Evaluation of MiniCollect® Z Serum Separator 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® Z Serum Separator 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 blood clotting activator (SiO_2).

MiniCollect® Z Serum Separator tubes are intended for use for testing analytes in clinical chemistry, Immunology and Serology.

Study Objective:

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

Study design:

The following tube types were used in this study:

Sample ID	Description
A	MiniCollect® Z Serum Sep. 0,8 ml, spray dried (item No.: 450472)
B	Microtainer® Z Serum Sep. 0,6 ml (item No.: 365968)

Directly after blood collection with venous blood, the tubes were carefully inverted according to the instructions given by the tube manufacturers. The listed analytes were tested using an ABBOTT 8200 CI. Analysis was performed with the instrument's accompanying reagents.

Determined parameters:

- Creatine Phosphokinase
- Lactate Dehydrogenase
- Glutamic-oxaloacetic Transaminase
- Glutamic-pyruvic Transaminase
- Gamma-glutamyl Transpeptidase
- Alkaline Phosphatase
- Uric Acid
- Total Bilirubin
- Cholesterol
- Triglyceride
- Sodium
- Potassium
- Chloride
- Calcium
- Phosphate
- Magnesium
- Iron
- Urea
- Blood Urea Nitrogen
- Creatinine
- Total Protein
- free Triiodothyronine
- free Thyroxine
- Thyroid-Stimulating Hormone
- Cortisol
- Glucose

Conclusion:

The MiniCollect® Z Serum Sep tube with spray-dried clot activator demonstrated equivalent performance to the Microtainer® Z Serum Sep tube.

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

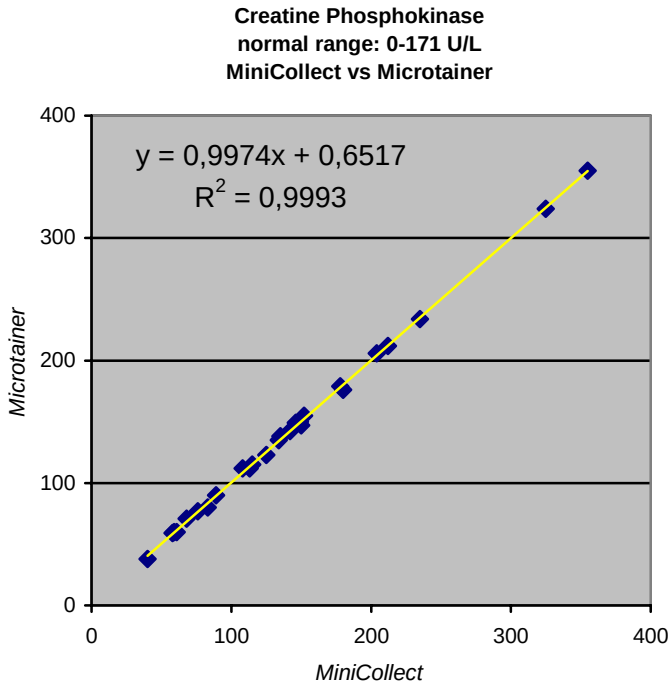
(5) ISO 6710:1995(E), *Single-use containers for venous blood specimen collection*. International Standard. Genève, Switzerland (1995)

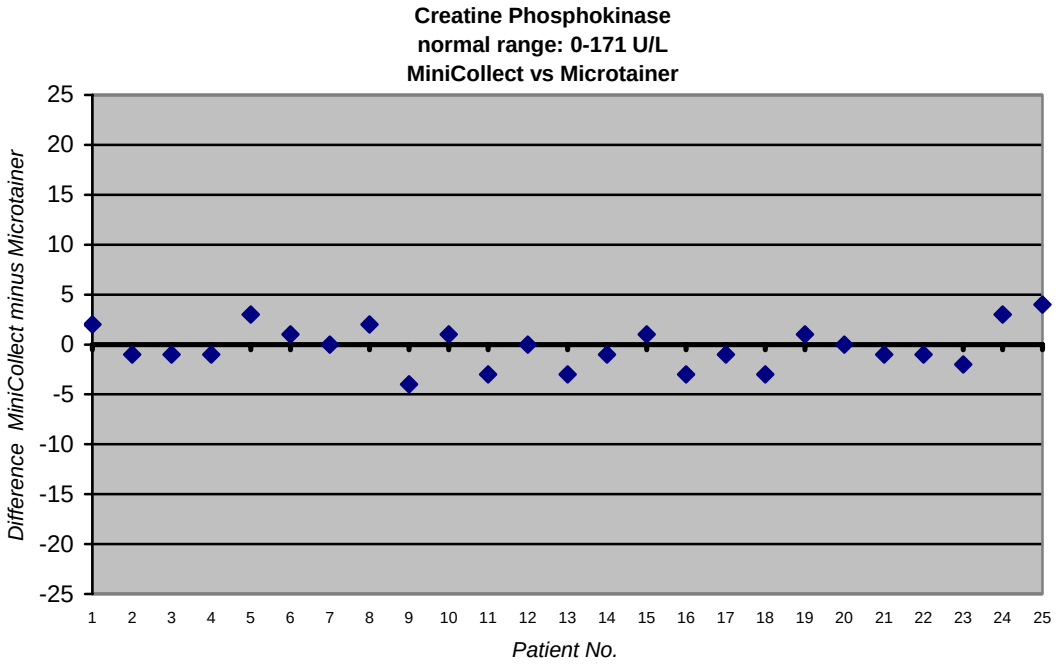
(6) EP7-A: *Interference Testing in Clinical Chemistry*; Approved Guideline. CLSI (formerly NCCLS) document (ISBN 1-56238-480-5). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898,USA 2002.

(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.

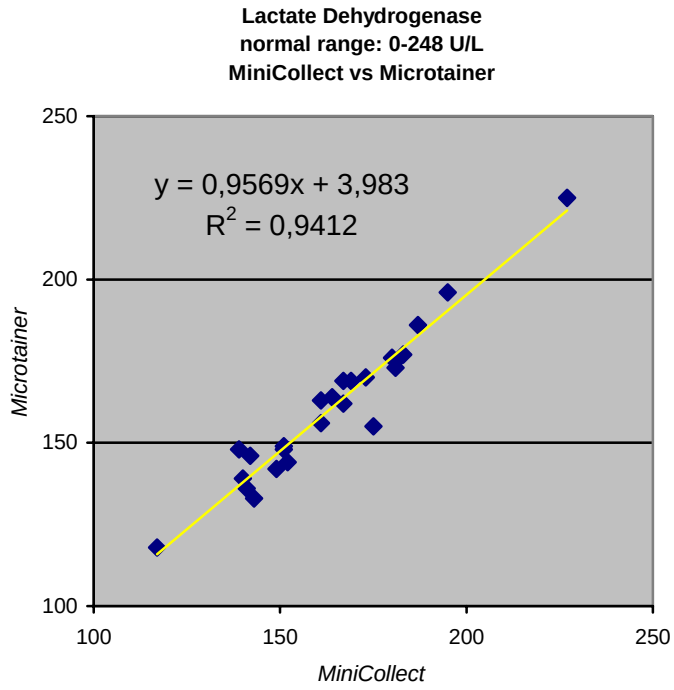
Results: Results in detail:

