NGAL concentrations of the spiked samples were compared to the control samples. The data are summarized in the following table.\*

Potentially Interfering Endogenous Substances	Interferent Concentration	% Difference	
		Within the Expected Range	Above the Expected Range
Acetone	100 mg/dL	-3.5	-0.3
Ascorbic Acid	1 g/dL	-0.6	0.0
Bicarbonate	35 mmol/L	-1.5	-0.6
Bilirubin	2.0 mg/dL	0.5	-1.5
Creatinine	1000 mg/dL	1.3	0.2
Ethanol	200 mg/dL	-1.6	-1.4
Glucose	1 g/dL	-0.7	-0.2
Hemoglobin	100 mg/L	1.4	0.4
Protein	1 g/dL	2.8	0.9
Riboflavin	7.5 mg/dL	1.9	-0.1
Sodium Chloride	6 g/dL	1.6	1.6
Urea	12 g/dL	-0.4	1.2

\* Representative data; results in individual laboratories may vary from these data.

#### Potentially Interfering Conditions

Potentially interfering conditions were evaluated to determine whether NGAL concentrations were affected when using the ARCHITECT Urine NGAL assay. Acidic or basic solutions were spiked into normal urine samples (control samples) and into two sample levels of NGAL (one level within the expected range and one level above the expected range [Refer to the **EXPECTED VALUES** section]). The samples were assayed and the NGAL concentrations of the spiked samples were compared to the control samples. The data are summarized in the following table.\*

Potentially Interfering Condition	Interferent Level	% Difference	
		Within the Expected Range	Above the Expected Range
Low pH	4.5	-6.1	-3.8
High pH	10.0	2.8	-2.6

\* Representative data; results in individual laboratories may vary from these data.

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