

Analysis of Total Haemoglobin on the HemoControl

Document Author/Reviewer	Jane Mason
Document Owner	Rachel Lampard
Approved By	Rachel Lampard
Review Interval	2 Years

Changes from last version of this document

Updated to new template and update of document references.

Table of Contents

1	Purpose and Principle	3
2	Patient Preparation & Sample Requirements	3
3	Tasks, Responsibilities and Authorisations	3
4	Equipment	3
5	Chemicals and Reagents.....	4
6	Risk Assessment (Environmental and Safety Controls).....	5
7	Calibration.....	5
8	Quality Control.....	6
9	External Quality Assurance (EQA).....	6
10	Procedural Steps.....	6
11	Reporting of Results	7
12	Reference Intervals	7
13	Performance Characteristics and Known Limitations	7
14	Related Forms/Templates and Documents	7
15	References.....	7

1 Purpose and Principle

The HemoControl is used to determine the total amount of haemoglobin in whole blood. The system consists of an analyzer and micro cuvettes containing dried reagents. The micro cuvette serves as a pipette, reaction vessel and measuring cuvette.

Reaction: Sodiumdeoxychlorate haemolyses the erythrocytes releasing the haemoglobin. Sodium nitrite converts haemoglobin to methaemoglobin which together with sodium azide gives azidemethaemoglobin. The absorbance is measured at two wavelengths (570nm and 880 nm) in order to compensate for turbidity.

2 Patient Preparation & Sample Requirements

Capillary, venous, or arterial blood may be used, and the cuvettes need 10ul of sample.

Appropriate anticoagulants in solid form may be used e.g., EDTA.

If the blood sample has been stored in a fridge the sample must be allowed to return to room temperature before analysis.

Haemoglobin levels in samples remains unchanged for days. All stored samples should be mixed on a mechanical mixer for at least two minutes prior to analysis.

- All human blood samples must be treated as potentially BIO-HAZARDOUS.
- Approved Personal Protective Equipment (PPE) including lab coats, gloves and eye-protection must be worn when handling open blood samples or derivatives thereof.

3 Tasks, Responsibilities and Authorisations

These procedures should only be carried out by staff who have been trained and deemed competent.

Tasks	Responsible	Authorised
Patient samples, QC samples, EQA samples	Members of staff trained to use equipment	POCT team

4 Equipment

HemoControl Hemoglobin Microcuvettes Catalogue number 3000-3012-0765

The cuvettes should be used before their expiry date, which is printed on each package. They should be stored at room temperature and **not** refrigerated. Once the seal on the package is broken the microcuvettes are stable for three months so **please date the container** and ensure the container is kept closed when not in use.

Control Solutions

HemoControl Control Solution Low (1x1ml): P-3000-6121

HemoControl Control Solution High (1x1ml): P-3000-6123

The ranges are clearly stated on the packaging.

The stock of controls should be stored 2-8 C stable until the expiry date printed on the vial. Open vials may be stored at room temperature for 30 days.

Supplies of cuvettes and quality control material are ordered from Point of Care Testing:

York: 772 5890

Scarborough: 771 2659

Bridlington: 771 3321

To clean the analyser, pull the cuvette holder out to the loading position. Using a pointed instrument i.e., tip of a ballpoint pen; carefully depress the small indentation in the catch located in the top left corner of the cuvette holder. Whilst the catch is depressed gently pull the cuvette holder out of the body of the analyser. The holder can then be removed completely and cleaned using an alcohol wipe or mild detergent. Please ensure the holder is dried thoroughly before replacing.

If the optical unit needs cleaning, please use the HemoControl cleaner swab provided. Push in and pull out the swab from the optical unit. If the swab is stained repeat with a fresh swab until the swab comes out unstained. Wait 15 minutes for the optics to dry before replacing the cuvette holder.

The outer surfaces of the analyser may be cleaned using a suitable disinfectant wipe.

In the event of instrument breakdown please contact the Point of Care Office on the above numbers.

Company Details

Prospect Diagnostics Limited

Viking court

31 Princess Road

Dromfield

DERBYSHIRE

S18 2LX

Tel 01246 296404

5 Chemicals and Reagents

The manufacturer indicates no hazard involved with use of the reagents.

Attention is, however, drawn to the fact that the reagents have not been fully examined and may be irritant. Serum/ blood samples may constitute a biohazard. Please take usual precautions, i.e., wear gloves and employ routine hygiene techniques.



GENERAL FIRST AID

The following first aid guidelines may be applied to all the substances detailed in this SOP.

Eyes: Irrigate thoroughly with water. At least 10 minutes is the recommended duration. Sterile saline is also available at the eye wash stations.

Lungs: Remove from exposure, rest and keep warm.

