

ADVISORY NOTICE

03_2026_Re-assignment of amylase (AMY)

| Cat. No.: | Pack Name | Packaging (Content) |
|-----------|-----------|--------------------------------|
| XSYS0003 | AMY 110 | R1: 5 × 22 mL |
| BLT00007 | AMY 250 | R1: 4 × 50 mL, R2: 1 × 50 mL |
| BLT00008 | AMY 500 | R1: 4 × 100 mL, R2: 1 × 100 mL |

Dear Customers,

we would like to inform you about re-assignment of amylase (AMY) values obtained on calibrators XL MULTICAL.

Re-assignment was done using reference material ERM-AD456/IFCC, where amylase catalytic activity was obtained by the IFCC primary reference measurement procedure at 37°C.

Due to this process values of AMY in calibrators as well as in control sera were changed. Please see new values obtained in our materials after re-assignment, in tables below. In calibrator XL MULTICAL, previously united values for amylase were divided into separate rows for each determination method. At the same time, the abbreviations for individual analytes have been modified to match the approved applications in our XL analyzers. This process will make the values in the sheet clearer and minimize the risk of error when manually entering values into the analyzers.

Please note that due to this change patient values may be impacted. Share this information with your laboratory staff and retain this notification as part of your laboratory Quality system documentation. For further information please contact your local representative.

AMY 110*Single-reagent method with maltotrioxide – CNP-G3**XL analyser abbreviation – AMY***Updated values in calibrators:**

| Calibrator | Lot no. | Expiry | AMY value |
|-------------|-------------------------------|---------|------------------------|
| XL MULTICAL | 2404135 2405057 2405058 | 2026-01 | 221 U/L 3,68 µkat/L |
| XL MULTICAL | 2407121 2409055 | 2026-03 | 220 U/L 3,66 µkat/L |
| XL MULTICAL | 2412108 2412109 | 2026-08 | 212 U/L 3,53 µkat/L |

Updates values in control sera:

| Control serum | Lot no. | Expiry | Unit | Mean | Interval | 1SD |
|---------------|--------------------|---------|---------------|--------------|----------------------------|-------------|
| ERBA NORM | 2302119 2302121 | 2025-12 | U/L µkat/L | 64,3 1,07 | 51,4 – 77,2 0,86 – 1,28 | 4,3 0,07 |
| ERBA NORM | 2310172 | 2026-06 | U/L µkat/L | 67,8 1,13 | 54,3 – 81,3 0,89 – 1,37 | 4,5 0,08 |
| ERBA NORM | 2502115 2510202 | 2027-10 | U/L µkat/L | 64,0 1,07 | 51,1 – 76,9 0,86 – 1,28 | 4,3 0,07 |
| ERBA PATH | 2302120 2302122 | 2025-12 | U/L µkat/L | 194 3,23 | 155 – 233 2,57 – 3,89 | 13 0,22 |
| ERBA PATH | 2310173 | 2026-07 | U/L µkat/L | 176 2,93 | 140 – 212 2,33 – 3,53 | 12 0,20 |
| ERBA PATH | 2502116 2504108 | 2027-10 | U/L µkat/L | 186 3,10 | 150 – 222 2,47 – 3,73 | 12 0,21 |

AMY 250, AMY 500

IFCC method with maltoheptaoside – PNP-G7

XL analyser abbreviation – AMY2R

Updated values in calibrators:

| Calibrator | Lot no. | Expiry | AMY2R value |
|-------------|-------------------------------|---------|------------------------|
| XL MULTICAL | 2404135 2405057 2405058 | 2026-01 | 209 U/L 3,48 µkat/L |
| XL MULTICAL | 2407121 2409055 | 2026-03 | 208 U/L 3,47 µkat/L |
| XL MULTICAL | 2412108 2412109 | 2026-08 | 200 U/L 3,33 µkat/L |

Updates values in control sera:

| Control serum | Lot no. | Expiry | Unit | Mean | Interval | 1SD |
|---------------|--------------------|---------|---------------|--------------|----------------------------|-------------|
| ERBA NORM | 2302119 2302121 | 2025-12 | U/L µkat/L | 76,0 1,27 | 60,7 – 91,3 1,03 – 1,51 | 5,1 0,08 |
| ERBA NORM | 2310172 | 2026-06 | U/L µkat/L | 80,8 1,35 | 64,6 – 97,0 1,08 – 1,62 | 5,4 0,09 |
| ERBA NORM | 2502115 2510202 | 2027-10 | U/L µkat/L | 75,5 1,26 | 60,5 – 90,5 1,02 – 1,50 | 5,0 0,08 |
| ERBA PATH | 2302120 2302122 | 2025-12 | U/L µkat/L | 230 3,84 | 185 – 275 3,06 – 4,62 | 15 0,26 |
| ERBA PATH | 2310173 | 2026-07 | U/L µkat/L | 210 3,50 | 168 – 252 2,81 – 4,19 | 14 0,23 |
| ERBA PATH | 2502116 2504108 | 2027-10 | U/L µkat/L | 223 3,72 | 178 – 268 2,97 – 4,47 | 15 0,25 |

Best regards,

Erba Lachema s.r.o.
Technical Product Management


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