Gateshead Health NHS
NHS Foundation Trust

Biochemistry Validation Form

Method: Piccolo Xpress Chemistry 13 panel

Manufacturer: Abaxis

Cat no: 400-0029

CE marked: **Yes:** [x] **No:** [ ]

Location of bench book: X:\Bio\Patricia\Piccollo Xpress evaluation (August 2012)

Evaluation performed by:
Patricia Lockett, Senior Biomedical Scientist for Point of Care Testing &
Caroline Addison, Principal Clinical Biochemist

Date of Evaluation: August 2012

Introduction

- *Background*

The point of care team was contacted by A&E with regard to increasing the point of care test repertoire in their department. The initial requirements were U&Es, LFTs, paracetamol & salicylate, Troponin T, BNP, INR, D-Dimer, CRP, βhCG and amylase. The department agreed to look for suitable analysers. The Abaxis Piccolo Xpress chemistry analyser is a point of care device that delivers clinical chemistry profiles. Profiles are available in disks and include lipid, liver enzymes, kidney function, glucose and electrolytes (see picture 1). It was decided to evaluate this instrument for the A&E department in particular the Chemistry 13 reagent disk which offers albumin, ALP, ALT, amylase, AST, urea, creatinine, calcium, GGT, glucose, total bilirubin, total protein and urate. Sample type is heparinised whole blood, heparinised plasma or serum.

- *Rationale for evaluation*

See background.

Picture 1: Piccolo Xpress chemistry analyser and reagent disk.

Method

	Current	New
Method	Various	Chemistry 13 reagent disk
Analyser	Roche cobas c701	Abaxis Piccolo Xpress

A limited number of reagent disks (50) was available for the evaluation. Patient comparison was performed by taking 10 random serum samples and analysing on both the Piccolo Xpress and laboratory analyser. A further 10 serum samples were then selected to ensure the measuring range had been evaluated (where possible).

Comparison of lithium heparin whole blood versus lithium heparin plasma was also performed. Patient samples which had been sent to the laboratory in lithium heparin sample tubes (i.e. for ketone analysis) were analysed as whole blood on the Piccolo Xpress. These samples were then centrifuged to obtain the plasma, which was then analysed for all parameters on the Roche cobas c701. Due to a limited number of reagent disks this could only be performed for 8 patient samples.

Precision was determined by analysing the 2 levels of Randox Chemistry internal quality control material which is used in the laboratory. Within day precision was assessed by measuring both levels of QC 5 times in one day. Between batch precision was assessed over a further 2 days, by measuring both levels of QC 3 times each.

Review of kit insert

- *Interferences/cross reactivities*
  Samples containing EDTA, fluoride, oxalate or any anticoagulant containing ammonium ions will interfere with at least 1 chemistry in the chemistry 13 reagent disc
  Sodium heparin is not suitable.
  Samples with haematocrits in excess of 62-65% packed red cell volume (volume fraction of 0.62-0.65) may give an inaccurate result –

these samples may be reported as haemolysed and can be re-spun and the plasma analysed.
Haemolysis, icterus and lipaemia can cause changes in reported concentrations of some analytes. The Piccolo Xpress suppresses any results that are affected by >10% interference from haemolysis, lipaemia or icterus.
Table 1 shows substances with >10% interference and their effect on the chemistry 13 test(s).
Refrigerating whole blood samples can cause significant changes in concentrations of AST, creatinine and glucose.
Total bilirubin may be adversely affected by photodegradation.
Samples not run immediately should be stored in the dark.
Glucose concentrations decrease approximately 5-12mg/dl (0.28 – 0.67mmol/L) in 1 hour in uncentrifuged samples at room temperature.

- *Linearity/dilutions*
  Each analyte in the Chemistry 13 reagent disc is linear over the measuring range as shown in table 2. Samples above or below this range are reported as greater than (>) or less than (<) with an asterisk e.g. ALT >2000* U/L or ALT <5* U/L
  Any samples that exceed the assay range should be analysed by another approved method. DO NOT dilute the sample and re-run on the Piccolo Xpress analyser.
  Samples which are grossly beyond the measuring range will be printed as'~~~' instead of a result.

- *Precision*
  Results for within-run and total precision were determined by testing two levels of control material. Controls were run in duplicate twice each day for 20 days over a four week period. Precision data is shown in table 3.

- *LOD/LOQ*
  The lower limit of the reportable range for each analyte is shown in table 2.

- *Sample type/handling*
  Minimum required volume is 100µl of heparinised whole blood, heparinised plasma, serum or control material. The reagent disc chamber can contain up to 120µl of sample.
  Samples containing EDTA, fluoride, oxalate or any anticoagulant containing ammonium ions will interfere with at least 1 chemistry in the chemistry 13 reagent disc
  Sodium heparin is not suitable.
  Whole blood samples must be homogenous before transferring to a sample disc. Gently invert the collection tubes several times prior to inversion. DO NOT shake the tube as this may cause haemolysis.

Whole blood venepuncture samples should be run within 60minutes of collection. If analysis cannot be performed in this time, the sample may be separated into plasma or serum and stored at 2-8°C.
The reagent disc should be analysed within 10 minutes of transferring the sample to the reagent disc.

- *Reagent storage/hazards*
  Store reagent discs in their sealed pouches at 2-8°C. Do not expose to direct sunlight or temperatures above 32°C. Do not use beyond the expiration date.
  Reagent discs may be used directly from the refrigerator without warming.
  Do not allow discs to remain at room temperature for more than 48hours.
  Be careful not to touch the barcode ring located on top of the disc.
  A disc not used within 20 minutes of opening should be discarded.
  The reagent discs are plastic and may crack or chip if dropped. Never use a dropped disc as this may spray biohazardous material throughout the interior of the analyser.

- *Level sensing?*
  Not applicable – Chemistry 13 discs contain all reagents

- *Other*
  In rare circumstances sample when applied to the disc may not flow smoothly into the sample chamber. Due to an uneven flow, an inadequate quantity of sample may be analysed and several results fall outside of the reference range. Re-run sample using new reagent disc.

Table 1: Substances with significant interference (>10%) in the Chemistry 13 reagent disc on the Piccolo Xpress analyser

	Physiologic/ Therapeutic Range[80-85] (mg/dL)	Concentration with > 10% Interference (mg/dL)	% Interference
Alanine Aminotransferase (ALT)			
Ascorbic acid	0.8-1.2	20	11% inc*
Oxaloacetate	—	132	843% inc
Albumin (ALB)			
Acetoacetate	0.05-3.60	102	18% dec*
Ampicillin	0.5	30	12% dec
Caffeine	0.3-1.5	10	14% dec
Calcium chloride	—	20	17% dec
Cephalothin (Keflin)	10	400	13% inc
Ibuprofen	0.5-4.2	50	28% inc
α-Ketoglutarate	—	5	11% dec
Nitrofurantoin	0.2	20	13% dec
Proline	—	4	12% inc
Sulfalazine	2-4	10	14% dec
Sulfanilamide	10-15	50	12% dec
Theophylline	1-2	20	11% dec
Alkaline Phosphatase (ALP)			
Theophylline	1-2	20	42% dec
Creatinine (CRE)			
Ascorbic acid	0.8-1.2	20	11% dec
Dopamine	—	19	80% dec
L-dopa	—	5	71% dec
Epinephrine	—	1	45% dec
Glutathione	—	30	13% dec
Glucose (GLU)			
Oxaloacetate	—	132	11% dec
Pyruvate	0.3-0.9	44	13% dec
Total Bilirubin (TBIL)			
Dopamine	—	19	55% dec
L-dopa	—	5	17% dec
Uric Acid			
Ascorbic acid	0.8–1.2	20	13% dec
Epinephrine	—	1	14% dec
L-dopa	—	5	78% dec
Methyldopa	0.1–0.5	0.5	12% dec
Rifampin	0.4–3	1.5	14% dec
Salicylic acid	15–30	25	20% dec

* inc=increase; dec=decrease.

