

Evaluation of MiniCollect® K2 EDTA Tubes with spray-dried additive

Background:

Greiner Bio-One has developed new MiniCollect® tubes incorporating spray-dried additives. The advantage of the new technology is that the additive is more uniformly coated on the inner tube walls and the mixing characteristics are improved

The MiniCollect® K2EDTA capillary blood collection tube is also featured with the unique cross-cut cap which does not need to be removed during the collection and sampling process.

The interior of the tube is coated with spray-dried K2EDTA anticoagulant.

MiniCollect® K2EDTA tubes are intended for use for testing parameters in haematology.

Study Objective:

A clinical evaluation was carried out to compare the performance of the new spray-dried MiniCollect® K2EDTA tube in comparison to the Becton Dickinson Microtainer® K2EDTA tube.

Study design:

The following tube types were used in this study:

| Sample ID | Description |
|-----------|--|
| A | MiniCollect® K2EDTA 0,5 ml, spray dried (item No.: 450480) |
| B | Microtainer® K2EDTA 0,5 ml (item No.: 365975) |

Directly after blood collection with venous blood, the tubes were carefully inverted according to the instructions given by the tube manufacturers. The tubes were transported to a laboratory within 6 hours after blood collection. A complete blood count was performed using the Bayer ADVIA® 2120 Haematology System. Analysis was performed with the instrument's accompanying reagents.

Determined parameters:

- Leucocytes
- Erythrocytes
- Haemoglobin
- Haematocrit
- Thrombocytes
- Mean Corpuscular Volume
- Mean Corpuscular Haemoglobin
- Mean Corpuscular Haemoglobin Concentration
- Segmented Neutrophile Granulocytes

- Lymphocytes
- Monocytes
- Eosinophile Granulocytes
- Basophile Granulocytes
- Large Undefined Cells

Conclusion:

The Greiner Bio-One MiniCollect® K2EDTA tube with spray-dried additive demonstrated equivalent performance to the Becton Dickinson Microtainer® K2EDTA tube for the haematology parameter studied.

The slight differences observed between these tube types may have been caused by either physiological, preanalytical and/or analytical attributes. Factors such as the preparation of the patient for specimen collection, blood collection technique and transport may have affected recovery of some of the analytes.

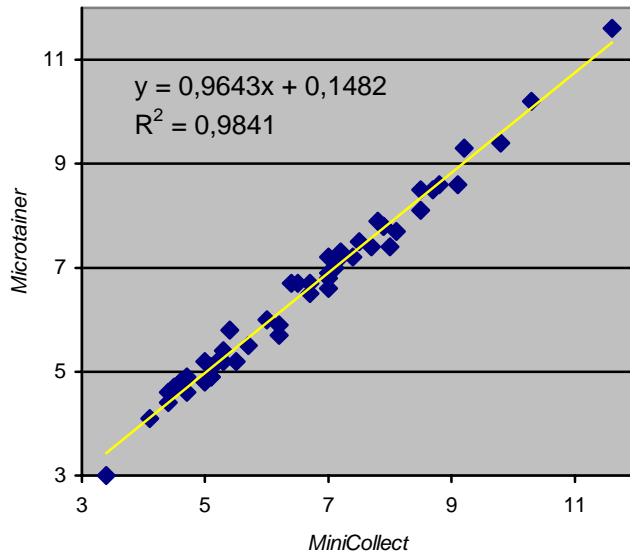
References:

- (1) Greiner Bio-One. MiniCollect® Capillary Blood Collection Product Range. Instructions for Use. Kremsmünster, Austria. 2006.
- (2) Greiner Bio-One. MiniCollect® Product Manual. Kremsmünster, Austria. 2003.
- (3) Becton Dickinson and Company, BD Microtainer® Chemistry Tubes. Instructions for Use, Franklin Lakes. 2006
- (4) Guideline published by the Chamber Association for Medical Practitioners of the State of Germany concerning the quality assurance of quantitative analyses of Medical Laboratories, Germany (2001). Rev.2003
- (5) ISO 6710:1995(E), *Single-use containers for venous blood specimen collection*. International Standard. Genève, Switzerland (1995)
- (6) EP7-A: *Interference Testing in Clinical Chemistry*, Approved Guideline. CLSI (formerly NCCLS) document (ISBN 1-56238-480-5). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2002.
- (7) EP9-A2: *Method Comparison and Bias Estimation Using Patient Samples*; Approved Guideline—Second Edition. CLSI (formerly NCCLS) document EP9-A2 (ISBN 1-56238-472-4). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.

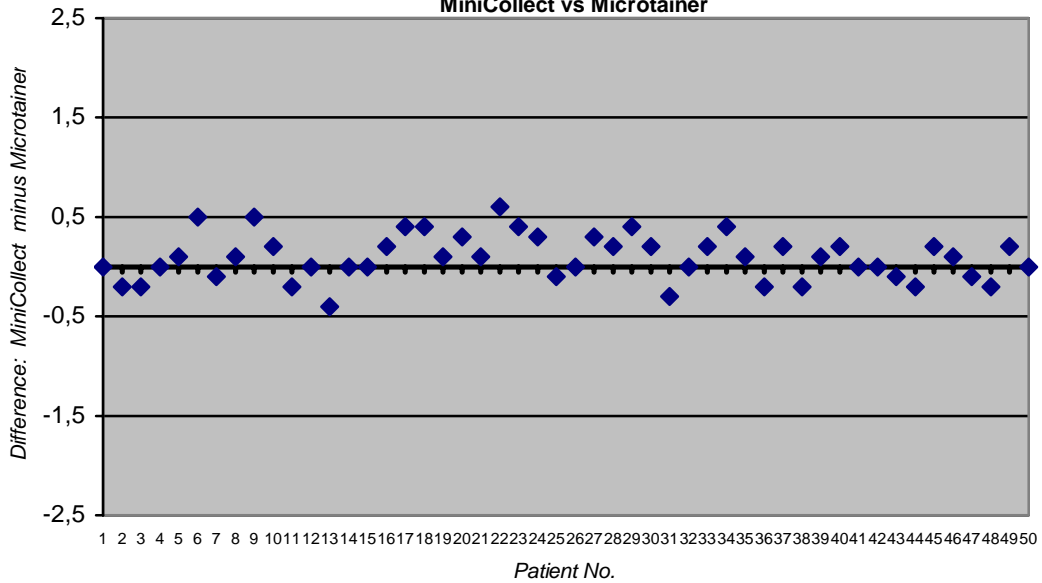
Results in detail:

