



HemoPoint[®] H2 Meter User Manual

4 Sampling and Testing Procedure

Sampling and Testing Procedure

4.1 Taking a Sample

4.1.1 Notes on Using the Alere Hemo Point[®] H2 Microcuvette

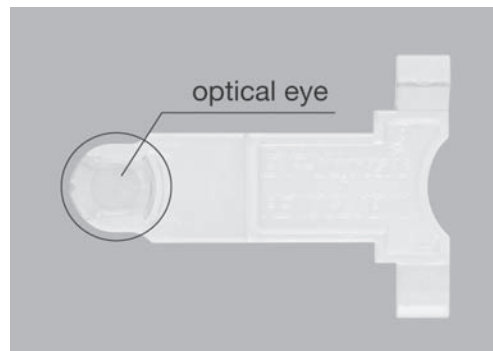


Illustration 7: Microcuvette

The Alere Hemo Point[®] H2 Microcuvette is the most sensitive component in the Alere Hemo Point[®] H2 System. It is therefore necessary to handle the cuvette carefully, paying particular attention to the following conditions:

1. Each Alere Hemo Point[®] H2 Microcuvette can only be used once!

The Alere Hemo Point[®] H2 Microcuvette is designed for single use. The cuvette is coated during manufacturing with all the reagents necessary for determining the hemoglobin concentration in the blood sample. As soon as the blood is taken into the Alere Hemo Point[®] H2 Microcuvette, a reaction occurs (within 1 minute).

2. The Alere Hemo Point[®] H2 Microcuvette is sensitive to moisture!

The Alere Hemo Point[®] H2 Microcuvette will absorb moisture therefore the cuvettes are supplied in a special airtight container that contains a drying agent. This drying agent assures that any moisture is readily absorbed during storage.

Pay attention to the following notes, to preserve the integrity of the Alere **HemoPoint® H2** Microcuvette:



- Store the cuvettes only in the original container and at room temperature (59-86°F / 15-30°C).
- Only remove one cuvette at a time from the container and then immediately close the lid. Make sure that the lid is completely closed by pressing it down as far as it will go.

The Alere **HemoPoint® H2** Microcuvette shelf life is reduced once the lid is opened. See the Alere **HemoPoint® H2** Microcuvette container label for additional information. Please make a note of the date of opening on the container label.

3. The Alere **HemoPoint® H2** Microcuvette is a precision optical component!

The Alere **HemoPoint® H2** Microcuvette is analyzed optically in the Alere **HemoPoint® H2** Meter. The measured absorption is proportional to the hemoglobin concentration. The light from the light source should penetrate through the sample to the photo detector with the least possible influence from the Alere **HemoPoint® H2** Microcuvette. Therefore it is important not to touch the optical eye of the cuvette with fingers or sharp objects (see Illustration 7).

4. The Alere **HemoPoint® H2** Microcuvette is only designed for in-vitro testing!
5. The reagents that coat the inner walls of the Alere **HemoPoint® H2** Microcuvette are harmful and must not be swallowed.

4.1.2 Taking a Sample of Capillary Blood

1. Take out a Alere **HemoPoint® H2** Microcuvette from the original container and immediately close the lid.



Please note Section 4.1.1
“Notes on Using the Alere **HemoPoint® H2** Microcuvette”.



Illustration 8: Preparing to take a blood sample.

2. Make sure that your patient is sitting comfortably. There should be good blood circulation in the hand from which you wish to take blood, i.e. it should be warm and relaxed.



If in doubt, the hands can be warmed in warm water.



Illustration 9: Stimulating the circulation.

3. Lightly massage the fingers, in order to stimulate the circulation.



Warning, Risk of Infection!

Please wear suitable protective gloves!



Only use the middle or ring finger. The patient should not be wearing a ring on the finger used for sampling.



Illustration 10: Disinfecting the puncture site.

4. Disinfect the puncture site and allow to dry.



Illustration 11: Sticking the finger.

