## MVZ Labor Dr. Limbach

MVZ Labor Dr. Limbach & Kollegen eGbR | Im Breitspiel 16 | 69126 Heidelberg

Geschäftsleitung Dr. med. Martina Fliser Dr. med. Martin Holfelder

#### Fachärzte

Heidelberg, 14. March 2025

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"Ärztliche Leitung

### Important safety information on Inhibin B test results

Dear Sir or Madam,

Due to a recent communication from Beckman Coulter GmbH, we would like to inform you about a potential inaccuracy in the determination of Inhibin B in serum for certain reagent batches that were also used in our laboratory.

**Situation:** The manufacturer Beckman Coulter has determined that incorrectly high values may have been measured when using certain batches for the determination of inhibin B. **This error** <u>could not be detected by the internal quality controls routinely carried out by us</u>. This error could not be detected by our routine internal quality controls. The average increase in test results was around 15 %, in one reported case even 44 %.

**Possible effects:** Due to this erroneous increase, patients may have been wrongly subjected to additional diagnostic tests. Inhibin B is generally not used in isolation for diagnostic decisions. Nevertheless, it can play an important role in specific clinical contexts (e.g. reproductive medicine, fertility diagnostics, tumour marker analyses).

Affected test period: 26/10/2024 to 21/02/2025: Enclosed you will find a list of your test orders in this period where the inhibin B values could be affected. Please check these findings in order to take further measures if necessary.

**Recommended action:** In cases where Inhibin B was relevant for further clinical decisions, we recommend that you carry out a critical review of the findings. If necessary, the parameter can be determined again free of charge for you. The manufacturer Beckman Coulter has now implemented corrective measures so that the test results are reliable again.

If you have any questions about specific patient results or would like a follow-up test, we will of course be happy to help you.

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We regret the inconvenience caused by this incident and thank you for your understanding and co-operation.

### Yours sincerely

Gill frile

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Prof. Dr. med. Peter Findeisen Medical Director of Laboratory

Enclosure: Laboratory results in the period mentioned