Leucocytes

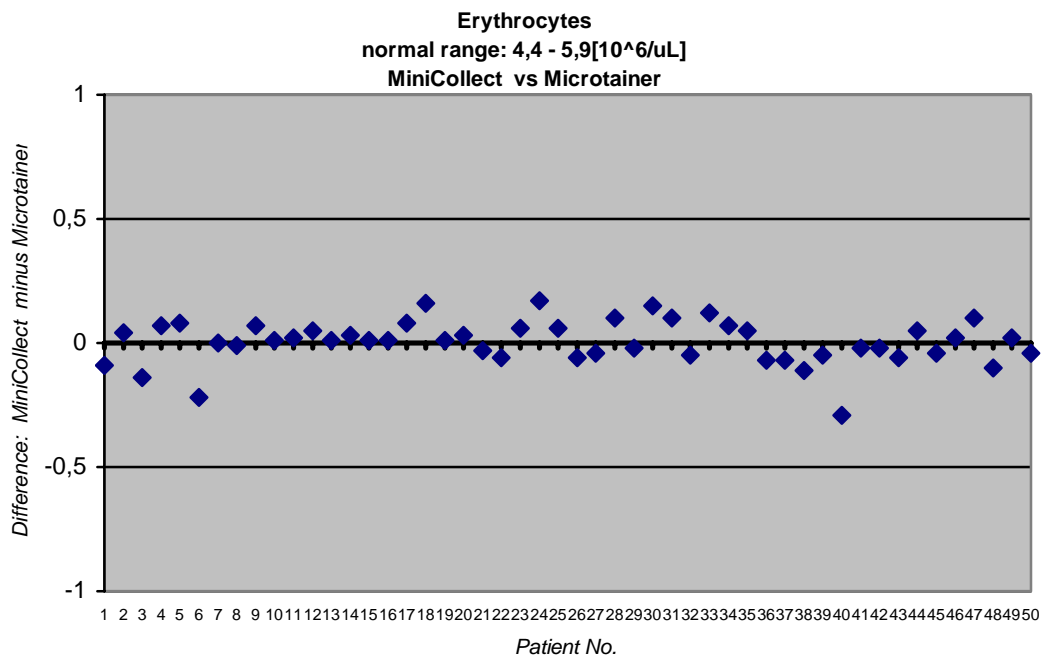
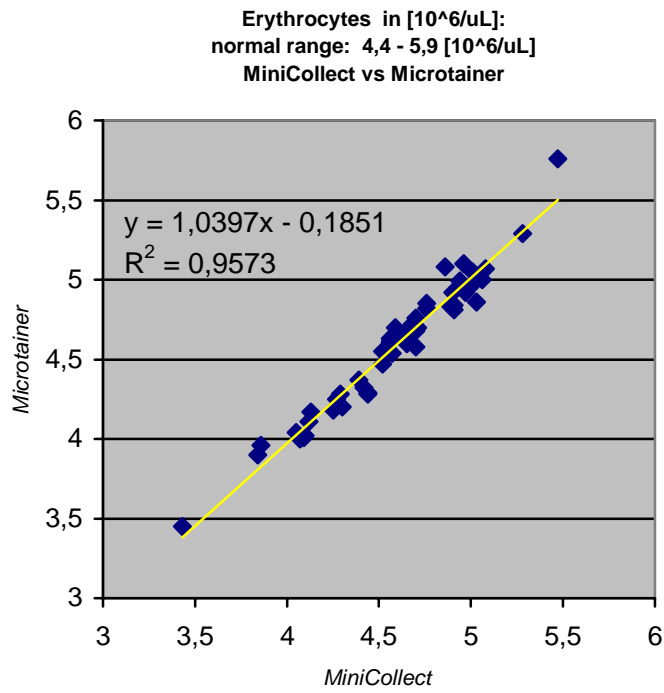
Leucocytes in [10³/uL]:
normal range: 4-10 [10³/uL]
MiniCollect vs Microtainer