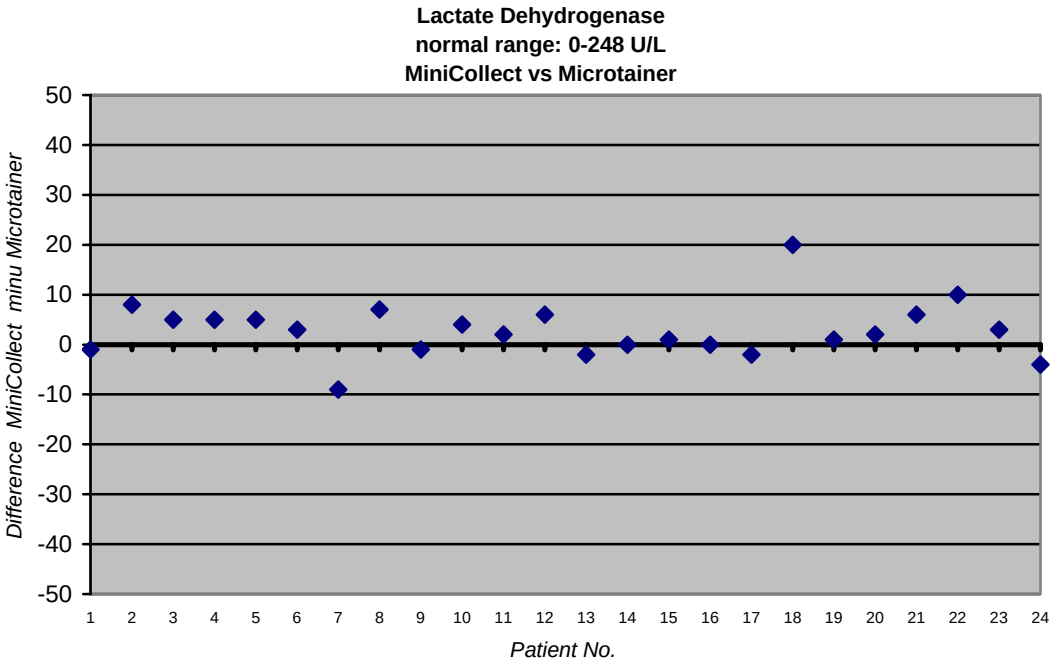
Creatine Phosphokinase



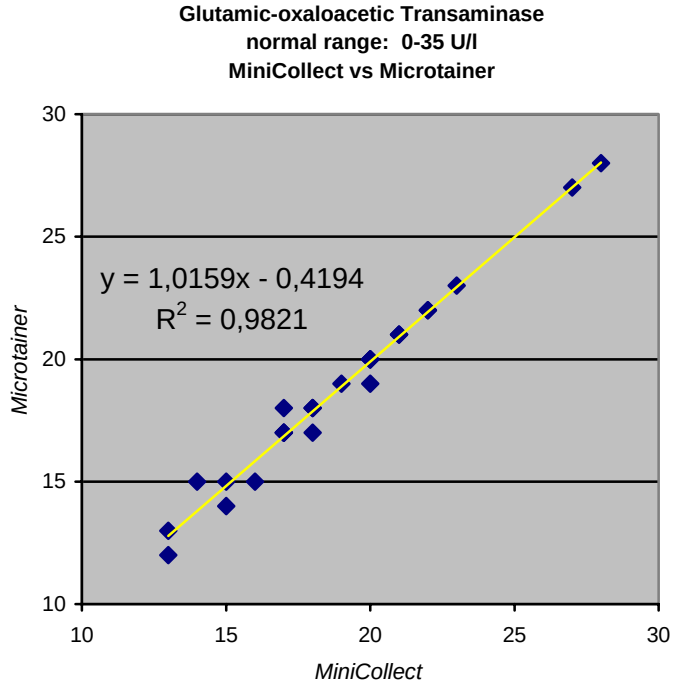


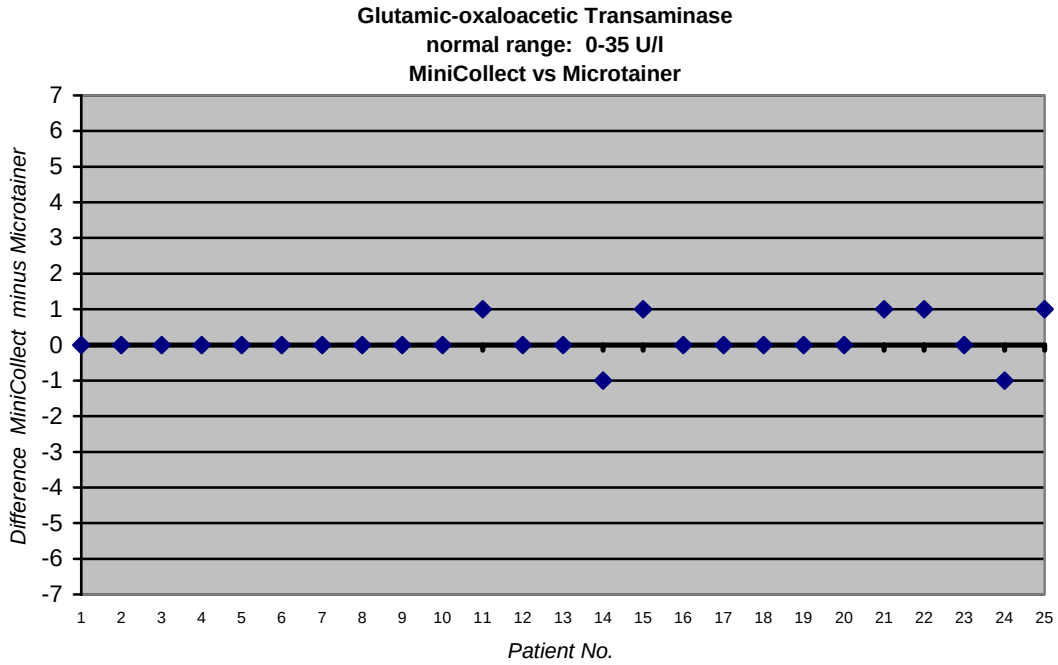
Lactate Dehydrogenase



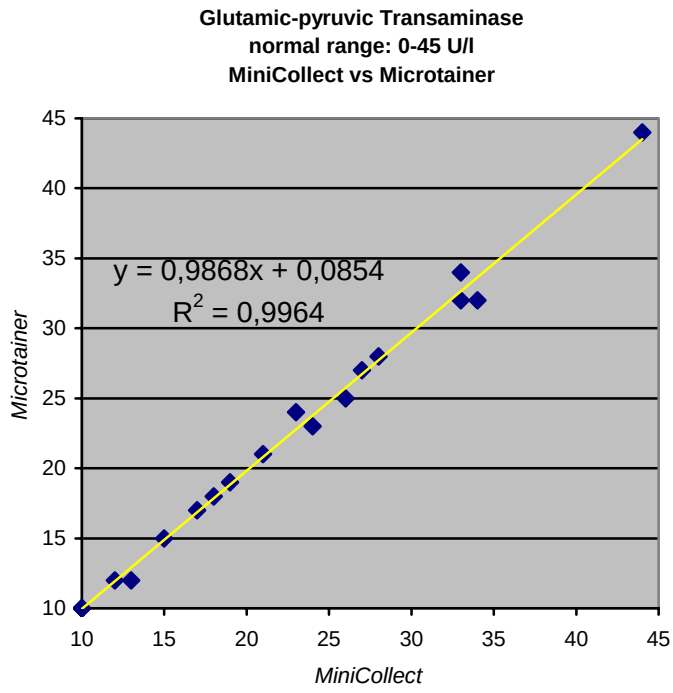


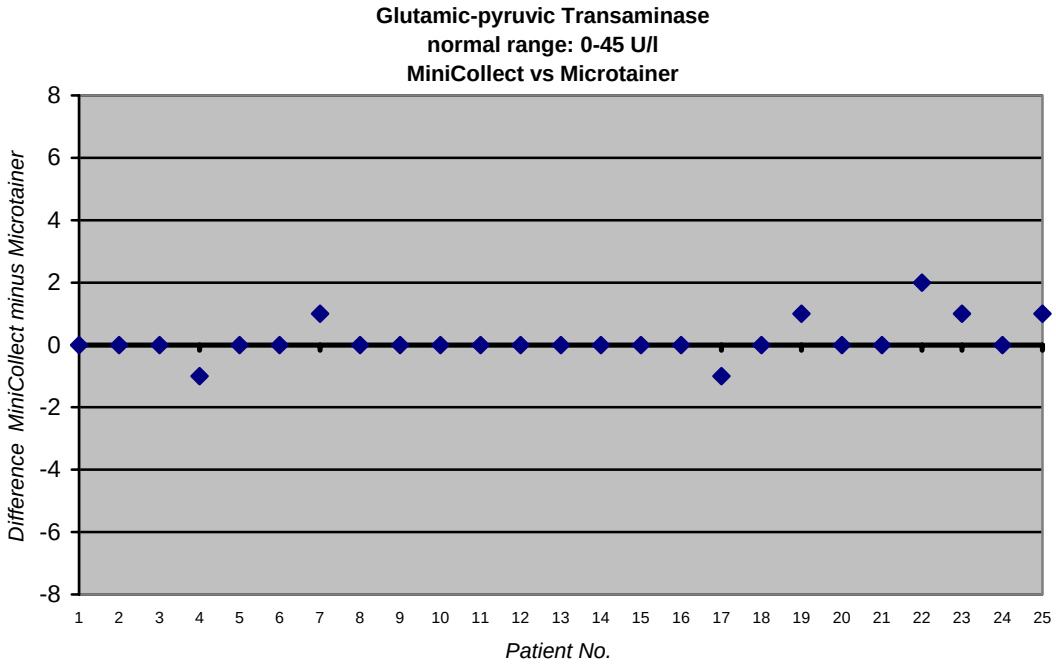
Glutamic-oxaloacetic Transaminase



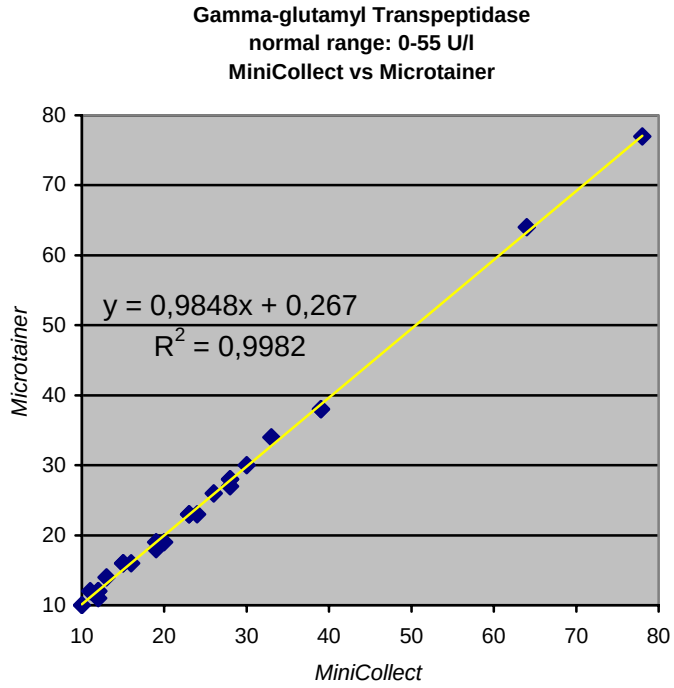


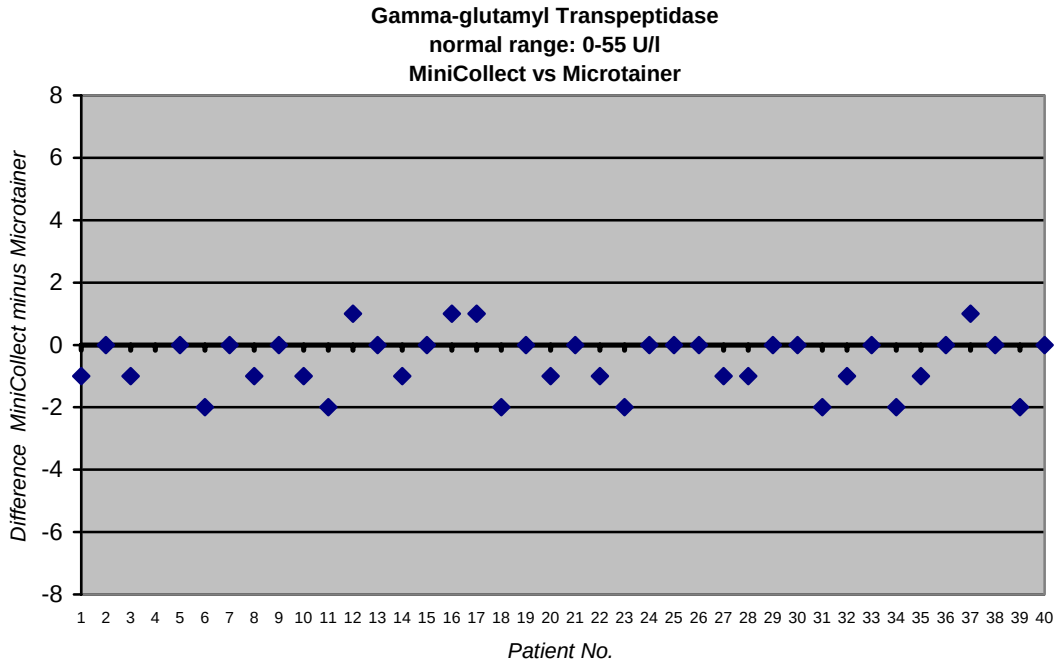
Glutamic-pyruvic Transaminase



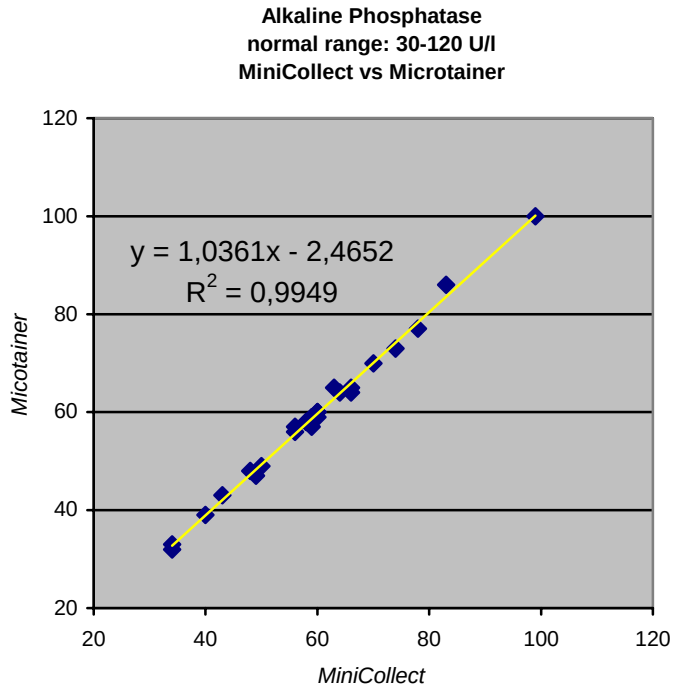


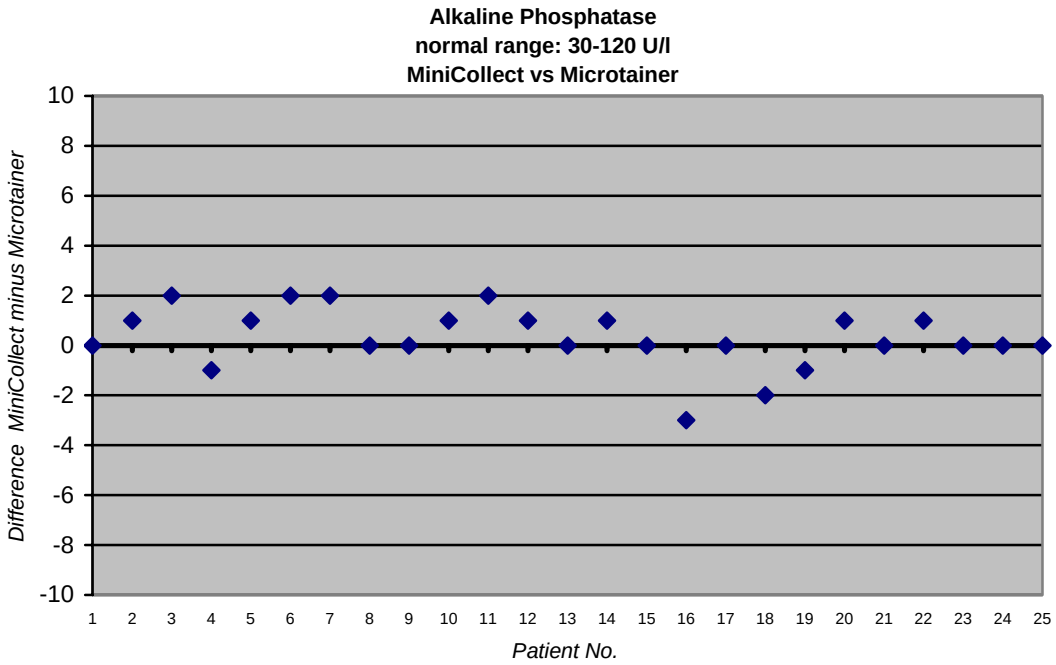
Gamma-glutamyl Transpeptidase



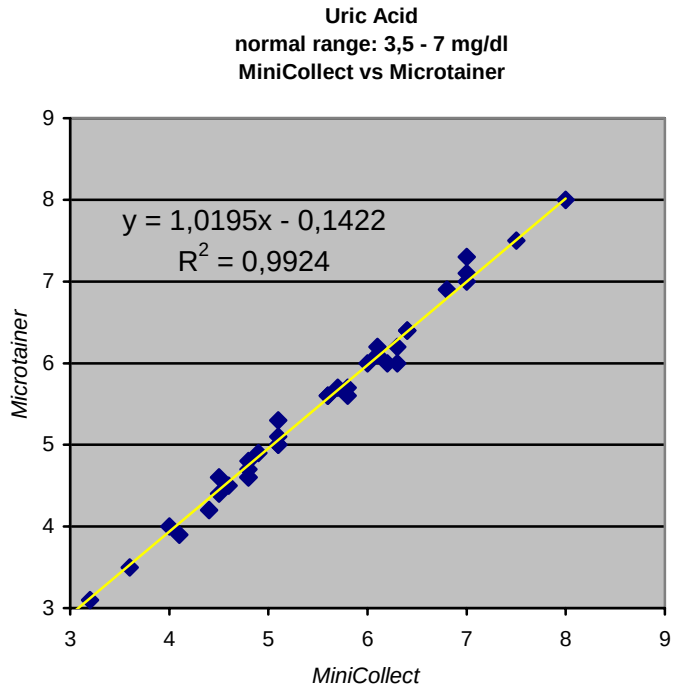