Table 2: Manufacturer measuring range for Chemistry 13 reagent disc on Piccolo Xpress analyser

Table 5: Piccolo Dynamic Ranges

Analyte	Common Units	SI Units
Alanine Aminotransferase (ALT)	5-2000 U/L	5-2000 U/L
Albumin (ALB)	1-6.5 g/dL	10-65 g/L
Alkaline Phosphatase (ALP)	5-2400 U/L	5-2400 U/L
Amylase (AMY)	5-4000 U/L	5-4000 U/L
Aspartate Aminotransferase (AST)	5-2000 U/L	5-2000 U/L
Calcium	4.0-16.0 mg/dL	1.0-4.0 mmol/L
Creatinine	0.2-20 mg/dL	18-1768 µmol/L
Gamma Glutamyltransferase (GGT)	5-3000 U/L	5-3000 U/L
Glucose	10-700 mg/dL	0.56-38.9 mmol/L
Total Bilirubin (TBIL)	0.1-30 mg/dL	1.7-513 µmol/L
Total Protein (TP)	2-14 g/dL	20-140 g/L
Urea Nitrogen (BUN)	2-180 mg/dL	0.7-64.3 mmol/urea/L
Uric Acid	1-15 mg/dL	0.1-0.9 mmol/L

Table 3: Manuafacturer Total precision data for the chemistry 13 reagent disc on the Piccolo Xpress analyser

	% CV (mean concentration)	
Analyte	**Level 1**	**Level 2**
ALT	13.5% (21 U/L)	6.2% (52 U/L)
Albumin	2.1% (56 g/L)	2.9% (37g/L)
ALP	5.8% (39 U/L)	3.1% (281 U/L)
Amylase	5.7% (46 U/L)	3.8% (300 U/L)
AST	1.9% (49 U/L)	1.2% (147 U/L)
Calcium	2.9% (8.6mg/dl/2.15mmol/L)	3.4% (11.8mg/dl/2.94mmol/L)
Creatinine	13.1% (1.1mg/dl/97µmol/L)	5.2% (5.2mg/dl/460µmol/L)
GGT	2.94% (25 U/L)	2.15% (106 U/L)
Glucose	1.6% (66 mg/dl/3.66mmol/L)	1.4% (278 mg/dl/15.43mmol/L)
Total bilirubin	9.3% (0.8 mg/dl/14µmol/L)	2.8% (5.2mg/dl/89µmol/L)
Total protein	1.2% (68 g/L)	2.0% (47 g/L)
Urea	2.1% (19mg/dl/6.8mmol/L)	1.8% (65mg/dl/23.2mmol/L)
Urate	4.8% (3.8 mg/dl/0.226mmol/L)	3.9% (7.5mg/dl/0.446mmol/L)

Instrument download/calculations

- *Details of information downloaded if applicable*
- *Details of results calculations if applicable*

Performed by: not applicable **Date:**
Checked by: not applicable **Date:**

Results/Data

N.B. ensure data use is raw data from analyser, not from middleware or LIMS, as this may be rounded.

- *Bias*
  - *Patient comparison*

Figures 1 -13 show the Passing & Bablok regression analysis for all analytes included in the chemistry 13 reagent disc.

Albumin shows a constant negative bias on the Piccolo Xpress compared to the laboratory assay (y = 0.9x -0.5). This bias was not considered to be significant.

A proportional negative bias was seen for ALP. Again this bias was not considered to be significant.

Good comparison was seen between the Piccolo Xpress and the laboratory for ALT (y = 1.01 + 0.01)

A positive bias was seen for amylase on the Piccolo Xpress (y = 1.36x + 4.76). This bias may be attributable to the differences in what each assay is measuring. The laboratory assay is specific for pancreatic amylase whereas the Piccolo Xpress measures total amylase.

A small constant positive bias was seen between the Piccolo Xpress and the laboratory for AST (y = 1.06x + 1.14) however, this was not considered to be significant.

Good comparison was seen between the Piccolo Xpress and the laboratory for urea (y = 1.03x – 0.35).

A mixed bias was seen for calcium when comparing the Piccolo Xpress and the laboratory assay. This assay would identify patients with calcium

concentrations at the extremes and therefore, is probably sufficient for a point of care device. It should be noted that a new calcium assay is currently under evaluation by the department. This new calcium assay is reported to be more stable than the current assay. A repeat comparison if this new assay is installed would be beneficial.

A constant negative bias was seen for Creatinine (y = 0.92x -7.00). Again this bias was not considered to be significant.

Good comparison was seen between the Piccolo Xpress and the laboratory for GGT (y = 1.01x + 0.81).

Good comparison was seen between the Piccolo Xpress and the laboratory for Glucose (y = 0.98x + 0.28).

A mixed bias was seen for total bilirubin (y = 0.88x + 4.98). This bias was not considered to be significant.

A small proportional positive bias was seen for total protein, again this was not considered to be significant.

Urate showed a small constant negative bias, but was not considered to be significant.

