

PRODUCT SPECIFICATION QUALITY CONTROL VERIFICATION

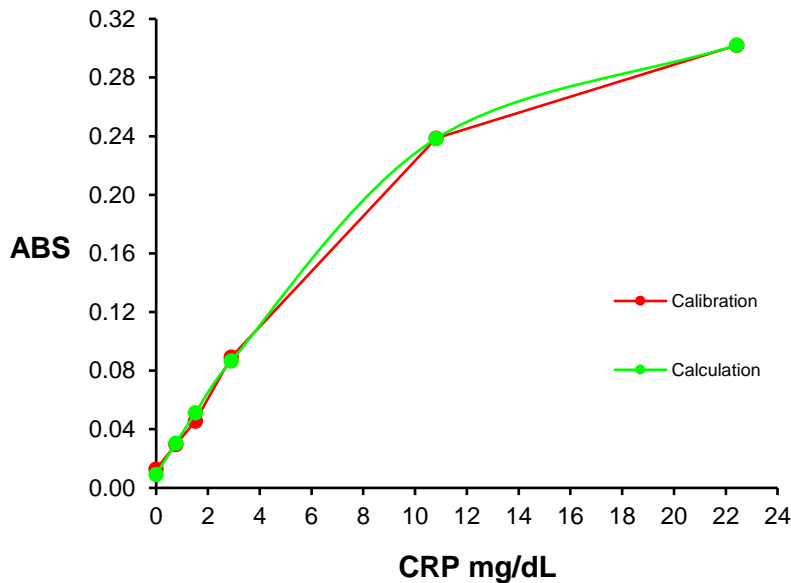
CRP Standard Set Lot AL04674

1. Specifications CRP Standard Set

Code:	CRP/STS-5X1
Lot number:	AL04674
Expiration Date:	November 2022
Grade:	Calibrator
Source:	Defibrinated human plasma and recombinant human C-reactive protein
Form:	Liquid, 0.2 µm filtered
Preservative:	0.095 % Na Azide
Storage:	2 - 8 °C. Do not freeze.
Date of Manufacture:	March 2020
Biohazard:	Each donor unit has been tested by an approved FDA method and found negative for HbsAg and antibodies to HIV 1/2 and HCV. However, because no test method can offer complete assurance that products derived from human sources will not transmit infectious agents, it is recommended that this product be handled with the same precautions used for patients specimens.



2. Quality Control Verification CRP Standard Set on Pentra 400



CRP AUT Antiserum Lot AL04447
 CRP Buffer Lot AL04184
 CRP Standard Set Lot AL03871

Controls	Lotnumber	CRP mg/dL	
		Assigned	Measured
APTEC Immunology Control Low	AL03845	2.37 (2.01 - 2.73)	2.32
APTEC Immunology Control High	AL04382	4.60 (3.91 - 5.29)	4.30
APTEC CRP Control Low	AL03206	1.85 (1.57 - 2.13)	1.88
APTEC CRP Control High	AL03633	3.44 (2.92 - 3.96)	3.44
ERM-DA474/IFCC	09261	4.12 (3.50 - 4.74)	3.89
SIEMENS Protein Control SL/M	199414	1.26 (1.07 - 1.45)	1.26
BIOKIT CRP Control	B32418	2.00 (1.60 - 2.40)	2.07

Assigned Value	CRP Standard Set Lot AL04674				
	mg/dL				
	STD 1	STD2	STD3	STD4	STD5
CRP*	0.66	1.40	2.88	11.65	20.00

* Titrated against to ERM-DA474/IFCC



APPROVED **YES**

PERFORMED BY: Nancy Van Gysel
 QC Manager

QCV/CRP/STS

v1-4/03/2020



CERTIFICATE OF ANALYSIS

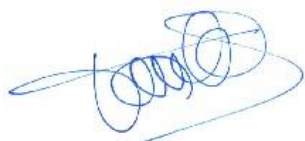
This certifies the product:

Description	Code	Lot#	Exp. Date	Man. Date
CRP Standard Set	CRP/STS	AL04674	2022/11	2020/03

Biohazard: Each donor unit has been tested by an approved FDA method and found negative for HBsAg and antibodies to HIV 1/2 and HCV. However, because no test method can offer complete assurance that products derived from human sources will not transmit infectious agents, it is recommended that this product be handled with the same precautions used for patient's specimens.

This product has met APTEC Quality Control requirements

APTEC Diagnostics nv issues this certificate



Nancy Van Gysel
Quality Control Manager

v1-4/03/2020