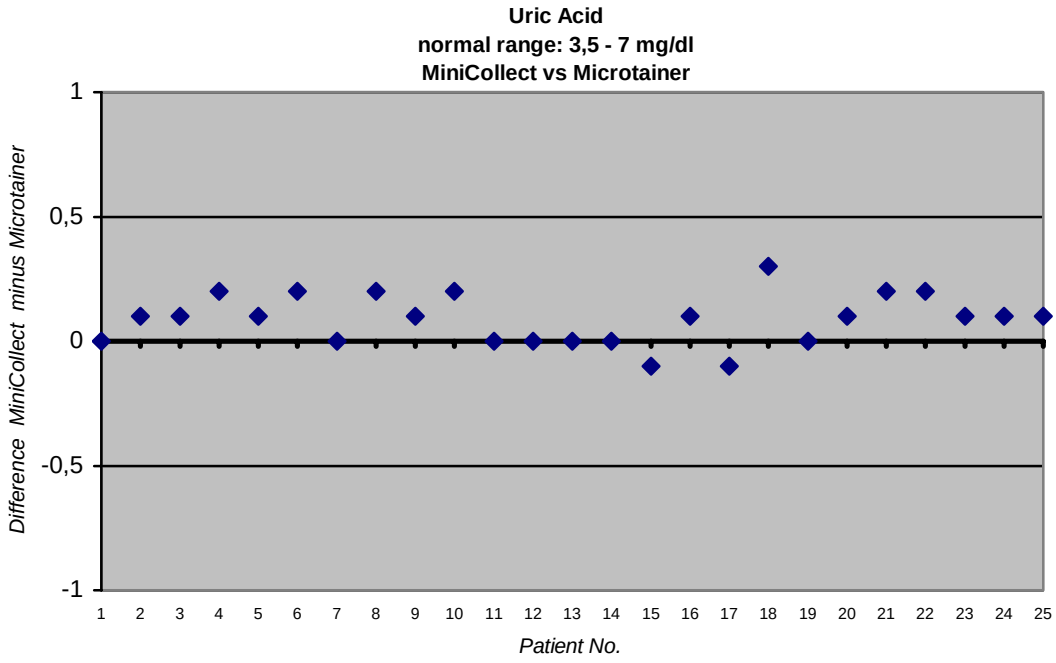
Alkaline Phosphatase



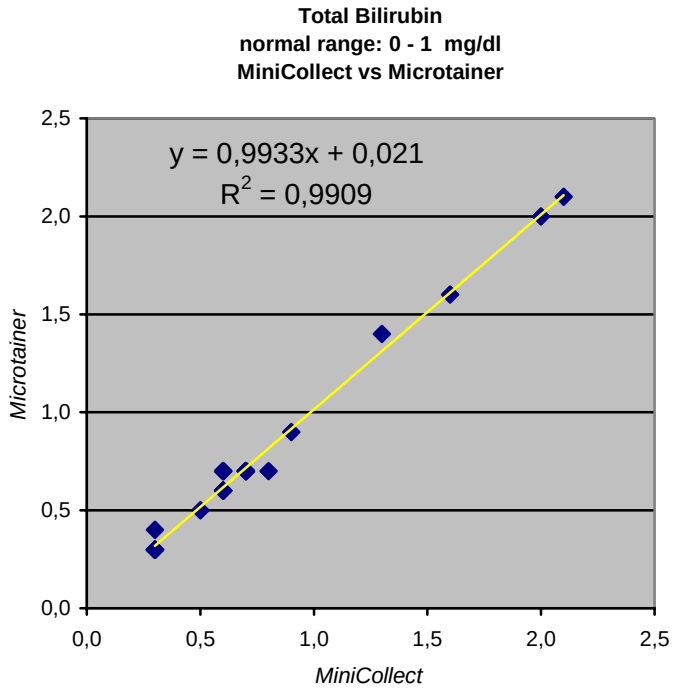


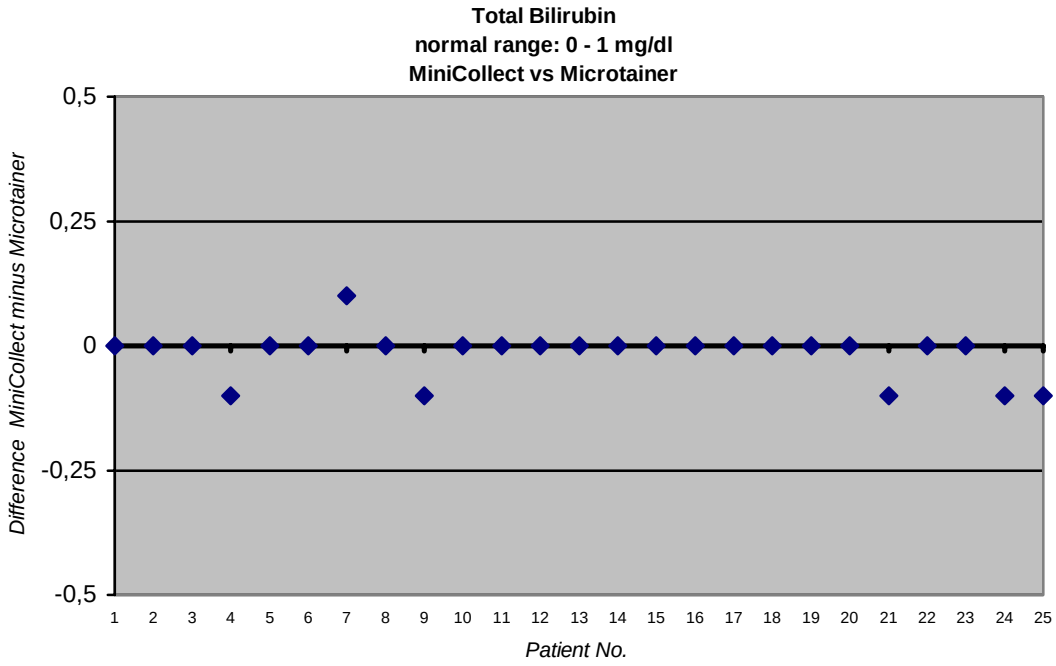
Uric Acid


Uric Acid
normal range: 3,5 - 7 mg/dl
MiniCollect vs Microtainer
y = 1,0195x - 0,1422
R2 = 0,9924
Microtainer
MiniCollect
9
8
7
6
5
4
3
3
4
5
6
7
8
9

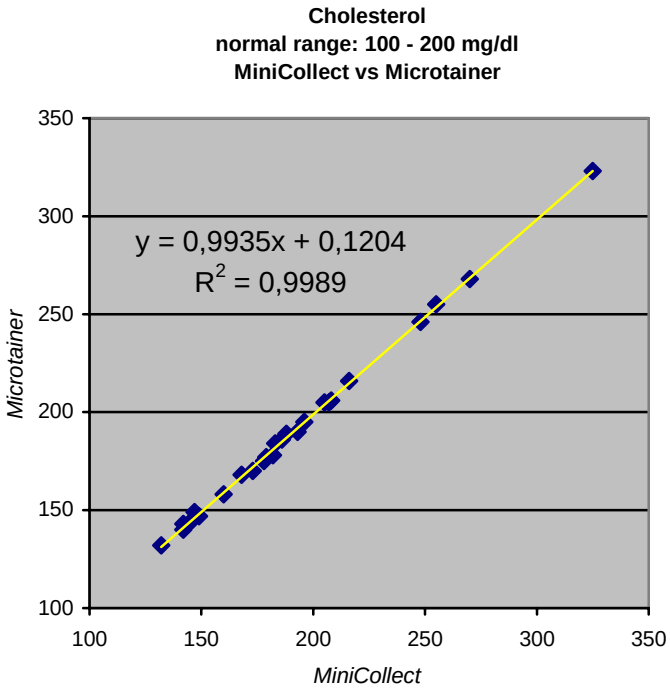

Uric Acid
normal range: 3,5 - 7 mg/dl
MiniCollect vs Microtainer
Difference MiniCollect minus Microtainer
Patient No.
1
0,5
0
-0,5
-1
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