Skin: Wash substance off skin thoroughly with water. Remove contaminated clothing and wash before re-use.

Mouth: Wash out mouth thoroughly with water and give plenty of water to drink.

Remember – If at all concerned about the nature or severity of the problem, **SEEK MEDICAL ADVICE.**

6 Risk Assessment (Environmental and Safety Controls)

For full risk assessment see:

PC/RA/YS-18



Staff carrying out this procedure should have read and understood the Local Rules or Health and Safety Manual applicable to their site which should be followed at all times during the procedure.

- All human samples must be treated as potentially BIO-HAZARDOUS.
- Approved Personal Protective Equipment (PPE) including laboratory coats, disposable gloves must be worn. Eye protection should also be considered and must be worn when directed within the procedure.

This SOP and the associated risk assessment(s) have considered all hazards and necessary precautions required to control any risks identified. Where appropriate this is detailed in the COSHH assessment and Risk Assessment. Any risk: where possible is mitigated and or monitored with health surveillance to ensure health and safety for all those affected by this procedure.

7 Calibration

The HemoControl Analyser has an inbuilt “Self-Test” for checking the electrical and optical units.

The HemoControl is factory calibrated against the reference cyanmethemoglobin method.

8 Quality Control

Quality controls should be stored between 2-8°C, stored unopened at this temperature it is guaranteed stable until the expiry date, as indicated on the vial and outer box. Once opened may be stored at room temp for 30 days.

- The control material must be used at room temperature and should not be sampled straight from the QC bottle. Mix the contents of the bottle and place 1 drop on to a hydrophobic surface. (i.e., plastic film or glass slide)
- Pull the cuvette holder out to its loading position.
- Fill the cuvette with the control solution. Wipe off excess solution from the outside of the cuvette. Make sure no solution is drawn out of the cuvette.
- Place the cuvette into the holder, ensure the angled handle of the microcuvette is pointing to the right and push the holder into the measuring position. This should be done within 40 seconds of sampling.
- After 15 –60 seconds the result will be displayed and will remain displayed as long as the cuvette remains in the measure position.
- Dispose of the cuvette in a sharps bin. The analyser will automatically revert to the measuring position and the QC symbol will disappear ready for patient sampling.
- Please record all QC results on the sheet provided which is kept with the analyser. (PC/FOR/YS-2)

If the QC results fall outside the Quoted ranges repeat the analysis, but do **NOT** analyse patient samples until a satisfactory result has been obtained.

9 External Quality Assurance (EQA)

The HemoControl analysers are enrolled in the UK NEQAS Haematology & Transfusion EQA scheme. Samples are sent monthly.

10 Procedural Steps

Performing Haemoglobin on a patient sample

- Capillary, venous, or arterial whole blood may be used.
- Touch screen to wake analyser.
- Pull the cuvette holder out to its loading position.
- Take the cuvette out of the container using the rear end and re-lid the container immediately. **DO NOT TOUCH THE CUVETTE AT THE REACTION END**
- Make sure the patient has been positively identified and consented. Clean the puncture site with disinfectant and allow to dry.
- Prick the chosen finger and wipe away the first drop of blood. Apply light pressure to obtain a second drop of blood.
- Make sure the drop of blood is big enough to fill the cuvette completely.
- Introduce the cuvette tip into the middle of the blood drop and allow the cuvette to fill completely. The cuvette should be filled in one continuous process and NEVER topped up.

- Wipe off excess blood from the outside of the cuvette tip. Make sure no blood is drawn out of the cuvette whilst doing this.
- The cuvette should be inspected for air bubbles, which may influence the results.
- Place the filled cuvette into the holder, ensure the angled handle on the microcuvette is facing to the right and push the holder into the measuring position. This should be done within 10 minutes of sampling.
- After 15 –60 seconds the result will be displayed and will remain displayed as long as the cuvette remains in the measure position. Please record all results in the patients' notes.
- Dispose of the microcuvette in a sharps bin.
- The analyser will enter standby mode after 5 minutes.

11 Reporting of Results

All results should be recorded in the patients notes alongside the date and time that the test was carried out and the name of the person carrying out the test.

The Clinician in charge of the patient should be alerted to any abnormal results.

12 Reference Intervals

Adult male 130-180 g/L

Adult (non-pregnant) female 115-165 g/L

13 Performance Characteristics and Known Limitations

Comparison data between the POCT HemoControl method and Sysmex XN-9100 main laboratory method can be found on Q-Pulse PC/VV/YS-12

14 Related Forms/Templates and Documents

PC/VV/YS-12

PC/ED/YS-16

PC/RS/YS-18

15 References

HemoControl Analyser User Manual: PC/ED/YS-16