5. Press lightly on the fingertip and puncture with a suitable sampling device on the side of the fingertip.



TIP

Sticking the fingertip on the side is less painful and the blood flow is better. To ensure having a spontaneous flow of blood use a sampling device with a proper depth size (2.25 mm).

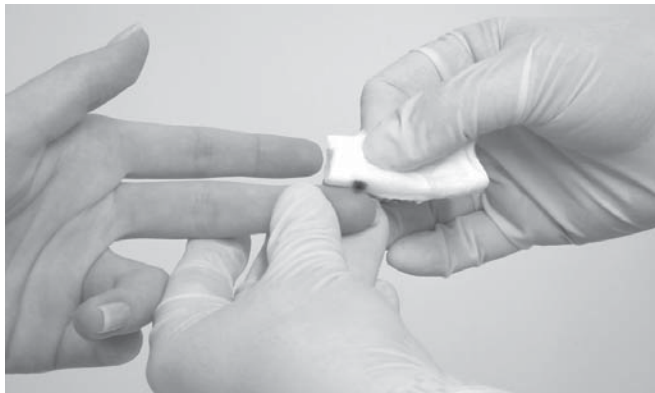


Illustration 12: Blotting the first drop of blood.

6. Blot away the first drop of blood then, if necessary, press gently once again to get a drop of blood which is large enough to fill the Alere **HemoPoint**[®] **H2** Microcuvette completely. Avoid “milking”. (For additional information about obtaining a capillary blood sample, read the latest CLSI guideline. Order information may be found at www.clsi.org.)

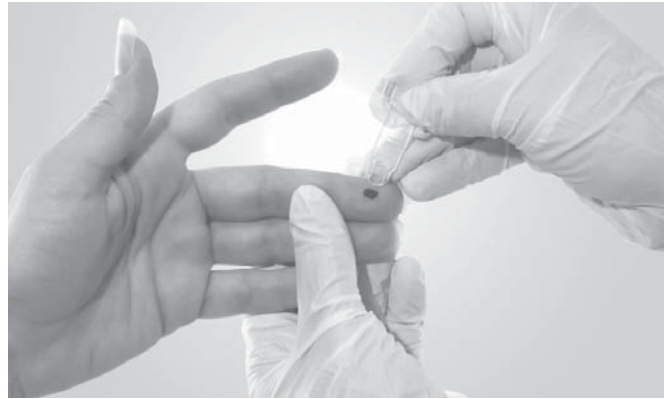


Illustration 13: Filling the cuvette.

7. Hold the center of the Alere **HemoPoint**[®] **H2** Microcuvette in the middle of the drop of blood and wait until the Alere **HemoPoint**[®] **H2** Microcuvette is filled completely. DO NOT fill from the side as this could create air bubbles in the Alere **HemoPoint**[®] **H2** Microcuvette optic window and result in an erroneous result.



WARNING!

Ensure that the Alere **HemoPoint**[®] **H2** Microcuvette cavity is completely filled and free of air bubbles. DO NOT try and top-off Alere **HemoPoint**[®] **H2** Microcuvette if not filled completely. Repeat the process with a new drop of blood and a new Alere **HemoPoint**[®] **H2** Microcuvette.

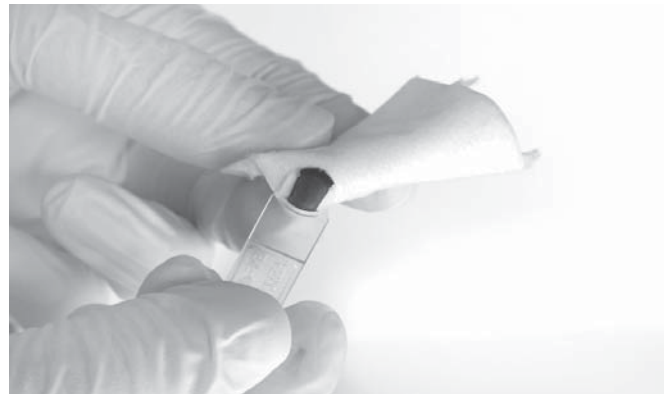


Illustration 14: Removing excess blood.