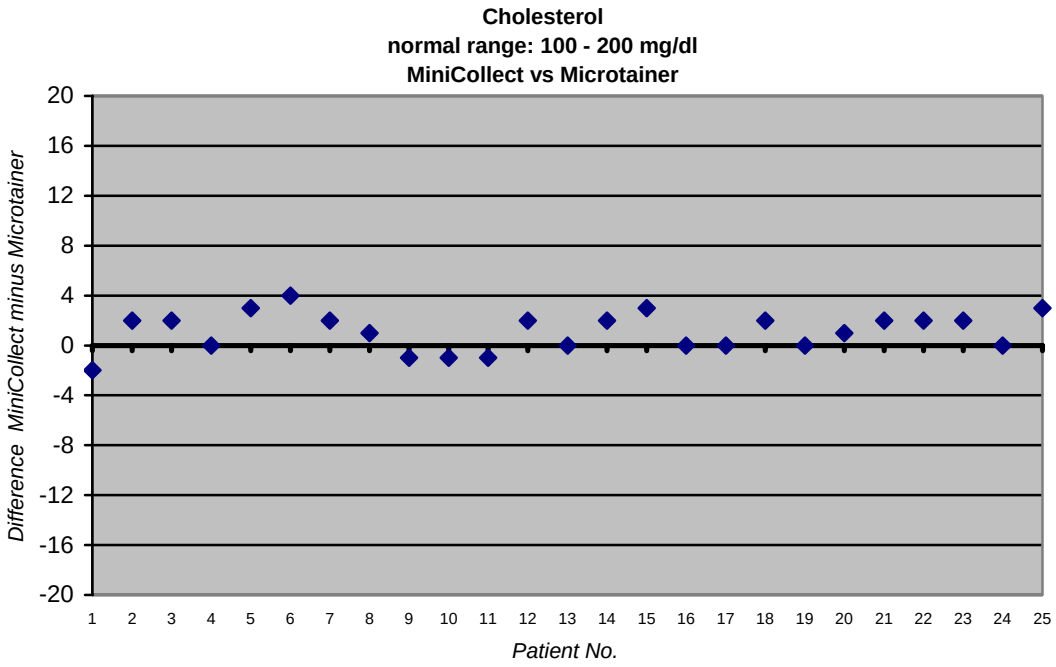
Total Bilirubin



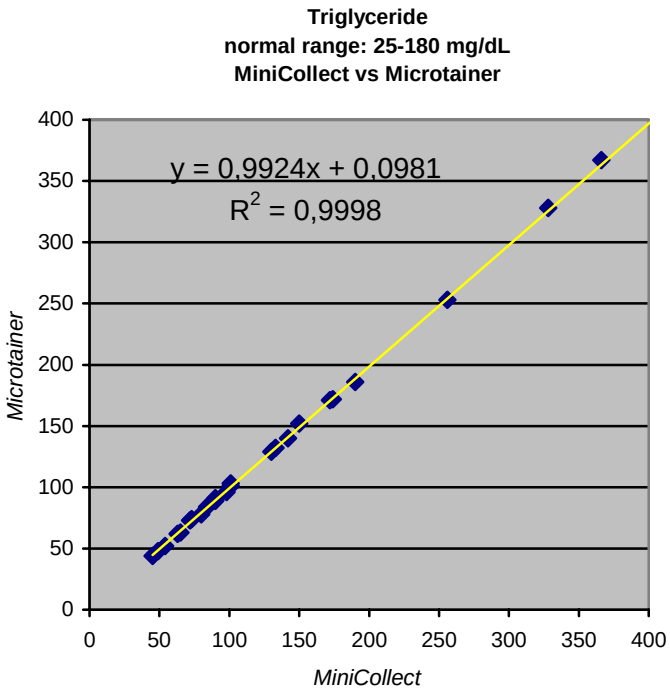


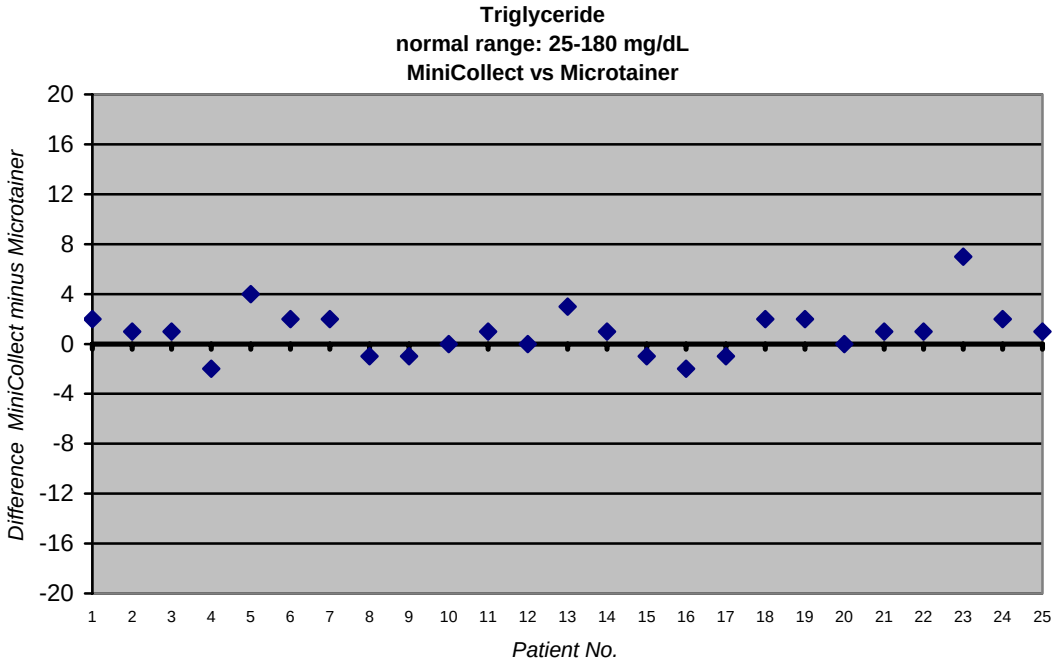
Cholesterol



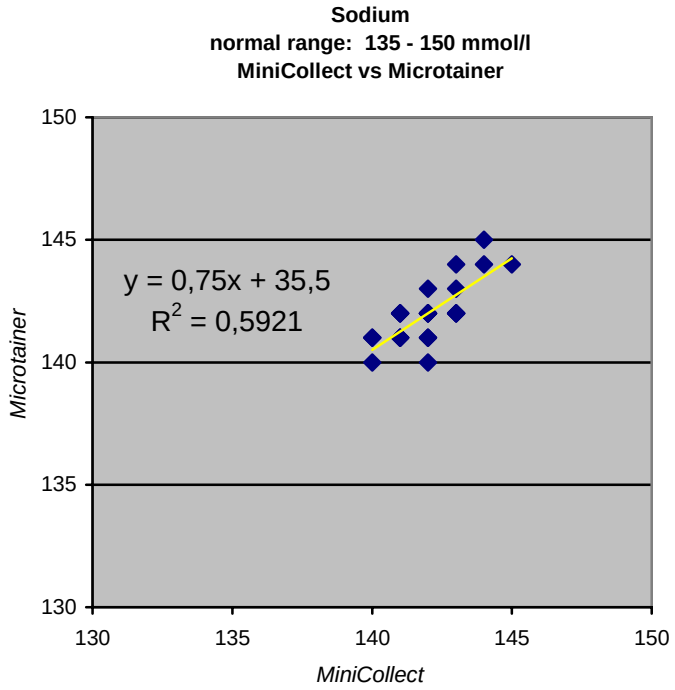


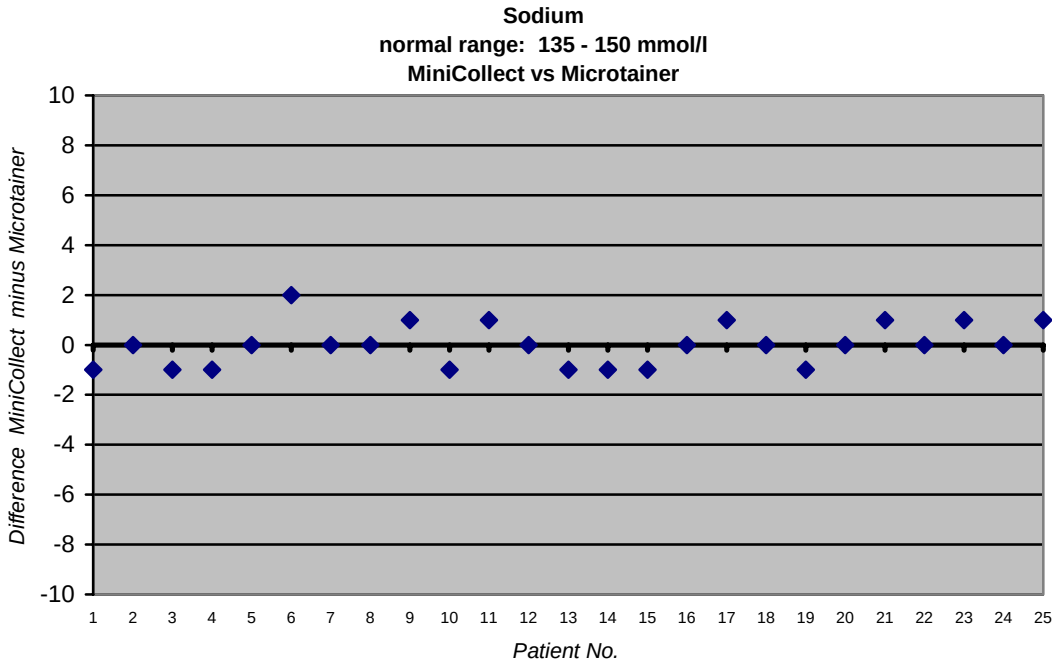
Triglyceride



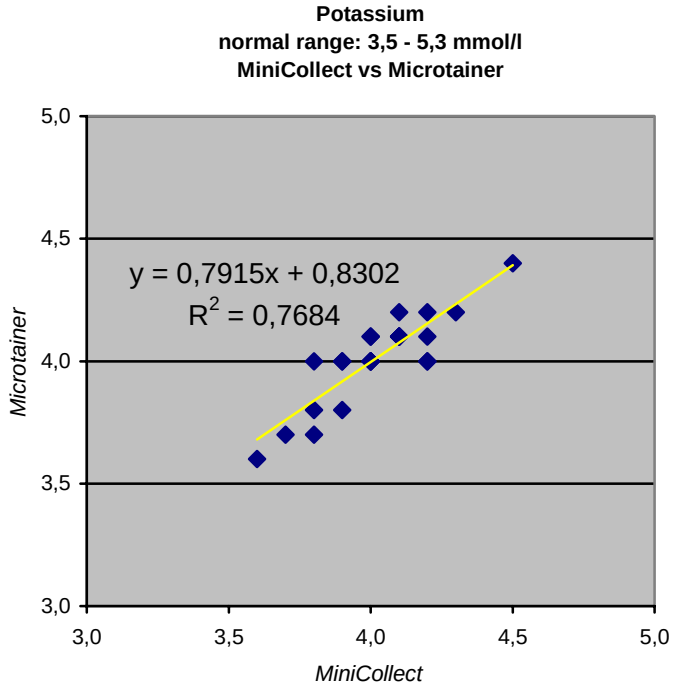


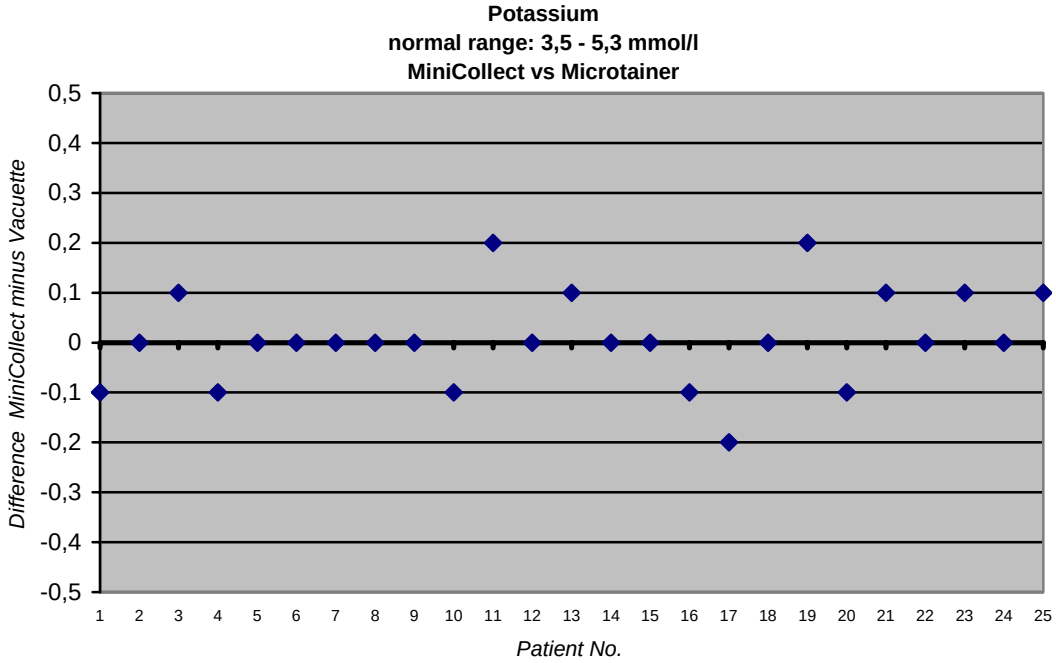
Sodium


Sodium
normal range: 135 - 150 mmol/l
MiniCollect vs Microtainer
y = 0,75x + 35,5
R2 = 0,5921
Microtainer
MiniCollect
150
145
140
135
130
130
135
140
145
150

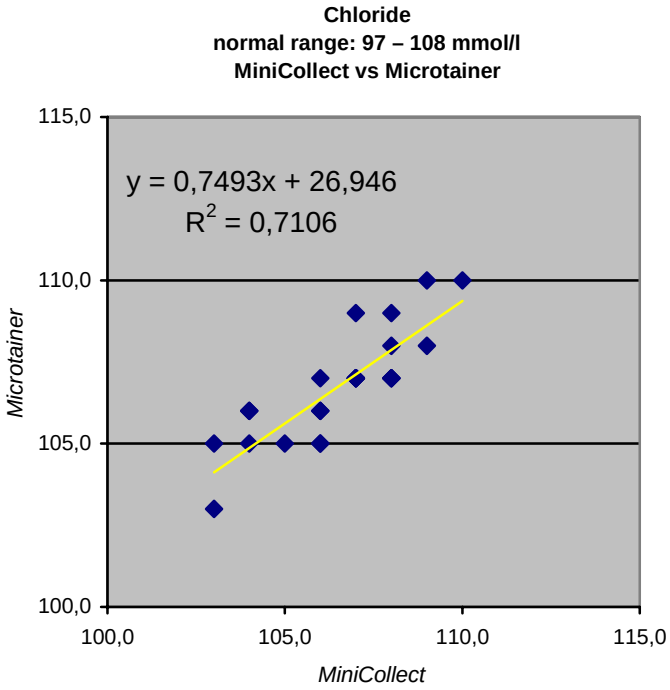

Sodium
normal range: 135 - 150 mmol/l
MiniCollect vs Microtainer
Difference MiniCollect minus Microtainer
Patient No.
10
8
6
4
2
0
-2
-4
-6
-8
-10
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

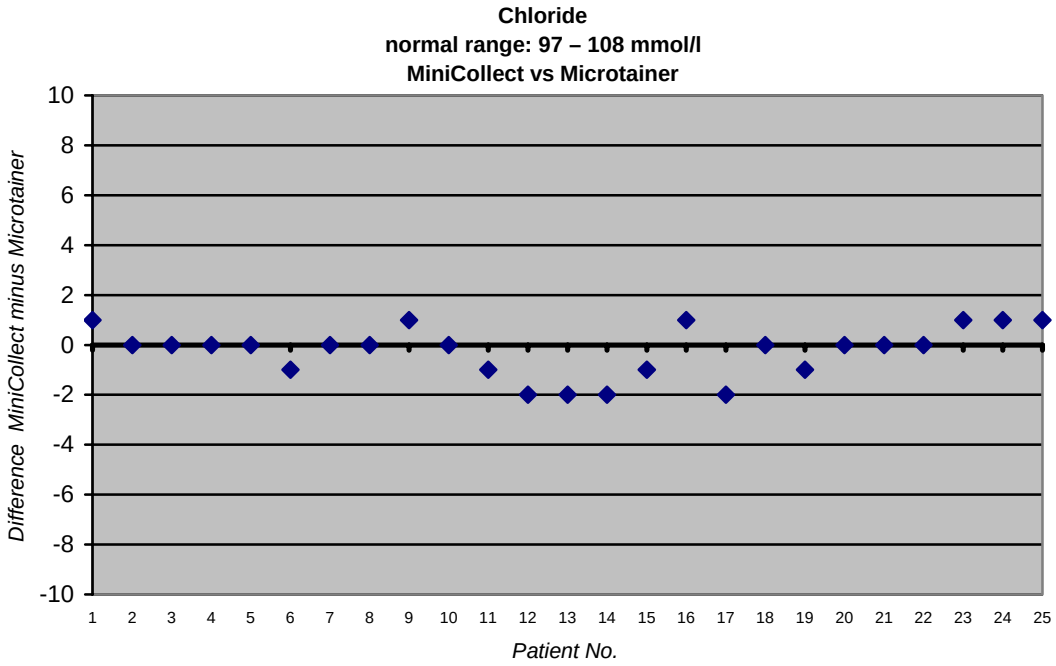
Potassium


Potassium
normal range: 3,5 - 5,3 mmol/l
MiniCollect vs Microtainer
y = 0,7915x + 0,8302
R2 = 0,7684
Microtainer
MiniCollect
5,0
4,5
4,0
3,5
3,0
3,0
3,5
4,0
4,5
5,0

