Alinity i

Urine NGAL Reagent Kit

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Urine NGAL
09P29
G90674R02
B9P290

Revised March 2018.

REF 09P2920

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

NAME

Alinity i Urine NGAL Reagent Kit

INTENDED USE

The Alinity i Urine NGAL assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative determination of neutrophil gelatinase-associated lipocalin (NGAL) in human urine on the Alinity i analyzer.

The Alinity i Urine NGAL assay is to be used for the *in vitro* determination of human NGAL in urine as an indication of kidney injury.

SUMMARY AND EXPLANATION OF THE TEST

The Alinity i 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.[1-4] 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.[5] Early detection of NGAL may be used as an aid in the diagnosis of AKI and patient management.[5]

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

This assay is a two-step immunoassay for the quantitative detection of NGAL in human urine using chemiluminescent microparticle immunoassay (CMIA) technology.

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 and incubated. The NGAL present in the sample binds to the anti-NGAL coated microparticles. The mixture is washed. Anti-NGAL acridinium-labeled conjugate is added to create a reaction mixture and incubated. Following a wash cycle, Pre-Trigger and Trigger Solutions are added.

The resulting chemiluminescent reaction is measured as relative light units (RLUs). There is a relationship between the amount of NGAL in the sample and the RLUs detected by the system optics.

For additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section 3.

REAGENTS

Kit Contents

Alinity i Urine NGAL Reagent Kit 09P29

Volumes (mL) listed in the table below indicate the volume per cartridge.

REF	09P2920
Tests per cartridge	100
Number of cartridges per kit	2
Tests per kit	200
MICROPARTICLES	6.6 mL
CONJUGATE	6.1 mL

MICROPARTICLES 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 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.

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[6-9]

The following warnings and precautions apply to: MICROPARTICLES

WARNING	Contains bis tris hydrochloride* and methylisothiazolones.
H317	May cause an allergic skin reaction.
H316*	Causes mild skin irritation.
Prevention	
P261	Avoid breathing mist / vapors / spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

* Not applicable where regulation EU 1272/2008 (CLP) or OSHA Hazard Communication 29CFR 1910.1200 (HCS) 2012 have been implemented.

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The following warnings and precautions apply to: CONJUGATE	
	
WARNING	Contains methylisothiazolones.
H317	May cause an allergic skin reaction.
Prevention	
P261	Avoid breathing mist / vapors / spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the Alinity ci-series Operations Manual, Section 8.

Reagent Handling

- Upon receipt, gently invert the unopened reagent kit by rotating it over and back for a full 180 degrees, 5 times with green label stripe facing up and then 5 times with green label stripe facing down. This ensures that liquid covers all sides of the bottles within the cartridges. During reagent shipment, microparticles can settle on the reagent septum.
  - Place a check in the square on the reagent kit to indicate to others that the inversions have been completed.
- After mixing, place reagent cartridges in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

For a detailed discussion of reagent handling precautions during system operation, refer to the Alinity ci-series Operations Manual, Section 7.

Reagent Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	Store in upright position. If cartridge does not remain upright, gently invert the cartridge 10 times and place in an upright position for 1 hour before use.
Onboard	System Temperature	30 days	
Opened	2 to 8°C	Until expiration date	Store in upright position. If cartridge does not remain upright during storage, discard the cartridge. Do not reuse original reagent caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance.

Reagents may be stored on or off the system. If removed from the system, store reagents with new replacement caps in an upright position at 2 to 8°C. For reagents stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright.

For information on unloading reagents, refer to the Alinity ci-series Operations Manual, Section 5.

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when a calibration error occurs or a control value is out of the specified range. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

For troubleshooting information, refer to the Alinity ci-series Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The Alinity i Urine NGAL assay file must be installed on the Alinity i analyzer prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, refer to the Alinity ci-series Operations Manual, Section 2.

