



## Urgent Field Safety Notice Product Correction

Immediate Action Required

**Date Issued** 31 December 2012

**Product**

Product Name	List Number	Serial/Lot Number
ARCHITECT Testosterone	7K73-20	11907JN01, 13909JN01, 15909JN01, 15916JN00, 18907JN01, 18907JN02, 21901JN01
	7K73-25	11907JN00, 13909JN00, 15909JN00, 15916JN01, 18907JN00, 21901JN00, 21901JN03, 21901JN04
	7K73-01	17342JN00, 19142JN00, 19142JN01, 19142JN02, 22270JN00, 23277JN00, 23277JN01
	7K73-10	17203JN00, 19075JN00, 22121JN00, 23199JN00

**Explanation**

The purpose of this letter is to communicate a field correction regarding the product labeling for safety precautions associated with the ARCHITECT Testosterone assay.

The current labels and package inserts for the ARCHITECT Testosterone Reagent, LN 7K73-20 and 7K73-25, ARCHITECT Testosterone Calibrators, LN 7K73-01 and ARCHITECT Testosterone Controls, LN 7K73-10 do not contain the warnings and precautions applicable to material containing methylisothiazolones which are classified as skin sensitizers.

**User Safety**

Exposure to the above ARCHITECT Testosterone material may cause an allergic skin reaction. General personal protective equipment should be used per your laboratory practices and will provide adequate protection against such an event.

This warning information may also be found in the ARCHITECT Testosterone Safety Data Sheets available at [www.abbottdiagnostics.com](http://www.abbottdiagnostics.com) or contact your local representative.

This notice is not a result of an adverse event reported for the marketed product.

**Necessary Actions**

- 1) Treat this product as a 'skin sensitizer'. The following hazard symbol applies to all ARCHITECT Testosterone product labeling:



**WARNING: SENSITIZER**

- 2) Refer to attachment 1 for additional safety precaution information that will be added to

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the next revision of the ARCHITECT Testosterone product inserts.

- 3) If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.
- 4) Please retain this letter for your laboratory records.
- 5) Corrected labeling will be included starting with the below lots:

ARCHITECT Testosterone Reagent, LN 7K73-20 from lot 24900UI01  
ARCHITECT Testosterone Reagent, LN 7K73-25 from lot 24900UI00  
ARCHITECT Testosterone Calibrators, LN 7K73-01 from lot 24912UI00  
ARCHITECT Testosterone Controls, LN 7K73-10 from lot 24911UI00

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**Contact  
Information**

We sincerely apologise for any inconvenience this may have caused you.

If you or any of the health care providers you serve have any questions regarding this information, please contact your local Customer Service Representative

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# Attachment 1: Safety Precautions:

## ARCHITECT Testosterone Reagents 7K73-20 and 7K73-25

### 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<sup>3</sup>. Biosafety Level 2<sup>4</sup> other appropriate biosafety practices<sup>5,6</sup> should be used for materials that contain or are suspected of containing infectious agents.
- The following warnings and precautions apply to these components:
- Microparticles
- Conjugate



**WARNING:** Contains methylisothiazolones.  
H317 May cause an allergic skin reaction.

**Prevention**  
P261 Avoid breathing mist / vapours / 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.  
P363 Wash contaminated clothing before reuse.  
This material and its container must be disposed of in a safe way.

- The following warnings and precautions apply to the Assay Diluent:



**WARNING:** Contains methylisothiazolones.  
H317 May cause an allergic skin reaction.  
H290 May be corrosive to metals.

**Prevention**  
P261 Avoid breathing mist / vapours / spray.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves / protective clothing / eye protection.  
P390 Absorb spillage to prevent material damage.

**Response**  
P302+P352 IF ON SKIN: Wash with plenty of water.  
P333+P313 If skin irritation or rash occurs: Get medical advice / attention.  
P363 Wash contaminated clothing before reuse.  
This material and its container must be disposed of in a safe way.

- Safety Data Sheets are available at [www.abbottdiagnostics.com](http://www.abbottdiagnostics.com) or contact your local representative.
- For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

## ARCHITECT Testosterone Calibrator 7K73-01

### PRECAUTIONS

- IVD** For In Vitro Diagnostic Use.
- WARNING: SENSITIZER** Warning: May cause an allergic reaction
- The following warnings and precautions apply to the Calibrators:



**WARNING:** Contains methylisothiazolones.  
H317 May cause an allergic skin reaction.

**Prevention**  
P261 Avoid breathing mist / vapours / 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.  
P363 Wash contaminated clothing before reuse.  
This material and its container must be disposed of in a safe way.

- Safety Data Sheets are available at [www.abbottdiagnostics.com](http://www.abbottdiagnostics.com) or contact your local representative.
- ARCHITECT Testosterone Calibrators are stable until the expiration date when stored and handled as directed. Do not use past expiration date.

## ARCHITECT Testosterone Control 7K73-10

### PRECAUTIONS

- IVD** For In Vitro Diagnostic Use.
- WARNING: SENSITIZER** Warning: May cause an allergic reaction
- The following warnings and precautions apply to the Controls



**WARNING:** Contains methylisothiazolones.  
H317 May cause an allergic skin reaction.

**Prevention**  
P261 Avoid breathing mist / vapours / 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.  
P363 Wash contaminated clothing before reuse.  
This material and its container must be disposed of in a safe way.

- Safety Data Sheets are available at [www.abbottdiagnostics.com](http://www.abbottdiagnostics.com) or contact your local representative.
- ARCHITECT Testosterone Controls are stable until the expiration date when stored and handled as directed. Do not use past expiration date.