8. In order to avoid contamination of the Alere **HemoPoint**[®] **H2** Microcuvette holder, remove excess blood from the outside of the Alere **HemoPoint**[®] **H2** Microcuvette by carefully wiping off with a gauze or lint-free tissue.



WARNING!

Please note, do not remove any blood from the Alere **HemoPoint**[®] **H2** Microcuvette cavity. DO NOT try and top-off Alere **HemoPoint**[®] **H2** Microcuvette if not filled completely. Repeat the process with a new drop of blood and a new Alere **HemoPoint**[®] **H2** Microcuvette.

The Alere **HemoPoint**[®] **H2** Microcuvette sample can now be tested immediately or within 10 minutes. DO NOT read Alere **HemoPoint**[®] **H2** Microcuvette after 10 minutes. For further steps, please read Section 4.2 “Performing the Test”.

4.1.3 Taking a Sample of Venous or Arterial Blood

The Alere **HemoPoint**[®] **H2** Meter can be used for determination of hemoglobin in venous or arterial blood samples if the blood collection date is not longer than 24 hours and the sample was stored refrigerated (2-8°C). Prepare the sample for testing as follows:

1. Remove sample tube from the refrigerator and bring it to room temperature (15-30°C).
2. Mix the sample well (i.e. by a mechanical rotator or by inverting by hand).
3. Take out a Alere **HemoPoint**[®] **H2** Microcuvette from the container and immediately close the lid.



Please note Section 4.1.1 “Notes on Using the Alere **HemoPoint**[®] **H2** Microcuvette”.

4. Pipette a sufficient drop of blood on a non-absorbent material (i.e. plastic film).
5. Hold the center of the Alere **HemoPoint**[®] **H2** Microcuvette in the middle of the drop of blood and wait until the Alere **HemoPoint**[®] **H2** Microcuvette is filled completely (see Illustration 15). **DO NOT** fill from the side as this could create air bubbles in the Alere **HemoPoint**[®] **H2** Microcuvette optic window and result in an erroneous result.

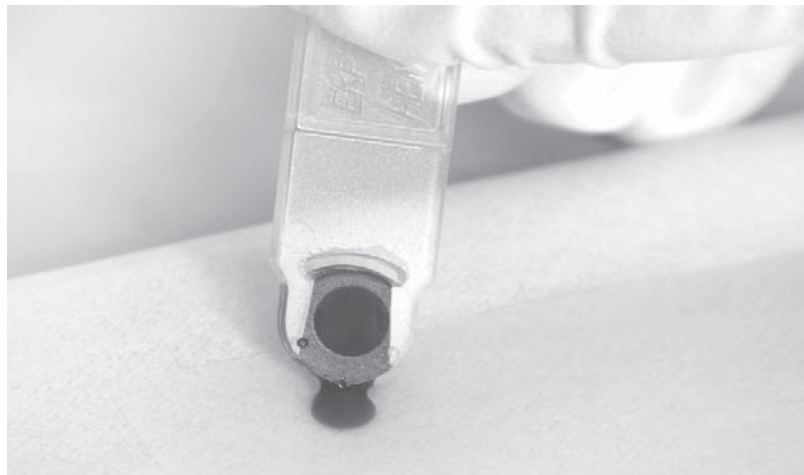


Illustration 15: Taking a sample of venous or arterial blood.



Ensure that the Alere **HemoPoint® H2** Microcuvette cavity is completely filled and free of air bubbles. **DO NOT** try and top-off Alere **HemoPoint® H2** Microcuvette if not filled completely. Repeat the process with a new drop of blood and a new Alere **HemoPoint® H2** Microcuvette.

6. In order to avoid contamination of the Alere **HemoPoint® H2** Microcuvette holder, remove excess blood from the outside of the Alere **HemoPoint® H2** Microcuvette by carefully wiping off with a gauze or lint-free tissue (see Illustration 14).