Figure 1: Passing and Bablok regression for Albumin

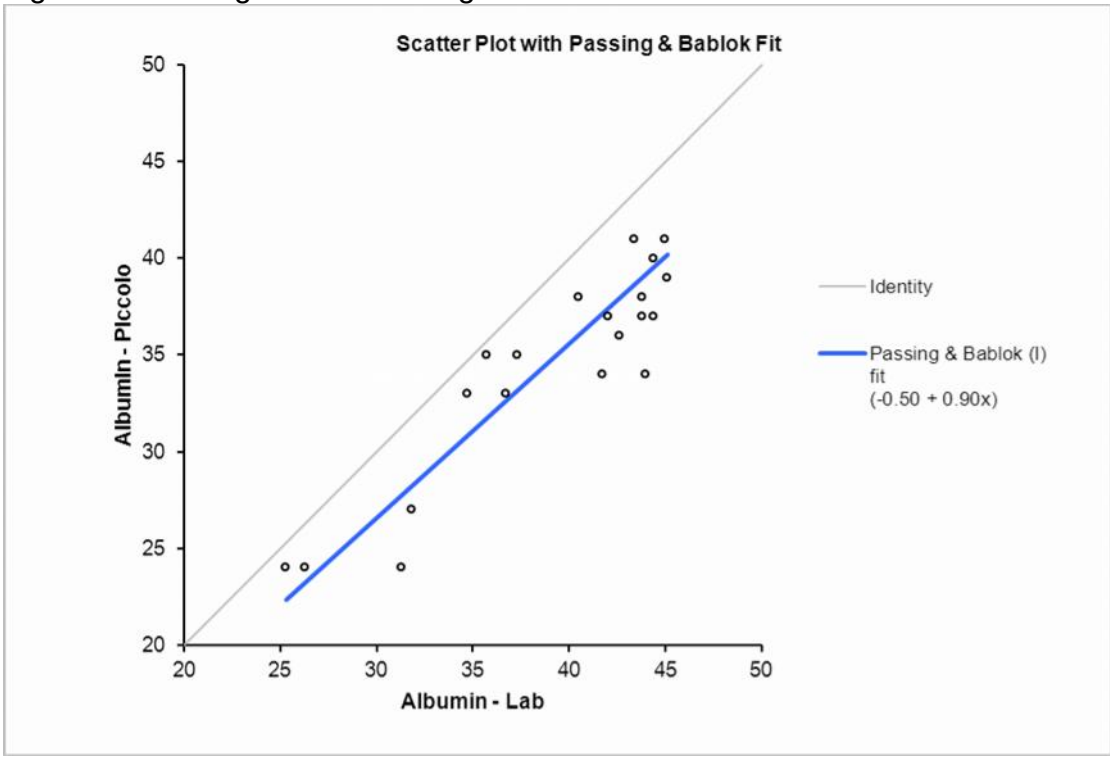


Figure 2: Passing and Bablok regression for ALP

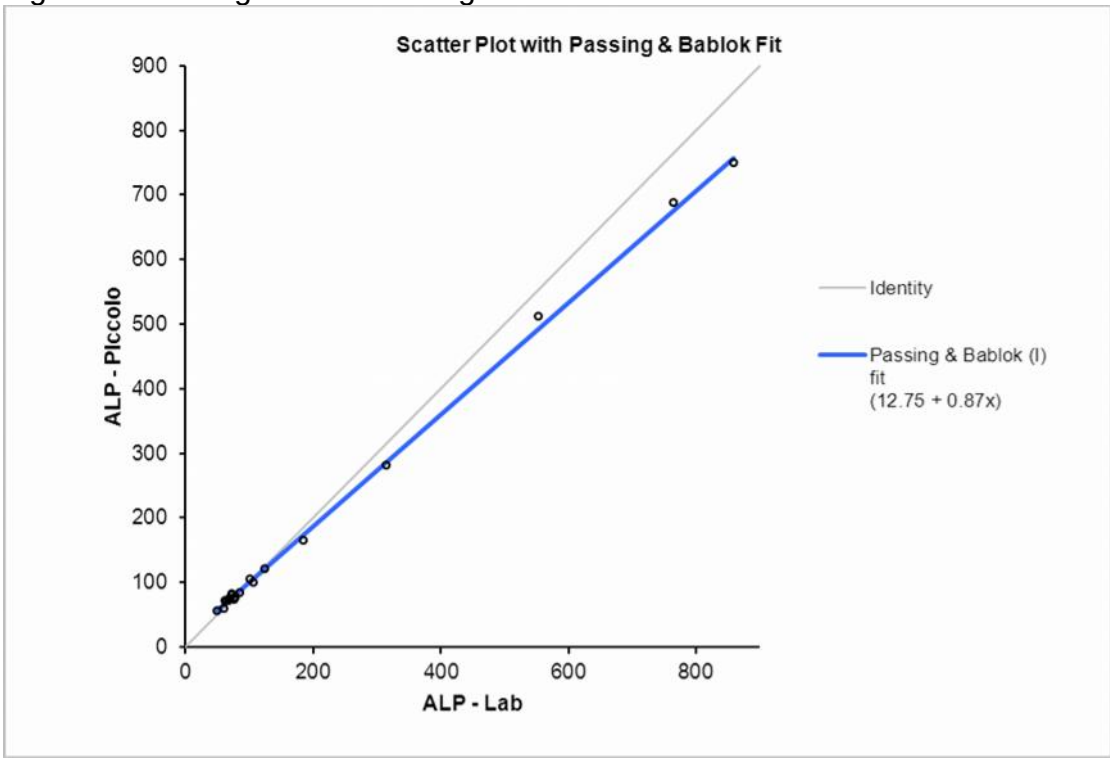


Figure 3: Passing and Bablok regression for ALT

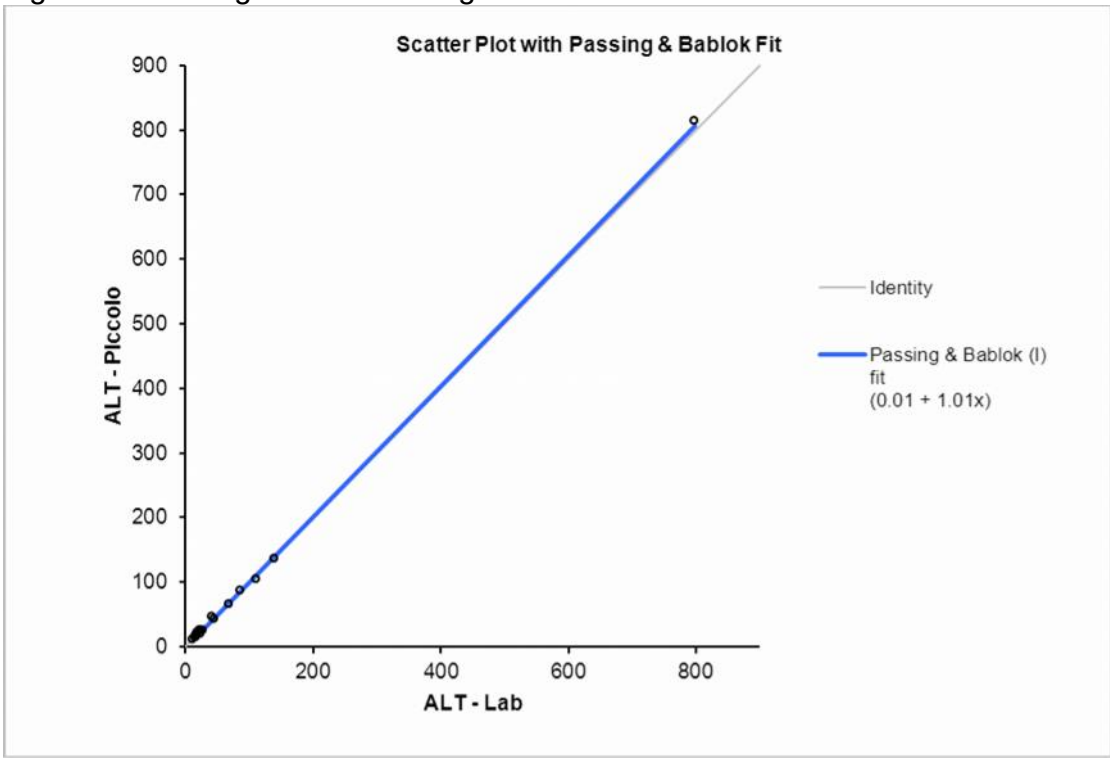


Figure 4: Passing and Bablok regression for Amylase

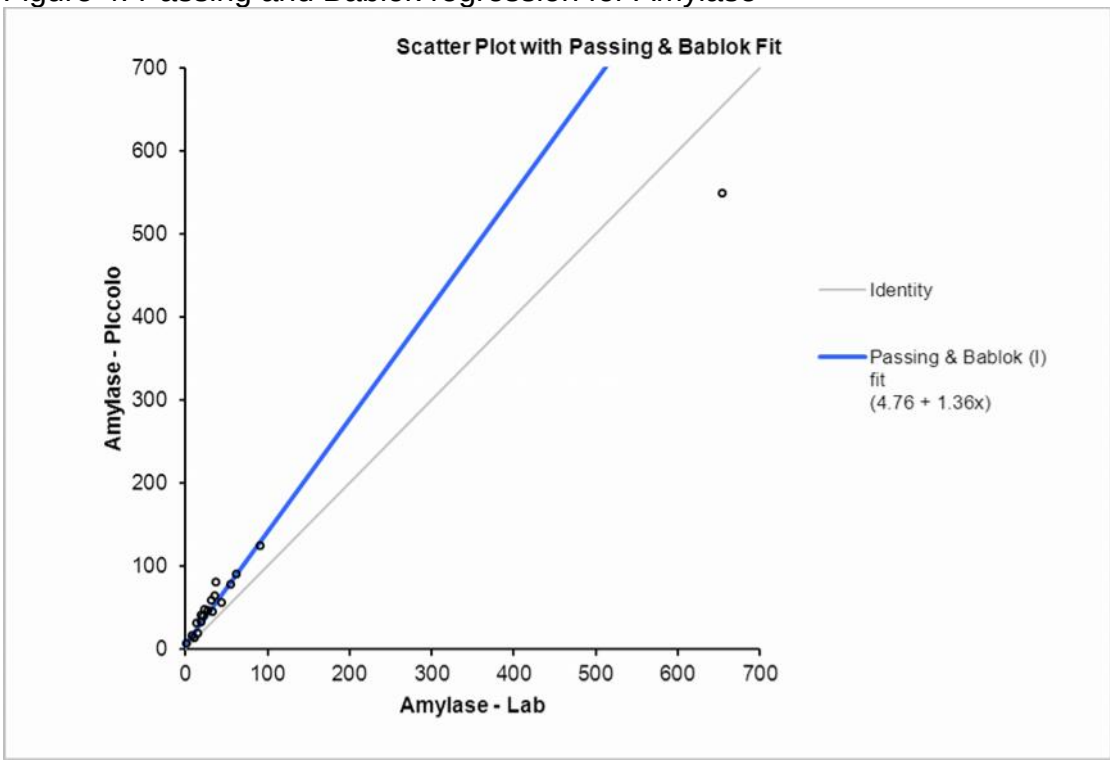


Figure 5: Passing and Bablok regression for AST

