

# CERTIFICATE

Survey of 11 November 2022

This certificate replaces the certificate from 14.12.2022

You have fulfilled the requirements of the External Quality Assessment with the following analysis

## Complement Analysis 02 - Functions and proteins (246):

Validity 12 months:

C1 inhibitor: activity

C1q proteine

C3-Complement

C4-Complement

Classical pathway

Complement factor H

Complement factor I

Lectin pathway

(R) analysis is subject to the RiliBÄK

Participant:

51071

The Japanese Association for Complement Research

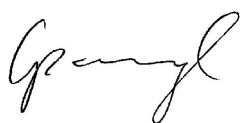
Wakayama Medical University

811-1 Kimiidera, Wakayama

641-8509 Wakayama



Düsseldorf, 15 December 2022



Prof. Dr. med. Michael Spannagl  
(Head of Reference Institution)



Prof. Dr. Zoltan Prohaszka  
(Adviser)

# CERTIFICATE OF PARTICIPATION

Survey of 11 November 2022

You have participated in the External Quality Assessment with the following analysis

## Complement Analysis 02 - Functions and proteins (246):

Alternative pathway  
C1 inhibitor: activity  
C1q proteine  
C3-Complement  
C4-Complement  
Classical pathway  
Complement factor H  
Complement factor I  
Lectin pathway

(R) analysis is subject to the RiliBÄK

Participant:  
51071  
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(Head of Reference Institution)



Prof. Dr. Zoltan Prohaszka  
(Adviser)

## Listing and evaluation of the results

51071: The Japanese Association for Complement Research  
Wakayama Medical University

Survey of 11 November 2022

Adviser:

Prof. Dr. Zoltan Prohaszka

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246

### Complement Analysis 02 - Functions and proteins

| Analyte                | Sam-<br>ple | Unit | Your<br>value | Target<br>value | TV-<br>Type | Lower<br>limit | Upper<br>limit | Deviation | Z-Score | Meets<br>criteria |         |
|------------------------|-------------|------|---------------|-----------------|-------------|----------------|----------------|-----------|---------|-------------------|---------|
| Alternative pathway    | 61          | %    | 5.00          | 28.2            | SV          | 11.3           | 45.1           | -82.3%    | -1,47   | -                 | ○ — •   |
|                        | 62          |      | 85.2          | 86.5            | SV          | 34.6           | 138            | -1.5%     | -0,066  | +                 | — ● —   |
| C1 inhibitor: activity | 61          | %    | 70.7          | 68.4            | SV          | 34.2           | 103            | 3.4%      | 0,344   | +                 | — ● —   |
|                        | 62          |      | 111           | 112             | SV          | 56.0           | 168            | -1.1%     | -0,176  | +                 | — ● —   |
| C1q proteine           | 61          | g/l  | 0.073         | 0.055           | SV          | 0.028          | 0.083          | 31.8%     | 0,337   | +                 | — • — ● |
|                        | 62          |      | 0.083         | 0.078           | SV          | 0.039          | 0.117          | 6.9%      | 0,068   | +                 | — ○ —   |
| C3-Complement          | 61          | g/l  | 1.18          | 1.19            | SV          | 0.904          | 1.48           | -0.5%     | -0,079  | +                 | — ● —   |
|                        | 62          |      | 1.20          | 1.22            | SV          | 0.927          | 1.51           | -1.7%     | -0,191  | +                 | — ● —   |
| C4-Complement          | 61          | g/l  | 0.233         | 0.252           | SV          | 0.176          | 0.328          | -7.5%     | -1,27   | +                 | — ○ • — |
|                        | 62          |      | 0.234         | 0.255           | SV          | 0.179          | 0.332          | -8.2%     | -1,11   | +                 | — ○ • — |
| Classical pathway      | 61          | %    | 30.8          | 34.3            | SV          | 20.6           | 48.0           | -10.2%    | -0,294  | +                 | — ○ • — |
|                        | 62          |      | 100           | 83.5            | SV          | 50.1           | 117            | 20.2%     | 1,05    | +                 | — • — ○ |
| Complement factor H    | 61          | mg/l | 375           | 377             | SV          | 189            | 566            | -0.5%     | -0,01   | +                 | — ● —   |
|                        | 62          |      | 417           | 364             | SV          | 182            | 546            | 14.5%     | 0,34    | +                 | — • — ○ |
| Complement factor I    | 61          | mg/l | 46.9          | 42.3            | SV          | 21.2           | 63.5           | 10.9%     | 0,258   | +                 | — • — ○ |
|                        | 62          |      | 24.3          | 22.7            | SV          | 11.4           | 34.1           | 7.0%      | 0,19    | +                 | — ● —   |
| Lectin pathway         | 61          | %    | 4.30          | 9.35            | SV          | 3.74           | 15.0           | -54.0%    | -0,693  | +                 | ○ — •   |
|                        | 62          |      | 31.9          | 36.6            | SV          | 14.6           | 58.6           | -12.8%    | -0,213  | +                 | — ○ •   |