Please note, do not remove any blood from the Alere **HemoPoint® H2** Microcuvette cavity. **DO NOT** try and top-off the Alere **HemoPoint® H2** Microcuvette if not filled completely. Repeat the process with a new drop of blood and a new Alere **HemoPoint® H2** Microcuvette.

The Alere **HemoPoint® H2** Microcuvette sample can now be tested immediately or within 10 minutes. **DO NOT** read Alere **HemoPoint® H2** Microcuvette after 10 minutes. For further steps, please read Section 4.2 “Performing the Test”.

4.2 Performing the Test

(“Hgb limit” mode ON with the “Hematocrit” mode ON)

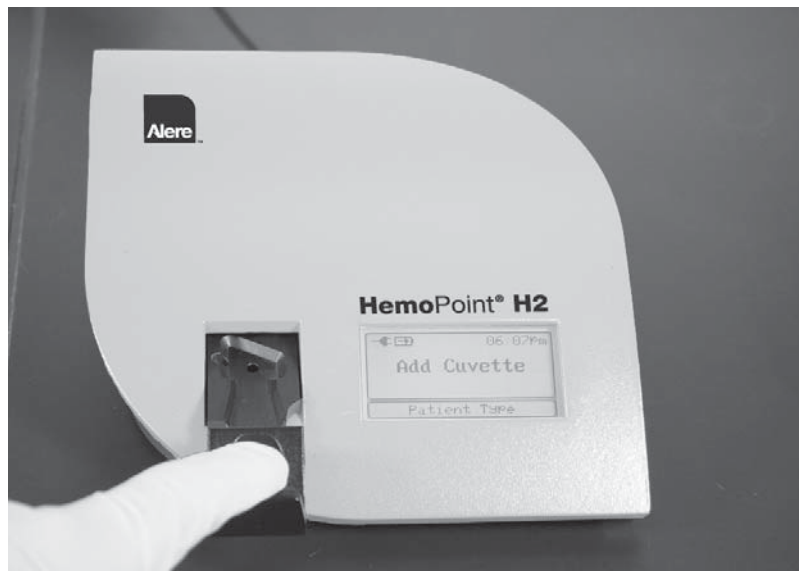


Illustration 16: Opening the Alere **HemoPoint® H2** Microcuvette holder.

1. Open the Alere **HemoPoint® H2** Microcuvette holder completely.

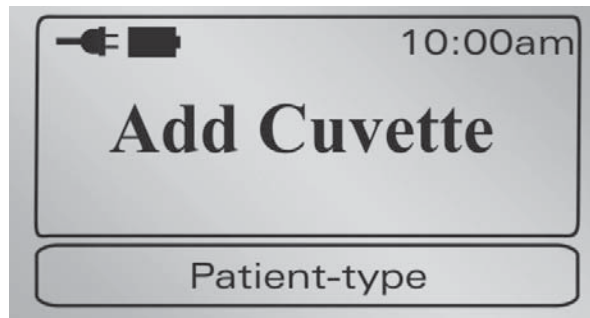


Illustration 17: Display "Add Cuvette".



The instrument will check the optical performance of the measuring system. This process takes approx. 1 – 2 seconds. Release the Alere **HemoPoint® H2** Microcuvette holder and do not touch it again until the process is finished and an audible signal (beep) occurs.

2. If you have the "Hgb limit" mode activated and set the normal range for each patient type (see Section 5.3.5 "Hgb Mode and Limits"), the display will show the "Patient type" buttons that can be selected before testing occurs. Select the patient type by touching the appropriate button. If you select "NO", then no patient range will be displayed or printed with the result.

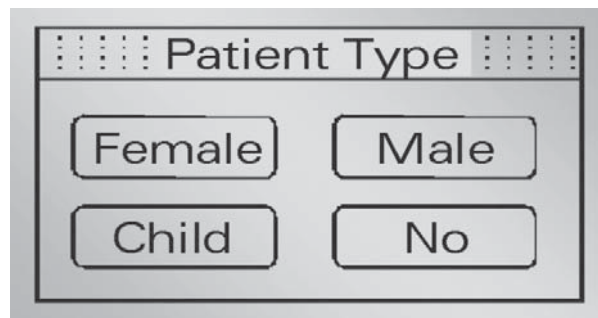


Illustration 18: Display to select "Patient Type".

