

# Beckman Coulter AU

## SYSTEM ASSAY PARAMETERS



### Procalcitonin FS

Application to be used with Beckman Coulter AU480, AU680, AU5800, DxC 700 AU, DxC 500 AU and DxC 500i

250 tests/kit; 125 tests/reagent set

Application for serum and lithium heparin plasma samples

#### Order information

Cat. No.  
1 7318 99 43 018

#### Notes

- Please refer to below mentioned sections of the package insert of Procalcitonin FS for detailed information about the test:

Intended Use/Indications for Use  
Method and Principle  
Composition of the Reagents/Reagent Preparation  
Storage and Reagent Stability  
Warnings and Precautions/Limitations  
Waste Management  
Materials required  
Calibrators and Controls

- The stability of the reagent onboard the analyzer is 91 days provided that contamination and evaporation are avoided.
- Calibration is stable for 42 days. Recalibrate when reagents lots change or quality control results fall outside the range as established by the individual laboratory.

#### 4. Distributed by:

Vidan Diagnostics LLC (exclusively in the U.S.A)  
4123 Boerne Stage Road, Suite 205  
San Antonio, Texas 78255 USA  
[www.vidandiagnostics.com](http://www.vidandiagnostics.com)



**For Technical Service Call**  
800.869.5992, ext. 102

#### 5. Manufactured by

DiaSys Diagnostic Systems GmbH  
Alte Strasse 9, 65558 Holzheim, Germany

Please read the instructions for use accompanying the product carefully. Each individual laboratory should validate the Procalcitonin assay on its system.

#### General

Test Name  Type  Operation

Sample Volume   $\mu$ l Dilution   $\mu$ l  
Reagents R1 Volume   $\mu$ l Dilution   $\mu$ l  
R2 Volume   $\mu$ l Dilution   $\mu$ l

Wavelength Pri  Sec

Method

Reaction Slope  %

Measuring point 1 First  Last

Measuring point 2 First  Last

Linearity  %

No-Lag-Time

Pre-dilution Rate

Min OD  Max OD

Reagent OD Limit

First L  First H

Last L  Last H

Dynamic Range L  H

Correlation Factor A  B

On-board stability period

Value/Flag  Level L  Level H

Normal Ranges Age L  Age H

Sex Year Month Year Month

1

2

3

4

5

6

7

L  H

Panic Value   Unit

Calibration Type  Formula  Counts

Cal.No OD CONC Factor OD-L Factor OD-H

Point 1

Point 2

Point 3

Point 4

Point 5

Point 6

Point 7

1-Point Cal. Point

MB Type Factor  Calibration Stability Period

#) Data entry by user

\*) Enter calibrator value

**Rx**  
ONLY

845 7318 43 02 95  
Version 01  
Revision Date February 2026

## Procalcitonin FS

### Data evaluated on Beckman Coulter AU680 analyzer

#### Linearity per the method of CLSI EP06-A:

Linearity in human serum and plasma is evaluated by assaying dilutions of stock solutions at least in quadruplicate. Mean values (y-axis) versus target values (x-axis) are plotted and linear regression is applied.

Measuring range from 0.294 ng/mL up to 50 ng/mL, depending on the concentration of the highest calibrator. Linearity < 0.5 ng/mL is given with  $\pm 0.1$  ng/mL, between 0.5 ng/mL to 5 ng/mL within  $\pm 20\%$ , at > 5 ng/mL within  $\pm 10\%$ .

#### LOQ per the method of CLSI EP17-A2:

LOQ was evaluated in human serum and plasma. Nine samples with different value are assayed on twenty consecutive days. On each day two replicates are measured nonconsecutively. For each sample mean, standard deviation and coefficient of variation are calculated. Acceptance criteria was;  $LoQ \leq 0.5$  ng/mL

|                       |             |
|-----------------------|-------------|
| Limit of quantitation | 0.277 ng/mL |
|-----------------------|-------------|

#### Calibration Stability per the method of CLSI EP25-A:

Open reagent bottles are placed on the analyzer and an initial calibration is performed at the beginning of testing period. Two controls and human serum (one level) are measured several times during the period. Recovery of controls and human serum has to be within defined limits without any recalibration.