| Analyte                | Sam-<br>ple | Your unit | Stated value | Conversion<br>factor | Method | Manu-<br>facturer | Device | Reference<br>range |
|------------------------|-------------|-----------|--------------|----------------------|--------|-------------------|--------|--------------------|
| Alternative pathway    | 61          | %         | 5.00         | 1.00                 | 190    | ZY                |        | 30-113             |
|                        | 62          |           | 85.2         | 1.00                 |        |                   |        |                    |
| C1 inhibitor: activity | 61          | %         | 70.7         | 1.00                 | 257    | BW                |        | 79.1-139.5         |
|                        | 62          |           | 111          | 1.00                 |        |                   |        |                    |
| C1q proteine           | 61          | mg/l      | 72.5         | 0.001                | 190    | ZY                |        | not determined     |
|                        | 62          |           | 83.4         | 0.001                |        |                   |        |                    |
| C3-Complement          | 61          | mg/l      | 1184         | 0.001                | 116    | ZY                |        | 604-1432           |
|                        | 62          |           | 1199         | 0.001                |        |                   |        |                    |
| C4-Complement          | 61          | mg/l      | 233          | 0.001                | 116    | ZY                |        | 91-359             |
|                        | 62          |           | 234          | 0.001                |        |                   |        |                    |
| Classical pathway      | 61          | %         | 30.8         | 1.00                 | 190    | ZY                |        | 31.7-50.5          |
|                        | 62          |           | 100          | 1.00                 |        |                   |        |                    |
| Complement factor H    | 61          | mg/l      | 375          | 1.00                 | 190    | ZY                |        | 285.9-710.7        |
|                        | 62          |           | 417          | 1.00                 |        |                   |        |                    |
| Complement factor I    | 61          | mg/l      | 46.9         | 1.00                 | 190    | ZY                |        | 28.8-55.6          |
|                        | 62          |           | 24.3         | 1.00                 |        |                   |        |                    |
| Lectin pathway         | 61          | %         | 4.30         | 1.00                 | 190    | ZY                |        | 0-125              |
|                        | 62          |           | 31.9         | 1.00                 |        |                   |        |                    |

## Individual summary of results

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Wakayama Medical University

Survey of 11 November 2022

246

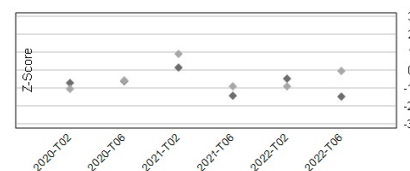
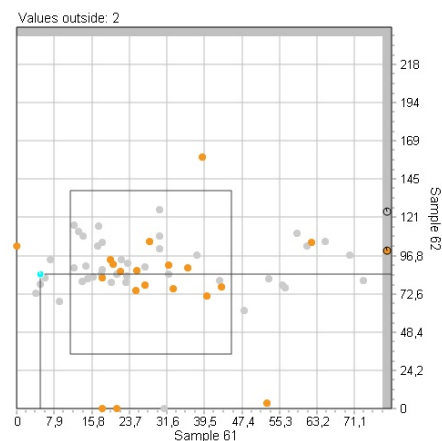
### Complement Analysis 02 - Functions and proteins

