Pancreatic amylase CC* FS**

Diagnostic reagent for quantitative in vitro determination of pancreatic amylase in serum or plasma on Sysmex BX-Series

Order Information

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Kit size</th>
<th>Number of tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>10551 99 10 972</td>
<td>R1 3 x 10.1 mL</td>
<td>BX-3010 3 x 75 tests</td>
</tr>
<tr>
<td></td>
<td>R2 3 x 4.5 mL</td>
<td>BX-3010 3 x 75 tests</td>
</tr>
<tr>
<td></td>
<td>R2 3 x 4.5 mL</td>
<td>BX-4000 3 x 52 tests</td>
</tr>
</tbody>
</table>

Method

Enzymatic photometric test, in which the substrate 4,6-ethylidene-(G7)-p-nitrophenyl (G7)-alpha-D-maltotetraose (EPS-G7) is cleaved by a-amylases into various fragments. These are further hydrolyzed in a second step by a-glucosidase producing glucose and p-nitrophenol [1,2]. As the salivary isoenzyme is inhibited selectively by a combination of two monoclonal antibodies during the preincubation phase, the increase in absorbance represents the pancreatic amylase activity in the sample [3-5].

Principle

5 EPS-G7 + 5 H2O \[\rightarrow\] \[\alpha\text{-Amylase}\]
2 Ethylidene-G7 + 2 G2PNP
2 Ethylidene-G4 + 2 G3PNP
2 Ethylidene-G3 + 4 G4PNP
\(\alpha\text{-Glucosidase}\)
5 PNP + 14 G
(PNP = p-Nitrophenol, G = Glucose)

Reagents

Components and Concentrations

R1: Good’s buffer pH 7.15 0 mol/L
NaCl 62.5 mmol/L
MgCl2 12.5 mmol/L
\(\alpha\text{-Glucosidase}\) \(\geq 2.5 \text{ kIU}\)
Monoclonal antibodies against salivary amylase (mouse)
R2: Good’s buffer pH 7.15 0 mol/L
EPS-G7 8.5 mmol/L

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

1. The remaining activity of salivary \(\alpha\text{-amylase}\) can be up to 3%. Very rarely extremely high activities of salivary \(\alpha\text{-amylase}\) may lead to increased readings of pancreatic \(\alpha\text{-amylase}\). However, saliva and skin do contain \(\alpha\text{-amylase}\), therefore avoid contact with the reagents.

2. The reagents contain sodium azide (0.95 mol/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.

3. Reagent 1 contains animal material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.

4. In very rare cases, samples of patients with gangromathy may give falsified results.

5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient’s medical history, clinical examinations and other findings.

6. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent trays.

Specimen

Serum, heparin plasma or EDTA plasma

Stability [6]:

- In serum/plasma 7 days at 20 – 25°C
- 7 days at 4 – 8°C
- 1 year at 0°C

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

For calibration the DiaSys TruCal U calibrator is recommended. This method is traceable to the molar extinction coefficient. For internal quality control DiaSys TruCal N and P controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics

Measuring range up to 2000 U/L (33.3 \(\mu\text{kat/L}\)) P-amylase (in case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).

Limit of detection** 1 U/L (0.017 \(\mu\text{kat/L}\)) P-amylase

On-board stability 6 weeks

Calibration stability 6 weeks

** lowest measurable activity which can be distinguished from zero mean + 3 SD (n=20) of an analytic free specimen

Interfering Substance

<table>
<thead>
<tr>
<th>Interfering Substance</th>
<th>Interference</th>
<th>Analyte concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascorbate</td>
<td>up to 30 mg/dL</td>
<td>23.6 U/L (0.393 (\mu\text{kat/L}))</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>up to 60 mg/dL</td>
<td>117 U/L (1.95 (\mu\text{kat/L}))</td>
</tr>
<tr>
<td>Bilirubin, conjugated</td>
<td>up to 20 mg/dL</td>
<td>71.5 U/L (1.18 (\mu\text{kat/L}))</td>
</tr>
<tr>
<td>Bilirubin, unconjugated</td>
<td>up to 35 mg/dL</td>
<td>71.1 U/L (1.18 (\mu\text{kat/L}))</td>
</tr>
<tr>
<td>Lipemia (triglycerides)</td>
<td>up to 2000 mg/dL</td>
<td>69.1 U/L (1.15 (\mu\text{kat/L}))</td>
</tr>
</tbody>
</table>