#### Onboard Stability per the method of CLSI EP25-A:

The reagent is placed on the analyzer for an intended period in open bottles. Calibration is made at the beginning of the period and repeated if necessary (depending on calibration stability). Two controls and human serum (one level) are measured several times during the period. Recovery of controls and human serum has to be within defined limits.

|                       |         |
|-----------------------|---------|
| Onboard stability     | 91 days |
| Calibration stability | 42 days |

#### Prozone Effect per the method of DiaSys internal protocol:

Absorbances of the highest calibrator and of several samples with concentrations above the one of the highest calibrator are measured.

No prozone effect up to 1000 ng/mL.

#### Interference per the method of CLSI EP07-A3:

Sequential dilutions of the interfering substances are mixed in equal parts with aliquots of human samples at approximate PCT concentrations of 0.5 and 2.0 ng/mL, and each mixture is tested in five replicates. The mean measured PCT values (y-axis) are plotted against the concentration of the interfering substance (x-axis). No significant interference was observed, defined as a shift in PCT concentration greater than  $\pm 15\%$ , when the following substances were tested at the concentrations indicated in the table below.

| Interferent Evaluated                                                                                                                                                                                                                                                             | Interferent concentration tested |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| Ascorbic acid                                                                                                                                                                                                                                                                     | 150 mg/dL                        |
| $\alpha$ -CGRP                                                                                                                                                                                                                                                                    | 12 $\mu$ g/mL                    |
| Azithromycin                                                                                                                                                                                                                                                                      | 1.44 mg/dL                       |
| $\beta$ -CGRP                                                                                                                                                                                                                                                                     | 12 $\mu$ g/mL                    |
| Bilirubin (conjugated)                                                                                                                                                                                                                                                            | 72 mg/dL                         |
| Bilirubin (unconjugated)                                                                                                                                                                                                                                                          | 72 mg/dL                         |
| Calcitonin                                                                                                                                                                                                                                                                        | 12 ng/mL                         |
| Cefotaxime                                                                                                                                                                                                                                                                        | 189 mg/dL                        |
| Cromolyn                                                                                                                                                                                                                                                                          | 28.8 mg/L                        |
| Dobutamine                                                                                                                                                                                                                                                                        | 22.4 $\mu$ g/mL                  |
| Dopamine                                                                                                                                                                                                                                                                          | 27.3 mg/dL                       |
| Doxycycline                                                                                                                                                                                                                                                                       | 6.61 mg/dL                       |
| Enoxaparin                                                                                                                                                                                                                                                                        | 24000 U/L                        |
| Ethanol                                                                                                                                                                                                                                                                           | 720 mg/dL                        |
| Furosemide                                                                                                                                                                                                                                                                        | 4.2 mg/dL                        |
| Hemolysis                                                                                                                                                                                                                                                                         | 1200 mg/dL                       |
| Ibuprofen                                                                                                                                                                                                                                                                         | 63.1 mg/dL                       |
| Imipenem                                                                                                                                                                                                                                                                          | 2.52 mg/mL                       |
| Katacalcin                                                                                                                                                                                                                                                                        | 10.8 ng/mL                       |
| Lipemia (triglycerides)                                                                                                                                                                                                                                                           | < 200 mg/dL                      |
| Noradrenalin                                                                                                                                                                                                                                                                      | 4.2 $\mu$ g/mL                   |
| Pantoprazole                                                                                                                                                                                                                                                                      | 4.32 mg/dL                       |
| Rheumatoid factor                                                                                                                                                                                                                                                                 | 1020 IU/mL                       |
| Salmeterol Xinafoate                                                                                                                                                                                                                                                              | 104.4 ng/mL                      |
| Scopolamine-N-butyl bromide                                                                                                                                                                                                                                                       | 72 mg/L                          |
| Vancomycin                                                                                                                                                                                                                                                                        | 3.78 mg/mL                       |
| N-Terminus interferes.                                                                                                                                                                                                                                                            |                                  |
| There is the possibility that other substances (e.g. ingestion, drugs or during specimen preparation) and medical conditions may lead to deviating results. Detailed information on every possible interfering substance or medical condition is beyond the scope of this script. |                                  |

# Beckmann Coulter AU

## PERFORMANCE CHARACTERISTICS



### Precision/Reproducibility per the method(s) of CLSI EP05-A3 and EP15-A3:

#### Repeatability

Five samples with different values over the measuring range assayed 20 times each.