#### Alternative pathway (% , N = 71)

| Collective                | Sample | Target value | Target range         | Participants collective |      |      | Rate (%) |       |  |
|---------------------------|--------|--------------|----------------------|-------------------------|------|------|----------|-------|--|
|                           |        |              |                      | AVG                     | CV   | Num. | Sam.     | total |  |
| deviant unit (U / ml) (1) | 61     |              | Sample not evaluated |                         |      | 1    |          |       |  |
|                           | 62     |              | Sample not evaluated |                         |      | 1    |          |       |  |
| BINDING SITE, THE         | 61     | 62.3         | 24.9 - 99.7          | 62.3                    | 15.5 | 10   | 100      | 90.0  |  |
|                           | 62     | 91.7         | 36.7 - 147           | 91.7                    | 24.9 | 10   | 90.0     |       |  |
| EURO DIAGNOSTICA / QUIDEL | 61     | 19.2         | 7.68 - 30.7          | 19.2                    | 57.8 | 37   | 70.3     | 70.3  |  |
|                           | 62     | 89.1         | 35.6 - 143           | 89.1                    | 20.4 | 37   | 91.9     |       |  |
| other providers           | 61     | 28.2         | 11.3 - 45.1          | 28.2                    | 56.0 | 23   | 73.9     | 56.5  |  |
|                           | 62     | 86.5         | 34.6 - 138           | 86.5                    | 22.7 | 23   | 78.3     |       |  |

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Rate of success: 68,6%

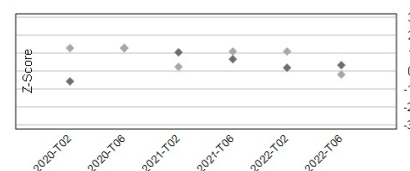
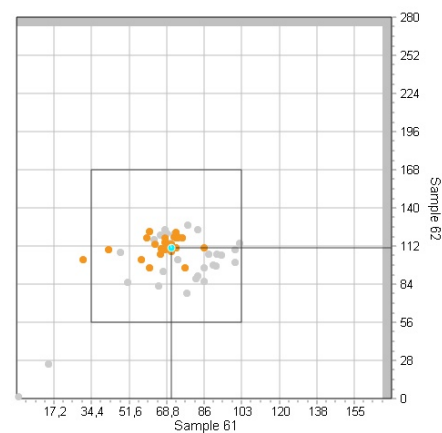


#### C1 inhibitor: activity (% , N = 68)

| Collective        | Sample | Target value | Target range | Participants collective |      |      | Rate (%) |       |  |
|-------------------|--------|--------------|--------------|-------------------------|------|------|----------|-------|--|
|                   |        |              |              | AVG                     | CV   | Num. | Sam.     | total |  |
| QUIDEL            | 61     | 91.3         | 45.7 - 137   | 91.3                    | 11.4 | 19   | 100      | 94.7  |  |
|                   | 62     | 102          | 51.0 - 153   | 102                     | 20.2 | 19   | 94.7     |       |  |
| SIEMENS           | 61     | 68.4         | 34.2 - 103   | 68.4                    | 9.77 | 28   | 96.4     | 96.4  |  |
|                   | 62     | 112          | 56.0 - 168   | 112                     | 6.09 | 28   | 100      |       |  |
| TECHNOCLONE       | 61     | 70.3         | 35.2 - 105   | 70.3                    | 12.7 | 14   | 92.9     | 92.9  |  |
|                   | 62     | 130          | 65.0 - 195   | 130                     | 21.2 | 14   | 92.9     |       |  |
| other methods (1) | 61     | 72.0         | 36.0 - 108   | 72.0                    | 65.6 | 7    |          |       |  |
|                   | 62     | 102          | 51.0 - 153   | 102                     | 27.1 | 7    |          |       |  |