Leucocytes
normal range: 4-10[10³/uL]
MiniCollect vs Microtainer

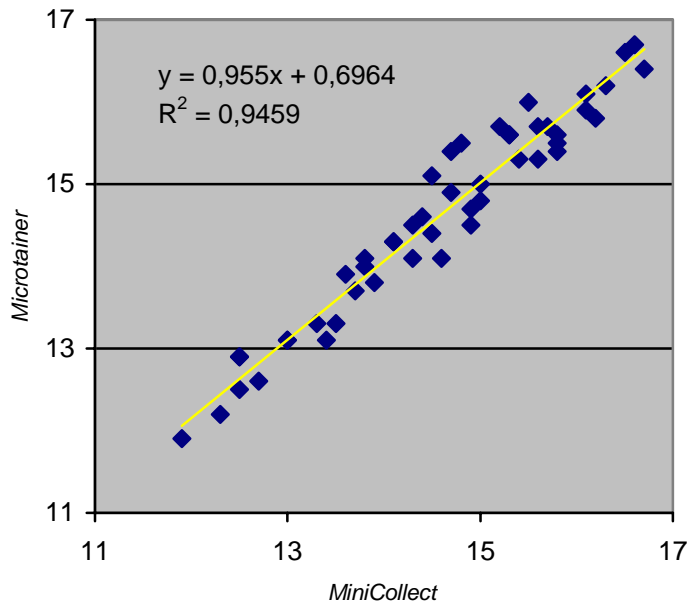


Erythrocytes

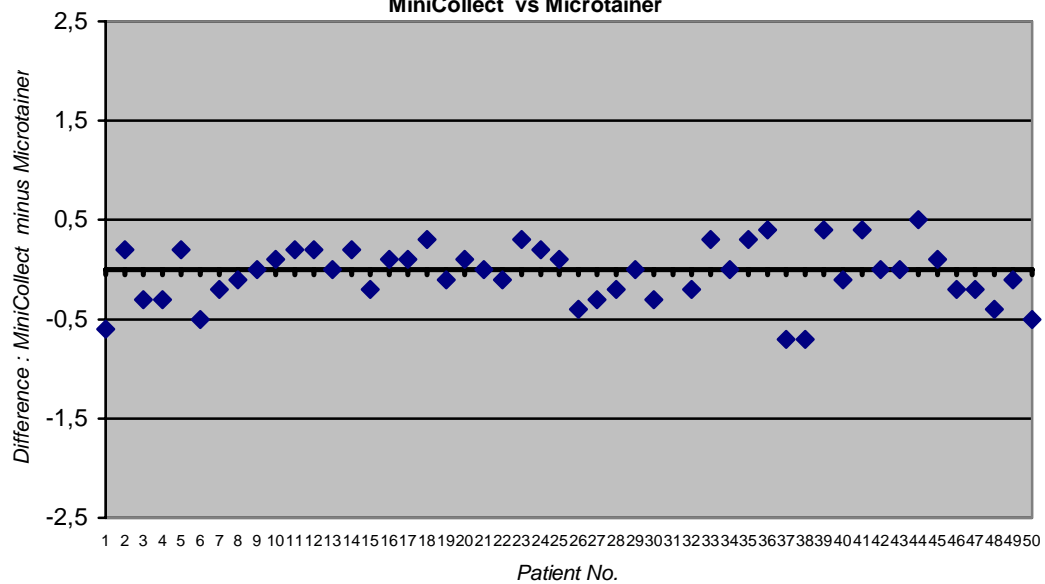


Haemoglobin

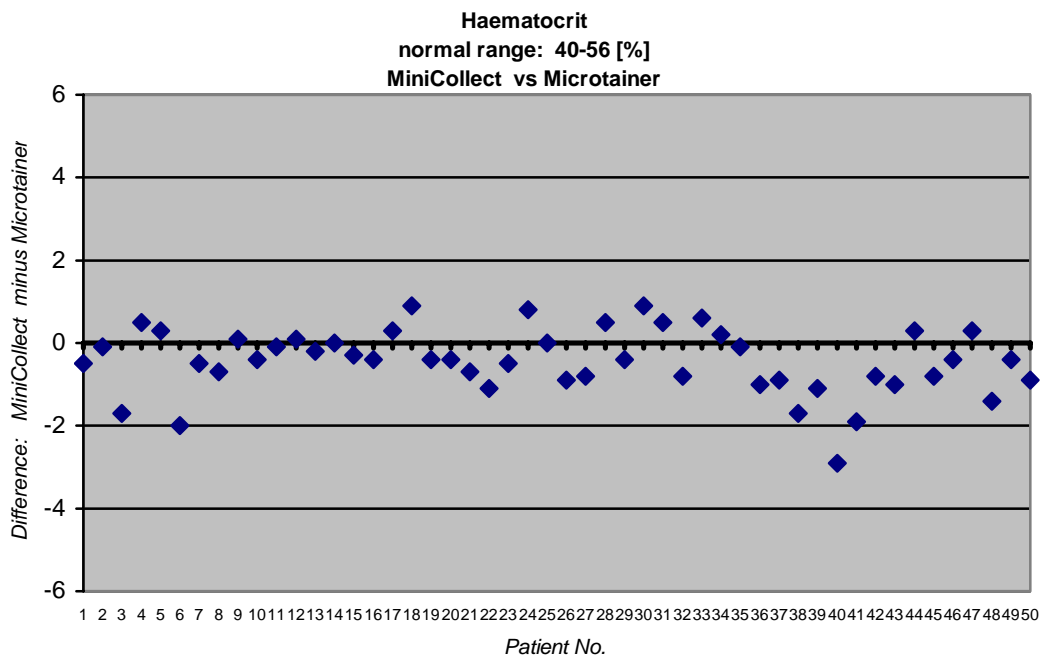
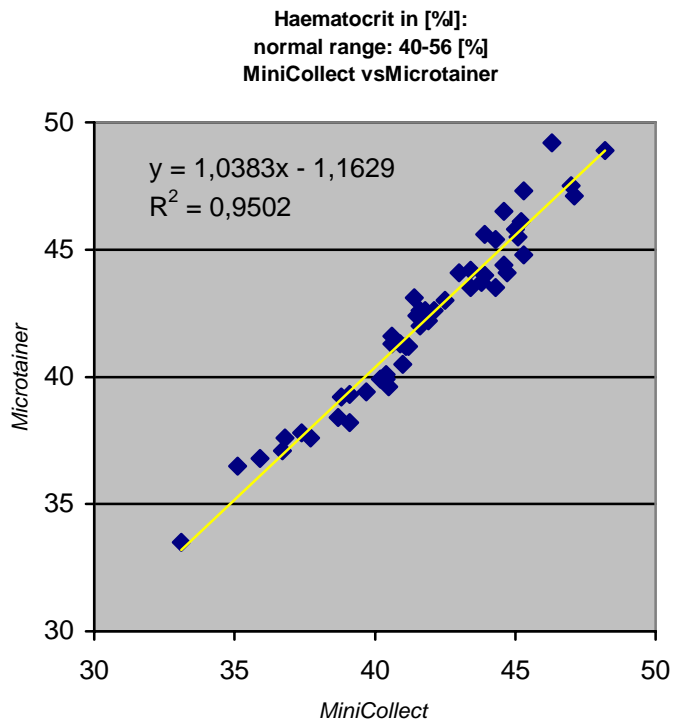
Haemoglobin in [g/dl]:
normal range: 13-18 [g/dl]
MiniCollect vs Microtainer



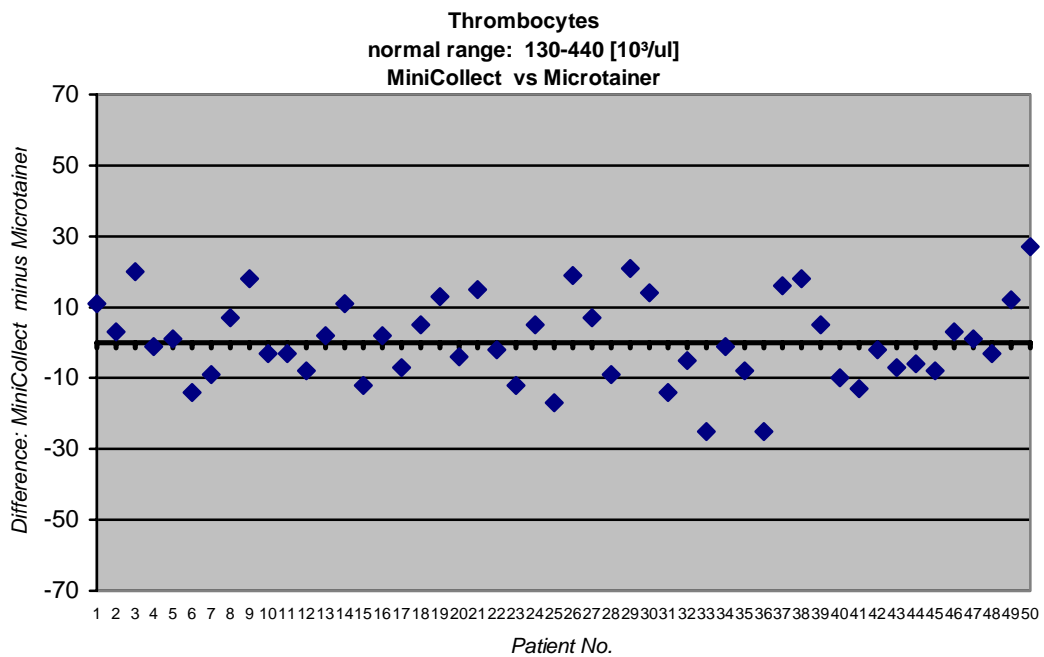
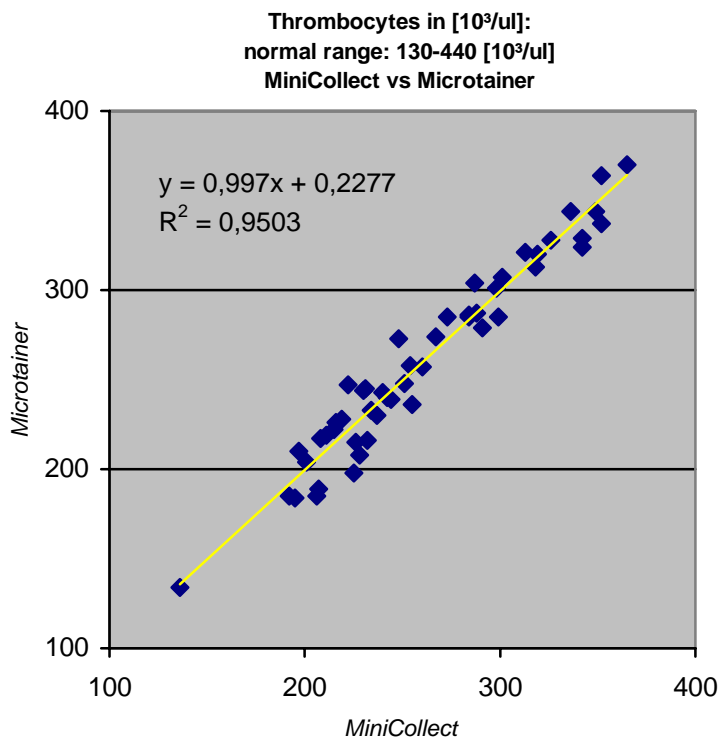
Haemoglobin
normal range: 13-18 [g/dl]
MiniCollect vs Microtainer