For further information on interfering substances refer to Young DS [10].

Precision BX-4000

Within run (n=20)

<table>
<thead>
<tr>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [U/L]</td>
<td>25.5</td>
<td>85.8</td>
</tr>
<tr>
<td>Mean [(\mu\text{kat/L})]</td>
<td>0.425</td>
<td>1.43</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>0.883</td>
<td>0.643</td>
</tr>
</tbody>
</table>
| Between run (n=20)
| Sample 1 | Sample 2 | Sample 3 |
| Mean [U/L] | 26.7 | 86.5 | 139 |
| Mean [\(\mu\text{kat/L}\)] | 0.444 | 1.37 | 2.31 |
| Coefficient of variation [%] | 1.38 | 1.05 | 0.799 |

Method comparison (n=111)

<table>
<thead>
<tr>
<th>Test (x)</th>
<th>P-amylase CC FS (BioMajesty 6010C)</th>
<th>Test (y)</th>
<th>P-amylase CC FS (BX-4000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slope</td>
<td>0.994</td>
<td>Intercept</td>
<td>-0.779 U/L (-0.013 (\mu\text{kat/L}))</td>
</tr>
<tr>
<td>Coefficient of correlation</td>
<td>0.99996</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Conversion factor

Pancreatic amylase [U/L] \(\times 0.0167 = \) Pancreatic amylase [\(\mu\text{kat/L}\)]

Reference Range [7]

<table>
<thead>
<tr>
<th>Women</th>
<th>Men</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum/plasma</td>
<td>&lt; 53 U/L (&lt; 0.88 (\mu\text{kat/L}))</td>
</tr>
</tbody>
</table>

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.
Literature


Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9  65558 Holzheim  Germany
### Pancreatic amylase CC FS

**Chemistry Parameters 1**

<table>
<thead>
<tr>
<th>Method No.</th>
<th>Method Name</th>
<th>PAMY</th>
<th>Reagent Name</th>
<th>Reagent (µL)</th>
<th>Water (µL)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>R1 PAMY</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>R2 PAMY</td>
<td>25</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Serum</th>
<th>Unit</th>
<th>Diluent</th>
<th>Disable</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Assay Type</th>
<th>Rate</th>
<th>Sample Ppt. Wash</th>
<th>Disable</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Measuring points</th>
<th>Start</th>
<th>End</th>
<th>Stirring Speed</th>
<th>R1</th>
<th>R2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>37</td>
<td>45</td>
<td>Middle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Disable</td>
<td></td>
<td>Middle</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Chemistry Parameters 2**

<table>
<thead>
<tr>
<th>Method No.</th>
<th>Method Name</th>
<th>PAMY</th>
<th>Sample Type</th>
<th>Serum</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Limit Checks</th>
<th>Blank measurement</th>
<th>Blank measurement:</th>
<th>Sensitivity Limit</th>
<th>mAbs/10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duplicate Limit</td>
<td>20 mAbs/10</td>
<td>Blank measurement:</td>
<td>Sensitivity Limit</td>
<td>mAbs/10</td>
</tr>
<tr>
<td>Sensitivity Limit</td>
<td>280 mAbs/10</td>
<td>Blank measurement:</td>
<td>Sensitivity Limit</td>
<td>mAbs/10</td>
</tr>
<tr>
<td>Linearity Limit</td>
<td>10 %</td>
<td>Blank measurement:</td>
<td>Sensitivity Limit</td>
<td>mAbs/10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prozone Limit</th>
<th>Higher</th>
<th>Absorbance Limit</th>
<th>Abs. in reaction</th>
<th>Increase</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Sensitivity Limit</th>
<th>mAbs/10</th>
<th>Absorbance Limit</th>
<th>Abs. in reaction</th>
<th>Increase</th>
</tr>
</thead>
</table>