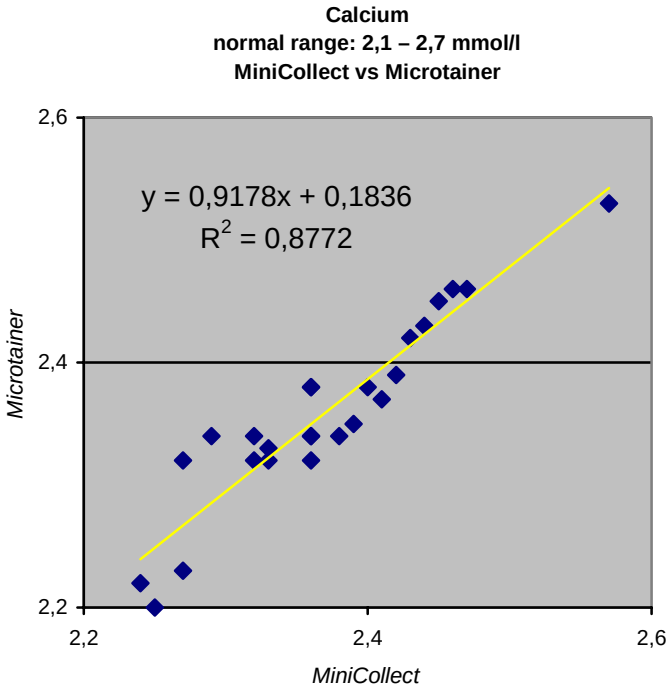

Potassium
normal range: 3,5 - 5,3 mmol/l
MiniCollect vs Microtainer
Difference MiniCollect minus Vacuette
Patient No.
0,5
0,4
0,3
0,2
0,1
0
-0,1
-0,2
-0,3
-0,4
-0,5
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

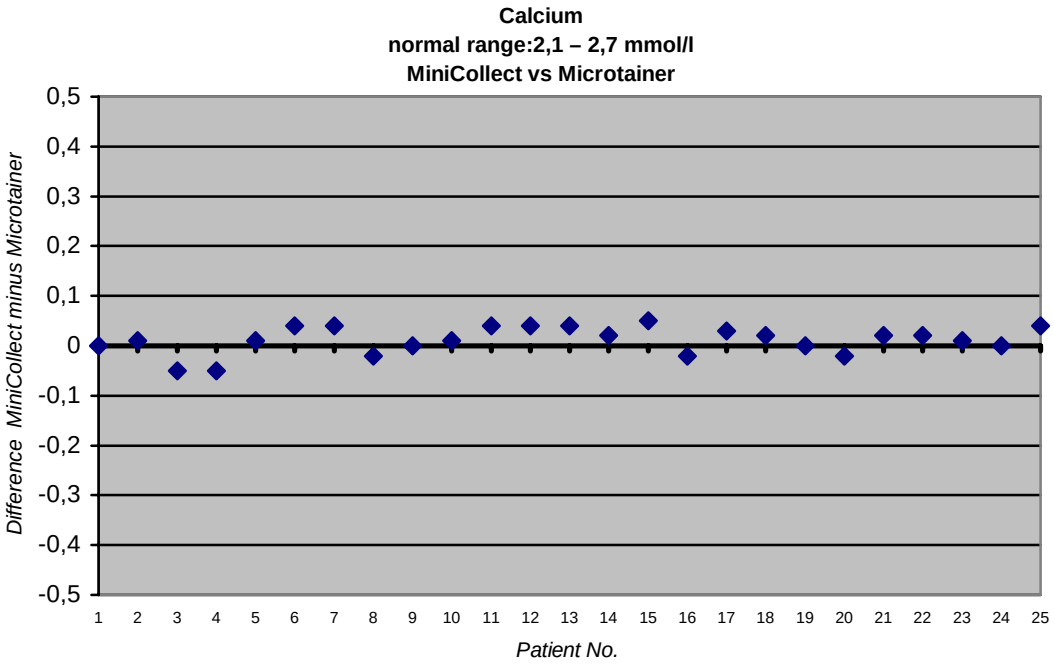
Chloride


Chloride
normal range: 97 – 108 mmol/l
MiniCollect vs Microtainer
y = 0,7493x + 26,946
R2 = 0,7106
115,0
110,0
105,0
100,0
Microtainer
100,0
105,0
110,0
115,0
MiniCollect

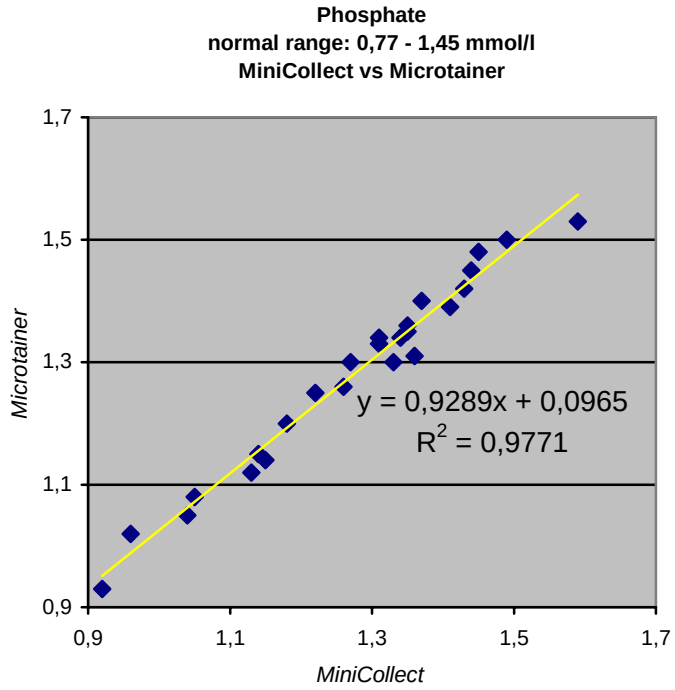

Chloride
normal range: 97 – 108 mmol/l
MiniCollect vs Microtainer
10
8
6
4
2
0
-2
-4
-6
-8
-10
Difference MiniCollect minus Microtainer
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
Patient No.

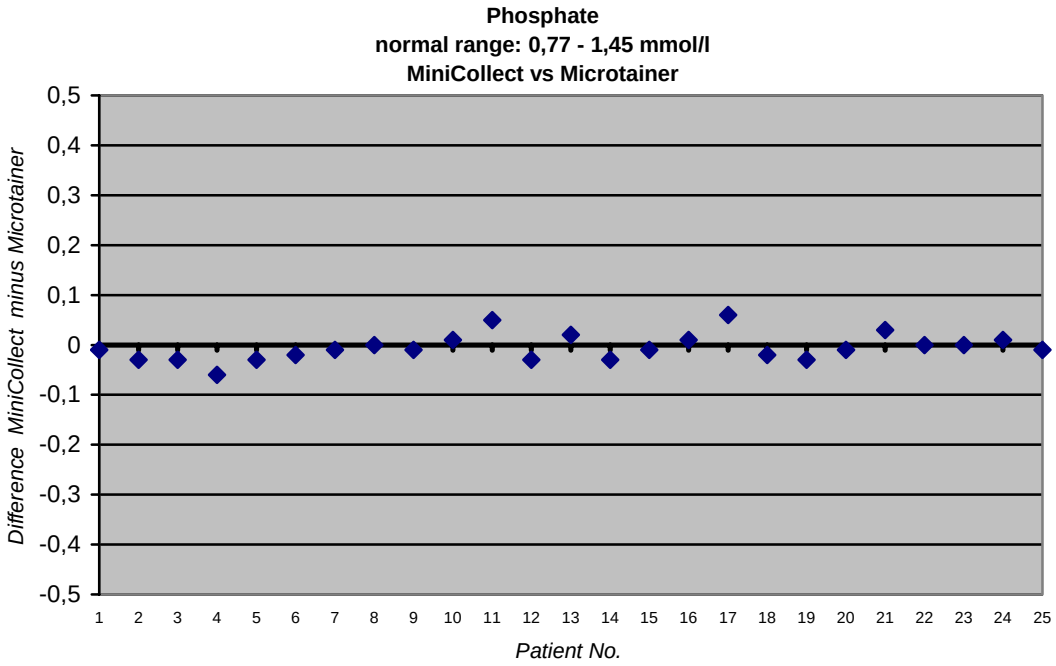
Calcium


Calcium
normal range: 2,1 – 2,7 mmol/l
MiniCollect vs Microtainer
y = 0,9178x + 0,1836
R2 = 0,8772
Microtainer
MiniCollect
2,2
2,4
2,6

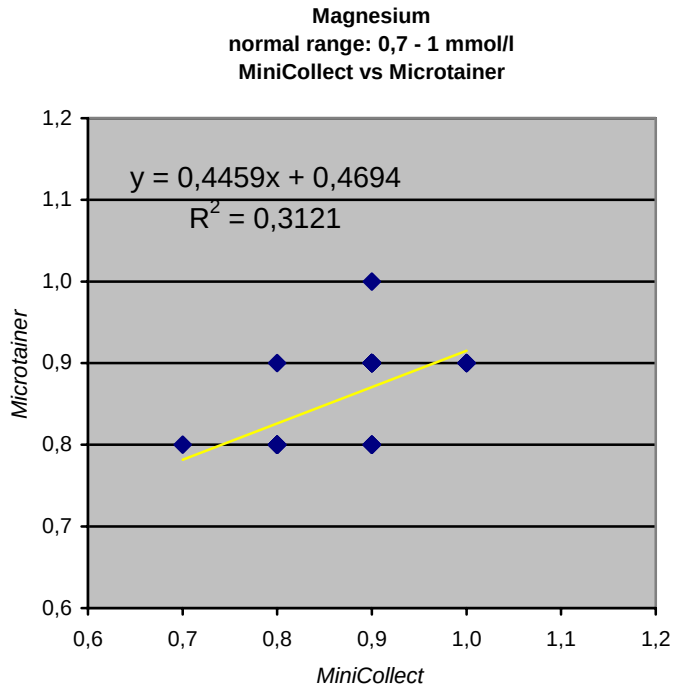

Calcium
normal range:2,1 – 2,7 mmol/l
MiniCollect vs Microtainer
Difference MiniCollect minus Microtainer
Patient No.
0,5
0,4
0,3
0,2
0,1
0
-0,1
-0,2
-0,3
-0,4
-0,5
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

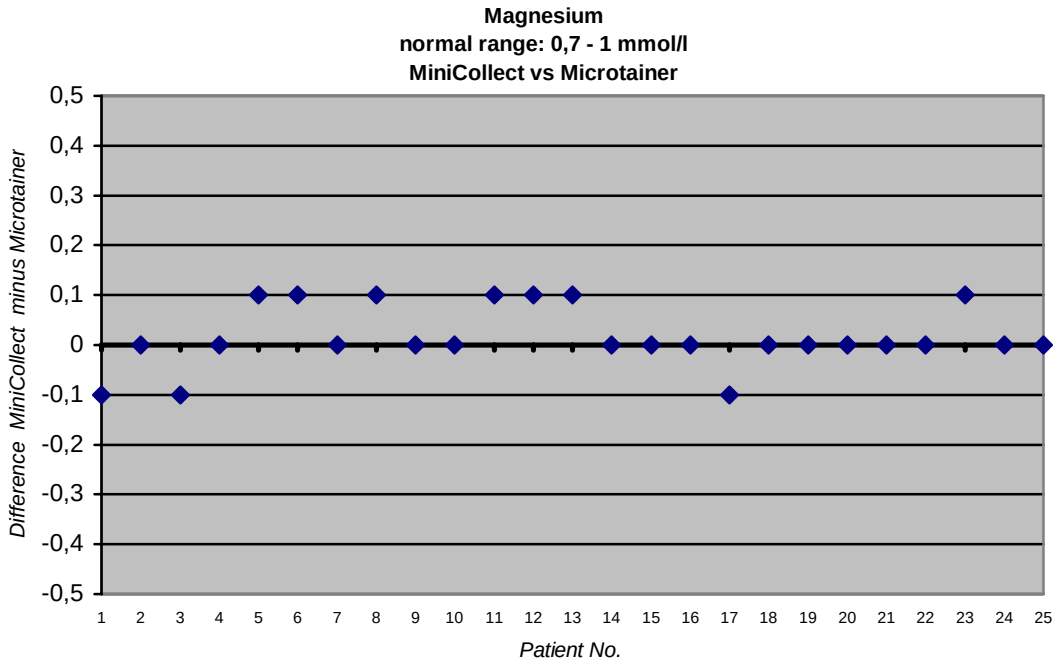
Phosphate


Phosphate
normal range: 0,77 - 1,45 mmol/l
MiniCollect vs Microtainer
Microtainer
MiniCollect
y = 0,9289x + 0,0965
R2 = 0,9771
1,7
1,5
1,3
1,1
0,9
0,9
1,1
1,3
1,5
1,7

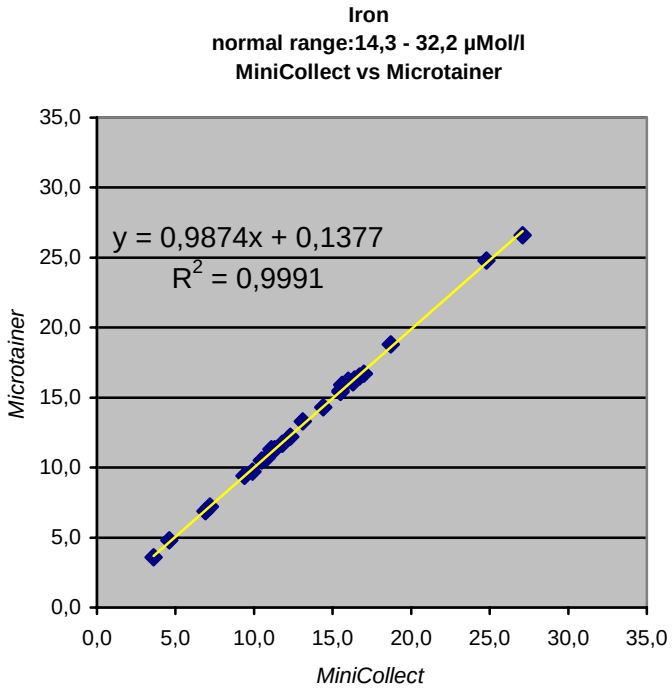

Phosphate
normal range: 0,77 - 1,45 mmol/l
MiniCollect vs Microtainer
Difference MiniCollect minus Microtainer
Patient No.
0,5
0,4
0,3
0,2
0,1
0
-0,1
-0,2
-0,3
-0,4
-0,5
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