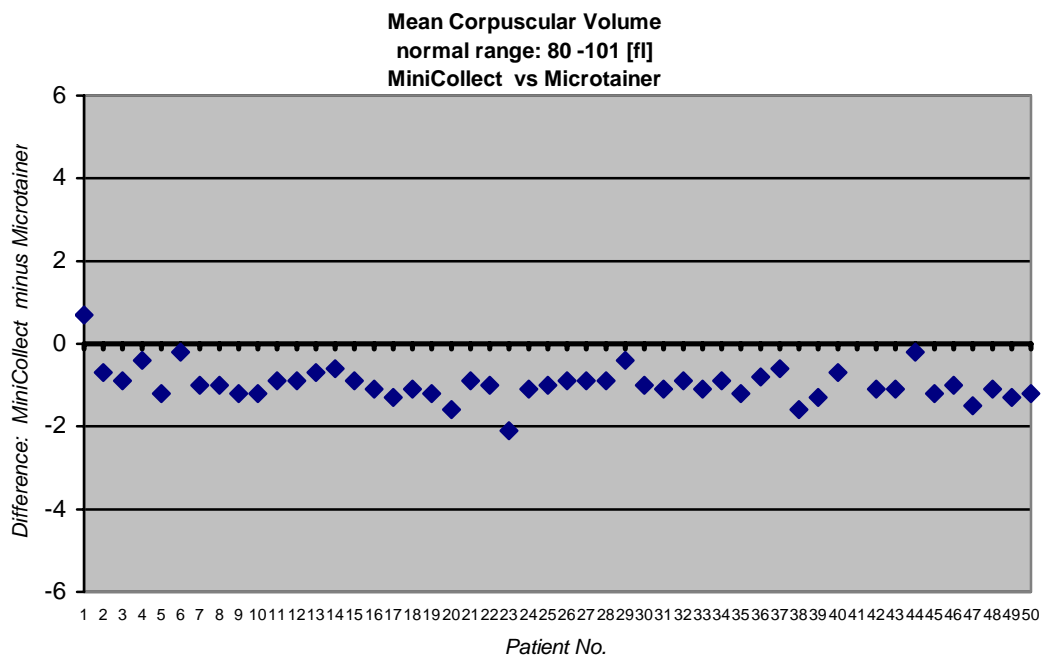
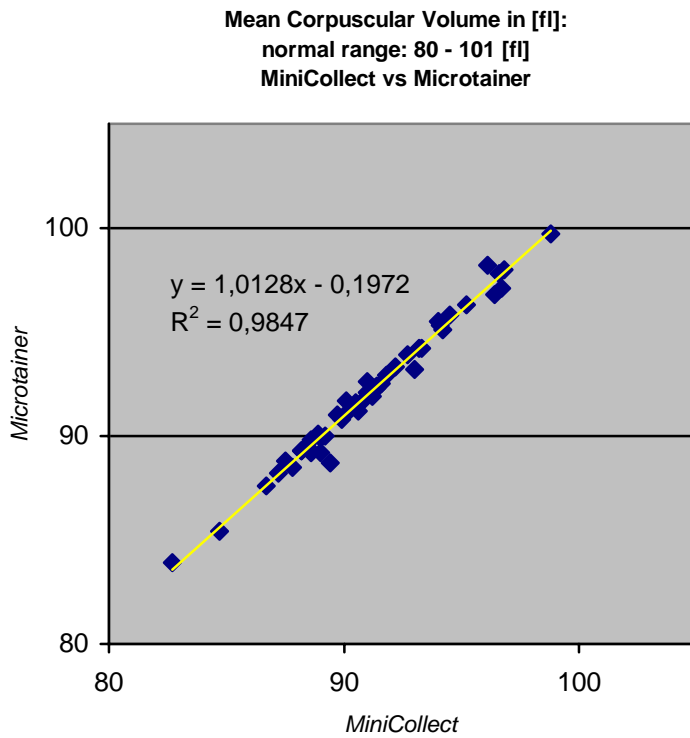
Haematocrit