| Absorbance Limit | Abs. in reaction | Increase | Limit | 26000 mAbs/10 |

### Analytical Parameters

- **Method No.:** *
- **Method Name:** PAMY
- **Reagent Name:** PAMY
- **Reagent (µL):** 100
- **Water (µL):**

- **Sample Type:** Serum
- **Unit:**

- **Assay Type:** Rate
- **Sample Ppt. Wash:** Disable

- **Measuring points:**
  - Start: 37, End: 45
  - Stirring Speed: R1 Middle, R2 Middle

**Limit Checks**

- **Duplicate Limit:** 20 mAbs/10
- **Sensitivity Limit:** 280 mAbs/10
- **Linearity Limit:** 10 %

**Prozone Limit:**

- **Higher:**

**Sensitivity Limit:**

- **mAbs/10:**

**Absorbance Limit**

- **Abs. in reaction:** Increase

**Limit:** 26000 mAbs/10

### Analytical Parameters (Cont.)

**Chemistry Parameters 1**

- **Method No.:** *
- **Method Name:** PAMY
- **Reagent Name:** PAMY
- **Reagent (µL):** 100
- **Water (µL):**

- **Sample Type:** Serum
- **Unit:**

- **Assay Type:** Rate
- **Sample Ppt. Wash:** Disable

- **Measuring points:**
  - Start: 37, End: 45
  - Stirring Speed: R1 Middle, R2 Middle

**Limit Checks**

- **Duplicate Limit:** 20 mAbs/10
- **Sensitivity Limit:** 280 mAbs/10
- **Linearity Limit:** 10 %

**Prozone Limit:**

- **Higher:**

- **Sensitivity Limit:**

**Absorbance Limit**

- **Abs. in reaction:** Increase

**Limit:** 26000 mAbs/10

### Analytical Parameters (Cont.)

**Chemistry Parameters 2**

- **Method No.:** *
- **Method Name:** PAMY
- **Sample Type:** Serum

**Limit Checks**

- **Duplicate Limit:** 20 mAbs/10
- **Sensitivity Limit:** 280 mAbs/10
- **Linearity Limit:** 10 %

- **Prozone Limit:**

**Sensitivity Limit:**

- **mAbs/10:**

**Absorbance Limit**

- **Abs. in reaction:** Increase

**Limit:** 26000 mAbs/10

### Analytical Parameters (Cont.)

**Chemistry Parameters 1**

- **Method No.:** *
- **Method Name:** PAMY
- **Reagent Name:** PAMY
- **Reagent (µL):** 100
- **Water (µL):**

- **Sample Type:** Serum
- **Unit:**

- **Assay Type:** Rate
- **Sample Ppt. Wash:** Disable

- **Measuring points:**
  - Start: 37, End: 45
  - Stirring Speed: R1 Middle, R2 Middle

**Limit Checks**

- **Duplicate Limit:** 20 mAbs/10
- **Sensitivity Limit:** 280 mAbs/10
- **Linearity Limit:** 10 %

**Prozone Limit:**

- **Higher:**

**Sensitivity Limit:**

- **mAbs/10:**

**Absorbance Limit**

- **Abs. in reaction:** Increase

**Limit:** 26000 mAbs/10

### Analytical Parameters (Cont.)

**Chemistry Parameters 2**

- **Method No.:** *
- **Method Name:** PAMY
- **Sample Type:** Serum

**Limit Checks**

- **Duplicate Limit:** 20 mAbs/10
- **Sensitivity Limit:** 280 mAbs/10
- **Linearity Limit:** 10 %