For information on printing assay parameters, refer to the Alinity ci-series Operations Manual, Section 5.

For a detailed description of system procedures, refer to the Alinity ci-series Operations Manual.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

The specimen type used for this assay is urine only.

- Performance has not been established for the use of cadaveric specimens or the use of bodily fluids other than human urine.
- The instrument does not provide the capability to verify specimen types. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

- Do not use:
  - pooled specimens
  - specimens with obvious microbial contamination
  - specimens with fungal growth
- 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 ≥ 400 RCF (Relative Centrifugal Force) for a minimum of five minutes.**[10]
- Transfer clarified specimen to a sample cup or secondary tube for testing and/or storage.

- If specimens were stored (refer to the Specimen 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 Alinity ci-series 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.**

Specimen Storage

Specimen Type	Temperature	Maximum Storage Time
Urine	Room temperature (22 to 30˚C)	24 hours
	2 to 8˚C	7 days

If testing will be delayed more than 24 hours at room temperature or more than 7 days at 2 to 8˚C, store specimens at -70˚C or colder. Avoid more than 3 freeze/thaw cycles.

Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

PROCEDURE

Materials Provided

09P29 Alinity i Urine NGAL Reagent Kit

Materials Required but not Provided

- Alinity i Urine NGAL assay file
- 09P2901 Alinity i Urine NGAL Calibrators
- 09P2910 Alinity i Urine NGAL Controls or other control material
- Alinity Trigger Solution
- Alinity Pre-Trigger Solution
- Alinity i-series Concentrated Wash Buffer

For information on materials required for operation of the instrument, refer to the Alinity ci-series Operations Manual, Section 1.

For information on materials required for maintenance procedures, refer to the Alinity ci-series Operations Manual, Section 9.

Assay Procedure

For a detailed description of how to run an assay, refer to the Alinity ci-series Operations Manual, Section 5.

- If using primary or aliquot tubes, refer to the Alinity ci-series Operations Manual, Section 4 to ensure sufficient specimen is present.
- To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.
- Maximum number of replicates sampled from the same sample cup: 10
  - Priority:
    - Sample volume for first test: 70 µL
    - Sample volume for each additional test from same sample cup: 20 µL
  - ≤ 3 hours on the reagent and sample manager:
    - Sample volume for first test: 150 µL
    - Sample volume for each additional test from same sample cup: 20 µL
  - > 3 hours on the reagent and sample manager:
    - Replace with a fresh aliquot of sample.
- Refer to the Alinity i Urine NGAL calibrator package insert and/or Alinity i Urine NGAL control package insert for preparation and usage.
- For general operating procedures, refer to the Alinity ci-series Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the Alinity ci-series Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Sample Dilution Procedures

Samples with a 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.

Samples with a 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

The system performs a 1:4 dilution of the sample and automatically calculates the concentration by multiplying the result by the dilution factor.

For detailed information on ordering dilutions, refer to the Alinity ci-series Operations Manual, Section 5.

Calibration

For instructions on performing a calibration, refer to the Alinity ci-series Operations Manual, Section 5.

Each assay control must be tested to evaluate the assay calibration.

Once a 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.
- Daily quality control results are outside of statistically-based quality control limits used to monitor and control system performance, as described in the Quality Control Procedures section of this package insert.
  - If statistically-based quality control limits are not available, then the calibration should not exceed a 30-day limit for recalibration frequency.

This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

Quality Control Procedures

The recommended control requirement for the Alinity i Urine NGAL assay is that a single sample of each control level be tested once every 24 hours each day of use.

Additional controls may be tested in accordance with local, state, and/or federal regulations or accreditation requirements and your laboratory's quality control policy.

