



HEMATOCRIT/HCT AND CALCULATED HEMOGLOBIN/HB

Hematocrit is determined conductometrically. The measured conductivity, after correction for electrolyte concentration, is inversely related to the hematocrit.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.¹

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for hematocrit, as part of the i-STAT® System, is intended for use in the *in vitro* quantification of packed red blood cell volume fraction in arterial, venous, or capillary whole blood.

Hematocrit measurements can aid in the determination and monitoring of normal or abnormal total red cell volume status including, but not limited to, conditions such as anemia, erythrocytosis, and blood loss related to trauma and surgery.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution of known conductance that contains known concentrations of analytes and preservatives.

Metrological Traceability

The i-STAT System test for hematocrit measures packed red blood cell volume fraction in arterial, venous, or capillary whole blood (expressed as the % packed cell volume) for *in vitro* diagnostic use. Hematocrit values assigned to i-STAT's working calibrators are traceable to the Clinical and Laboratory Standards Institute (CLSI) H7-A3 procedure for determining packed cell volume by the microhematocrit method.² Further information regarding metrological traceability is available from Abbott Point of Care Inc.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range ³
Hematocrit/Hct	%PCV	15 – 75	38 – 51**
	Fraction	0.15 – 0.75	0.38 – 0.51
Hemoglobin/Hb	g/dL	5.1 – 25.5	12 – 17
	g/L	51 – 255	120 – 170
	mmol/L	3.2 – 15.8	7 – 11

* The i-STAT System can be configured with the preferred units.

**The reference ranges for hematocrit and hemoglobin span both female and male populations.

To convert a result from %PCV to fraction packed cell volume, divide the %PCV result by 100. For the measurement of hematocrit, the i-STAT System can be customized to agree with methods calibrated by the microhematocrit reference method using either K₃EDTA or K₂EDTA anticoagulant. Mean cell volumes of K₃EDTA anticoagulated blood are approximately 2-4% less than K₂EDTA anticoagulated blood.² While the choice of anticoagulant affects the microhematocrit method to which all hematocrit methods are calibrated, results from routine samples on hematology analyzers are independent of the anticoagulant used. Since most clinical hematology analyzers are calibrated by the microhematocrit method using K₃EDTA anticoagulant, the i-STAT System default customization is K₃EDTA.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Hematocrit is a measurement of the fractional volume of red blood cells. This is a key indicator of the body's state of hydration, anemia or severe blood loss, as well as the blood's ability to transport oxygen. A decreased hematocrit can be due to either overhydration, which increases the plasma volume, or a decrease in the number of red blood cells caused by anemias or blood loss. An increased hematocrit can be due to loss of fluids, such as in dehydration, diuretic therapy, and burns, or an increase in red blood cells, such as in cardiovascular and renal disorders, polycythemia vera, and impaired ventilation.

Performance Characteristics

The typical performance data summarized below were collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A⁴. Venous blood samples, collected in lithium heparin Vacutainer® tubes, were analyzed in duplicate on the i-STAT System and on the comparative methods for hematocrit within 20 minutes of collection.

Deming regression analysis⁵ was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on CLSI guideline EP7-P⁶.

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".⁵ The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (%PCV)

Whole Blood Control	Mean	SD	%CV
Low	30.0	0.44	1.5
High	49.0	0.50	1.0

Method Comparison (%PCV)

	Coulter® S Plus	Nova STAT Profile® 5	Abbott Cell-Dyn 4000	Sysmex SE9500
n	142	192	29	29
Sxx	0.50	0.46	0.41	0.53
Syy	1.09	1.31	0.77	0.76
Slope	0.98	1.06	1.06	1.11
Int't	1.78	-3.98	-1.42	-4.19
Sy.x	2.03	2.063	1.13	0.98
Xmin	18	21	19	24
Xmax	51	50	46	47
r	0.952	0.932	0.993	0.980

Factors Affecting Results*

The measurement of certain blood samples with high erythrocyte sedimentation rates (ESR) may be affected by analyzer angle. While testing blood samples, beginning ninety (90) seconds after the cartridge is inserted, the analyzer should remain level until a result is obtained. A level surface includes running the handheld in the downloader/recharger.

Interferent Effect

WBC Grossly elevated white blood cell counts may increase results.