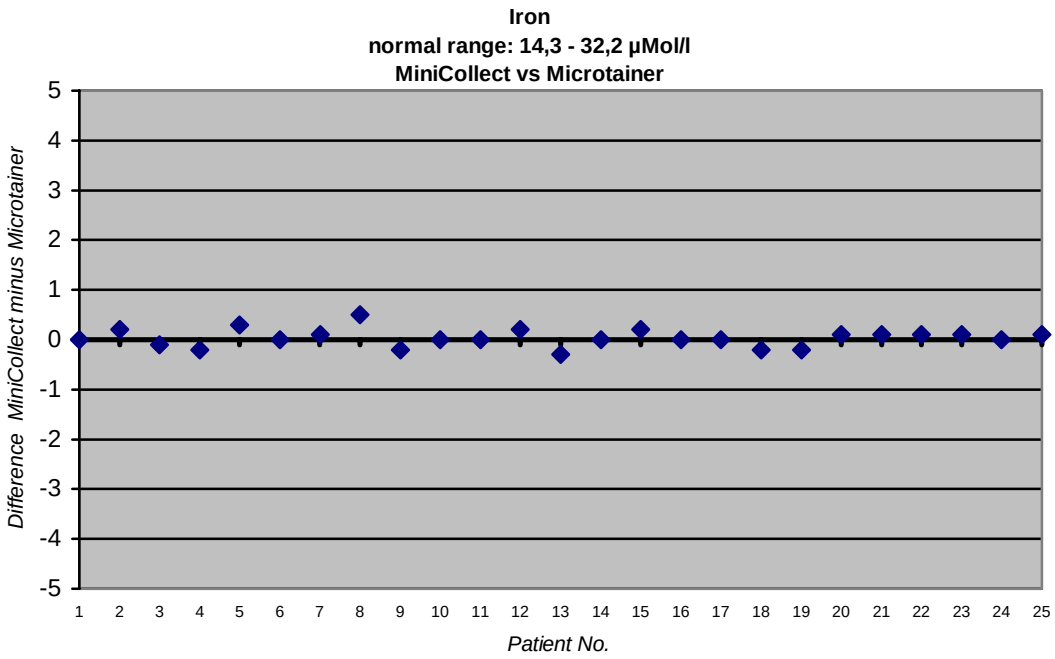
Magnesium


Magnesium
normal range: 0,7 - 1 mmol/l
MiniCollect vs Microtainer
y = 0,4459x + 0,4694
R2 = 0,3121
Microtainer
MiniCollect
1,2
1,1
1,0
0,9
0,8
0,7
0,6
0,6
0,7
0,8
0,9
1,0
1,1
1,2

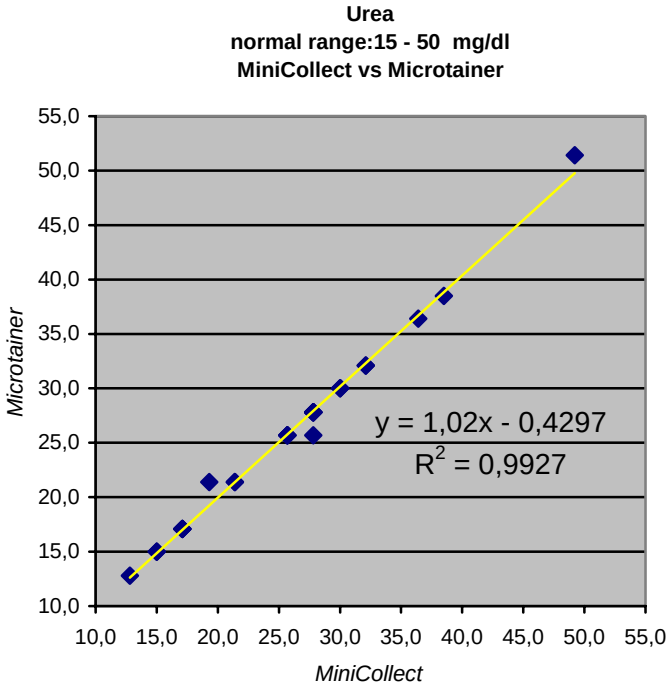

Magnesium
normal range: 0,7 - 1 mmol/l
MiniCollect vs Microtainer
Difference MiniCollect minus Microtainer
Patient No.
0,5
0,4
0,3
0,2
0,1
0
-0,1
-0,2
-0,3
-0,4
-0,5
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

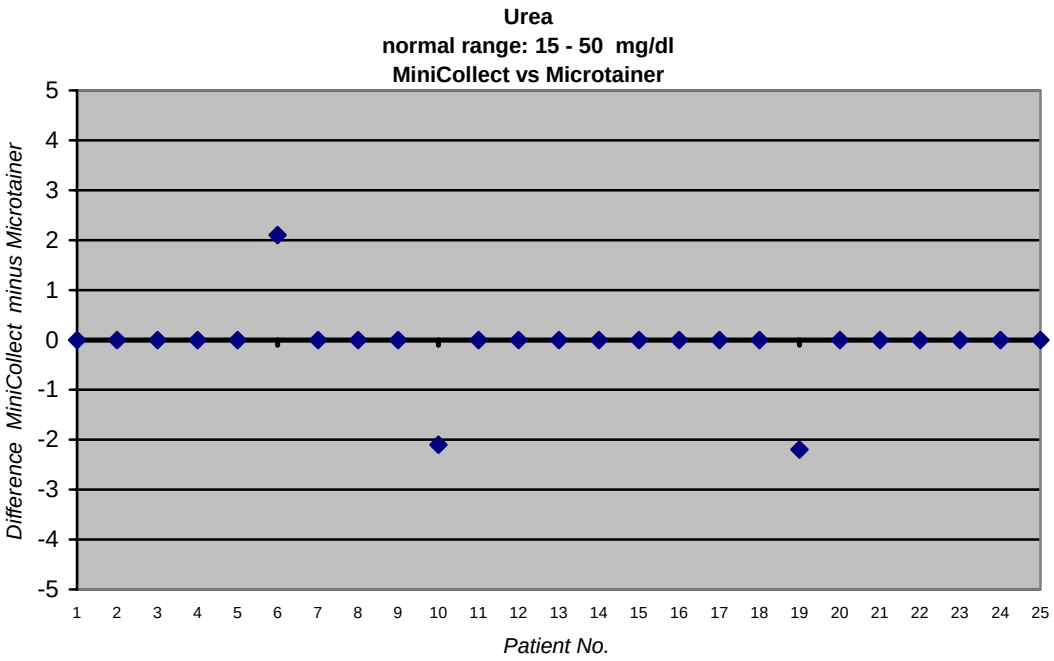
Iron


Iron
normal range:14,3 - 32,2 µMol/l
MiniCollect vs Microtainer
y = 0,9874x + 0,1377
R2 = 0,9991
Microtainer
MiniCollect
35,0
30,0
25,0
20,0
15,0
10,0
5,0
0,0
0,0
5,0
10,0
15,0
20,0
25,0
30,0
35,0

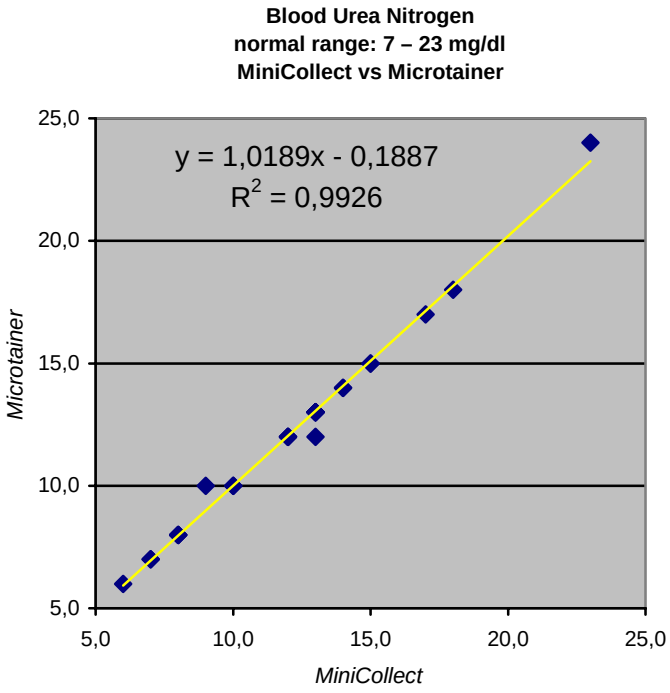

Iron
normal range: 14,3 - 32,2 µMol/l
MiniCollect vs Microtainer
Difference MiniCollect minus Microtainer
Patient No.
5
4
3
2
1
0
-1
-2
-3
-4
-5
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

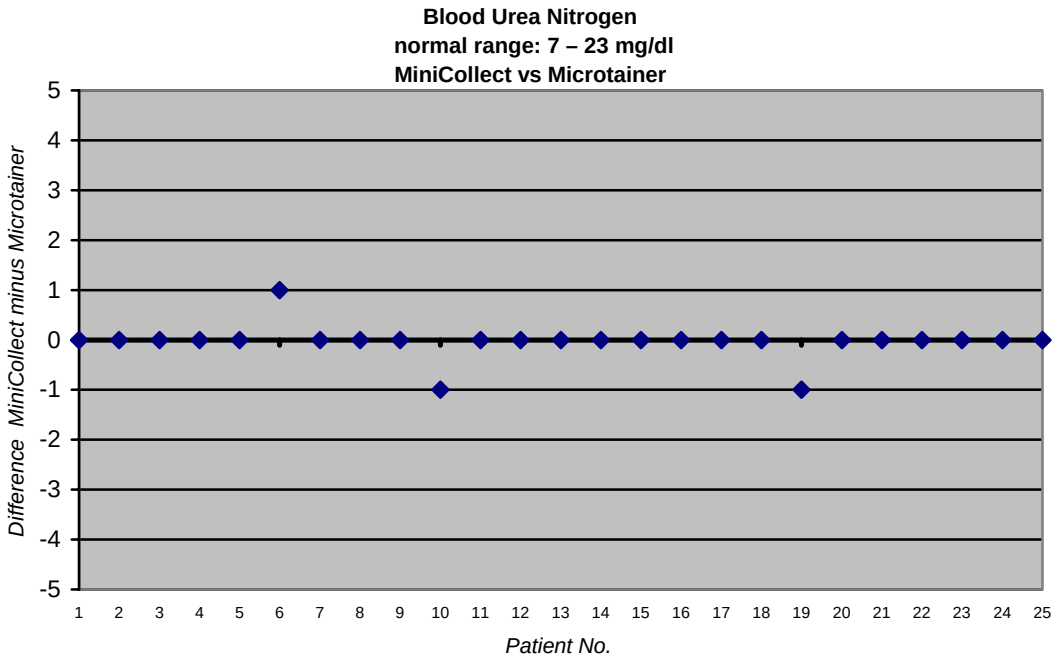
Urea


Urea
normal range:15 - 50 mg/dl
MiniCollect vs Microtainer
55,0
50,0
45,0
40,0
35,0
30,0
25,0
20,0
15,0
10,0
Microtainer
y = 1,02x - 0,4297
R2 = 0,9927
10,0 15,0 20,0 25,0 30,0 35,0 40,0 45,0 50,0 55,0
MiniCollect

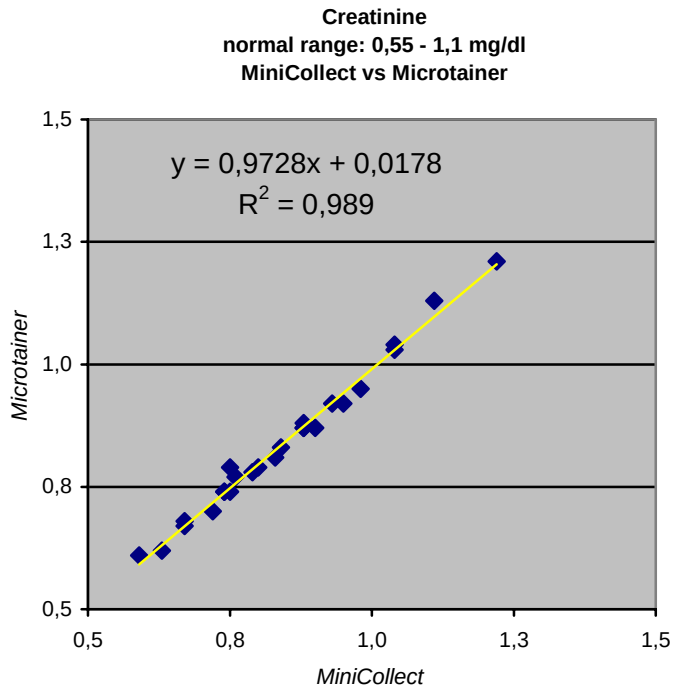

Urea
normal range: 15 - 50 mg/dl
MiniCollect vs Microtainer
5
4
3
2
1
0
-1
-2
-3
-4
-5
Difference MiniCollect minus Microtainer
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
Patient No.