#### Within-laboratory

Five samples with different values over the measuring range assayed in duplicate over 20 days.

| Precision                |          |          |          |          |          |
|--------------------------|----------|----------|----------|----------|----------|
| Repeatability (n=20)     | Sample 1 | Sample 2 | Sample 3 | Sample 4 | Sample 5 |
| Mean [ng/mL]             | 0.191    | 0.670    | 1.80     | 9.73     | 21.1     |
| CV [%]                   | 23.2     | 4.07     | 2.45     | 2.58     | 3.82     |
| Within-laboratory (n=80) | Sample 1 | Sample 2 | Sample 3 | Sample 4 | Sample 5 |
| Mean [ng/mL]             | 0.307    | 0.682    | 1.96     | 10.8     | 20.9     |
| CV [%]                   | 15.2     | 9.62     | 2.71     | 3.98     | 4.06     |

### Method Comparison per the method of CLSI EP09-A3:

Method comparison study was performed with predicate device – VIDAS Brahms PCT Assay (K071146).

#### Method comparison study

At least 100 native patient samples were measured two times with each method. Analysis of the mean patient recovery measured by validated method (x-axis) against mean patient recovery measured by evaluation method (y-axis) by Passing/Bablok.

| Method comparison (n=120)  |                                         |
|----------------------------|-----------------------------------------|
| Test x                     | Competitor Procalcitonin (VIDAS®)       |
| Test y                     | DiaSys Procalcitonin FS (Olympus AU680) |
| Slope                      | 0.943                                   |
| Slope 95% CI               | 0.089 – 0.990                           |
| Intercept                  | 0.097 ng/mL                             |
| Intercept 95% CI           | 0.092 – 0.102                           |
| Coefficient of correlation | 0.990                                   |

| Concordance at 0.5 ng/mL cutoff |                                 |                 |       |
|---------------------------------|---------------------------------|-----------------|-------|
|                                 | Competitor Procalcitonin VIDAS® |                 |       |
| Procalcitonin FS DiaSys         | PCT < 0.5 ng/mL                 | PCT ≥ 0.5 ng/mL | Total |
| PCT < 0.5 ng/mL                 | 33                              | 1               | 34    |
| PCT ≥ 0.5 ng/mL                 | 0                               | 86              | 86    |
| Total                           | 33                              | 87              | 120   |

Negative percent agreement (NPA) = 100.0% (33/33),

95% CI: 89.4% to 100%

Positive percent agreement (PPA) = 98.9% (86/87),

95% CI: 93.8% to 100%

| Concordance at 2.0 ng/mL cutoff |                                 |                 |       |
|---------------------------------|---------------------------------|-----------------|-------|
|                                 | Competitor Procalcitonin VIDAS® |                 |       |
| Procalcitonin FS DiaSys         | PCT < 2.0 ng/mL                 | PCT ≥ 2.0 ng/mL | Total |
| PCT < 2.0 ng/mL                 | 70                              | 3               | 73    |
| PCT ≥ 2.0 ng/mL                 | 5                               | 42              | 47    |
| Total                           | 75                              | 45              | 120   |

Negative percent agreement (NPA) = 93.3% (70/75),

95% CI: 85.1% to 97.8%

Positive percent agreement (PPA) = 93.3% (42/45),

95% CI: 81.7% to 98.6%



DiaSys Diagnostic Systems GmbH  
Alte Strasse 9 65558 Holzheim  
Germany  
[www.diasys-diagnostics.com](http://www.diasys-diagnostics.com)

Distributed exclusively in the U.S.A. by:  
Vidan Diagnostics, LLC 24123 Boerne Stage Rd  
Ste 205 San Antonio, TX 78255 USA



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