Total Protein Hematocrit results are affected by the level of total protein as follows:

Displayed Result	TP < 6.5 g/dL	TP > 8.0 g/dL
HCT < 40 %PCV	Hct decreased by ~1% PCV for each decrease of 1 g/dL TP	Hct increased by ~1% PCV for each increase 1 g/dL TP
HCT > 40 % PCV	Hct decreased by ~0.75 % PCV for each decrease of 1 g/dL TP	Hct increased by ~0.75 %PCV for each increase 1 g/dL TP

Total protein levels may be low in neonatal and burn patient populations, as well as in additional clinical populations listed in Statland.³ Total protein levels may also be decreased in patients undergoing cardiopulmonary bypass (CPB) or ECMO, and with patients receiving large volumes of saline-based IV fluids. Care should be taken when using hematocrit results from patients with total protein levels below the adult reference range (6.5 to 8 g/dL).

The CPB sample type can be used to correct the hematocrit result for the dilutional affect of the pump prime in cardiovascular surgery. The CPB algorithm assumes that cells and plasma are diluted equally and that the pump priming solution has no added albumin or other colloid or packed red blood cells. Since perfusion practices vary, it is recommended that each practice verify the use of the CPB sample type and the length of time in which the CPB sample type should be used during the recovery period. Note that for hematocrit values above 30 %PCV, the CPB correction is ≤ 1.5 %PCV; the size of the correction at this level should not impact transfusion decisions.

Lipids

Abnormally high lipids may increase results. Interference from lipids will be about two-thirds the size of the interference from protein.

Sodium	The sample electrolyte concentration is used to correct the measured conductivity prior to reporting hematocrit results. Factors that affect sodium will therefore also affect hematocrit.
Bromide	Bromide (37.5 mmol/L) is known to result in an increased rate of star (***) outs. Bromide has been tested at two levels: the CLSI recommended level and a therapeutic plasma concentration level of 2.5 mmol/L. The latter is the peak plasma concentration associated with halothane anesthesia, in which bromide is released. APOC has not identified a therapeutic condition that would lead to levels consistent with the CLSI recommended level. Bromide at a concentration of 37.5 mmol/L increased the rate of HCT star (***) outs, while a therapeutic range of bromide (2.5 mmol/L) did not significantly interfere with i-STAT HCT results.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Sample Collection and Handling

Erroneous hematocrit results can be obtained by improper sample handling.

- Hematocrit results can be affected by the settling of red blood cells in the collection device. The best way to avoid the effect of settling is to test the sample immediately. If there is a delay in testing of a minute or more, the sample must be remixed thoroughly:
 - If the sample is in a collection tube, invert the tube gently 10 times.
 - If the sample is in a syringe, roll the syringe between the palms for five seconds in one direction, then roll in a second direction for five seconds, then gently invert repeatedly for five seconds. Note that it may not be possible to adequately mix a blood sample in a 1 mL syringe. Samples from 1 mL syringes should not be used to determine hematocrit if testing is delayed. Discard one or two drops of blood from a syringe before filling a cartridge.
- Low hematocrit results can be caused by contamination of flush solutions in an arterial or venous line.
 - Back flush a line with a sufficient amount of blood to remove intravenous solutions, heparin or medications that may contaminate the sample. Five to six times the volume of the catheter, connectors and needle is recommended.

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT E3+ cartridges. In the 15–30 %PCV range the average difference was 0.462. In the 30–50 %PCV range the average difference was 0.097.

Calculated Result for Hemoglobin

The i-STAT System provides a calculated hemoglobin result which is determined as follows:

$$\text{hemoglobin (g/dL)} = \text{hematocrit (\% PCV)} \times 0.34$$

$$\text{hemoglobin (g/dL)} = \text{hematocrit (decimal fraction)} \times 34$$

To convert a hemoglobin result from g/dL to mmol/L, multiply the displayed result by 0.621. The calculation of hemoglobin from hematocrit assumes a normal MCHC.

References

1. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).
2. CLSI. *Procedure for Determining Packed Cell Volume by the Microhematocrit Method; Approved Standard - Third Edition.* CLSI document H7-A3 [ISBN 1-56238-413-9]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2000.
3. B.E. Statland, Clinical Decision Levels for Lab Tests (Oradell, NJ: Medical Economic Books, 1987).
4. CLSI. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.* CLSI document EP9-A [ISBN 1-56238-283-7]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.
5. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," *Clinical Chemistry* 25:3, 432 (1979).
6. CLSI. *Interference Testing in Clinical Chemistry; Proposed Guideline.* CLSI document EP7-P [ISBN 1-56238-020-6]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1986.
7. J.D. Bower, P.G. Ackerman and G. Toto, eds., "Evaluation of Formed Elements of Blood," in *Clinical Laboratory Methods* (St. Louis: The C.V. Mosby Company, 1974).

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