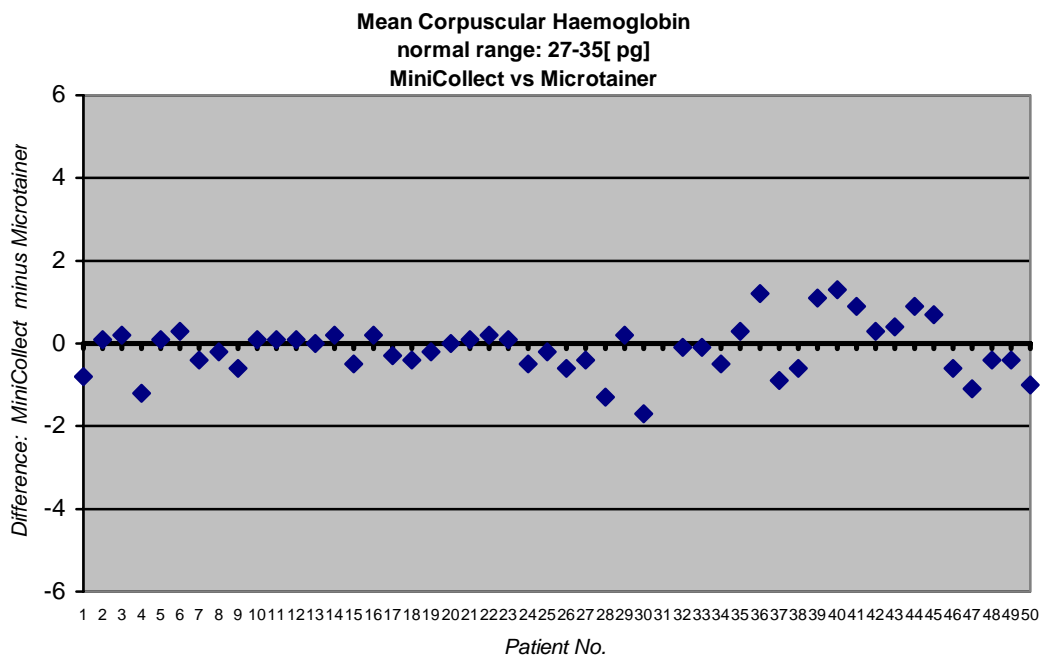
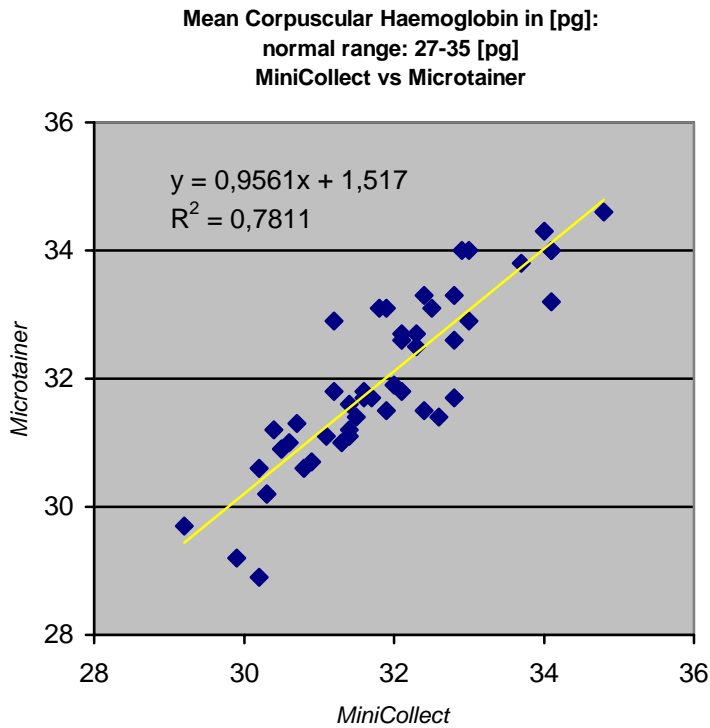
Thrombocytes



Mean Corpuscular Volume (calculated from Hematocrit and Erythrocytes)

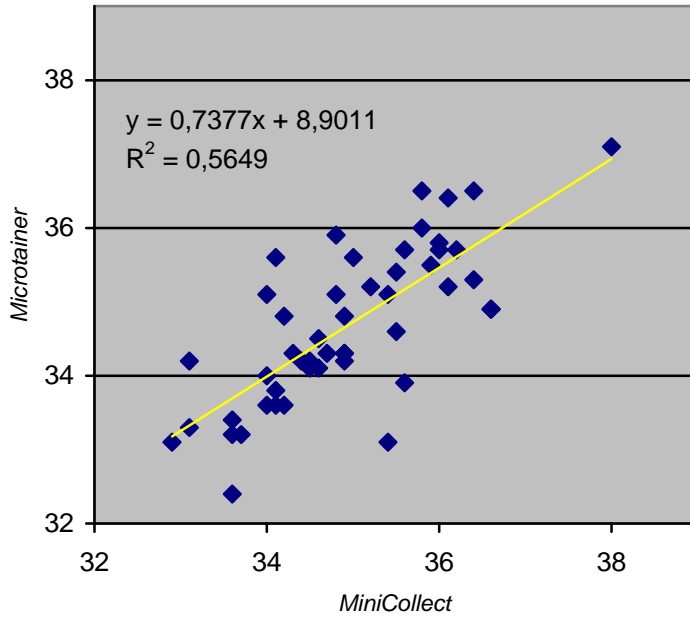


Mean Corpuscular Haemoglobin (calculated from Haemoglobin and Erythrocytes)

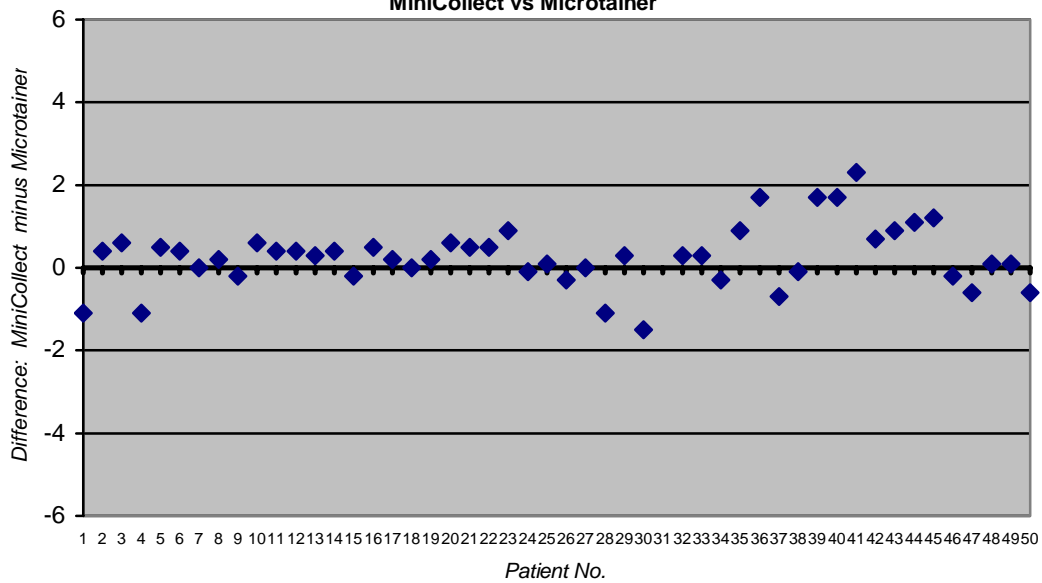


Mean Corpuscular Haemoglobin Concentration (calculated from Haemoglobin and Haematocrit)