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Rate of success: 94,1%

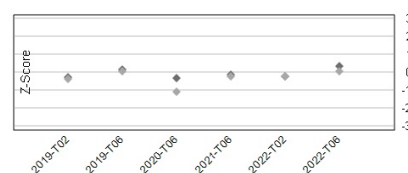
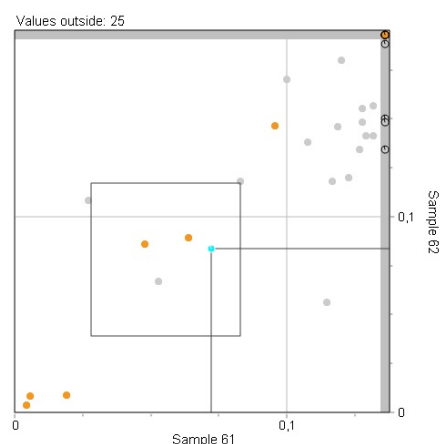


### C1q proteine (g/l, N = 52)

| Collective                     | Sample | Target value | Target range         | Participants collective |      |      | Rate (%) |       |  |
|--------------------------------|--------|--------------|----------------------|-------------------------|------|------|----------|-------|--|
|                                |        |              |                      | AVG                     | CV   | Num. | Sam.     | total |  |
| deviant unit (percent) (1)     | 61     |              | Sample not evaluated |                         |      | 2    |          |       |  |
|                                | 62     |              | Sample not evaluated |                         |      | 2    |          |       |  |
| Immunodiffusion (Binding Site) | 61     | 0.117        | 0.059 - 0.176        | 0.117                   | 53.0 | 16   | 68.8     | 62.5  |  |
|                                | 62     | 0.137        | 0.069 - 0.206        | 0.137                   | 15.3 | 16   | 93.8     |       |  |
| Immunodiffusion (1)            | 61     | 0.122        | 0.061 - 0.183        | 0.122                   | 42.6 | 5    |          |       |  |
|                                | 62     | 0.160        | 0.080 - 0.240        | 0.160                   | 40.6 | 5    |          |       |  |
| Nephelometry / Turbidimetry    | 61     | 0.164        | 0.082 - 0.246        | 0.164                   | 23.2 | 21   | 90.5     | 85.7  |  |
|                                | 62     | 0.254        | 0.127 - 0.381        | 0.254                   | 28.0 | 21   | 90.5     |       |  |
| other methods                  | 61     | 0.055        | 0.028 - 0.083        | 0.055                   | 94.5 | 8    | 37.5     | 37.5  |  |
|                                | 62     | 0.078        | 0.039 - 0.117        | 0.078                   | 101  | 8    | 37.5     |       |  |

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

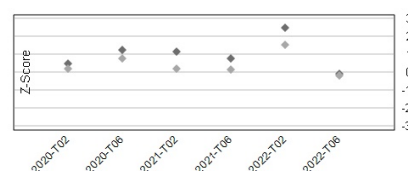
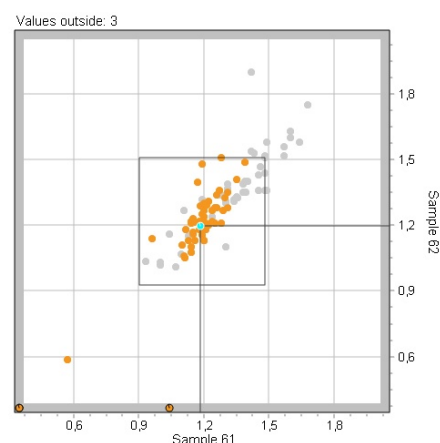
Rate of success: 70%