In case you wish to change or cancel the selected patient type, simply touch the "Patient Type" button and make another selection.

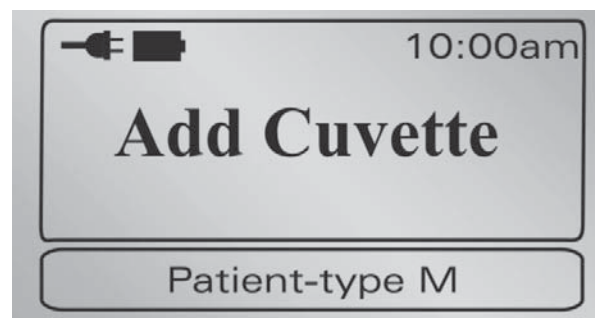


Illustration 19: Display after a patient type (male) is chosen.



Illustration 20: Inserting the cuvette.

3. Insert the appropriate patient microcuvette (example, Male) into the Alera **HemoPoint® H2** Microcuvette holder as shown in Illustration 20, making sure the Alera **HemoPoint® H2** Microcuvette is properly inserted into the holder.
4. Push gently on the Alera **HemoPoint® H2** Microcuvette holder and it will close automatically. **DO NOT** force!
5. Testing of the Alera **HemoPoint® H2** Microcuvette begins automatically (see Illustration 21).



WARNING!

Ensure the Alera **HemoPoint® H2** Microcuvette holder closes completely, otherwise the Alera **HemoPoint® H2** Microcuvette will not be positioned correctly in the Alera **HemoPoint® H2** Meter and this will cause an incorrect result.

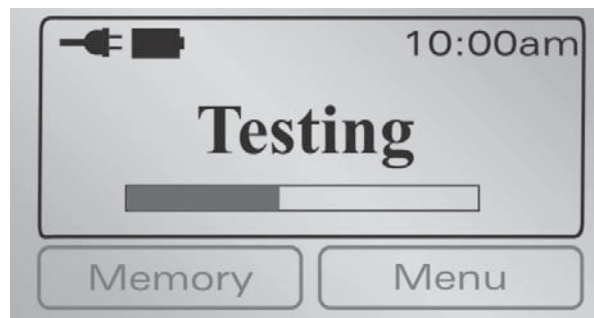


Illustration 21: Display during the testing cycle.



TIP

The testing time varies according to the hemoglobin concentration and can take between 10 – 60 seconds.



Patient Types: M ... Male, F ... Female, C ... Child
Symbols for exceeding Hgb-limits: H... Result above upper limit threshold
 L ... Result below lower limit threshold

Illustration 22: Display showing the test result.

6. Read the test result.



You can now make a note of the result(s). Pressing the OK button is not absolutely necessary. It merely produces a confirmation of the result, while the meter changes to the ready mode display. Opening the Alere **HemoPoint® H2** Microcuvette holder will start a new testing cycle.

The hemoglobin result is displayed with the selected patient type and may be marked with an (H) High or (L) Low if the result falls outside the selected patient normal range. An estimated Hematocrit result will be displayed if the “Hct mode” is activated (see Section 5.3.8.1 Hematocrit Mode). The measured result(s) is stored and can be recalled later from the memory (data storage) which can hold up to 4000 patient results (see Section 5.2.1 “Displaying Results from Memory”).

If you have connected a printer, the current test result will be printed out immediately. Further information about connecting a printer can be found in Section 5.4.1 “Connecting a Printer”.

If you prefer the display shows the result in another type of unit, you can change it as described in Section 5.3.4 “Setting the Units”.

7. Open the Alere **HemoPoint® H2** Microcuvette holder, take out the used Alere **HemoPoint® H2** Microcuvette and dispose properly (see Section 6.4 “Proper Disposal”). Keep the Alere **HemoPoint® H2** Microcuvette holder closed when meter is not in use.