

Фотографические изображения общего вида на медицинское изделие

**Набор контрольных материалов для подтверждения воспроизводимости и правильности
качественного определения антител класса IgG к вирусу SARS-CoV-2
иммунохемилюминесцентным методом в сыворотке и плазме крови человека на
иммунохимических анализаторах ARCHITECT «SARS-CoV-2 IgG Контрольные материалы
для ARCHITECT (SARS-CoV-2 IgG Control Kit)»**

(размером не менее 18 x 24 сантиметра)

SARS-CoV-2 IgG Control Kit

FOR USE WITH ARCHITECT

PROTECT FROM LIGHT

Abbott Diagnostic Division
Siège Social
13851 Boulevard
+33-1-69-73-12-12

PRODUCT OF USA

Abbott

CONTAINS AZIDE

UNTIL FIRST USE

20°C

AFTER THAW

2°C

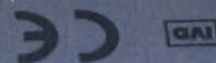
8°C

1 x 4.0 mL

1 x 4.0 mL

CONTROL -

CONTROL +



REF

6R86-12 CoV-2 IgG Control



www.corelaboratory.abbott/IFU R01



Exp.

2020-08-01

LOT

17226FN00

GTIN

00380740192204

(01) 00380740192204 (17) 200801
(10) 17226FN00 (240) 6R8612



H07881R02





Revised April 2020

SARS-CoV-2 IgG Control Kit

FOR USE WITH
ARCHITECT

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.
For laboratory professional use only.

NAME

SARS-CoV-2 IgG Control Kit (also referred to as CoV-2 IgG Cnls)

INTENDED USE

The SARS-CoV-2 IgG Control Kit is for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT i System when used for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma.
For additional information, refer to the SARS-CoV-2 IgG reagent package insert and the ARCHITECT System Operations Manual.

NTENTS

CONTROL - contains human plasma.

CONTROL + contains inactivated, cell-free, human blood-derived IL reactive for anti-SARS-CoV-2 IgG.

alives: sodium azide and antimicrobial agents.

ols are at the following ranges. The ranges may be used
full replicate control specifications on the ARCHITECT i

Safety Precautions



CAUTION: This product contains human-sourced and/or potentially infectious components. Refer to the CONTENTS section of this package insert. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection.

Therefore, all human-sourced materials should be considered potentially infectious. It is recommended that this product, human specimens, and all consumables contaminated with potentially infectious materials be handled in accordance with the OSHA Standard on Bloodborne Pathogens: Biosafety Level 2 or other appropriate regional, national, and institutional biosafety practices should be used for materials that contain, are suspected of containing, or are contaminated with infectious agents.^{1,4}

The human-sourced materials used in the **CONTROL -** have been tested and found to be reactive for anti-SARS-CoV-2 IgG and nonreactive for HBsAg, HIV-1 RNA or HIV-1 Ag, anti-HIV-1/HIV-2, and anti-HCV.

The human-sourced material used in the **CONTROL +** has been tested and found to be nonreactive for anti-SARS-CoV-2 IgG, HBsAg, HIV-1 RNA or HIV-1 Ag, anti-HIV-1/HIV-2, and anti-HCV.

CONTROL +

ARCHITECT i

SARS-CoV-2 IgG Control Kit

FOR USE WITH
ARCHITECT



1 x 4.0 mL
1 x 4.0 mL

CONTROL -
CONTROL +



(CONTAMINATED)

(DO NOT TOUCH)



CoV-2 IgG

REF: 6R86-12

H07889R01

C6R860



ARCHITECT

ARCHITECT

ARCHITECT