### C3-Complement (g/l, N = 96)

| Collective                     | Sample | Target value | Target range | Participants collective |      |      | Rate (%) |       |  |
|--------------------------------|--------|--------------|--------------|-------------------------|------|------|----------|-------|--|
|                                |        |              |              | AVG                     | CV   | Num. | Sam.     | total |  |
| Nephelometry - BECKMAN COULTER | 61     | 1.14         | 0.866 - 1.41 | 1.14                    | 13.2 | 9    | 88.9     | 88.9  |  |
|                                | 62     | 1.14         | 0.866 - 1.41 | 1.14                    | 12.2 | 9    | 88.9     |       |  |
| Nephelometry - other providers | 61     | 1.41         | 1.07 - 1.75  | 1.41                    | 9.08 | 34   | 97.1     | 94.1  |  |
|                                | 62     | 1.42         | 1.08 - 1.76  | 1.42                    | 9.44 | 34   | 94.1     |       |  |
| Turbidimetry (and other)       | 61     | 1.19         | 0.904 - 1.48 | 1.19                    | 6.39 | 53   | 94.3     | 92.5  |  |
|                                | 62     | 1.22         | 0.927 - 1.51 | 1.22                    | 9.02 | 53   | 92.5     |       |  |

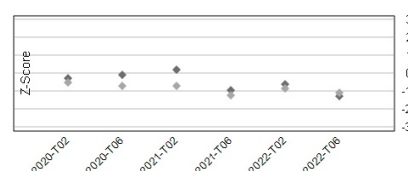
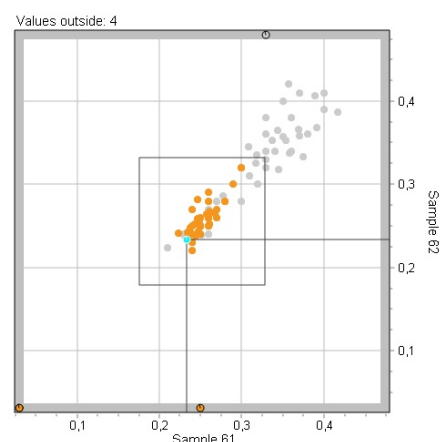
Rate of success: 92,7%



### C4-Complement (g/l, N = 94)

| Collective                     | Sample | Target value | Target range  | Participants collective |      |      | Rate (%) |       |  |
|--------------------------------|--------|--------------|---------------|-------------------------|------|------|----------|-------|--|
|                                |        |              |               | AVG                     | CV   | Num. | Sam.     | total |  |
| Nephelometry - BECKMAN COULTER | 61     | 0.252        | 0.176 - 0.328 | 0.252                   | 8.33 | 10   | 90.0     | 90.0  |  |
|                                | 62     | 0.254        | 0.178 - 0.330 | 0.254                   | 9.06 | 10   | 90.0     |       |  |
| Nephelometry - other providers | 61     | 0.345        | 0.241 - 0.448 | 0.345                   | 10.4 | 35   | 97.1     | 94.3  |  |
|                                | 62     | 0.351        | 0.246 - 0.456 | 0.351                   | 12.8 | 35   | 94.3     |       |  |
| Turbidimetry (and other)       | 61     | 0.252        | 0.176 - 0.328 | 0.252                   | 5.95 | 49   | 95.9     | 93.9  |  |
|                                | 62     | 0.255        | 0.179 - 0.332 | 0.255                   | 7.45 | 49   | 93.9     |       |  |

