ARCHITECT
Urine NGAL Controls

REF 1P37-10

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Urine NGAL
1P37
G60460R05
C1P370

Read Highlighted Changes: Revised April 2022.

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

For laboratory professional use only.

INTENDED USE

The ARCHITECT Urine NGAL Controls are used for the verification of the accuracy and precision of the ARCHITECT iSystem when used for the quantitative determination of neutrophil gelatinase-associated lipocalin (NGAL) in human urine.

Refer to the ARCHITECT Urine NGAL reagent package insert and ARCHITECT System Operations Manual for additional information.

CONTENTS

3 Bottles (8.0 mL each) of ARCHITECT Urine NGAL Controls. The Low Control, Medium Control, and High Control are prepared in phosphate buffer with protein (bovine) stabilizers. Low, Medium, and High Controls contain recombinant human NGAL. Preservative: ProClin 300.

The controls are at the following concentrations:

Controls	Concentration Target (ng/mL)	Concentration Range (ng/mL)
CONTROL L	20.0	11.0 - 29.0
CONTROL M	200.0	110.0 - 290.0
CONTROL H	1200.0	660.0 - 1500.0

Each laboratory should establish its own concentration ranges for new control lots at each control level. This can be accomplished by assaying a minimum of 20 replicates over several (3-5) days. Sources of variation that can be expected should be included in this study in order to be representative of future system performance. These may include:

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

These results should be applied to your laboratory's quality control practices.

TRACEABILITY

The ARCHITECT Urine NGAL Controls are traceable to an internal reference that has been value assigned spectrophotometrically using recombinant human NGAL.

PRECAUTIONS

- IVD
- For *In Vitro* Diagnostic Use

The following warnings and precautions apply to: CONTROL L / CONTROL M / CONTROL H

WARNING	Contains methylisothiazolones.
H317	May cause an allergic skin reaction.
H402*	Harmful to aquatic life.
H412	Harmful to aquatic life with long lasting effects.
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.
P273	Avoid release to the environment.
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 EC 1272/2008 (CLP) has been implemented.

Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at www.corelaboratory.abbott or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

QUALITY CONTROL PROCEDURES

The recommended control requirement for the assay is that a single sample of each control level 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.

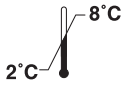
Additional controls may be tested in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory's quality control policy.

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.

PREPARATION FOR USE

- Controls are liquid ready-to-use.
  No preparation is required.
- Prior to each use, mix by gentle inversion.
- To obtain the recommended volume requirements for the controls, hold the bottles **vertically** and dispense 5 drops of each control into each respective sample cup.
- After each use, tightly close the caps and return the controls to 2-8°C storage.
- For information on ordering controls, 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.

STORAGE

- Controls are stable until the expiration date when stored and handled as directed.
- Do not use past expiration date.
- Controls must be stored at 2-8°C in an upright position and may be used immediately after removal from 2-8°C storage.
- 

INDICATIONS OF INSTABILITY OR DETERIORATION

Instability or deterioration should be suspected if there are precipitates, visible signs of leakage, turbidity, or if controls do not meet the appropriate package insert and/or ARCHITECT System Operations Manual criteria.

Key to Symbols

ISO 15223 Symbols

	Consult instructions for use
	Manufacturer
	Temperature limitation
	Use by/Expiration date
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
REF	List Number

Other Symbols

CONC	Concentration
CONTROL L	Control Low, Medium, High (L,M,H)
PRODUCT OF IRELAND	Product of Ireland
RANGE	Range
WARNING: SENSITIZER	Warning: May cause an allergic reaction.

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DN: c=VN, st=THÀNH PHỐ HÀ NỘI, o=Văn phòng đại diện ABBOTT LABORATORIES GMBH tại thành phố Hà Nội, title=Trưởng Đại Diện, cn=Cruz Bella Rose Navarro, 0.9.2342.19200300.100.1.1=MST:P5954425A
Date: 2022.05.05 16:08:58 +07'00'

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

For customers in the European Union: if, in the course of using this device, you have reason to believe that a serious incident has occurred, report it to the manufacturer and to your national authority. A summary of safety and performance (SSP) for this device is available at https://ec.europa.eu/tools/eudamed. This is the SSP location after the launch of European Database on Medical Devices. Search for the device using the UDI-DI provided on the outer packaging of the device.

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