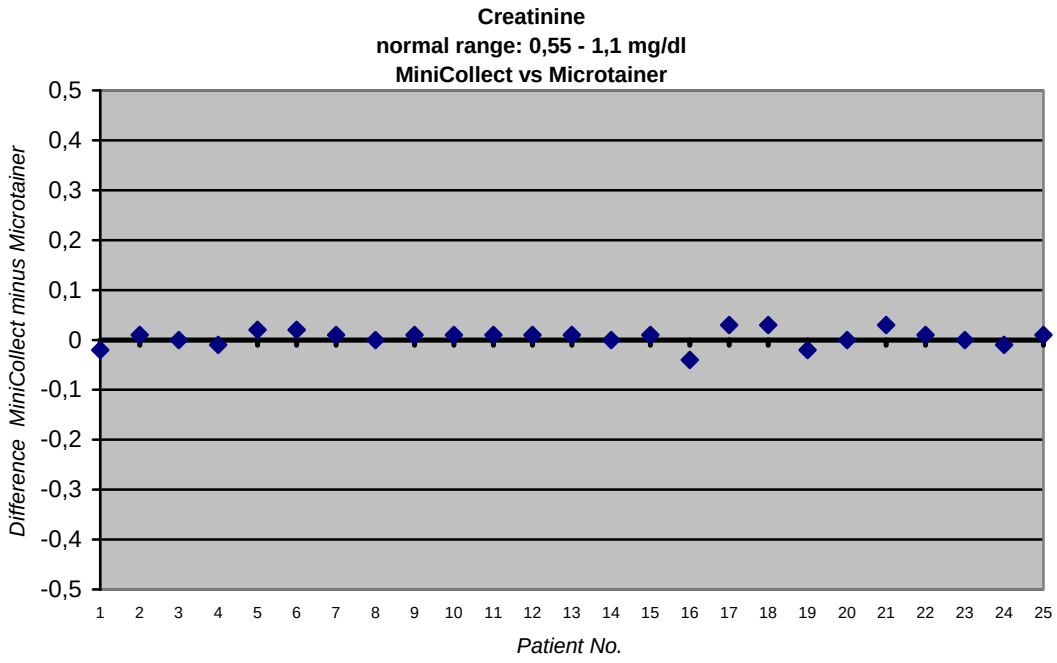
Blood Urea Nitrogen



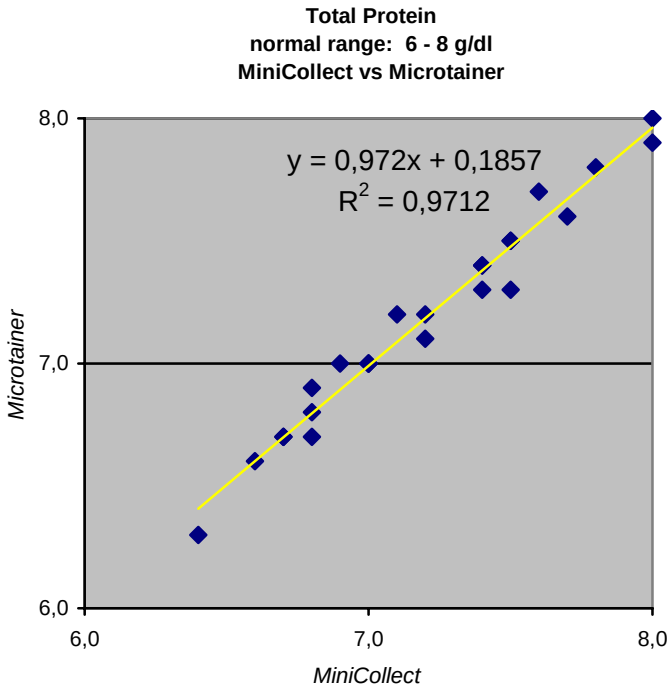


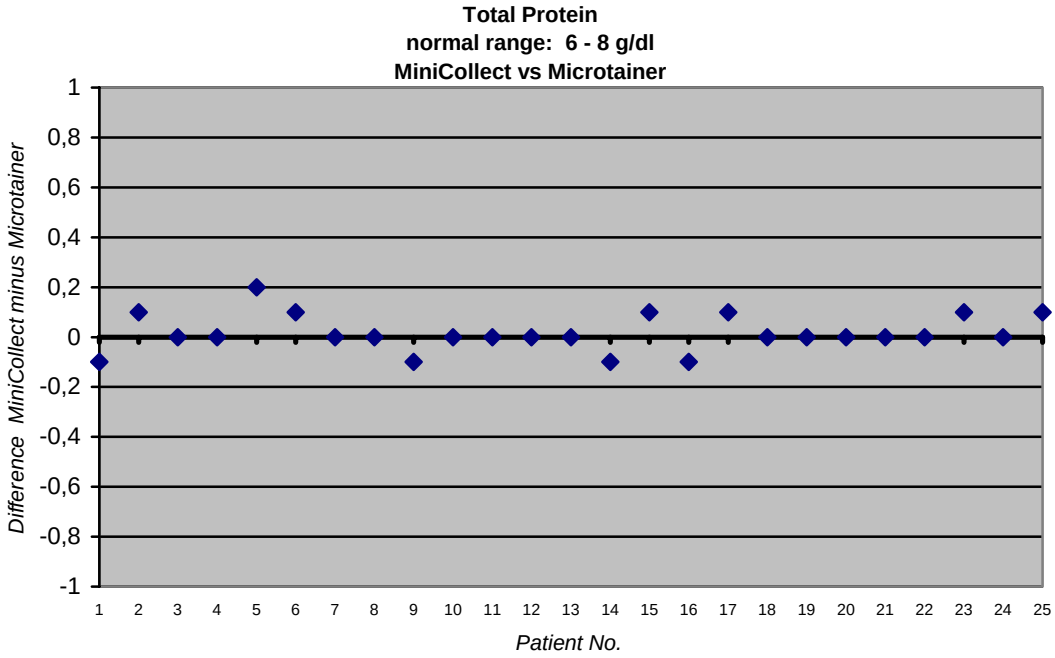
Creatinine


Creatinine
normal range: 0,55 - 1,1 mg/dl
MiniCollect vs Microtainer
y = 0,9728x + 0,0178
R2 = 0,989
Microtainer
MiniCollect
1,5
1,3
1,0
0,8
0,5
0,5
0,8
1,0
1,3
1,5

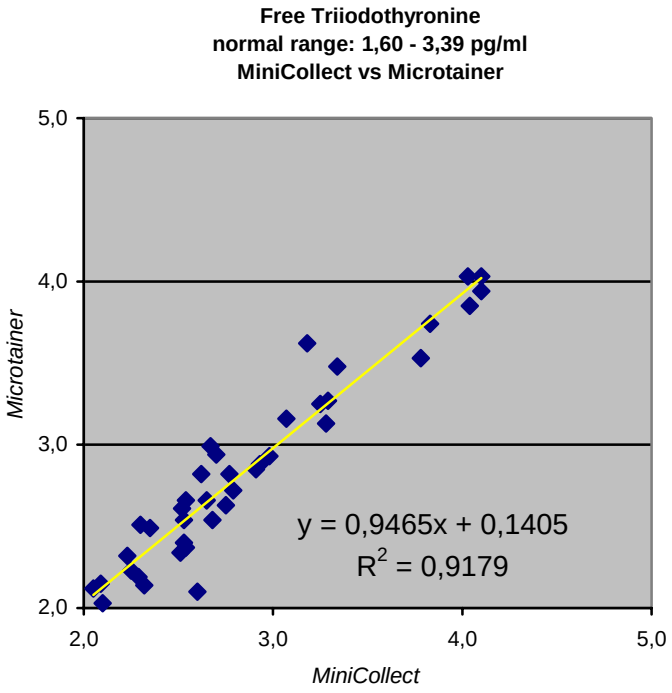

Creatinine
normal range: 0,55 - 1,1 mg/dl
MiniCollect vs Microtainer
Difference MiniCollect minus Microtainer
Patient No.
0,5
0,4
0,3
0,2
0,1
0
-0,1
-0,2
-0,3
-0,4
-0,5
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