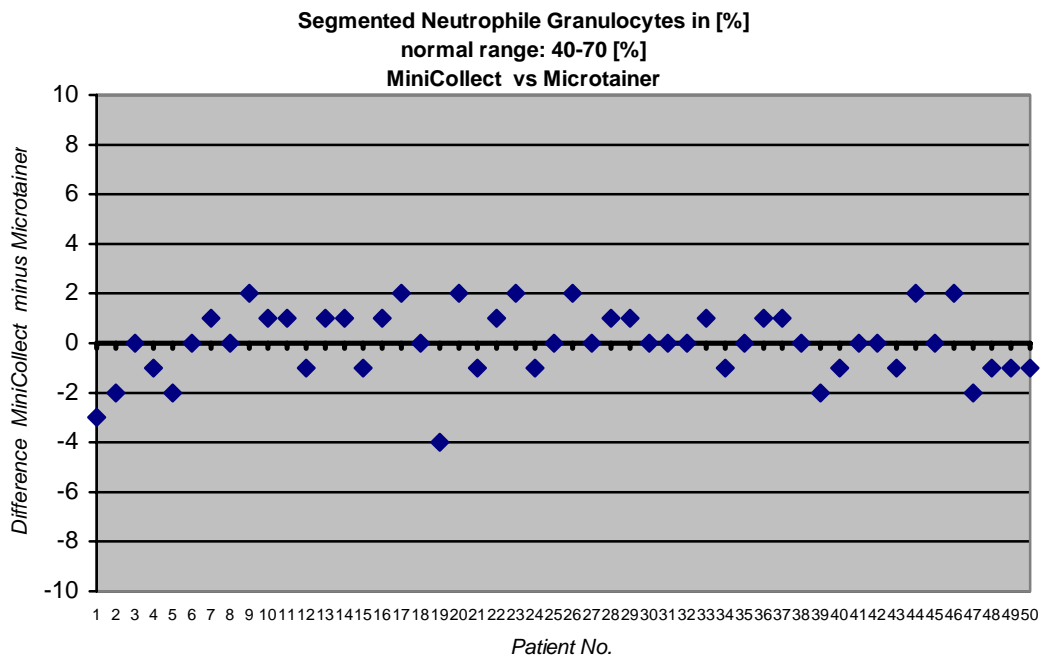
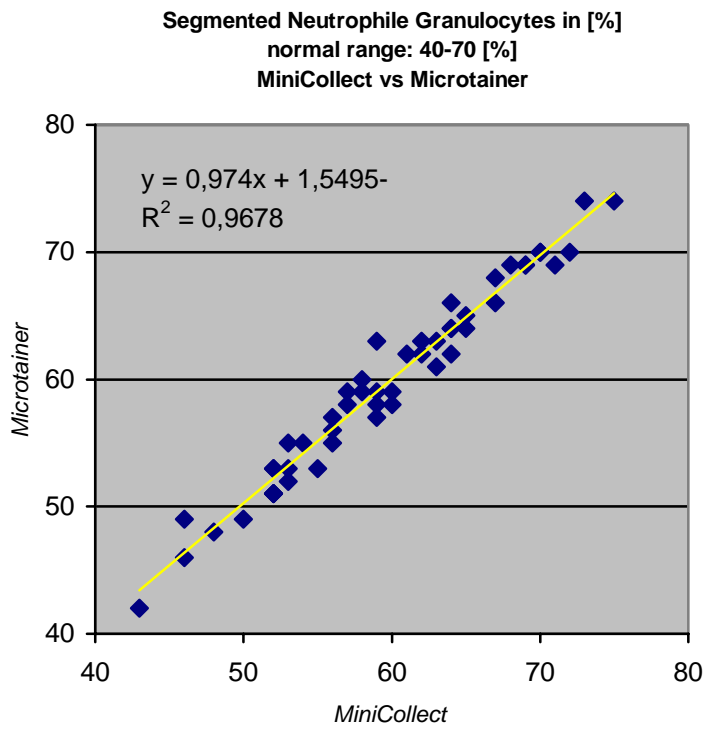
Mean Corpuscular Haemoglobin Concentration in [g/dl]:
normal range: 29 - 36 [g/dl]
MiniCollect vs Microtainer



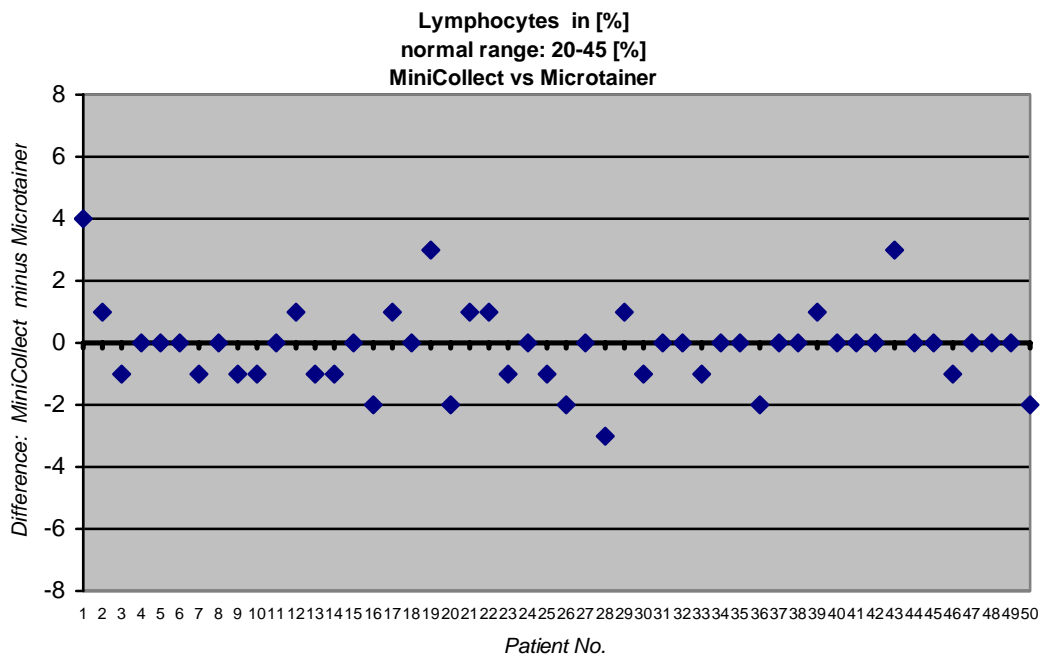
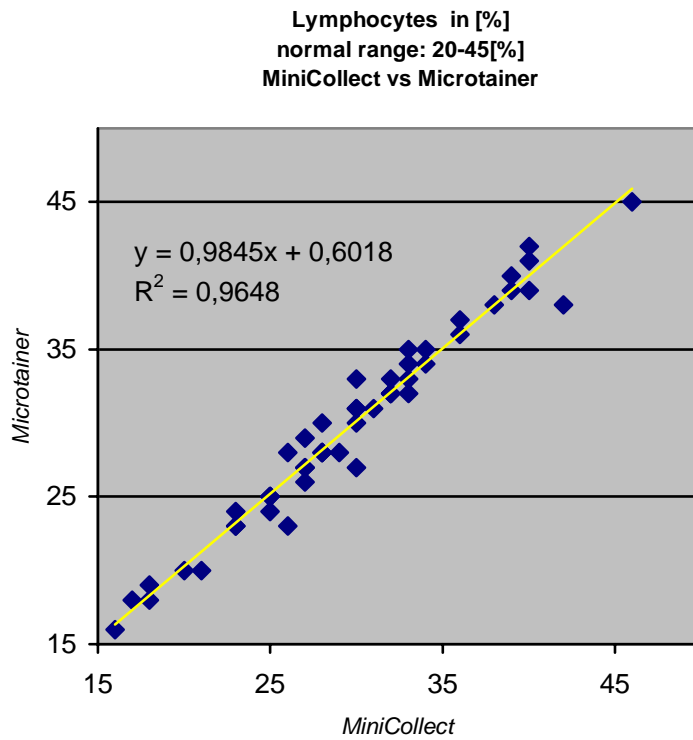
Mean Corpuscular Haemoglobin concentration
normal range: 29 - 36 [g/dl]
MiniCollect vs Microtainer