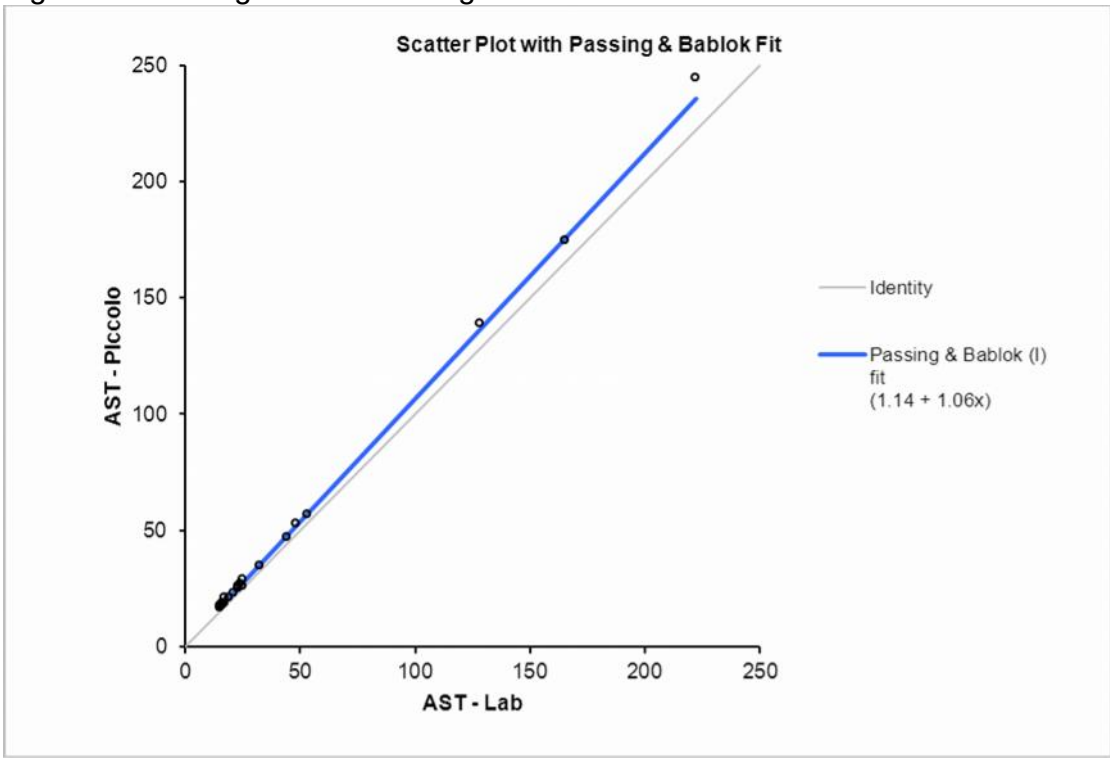


Figure 6: Passing and Bablok regression for Urea

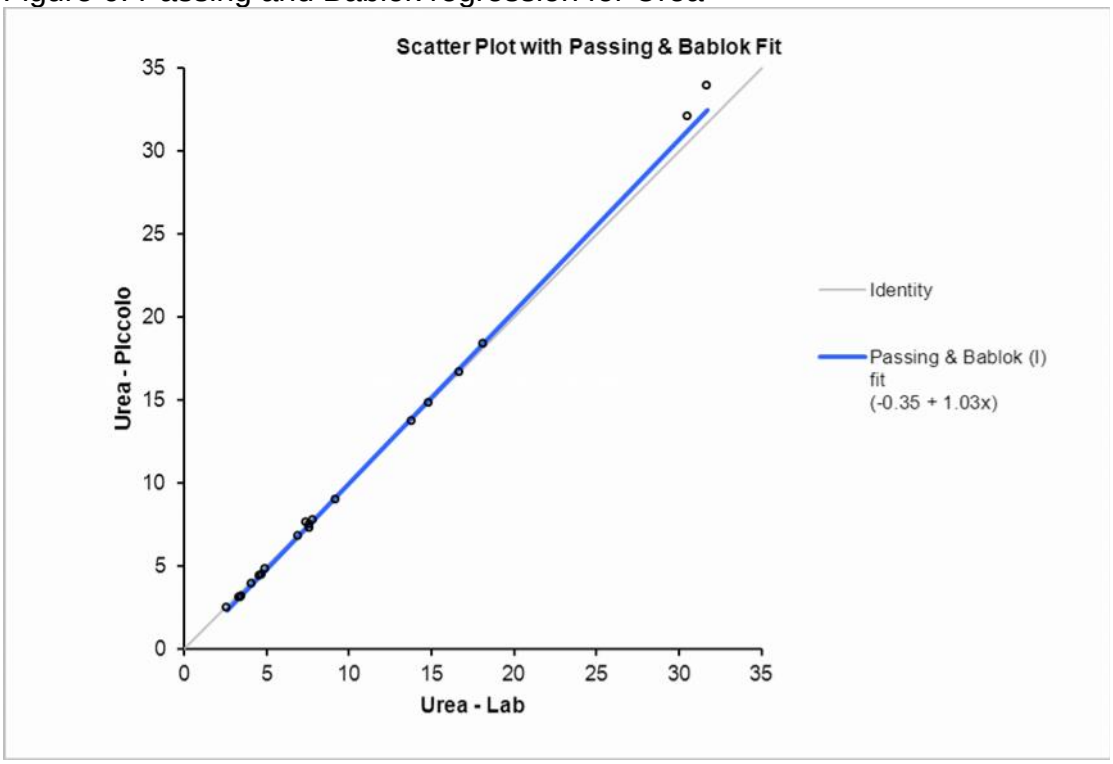


Figure 7: Passing and Bablok regression for Calcium

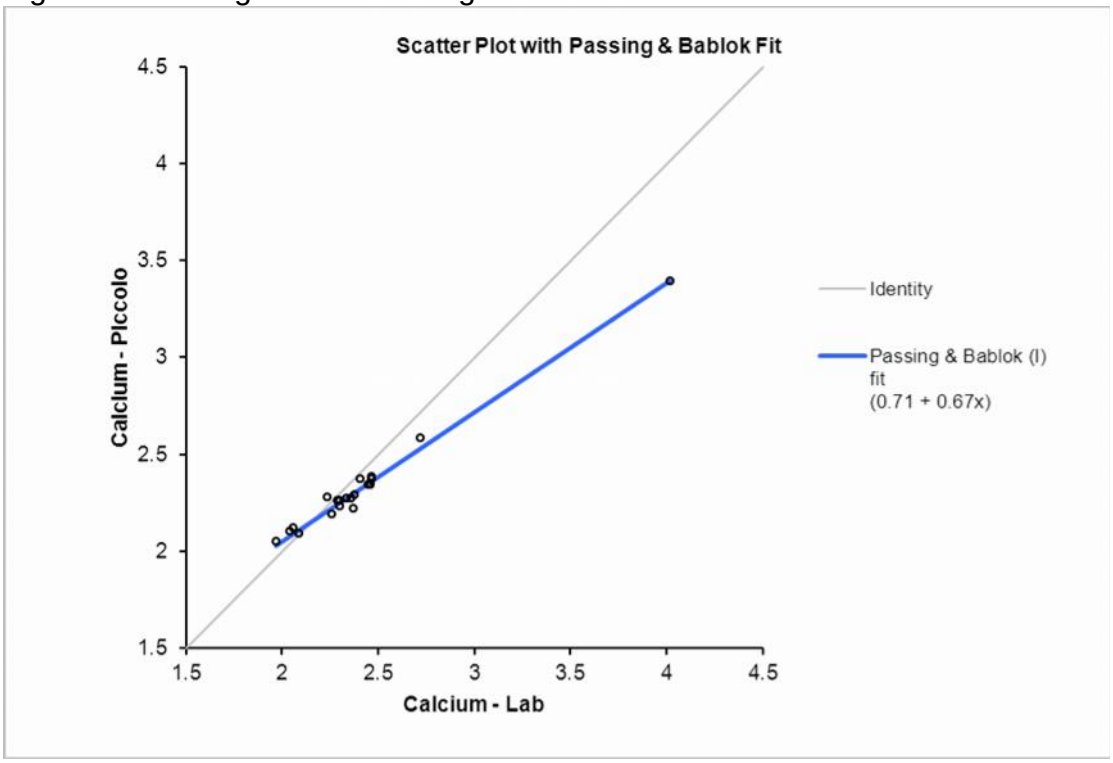


Figure 8: Passing and Bablok regression for Creatinine

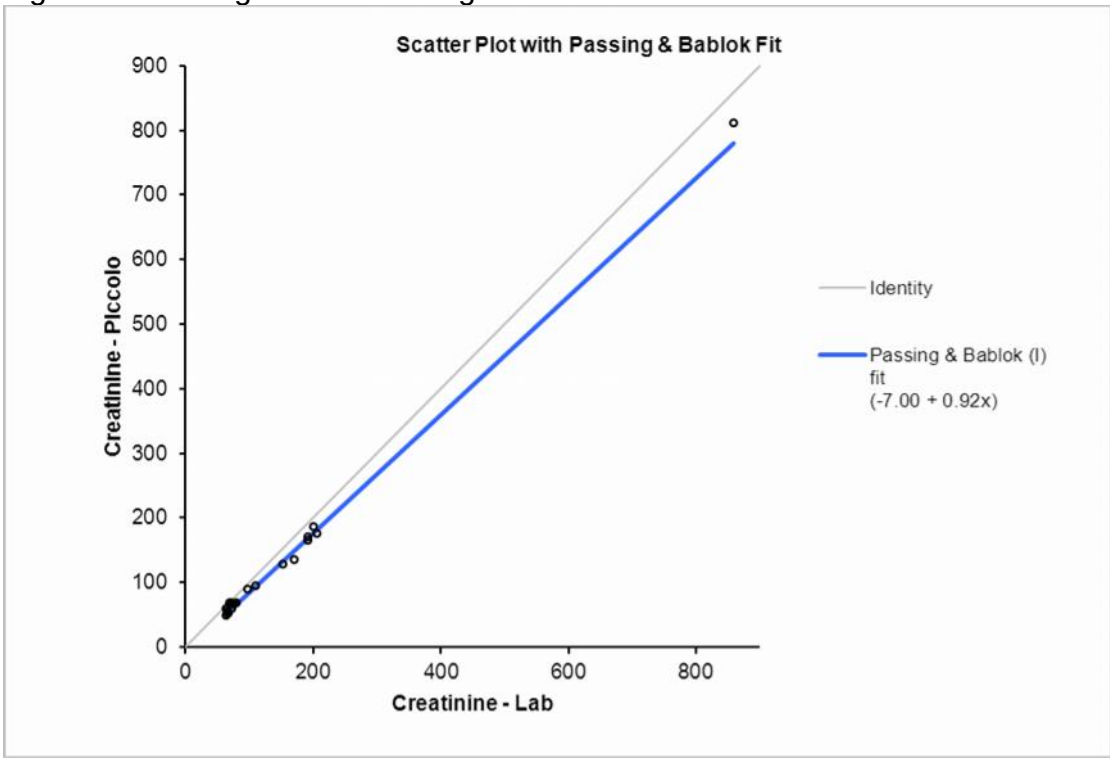


Figure 9: Passing and Bablok regression for GGT

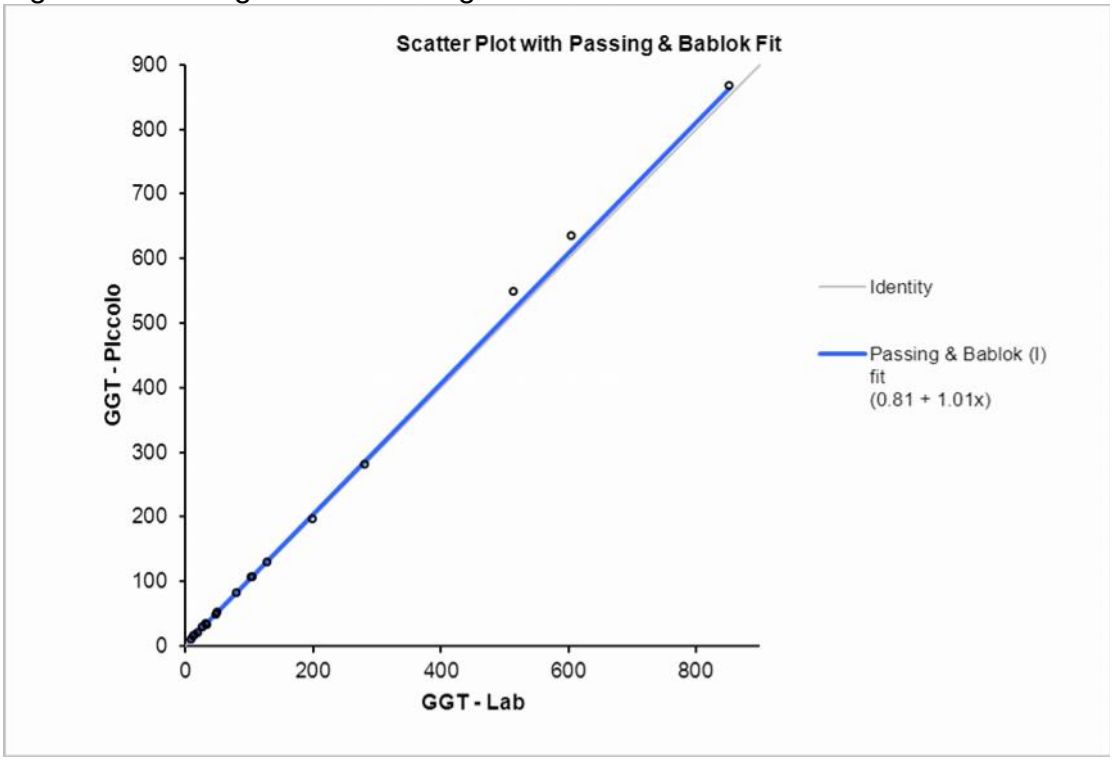


