Omnitest® plus
CHECKLIST: ACCURACY COMPLAINTS

PROBLEM:

ASSUMED ABNORMAL VALUE
(CHAPTER A, B, C, D)

DIFFERENT VALUE THAN REFERENCE DEVICE
(CHAPTER E, F)

HAVE READY:

Device, a test strip from the same vial as the used test strip, check strip and control solution Omnitest® plus Control.

Omnitest® plus
serial number SN

_________________

Omnitest® plus
test strip lot LOT

_________________

PROBLEM: ASSUMED ABNORMAL VALUE

A: HANDLING CHECK

Did you wash your hands?

YES

NO

Even invisible food residues affect the measurement results. Please repeat test.

Did you use a fresh drop of blood?

YES

NO

A smeared drop of blood may affect the result. Please repeat test.

Did you apply your sample in one step?

YES

NO

Do not add blood to the test strip more than once. Please repeat test.

Did you remove your finger after the countdown has started?

YES

NO

The test strip had enough blood when the countdown started. Applying blood afterwards may affect the measurement.

IT APPEARS THIS IS NOT A HANDLING PROBLEM. SEE SECTION B: DEVICE
PROBLEM: ASSUMED ABNORMAL VALUE

B: DEVICE CHECK

Let's check the device.

Please insert the check strip (the check strip is part of the packaging).

**OKAY:**
OK is displayed.

**NOT OKAY:**
Error message is displayed.

- **DEVICE IS WORKING PROPERLY.**
  PLEASE SEE SECTION C: TEST STRIP

- **DEVICE IS DEFECTIVE.**
  PLEASE START COMPLAINT PROCESS:
  SEND THE METER IN FOR REPLACEMENT

C: TEST STRIP CHECK

Let's check the test strip.

Have you measured a second time with a new test strip?

- **NO**
  Please measure again with a new test strip.

- **YES**
  Please check expiry date **and** shelf life **on** the test strip label of the vial. Shelf life is always six months after first opening, but no longer than the expiry date.
  Are your strips still within the shelf life and expiry date?

  - **NO**
    Were the test strips stored at the correct temperature?
    Are you sure the test strip vial has not been opened and the test strips have not gotten damp?

  - **YES**
    WE ASSUME THE TEST STRIPS ARE OKAY.
    PLEASE SEE SECTION D: DEVICE AND TEST STRIP

  - **YES**
    CODE: C21
    YEAR: 2017
    MONTH: 12
    LOT: B1GA12
    WE USE NEW TEST STRIPS FROM A NEW TEST STRIP VIAL.
    YOUR CURRENT TEST STRIPS CAN NO LONGER BE USED.
PROBLEM: ASSUMED ABNORMAL VALUE

D: DEVICE AND TEST STRIP CHECK

Do you have the control solution Omnitest® plus Control for your meter?

YES

We will send the control solution. FOLLOW UP CALL WHEN DELIVERED!

NO

Please measure with the control solution. The measurement result should be within the range shown at the test strip vial of the used test strip.

Measurement okay, in range.

Measurement not okay, not in range.

ASK YOUR DIABETES CARE PROFESSIONAL FOR ADVICE AS TEST STRIP, DEVICE AND HANDLING WERE CORRECT!

Did you clean the tip before using the control solution?

YES

Please clean the tip and repeat the test with the control solution.

NO

Please check expiry date and shelf life on the control solution label on the container of your control solution. Shelf life is always three months after first opening, but no longer than the expiry date. Is your control solution still within the shelf life and expiry date?

YES

Was the control solution stored at the correct temperature?

YES

NO

Was the temperature of the measurement components (control solution, meter, test strip) in a range of 20-25°C?

YES

NO

Do not use this control solution, since the results may be inaccurate.

THERE IS AN ISSUE WITH THE DEVICE OR TEST STRIP. PLEASE START COMPLAINT PROCESS: SEND IN THE TEST STRIPS OF THE VIAL USED FOR THE MEASUREMENTS AS WELL AS THE EXACT MEASURED VALUES OF THE PATIENT.
PROBLEM: DIFFERENT VALUE THAN REFERENCE DEVICE

E: DIFFERENT VALUE THAN COMPETITOR HANDHELD METER

DO NOT COMPARE TWO HANDHELD METERS!

We cannot determine whether one or both devices are wrong or both devices show the right result within the tolerance range. The correct result might also be in between.

IF YOU WANT TO COMPARE THE RESULTS WITH ANOTHER METER, PLEASE USE A LABORATORY DEVICE IN THE CORRECT WAY ACCORDING TO SECTION F: LABORATORY DEVICE

TO CHECK THE CORRECT FUNCTIONALITY OF YOUR DEVICE, PLEASE SEE ALSO SECTION B: DEVICE

F: DIFFERENT VALUE THAN LABORATORY DEVICE

Laboratory device (name, manufacturer):

Were both samples taken at the same time and from the same puncture site?
- NO
  - Repeat the measurement with a blood sample taken at the same time with the same puncture site.
  - NO
  - Repeat the measurement with the same blood sample.

Were both samples taken from the same blood sample (both capillary blood)?
- YES
  - What type of blood was used for the lab device?
    - Plasma
      - Plasma is okay, since Omnitest® plus is calibrated against plasma.
      - What are the measured values of both devices?
        - Laboratory device: ____________________ Omnitest® plus: ___________________
          - Was the blood sample centrifuged immediately after collecting the blood sample (within 10 min.)?
            - YES
            - Was the natural glycolysis inhibited?
              - NO
                - Repeat the measurement with a new blood sample. The glycolysis may lead to a wrong low reading.
              - YES

What are the measured values of both devices?
- Laboratory device: ____________________ Omnitest® plus: ___________________

We assume that the laboratory device test result is correct. Please compare: Is the Omnitest® plus result within the ISO standard?

Blood glucose level Tolerance range
≥ 100 mg/dL (5.55 mmol/L) ± 15%< 100 mg/dL (5.55 mmol/L) ± 15 mg/dL (0.83 mmol/L)
- YES
  - THE OMNITEST® PLUS DEVICE IS WORKING PROPERLY
- NO
  - THE OMNITEST® PLUS DEVICE MAY BE INACCURATE. PLEASE FOLLOW THE INSTRUCTIONS IN SECTION A: HANDLING

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