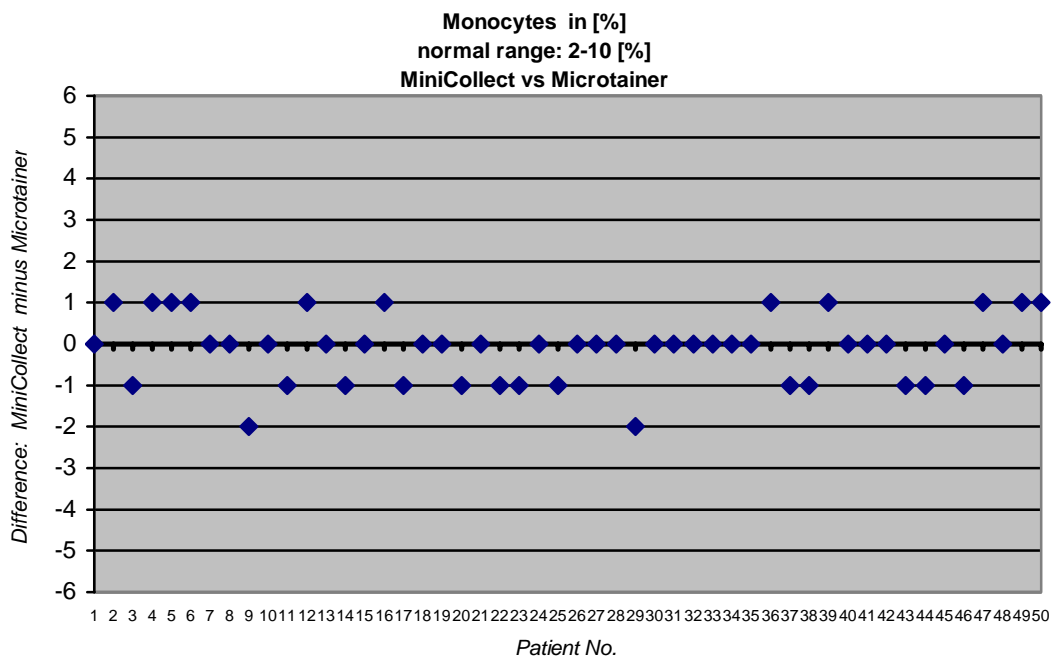
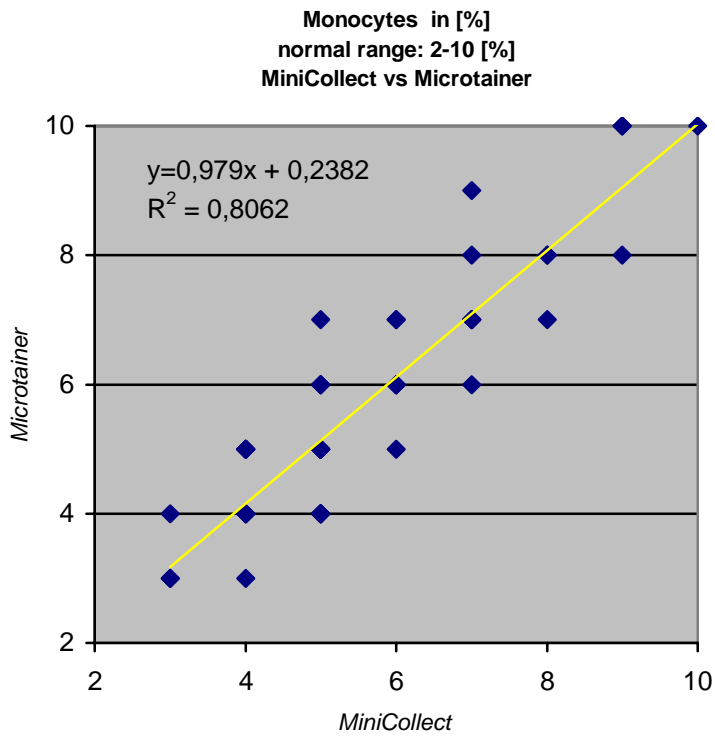
Segmented Neutrophile Granulocytes (in percentage of quantity Leucocytes)