**Prozone Limit:**

- **Higher:**

**Sensitivity Limit:**

- **mAbs/10:**

**Absorbance Limit**

- **Abs. in reaction:** Increase

**Limit:** 26000 mAbs/10

### Analytical Parameters (Cont.)

**Chemistry Parameters 1**

- **Method No.:** *
- **Method Name:** PAMY
- **Reagent Name:** PAMY
- **Reagent (µL):** 100
- **Water (µL):**

- **Sample Type:** Serum
- **Unit:**

- **Assay Type:** Rate
- **Sample Ppt. Wash:** Disable

- **Measuring points:**
  - Start: 37, End: 45
  - Stirring Speed: R1 Middle, R2 Middle

**Limit Checks**

- **Duplicate Limit:** 20 mAbs/10
- **Sensitivity Limit:** 280 mAbs/10
- **Linearity Limit:** 10 %

**Prozone Limit:**

- **Higher:**

**Sensitivity Limit:**

- **mAbs/10:**

**Absorbance Limit**

- **Abs. in reaction:** Increase

**Limit:** 26000 mAbs/10
### Pancreatic amylase CC FS

**Chemistry Code 100 64**

#### Calibration Registration

- **Method No.:**
- **Method Name:** PAMY
- **Sample Type:** Serum
- **Replication:** Duplicate
- **Check Interval:** 42
- **Test without calibration:** Disable
- **Calibration Type:** Linear
- **Reagent Lot:** New
- **Calibrator Name:** TruCal U

<table>
<thead>
<tr>
<th>Conc.</th>
<th>WORK</th>
<th>MASTER</th>
<th>Calibr. Lot No.</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td></td>
<td></td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>C2</td>
<td></td>
<td></td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>C3</td>
<td></td>
<td></td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>C4</td>
<td></td>
<td></td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>C5</td>
<td></td>
<td></td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>C6</td>
<td></td>
<td></td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>C7</td>
<td></td>
<td></td>
<td>*</td>
<td></td>
</tr>
</tbody>
</table>

- **K**
  - `C1 Blank`
  - `Reagent Blank for C1`

*Entered by user*

#### Analytical Parameters

- **Reagent Lot No.**
  - (R1) [ ]
  - (R2) [ ]
  - Last [ ]

The calibration curve is lot dependent

- **Reagent blank**
  - mAbs/10
  - Last [ ]

- **Blank**
  - mAbs/10
  - Last [ ]

- **Calibration Curve**
  - Conc. [ ]

- **Absorbance**
  - mAbs/10
  - Recalculation [ ]
**Pancreatic amylase CC FS**

**Chemistry Code 100 64**

### Registration Calibration

<table>
<thead>
<tr>
<th>Method</th>
<th>Name</th>
<th>R Lot No.</th>
<th>R1</th>
<th>R2</th>
<th>Last</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PAMY</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Sample**

| Serum |

**Sampling**

| Duplicate |

**Check Interval**

| 42 days |

**Auto Change Lot**

| Full Calibration |

**Auto Interval**

| hours |

**Type**

| Linear | Lot | New |

**Material Name**

| TruCal U |

### Analytical Parameters

#### Method Name

| PAMY |

#### R Lot No.

| R1 |

#### Last

| R2 |

#### Check Interval

| 42 days |

#### Auto Change Lot

| Full Calibration |

#### Auto Interval

| hours |

#### Type

| Linear |

#### Material Name

| TruCal U |

#### Conc. | WORK | MASTER | Lot No. (S) | All |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>S1 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S2 *</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S3 *</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S4 *</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S5 *</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S6 *</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S7 *</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Absorbance

| mAbs/10 |

#### K

| ☐ S1 Blank | ☐ Reagent Blank for S1 |

*Entered by user*