To establish statistically-based control limits, each laboratory should establish its own concentration target and ranges for new control lots at each clinically relevant control level. This can be accomplished by assaying a minimum of 20 replicates over several (3-5) days and using the reported results to establish the expected average (target) and variability about this average (range) for the laboratory. Sources of variation that should be included in this study in order to be representative of future system performance include:

- Multiple stored calibrations
- Multiple reagent lots
- Multiple calibrator lots
- Multiple processing modules (if applicable)
- Data points collected at different times of the day

Refer to published guidelines for information or general control recommendation, for example Clinical and Laboratory Standards Institute (CLSI) Document C24-A3 or other published guidelines, for general quality control recommendations.[11]

- If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.

- If quality control results do not meet the acceptance criteria defined by your laboratory, sample results may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary. For troubleshooting information, refer to the Alinity ci-series Operations Manual, Section 10.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Quality Control Guidance

Refer to "Basic QC Practices" by James O Westgard, Ph.D. for guidance on laboratory quality control practices.[12]

Verification of Assay Claims

For protocols to verify package insert claims, refer to Verification of Assay Claims in the Alinity ci-series Operations Manual.

RESULTS

Calculation

The Alinity i Urine NGAL assay utilizes a 4 Parameter Logistic Curve fit data reduction method (4PLC, Y-weighted) to generate a calibration and results.

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 Alinity ci-series Operations Manual, Section 5.

Measuring Interval

Measuring interval is defined as the range of values in ng/mL which meets the limits of acceptable performance for linearity, imprecision, and bias.

The measuring interval of the Alinity i Urine NGAL assay is 10.0 to 1500.0 ng/mL.

LIMITATIONS OF THE PROCEDURE

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

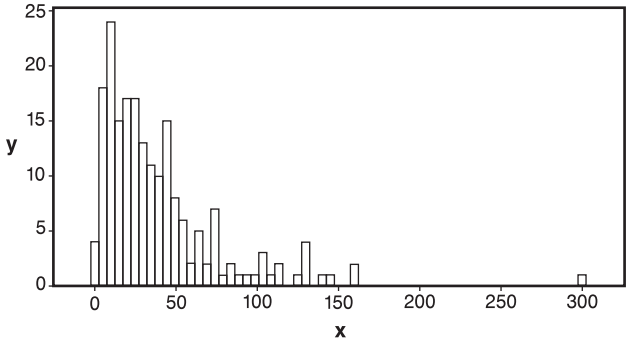
EXPECTED VALUES

This study was performed on the ARCHITECT i System.

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

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 (95th percentile). The data are summarized in the following graph.



x = ARCHITECT Urine NGAL (ng/mL)

y = Count (N)

SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

The Alinity i analyzer and the ARCHITECT i System utilize the same reagents and sample/reagent ratios.

Unless otherwise specified, all studies were performed on the Alinity i analyzer.

Precision

Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A2.[13] Testing was conducted using 1 lot of the Alinity i Urine NGAL Reagent Kit, 1 lot of the Alinity i Urine NGAL Calibrators, and 1 lot of the Alinity i Urine NGAL Controls and 1 instrument. Three controls and 5 human urine panels were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days.

			Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
Sample	n	Mean (ng/mL)	SD	%CV	SD	%CV
Low Control	120	19.4	0.49	2.5	0.53	2.8
Medium Control	120	191.8	3.00	1.6	3.65	1.9
High Control	120	1209.9	16.65	1.4	18.98	1.6
Panel 1	120	11.9	0.35	2.9	0.75	6.3
Panel 2	120	23.5	0.49	2.1	0.77	3.3
Panel 3	120	171.7	3.03	1.8	3.64	2.1
Panel 4	119	287.5	4.39	1.5	5.15	1.8
Panel 5	120	1446.1	21.67	1.5	23.30	1.6

[a] Includes within-run, between-run, and between-day variability.

Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.[14] Testing was conducted using 3 lots of the Alinity i Urine NGAL Reagent Kit on each of 2 instruments over a minimum of 3 days. The Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) values are summarized below. These representative data support the lower limit of the measuring interval.

	ng/mL
LoB[a]	0.3
LoD[b]	0.5
LoQ[c,d]	3.0

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ is defined as the lowest concentration at which a maximum allowable precision of 20 %CV was met.