Figure 10: Passing and Bablok regression for Glucose

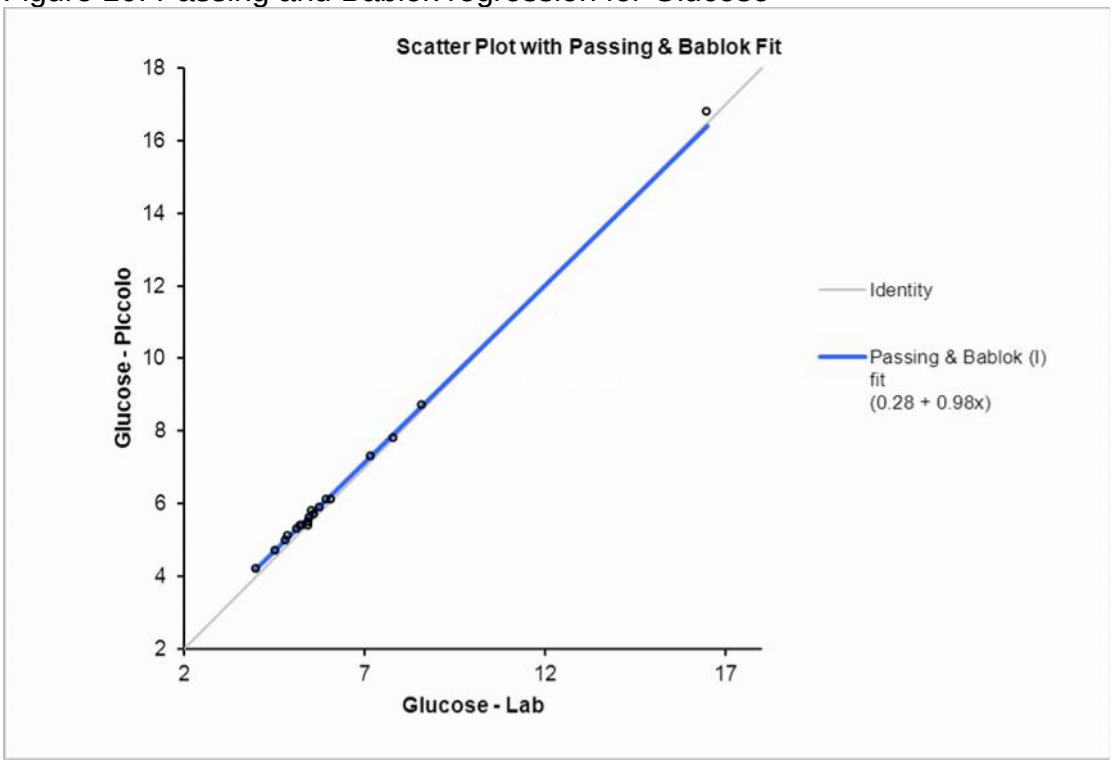


Figure 11: Passing and Bablok regression for Total bilirubin

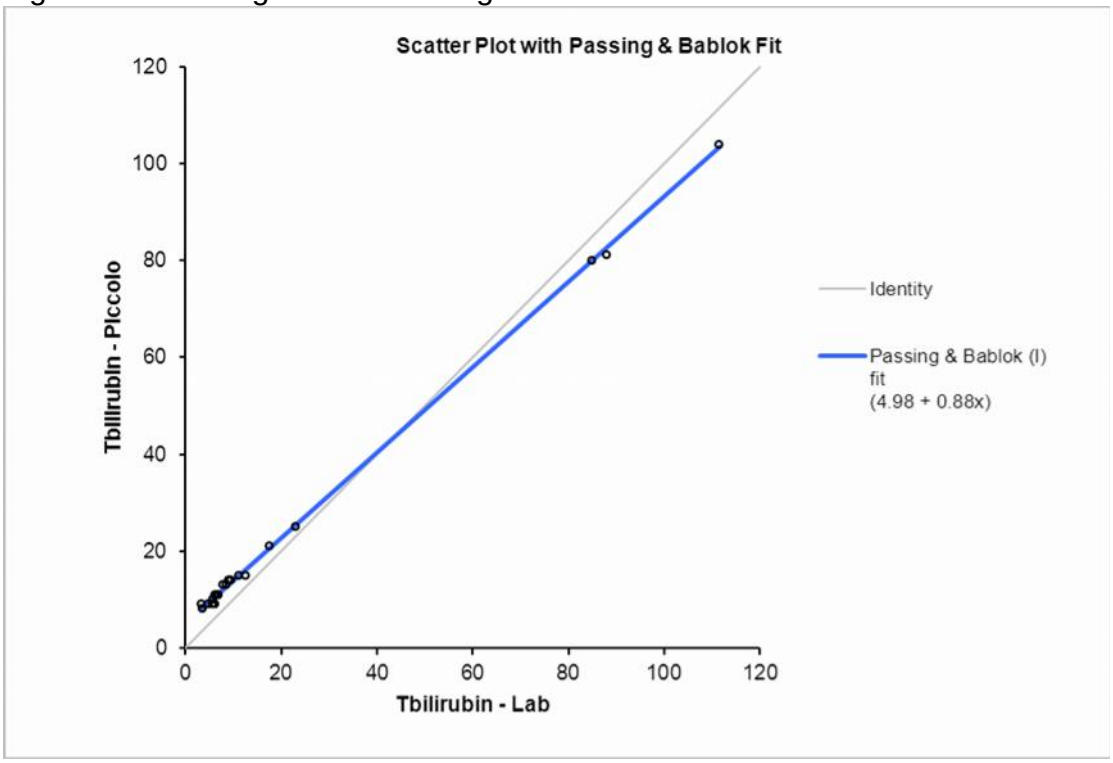


Figure 12: Passing and Bablok regression for Total protein

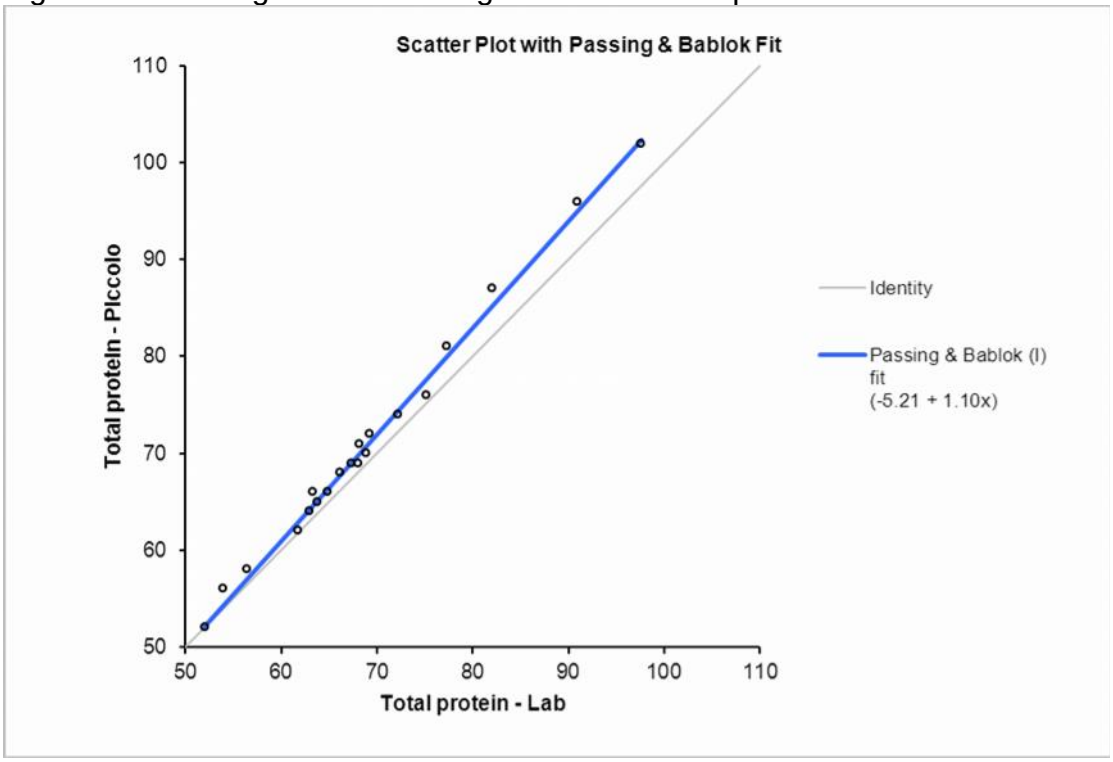
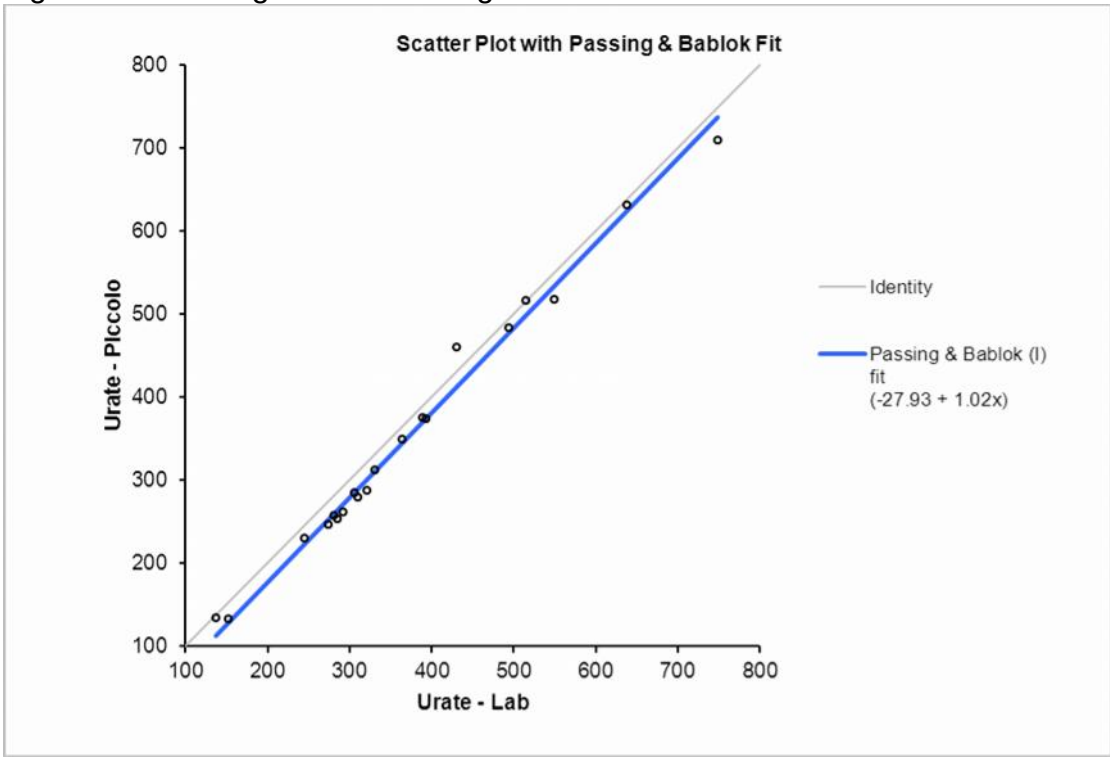


Figure 13: Passing and Bablok regression for Urate



- Patient comparison – lithium heparin whole blood vs Lithium heparin plasma

Patient samples which had been sent to the laboratory in lithium heparin sample tubes (i.e. for ketone analysis) were analysed as whole blood on the Piccolo Xpress. These samples were then centrifuged to obtain the plasma, which was then analysed for all parameters on the Roche cobas c701. Due to a limited number of reagent disks this could only be performed for 8 patient samples. Further comparison may be appropriate.

Figures 14-26 show the Passing & Bablok regression analysis for lithium heparin whole blood versus lithium heparin plasma for all analytes included in the chemistry 13 reagent disk.

Good comparison was seen between lithium heparin whole blood and plasma samples for albumin (y = 0.97x + 1.13).

Good comparison was seen between lithium heparin whole blood and plasma samples for ALP (y = 0.97x + 1.13).