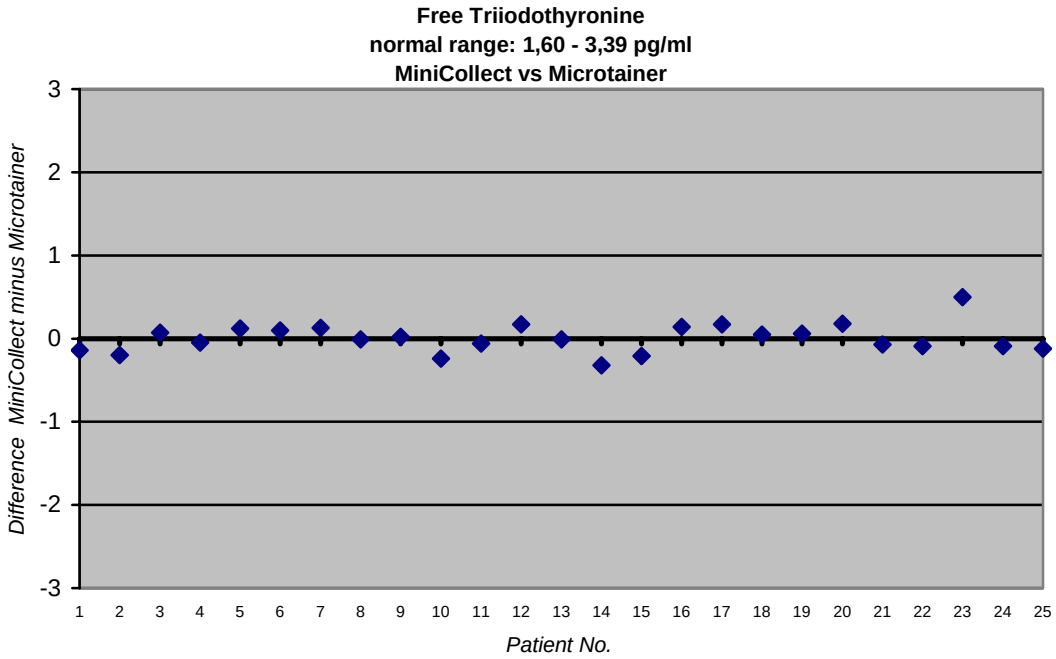
Total Protein



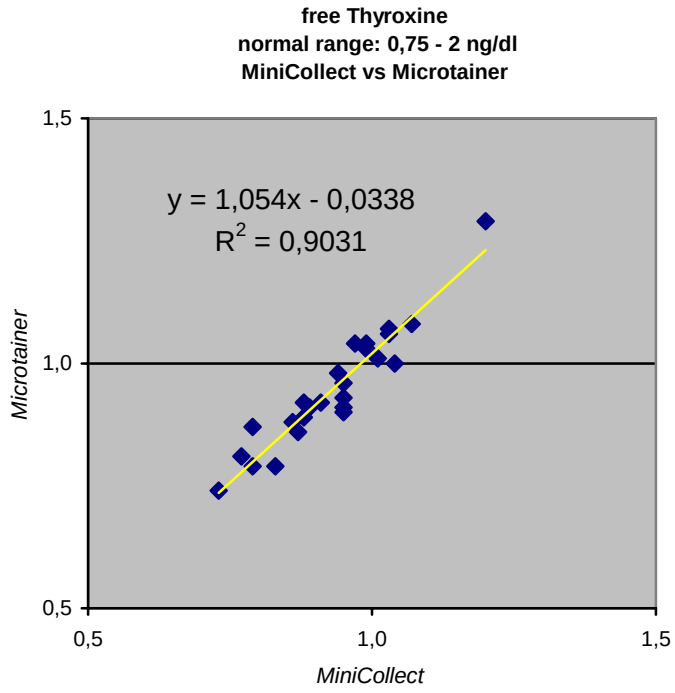


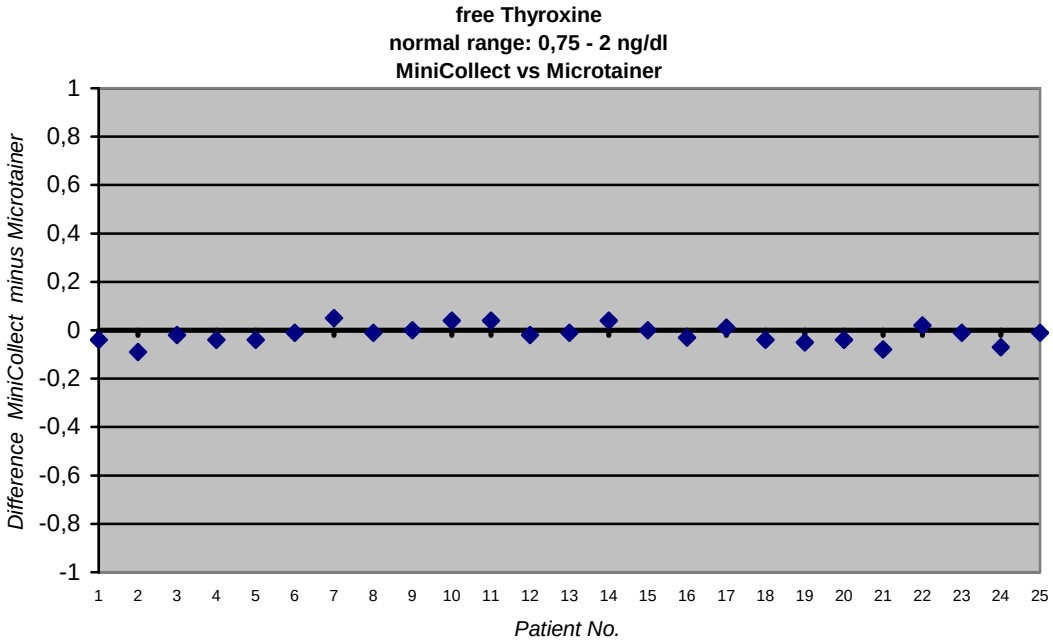
Free Triiodothyronine



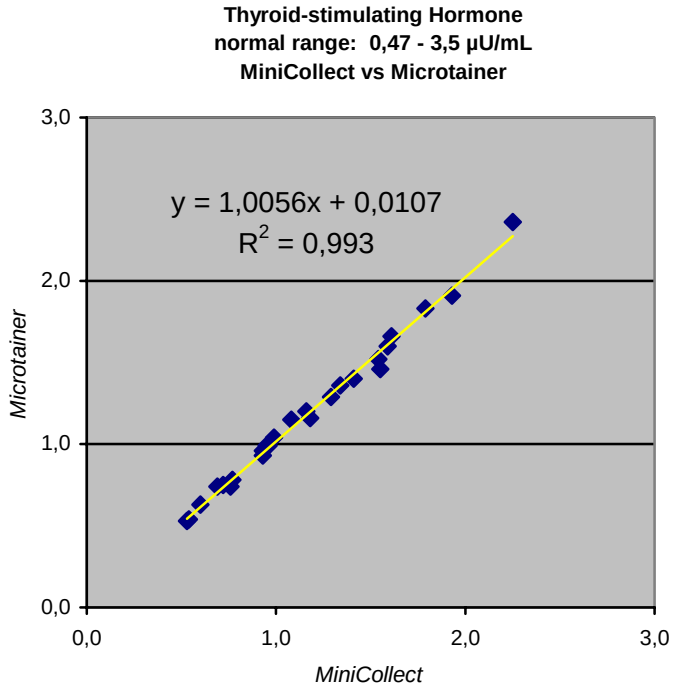


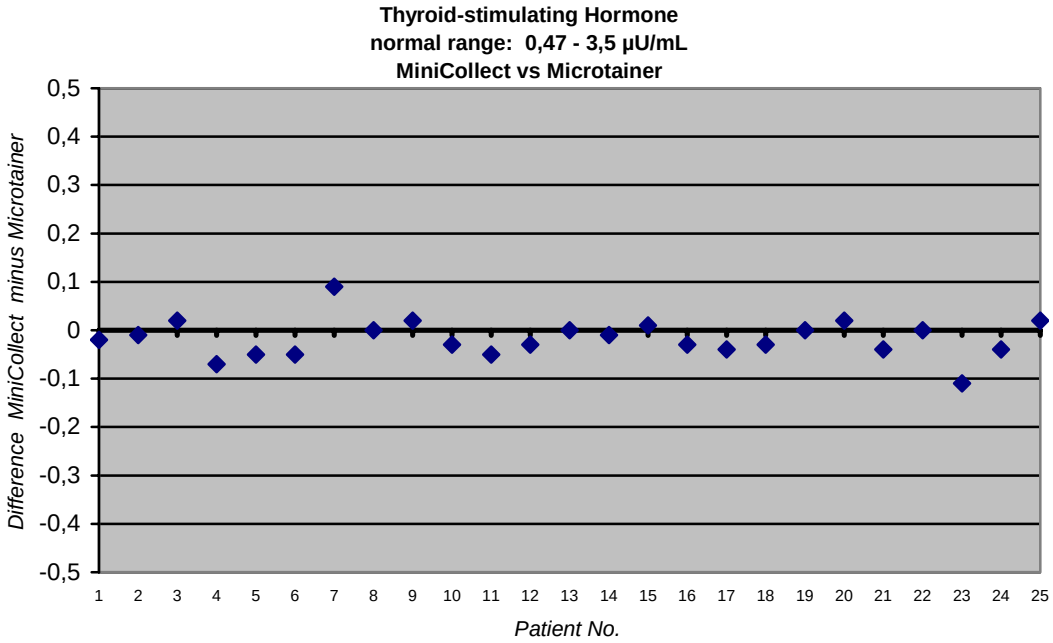
Free Thyroxine



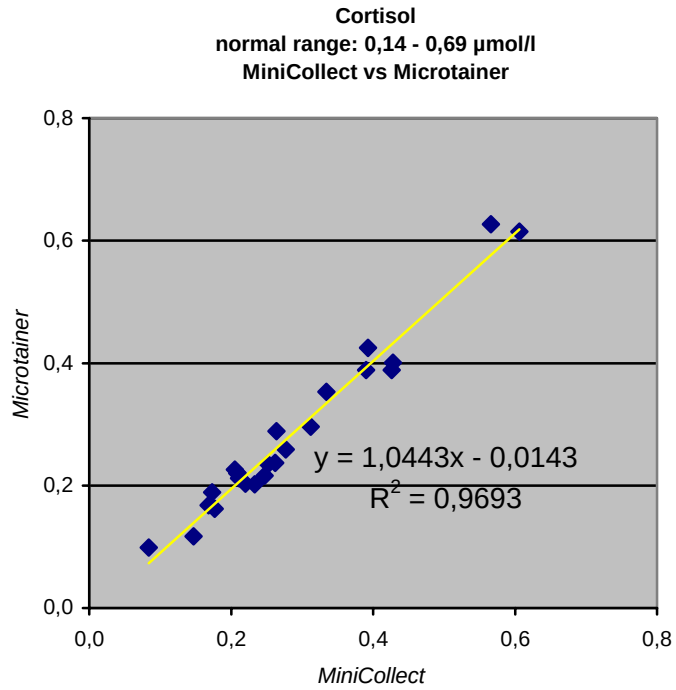


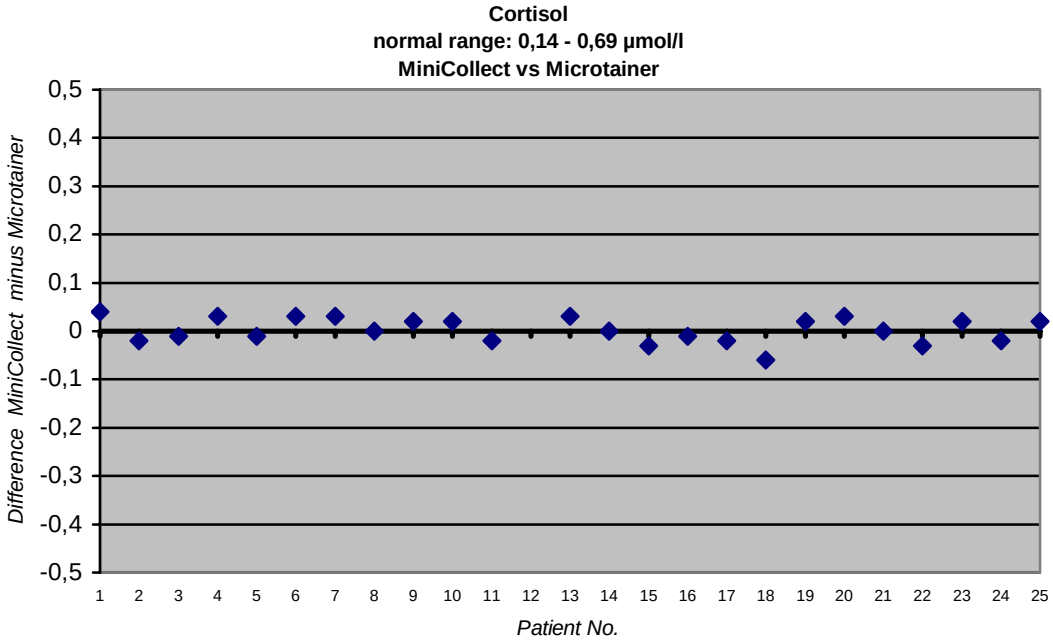
Thyroid-stimulating Hormone



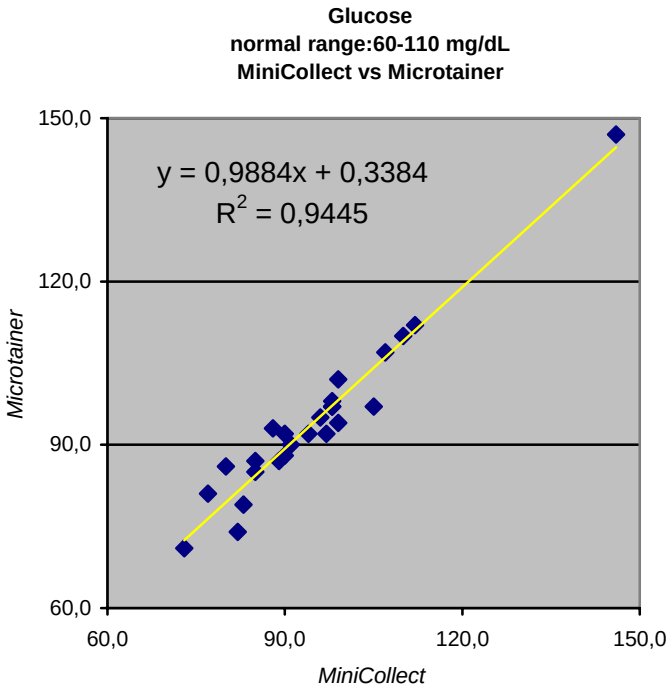


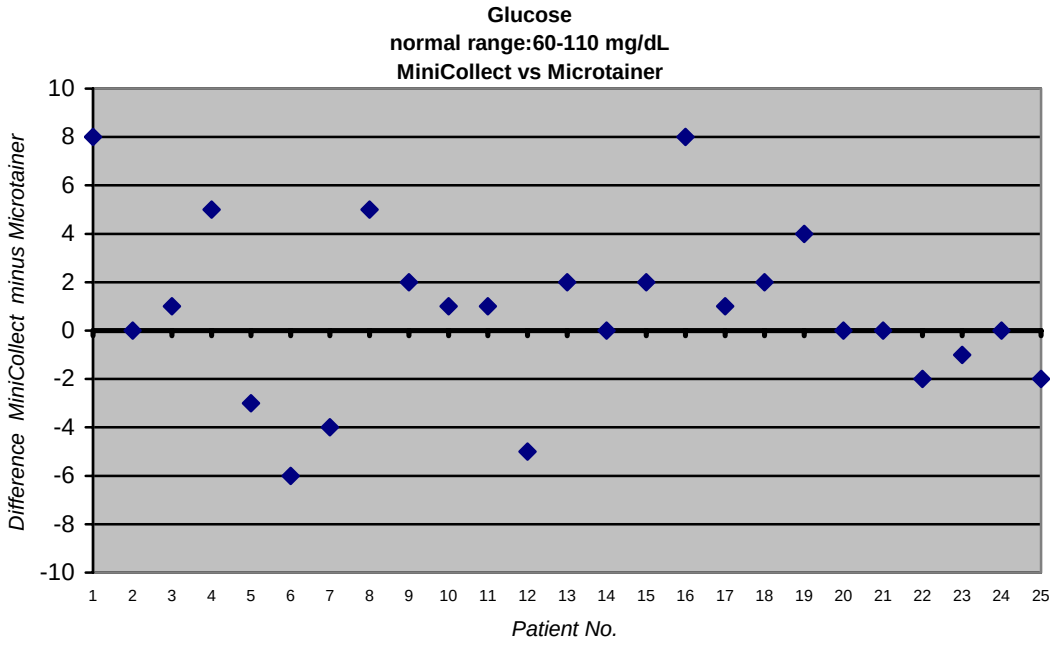
Cortisol


Cortisol
normal range: 0,14 - 0,69 µmol/l
MiniCollect vs Microtainer
0,8
0,6
0,4
0,2
0,0
Microtainer
y = 1,0443x - 0,0143
R2 = 0,9693
0,0
0,2
0,4
0,6
0,8
MiniCollect


Cortisol
normal range: 0,14 - 0,69 µmol/l
MiniCollect vs Microtainer
0,5
0,4
0,3
0,2
0,1
0
-0,1
-0,2
-0,3
-0,4
-0,5
Difference MiniCollect minus Microtainer
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
Patient No.

Glucose


Glucose
normal range:60-110 mg/dL
MiniCollect vs Microtainer
y = 0,9884x + 0,3384
R2 = 0,9445
150,0
120,0
90,0
60,0
Microtainer
60,0
90,0
120,0
150,0
MiniCollect


Glucose
normal range:60-110 mg/dL
MiniCollect vs Microtainer
10
8
6
4
2
0
-2
-4
-6
-8
-10
Difference MiniCollect minus Microtainer
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
Patient No.