[d] This value represents the observed LoQ on the ARCHITECT System. The LoQ observed on the Alinity i analyzer supports this LoQ.

Linearity

A study was performed based on guidance from CLSI EP06-A.[15]

This assay is linear across the measuring interval of 10.0 to 1500.0 ng/mL.

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Analytical Specificity

This study was performed on the ARCHITECT i System.

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[a]	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

[a] Urine specimens from patients with Urinary Tract Infection may yield elevated NGAL concentrations.

Interference

These studies were performed on the ARCHITECT i System.

Potentially Interfering Endogenous Substances

Potentially interfering endogenous substances were evaluated to determine whether NGAL concentrations were affected when using the ARCHITECT Urine NGAL assay. Two sample levels of NGAL (one level within the expected range and one level above the expected range [Refer to the EXPECTED VALUES section]) were used in the interference study. Each sample level was spiked with the individual endogenous substances listed below to create spiked samples. The spiked samples were assayed and their NGAL concentrations were compared to their respective un-spiked sample (Control samples) NGAL concentrations. 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

Potentially Interfering Antibiotics

Potentially interfering antibiotics were evaluated to determine whether NGAL concentrations were affected when using the ARCHITECT Urine NGAL assay. Two sample levels of NGAL (one level within the expected range and one level above the expected range [Refer to the EXPECTED VALUES section]) were used in the interference study. Each sample level was spiked with the individual antibiotics listed below to create spiked samples. The spiked samples were assayed and their NGAL concentrations were compared to their respective un-spiked sample (Control samples) NGAL concentrations. 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
Cephradine	100 µg/mL	-2.9	-2.1
Ciprofloxacin	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
Penicillin 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

Potential Cross-Reactants

Potential cross-reactants were evaluated to determine whether NGAL concentrations were affected when using the ARCHITECT Urine NGAL assay. Two sample levels of NGAL (one level within the expected range and one level above the expected range [Refer to the EXPECTED VALUES section]) were used in the interference study. Each sample level was spiked with the individual cross-reactants listed below to create spiked samples. The spiked samples were assayed and their NGAL concentrations were compared to their respective un-spiked sample (Control samples) NGAL concentrations. The data are summarized in the following table.

Potential Cross-Reactant	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

Potentially Interfering Conditions

Potentially interfering conditions were evaluated to determine whether NGAL concentrations were affected when using the ARCHITECT Urine NGAL assay. Two sample levels of NGAL (one level within the expected range and one level above the expected range [Refer to the EXPECTED VALUES section]) were used in the interference study. Each sample level was spiked with acidic or basic solutions to create spiked samples. The spiked samples were assayed and their NGAL concentrations were compared to their respective un-spiked sample (Control samples) NGAL concentrations. 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

Method Comparison

A study was performed based on guidance from CLSI EP09-A3 using the Passing-Bablok regression method.[16]

		Units	n	Correlation Coefficient	Intercept	Slope	Concentration Range
Alinity i Urine NGAL vs ARCHITECT Urine NGAL	Urine	ng/mL	147	1.00	0.85	1.03	17.7 - 1317.1

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15. Clinical and Laboratory Standards Institute (CLSI). *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline*. CLSI Document EP06-A. Wayne, PA: CLSI; 2003.
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Note for number formatting:

- A space is used as thousands separator (example: 10 000 specimens).
- A period is used to separate the integer part from the fractional part of a number written in decimal form (example: 3.12%).

Key to Symbols

	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
CONJUGATE	Conjugate
INVERSIONS PERFORMED	Inversions Performed
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
MICROPARTICLES	Microparticles
PRODUCT OF IRELAND	Product of Ireland
REF	List Number
SN	Serial number

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Customer Service: Contact your local representative or find country-specific contact information on www.abbottdiagnostics.com

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