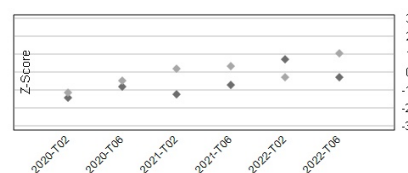
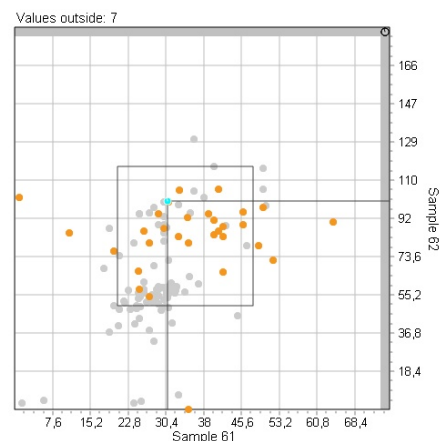
Rate of success: 93,6%



### Classical pathway (% , N = 143)

| Collective                          | Sam-<br>ple | Target<br>value | Target range | Participants collective |      |      | Rate (%) |       |  |
|-------------------------------------|-------------|-----------------|--------------|-------------------------|------|------|----------|-------|--|
|                                     |             |                 |              | AVG                     | CV   | Num. | Sam.     | total |  |
| M.333, 335, R.B5, artificial "U/ml" | 61          | 366             | 220 - 512    | 366                     | 34.7 | 8    | 87.5     | 62.5  |  |
|                                     | 62          | 545             | 327 - 763    | 545                     | 65.9 | 8    | 62.5     |       |  |
| BINDING SITE, THE                   | 61          | 29.7            | 17.8 - 41.6  | 29.7                    | 9.33 | 47   | 95.7     | 91.5  |  |
|                                     | 62          | 55.3            | 33.2 - 77.4  | 55.3                    | 8.19 | 47   | 91.5     |       |  |
| EURO DIAGNOSTICA / QUIDEL           | 61          | 29.7            | 17.8 - 41.6  | 29.7                    | 27.9 | 33   | 84.8     | 72.7  |  |
|                                     | 62          | 85.5            | 51.3 - 120   | 85.5                    | 25.5 | 33   | 84.8     |       |  |
| WAKO                                | 61          | 25.1            | 15.1 - 35.1  | 25.1                    | 18.6 | 22   | 90.9     | 86.4  |  |
|                                     | 62          | 48.9            | 29.3 - 68.5  | 48.9                    | 17.6 | 22   | 90.9     |       |  |
| other providers                     | 61          | 34.3            | 20.6 - 48.0  | 34.3                    | 34.7 | 33   | 72.7     | 69.7  |  |
|                                     | 62          | 83.5            | 50.1 - 117   | 83.5                    | 19.3 | 33   | 90.9     |       |  |

Rate of success: 79,7%

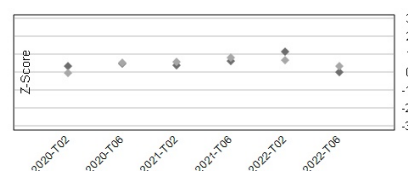
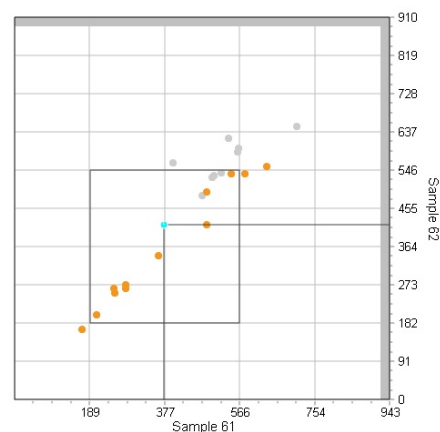