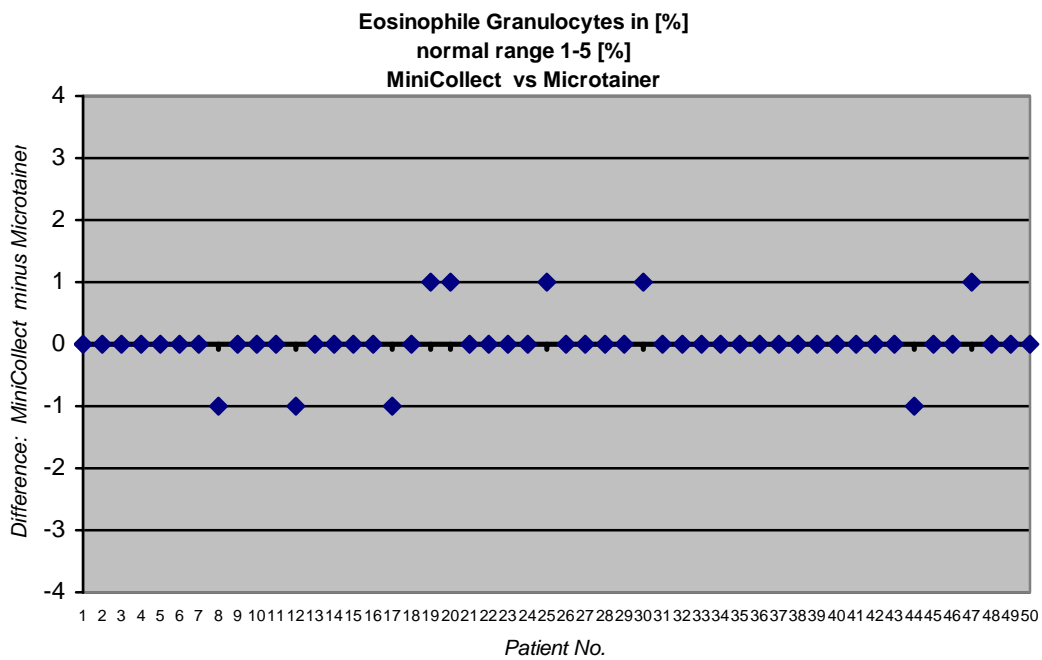
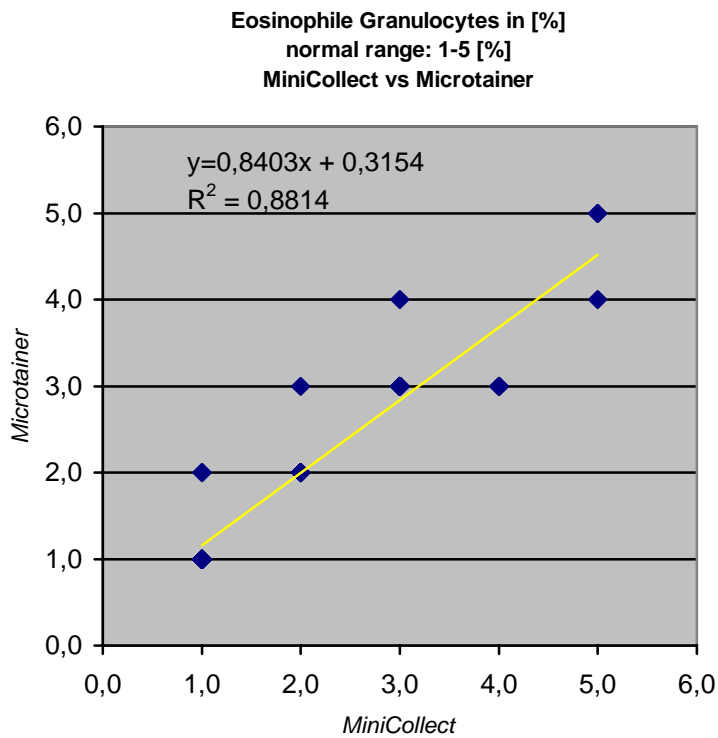
Lymphocytes (in percentage of quantity Leucocytes)



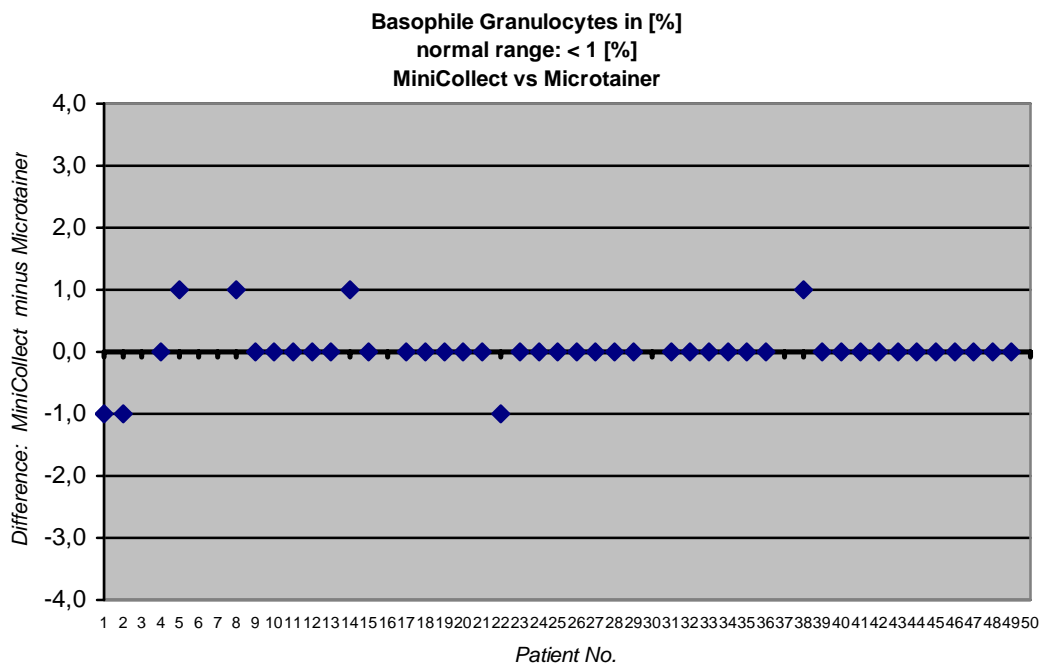
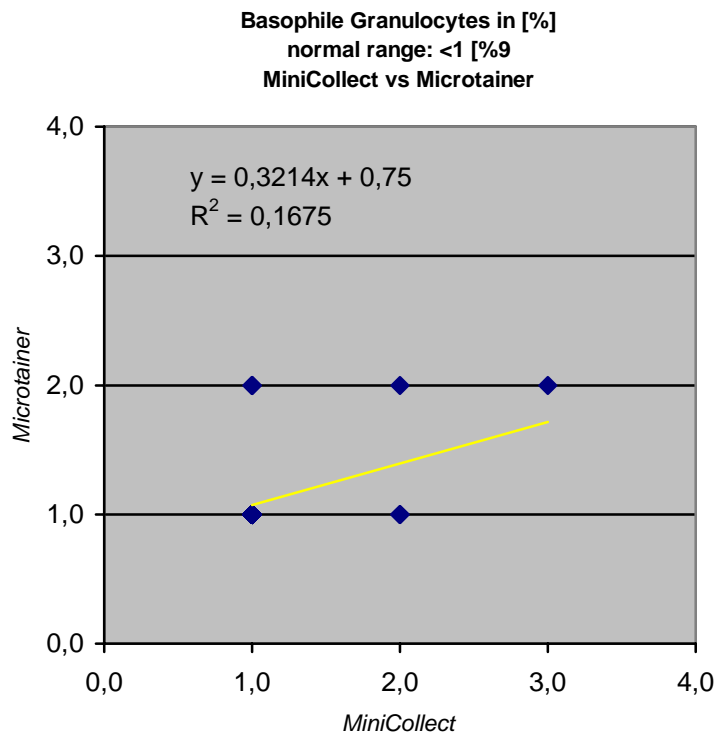
Monocytes (in percentage of quantity Leucocytes)



Eosinophile Granulocytes (in percentage of quantity Leucocytes)



Basophile Granulocytes (in percentage of quantity Leucocytes)



Large Undefined Cells (in percentage of quantity Leucocytes)

