

# PRODUCT SPECIFICATION QUALITY CONTROL VERIFICATION

## CRP AUT Antiserum Lot AL05179

### 1. Specifications CRP Crude Antiserum

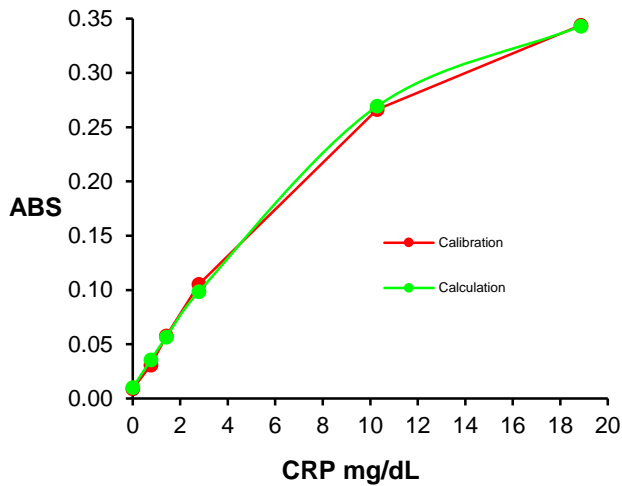
|               |                              |
|---------------|------------------------------|
| Source:       | Goat                         |
| Form:         | Delipidated and defibrinated |
| Antigen:      | Purified human CRP           |
| Filtration:   | 0.2 micron                   |
| Preservative: | 0.05% Na Azide               |
| Specificity:  | Monospecific on crossed IEP  |
| Storage:      | 2 - 8 DegC                   |

### 2. Specifications CRP AUT Antiserum

|                      |                           |
|----------------------|---------------------------|
| Lot number:          | AL05179                   |
| Expiration Date:     | December 2025             |
| Form:                | CRP Antiserum             |
| Buffer:              | Phosphate buffered saline |
| Preservative:        | 0.095 % Na Azide          |
| Date of Manufacture: | December 2020             |
| Storage:             | 2 - 8 DegC                |



### 3. Quality Control Verification CRP AUT Antiserum on Pentra 400



CRP AUT Antiserum Lot AL05179  
 CRP Buffer Lot AL04809  
 CRP Standard Set Lot AL05157

|   | X (CONC) | Y (ABS) |
|---|----------|---------|
| 1 | 0.00     | 0.00905 |
| 2 | 0.76     | 0.03075 |
| 3 | 1.41     | 0.05768 |
| 4 | 2.78     | 0.10526 |
| 5 | 10.29    | 0.26626 |
| 6 | 18.87    | 0.34394 |

| Parameter                         | Result |
|-----------------------------------|--------|
| delta ABS (14 - 2 mg/dL)          | 0.2422 |
| Intra Reproducibility (V.C.) in % | 1.20   |

| Controls                      | Lotnumber | Assigned           | Measured |
|-------------------------------|-----------|--------------------|----------|
| APTEC Immunology Control Low  | AL04658   | 2.27 (1.93 - 2.61) | 2.34     |
| APTEC Immunology Control High | AL04657   | 4.24 (3.60 - 4.88) | 4.31     |
| APTEC CRP Control Low         | AL05173   | 1.82 (1.55 - 2.09) | 1.95     |
| APTEC CRP Control High        | AL04934   | 3.54 (3.01 - 4.07) | 3.59     |
| ERM-DA474/IFCC                | 10172     | 4.12 (3.50 - 4.74) | 4.06     |



|          |     |
|----------|-----|
| APPROVED | YES |
|----------|-----|

PERFORMED BY:

Nancy Van Gysel  
 QC Manager

QCV/CRP/AUT

v1-8/12/2020



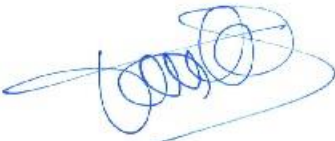
**CERTIFICATE OF ANALYSIS**

This certifies the product:

| <b>Description</b> | <b>Code</b> | <b>Lot#</b> | <b>Exp. Date</b> | <b>Man. Date</b> |
|--------------------|-------------|-------------|------------------|------------------|
| CRP AUT Antiserum  | CRP/AUT     | AL05179     | 2025/12          | 2020/12          |

This product has met APTEC Quality Control requirements

APTEC Diagnostics nv issues this certificate



Nancy Van Gysel  
Quality Control Manager

v1-8/12/2020



## QUALITY CONTROL VERIFICATION

### CRP BUFFER

|                     |         |
|---------------------|---------|
| <b>Lot:</b>         | AL05774 |
| <b>Expiry Date:</b> | 2026/07 |

|                     |            |
|---------------------|------------|
| Date of production: | 14/07/2021 |
| Volume:             | 350 L      |

#### 1. Quality Control Specifications 1

| Parameter | Specification | Result |
|-----------|---------------|--------|
| Colour    | Colourless    | OK     |
| Odour     | Odourless     | OK     |
| Clarity   | Clear         | OK     |
| pH        | 7.43 +/- 0.05 | 7.43   |

#### 2. Quality Control Specification 2 on Pentra 400

| Parameter          | Specification            | Result |
|--------------------|--------------------------|--------|
| Delta ABS (14 - 2) | 0.2163 (0.1839 - 0.2487) | 0.2289 |
| Negative Sera      | < 0.5 mg/dL              | OK     |

|             |    |
|-------------|----|
| Approved    | OK |
| Quarantaine | /  |
| Rejected    | /  |



|               |            |
|---------------|------------|
| Performed by: | NVG        |
|               | 14/07/2021 |



## CERTIFICATE OF ANALYSIS

This certifies the product:

| Description | Code    | Lot#    | Exp. Date | Man. Date |
|-------------|---------|---------|-----------|-----------|
| CRP Buffer  | CRP/BUF | AL05774 | 2026/07   | 2021/07   |

This product has met APTEC Quality Control requirements

APTEC Diagnostics nv issues this certificate



Nancy Van Gysel  
Quality Control Manager

v1-14/07/2021