### Complement factor H (mg/l, N = 25)

| Collective                 | Sam-<br>ple | Target<br>value | Target range         | Participants collective |      |      | Rate (%) |       |  |
|----------------------------|-------------|-----------------|----------------------|-------------------------|------|------|----------|-------|--|
|                            |             |                 |                      | AVG                     | CV   | Num. | Sam.     | total |  |
| deviant unit (percent) (1) | 61          |                 | Sample not evaluated |                         |      | 3    |          |       |  |
|                            | 62          |                 | Sample not evaluated |                         |      | 3    |          |       |  |
| BindingSite                | 61          | 522             | 261 - 783            | 522                     | 12.3 | 9    | 100      | 100   |  |
|                            | 62          | 568             | 284 - 852            | 568                     | 10.3 | 9    | 100      |       |  |
| other providers            | 61          | 377             | 189 - 566            | 377                     | 46.2 | 13   | 76.9     | 76.9  |  |
|                            | 62          | 364             | 182 - 546            | 364                     | 42.6 | 13   | 84.6     |       |  |

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Rate of success: 86,4%

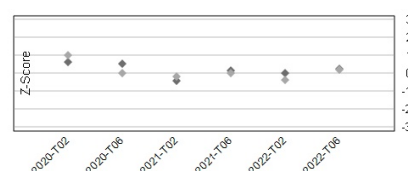
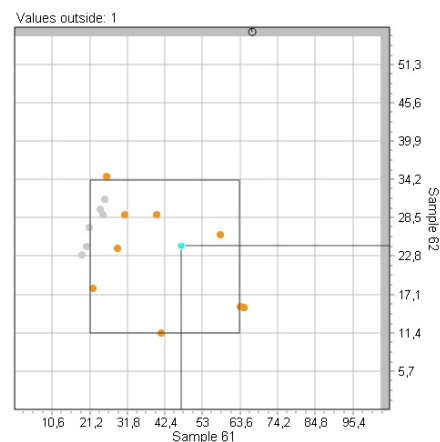


### Complement factor I (mg/l, N = 21)

| Collective                 | Sam-<br>ple | Target<br>value | Target range         | Participants collective |      |      | Rate (%) |       |  |
|----------------------------|-------------|-----------------|----------------------|-------------------------|------|------|----------|-------|--|
|                            |             |                 |                      | AVG                     | CV   | Num. | Sam.     | total |  |
| deviant unit (percent) (1) | 61          |                 | Sample not evaluated |                         |      | 4    |          |       |  |
|                            | 62          |                 | Sample not evaluated |                         |      | 4    |          |       |  |
| BindingSite (1)            | 61          | 23.5            | 11.8 - 35.3          | 23.5                    | 18.3 | 7    |          |       |  |
|                            | 62          | 28.7            | 14.4 - 43.1          | 28.7                    | 17.8 | 7    |          |       |  |
| other providers            | 61          | 42.3            | 21.2 - 63.5          | 42.3                    | 42.1 | 10   | 80.0     | 70.0  |  |
|                            | 62          | 22.7            | 11.4 - 34.1          | 22.7                    | 37.1 | 10   | 90.0     |       |  |

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Rate of success: 76,5%





| Lectin pathway (% , N = 39)             |             |                 |                      |                         |      |      |          |       |  |
|-----------------------------------------|-------------|-----------------|----------------------|-------------------------|------|------|----------|-------|--|
| Collective                              | Sam-<br>ple | Target<br>value | Target range         | Participants collective |      |      | Rate (%) |       |  |
|                                         |             |                 |                      | AVG                     | CV   | Num. | Sam.     | total |  |
| deviant<br>unit (ng / ml)               | (1) 61      |                 | Sample not evaluated |                         |      | 3    |          |       |  |
|                                         | 62          |                 | Sample not evaluated |                         |      | 3    |          |       |  |
| Immunological / functional test (ELISA) | 61          | 9.35            | 3.74 - 15.0          | 9.35                    | 78.0 | 36   | 66.7     | 47.2  |  |
|                                         | 62          | 36.6            | 14.6 - 58.6          | 36.6                    | 60.4 | 36   | 72.2     |       |  |

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Rate of success: 47,2%