Good comparison was seen between lithium heparin whole blood and plasma samples for ALT (y = 0.97x + 1.13).

A positive bias was seen for amylase on whole blood lithium heparin versus lithium heparin plasma. Again, this bias may be attributable to the differences in what each assay is measuring. The laboratory assay is specific for pancreatic amylase whereas the Piccolo Xpress measures total amylase.

A small constant positive bias was seen between whole blood lithium heparin versus lithium heparin plasma for AST, however, this was not considered to be significant.

Good comparison was seen between lithium heparin whole blood and plasma samples for urea (y = 1.03x – 0.35).

A mixed bias was seen for calcium on whole blood lithium heparin versus lithium heparin plasma. Further comparison of samples would be beneficial, especially if the more stable laboratory calcium assay is introduced.

A negative bias was seen for Creatinine (y = 0.92x -7.00). Again this bias was not considered to be significant.

Good comparison was seen between lithium heparin whole blood and plasma samples for GGT (y = 1.10x - 4.82).

Good comparison was seen between lithium heparin whole blood and plasma samples for Glucose (y = 0.98x + 0.29).
A positive bias was seen for total bilirubin. This bias was not considered to be significant.

A positive bias was seen for total protein, again this was not considered to be significant.

Good comparison was seen between lithium heparin whole blood and plasma samples for Urate.

Figure 14: Passing and Bablok regression for Albumin, lithium heparin whole blood vs lithium heparin

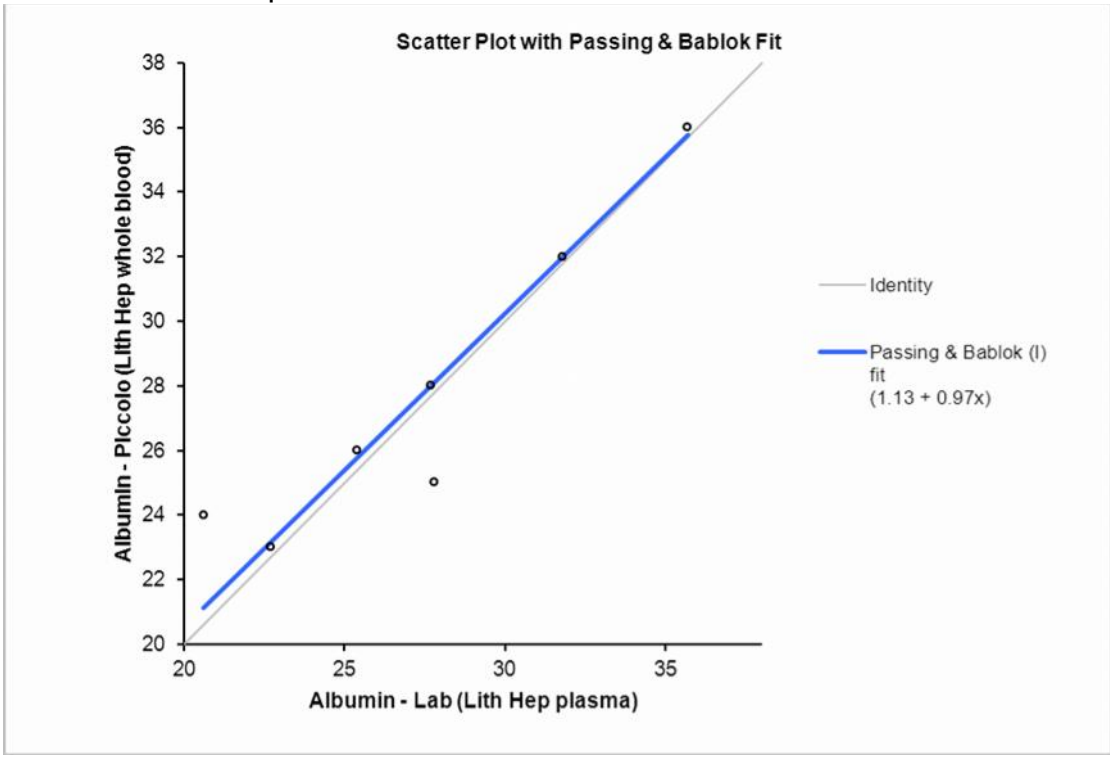


Figure 15: Passing and Bablok regression for ALP, lithium heparin whole blood vs lithium heparin

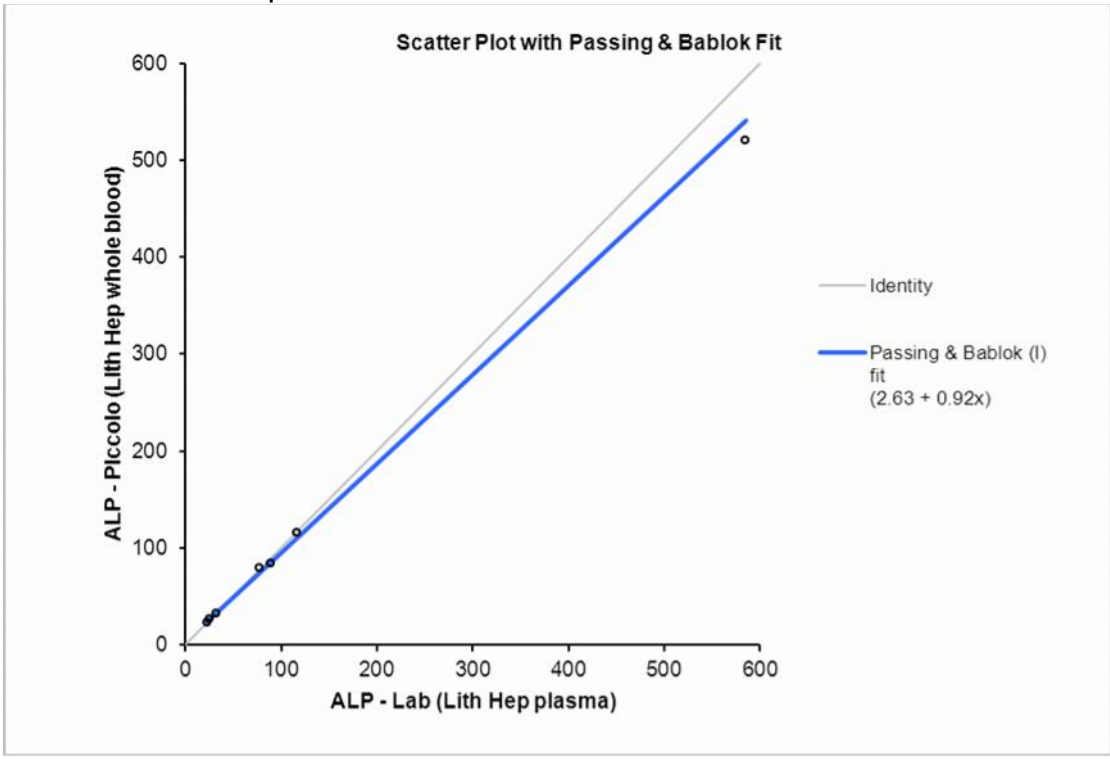


Figure 16: Passing and Bablok regression for ALT, lithium heparin whole blood vs lithium heparin

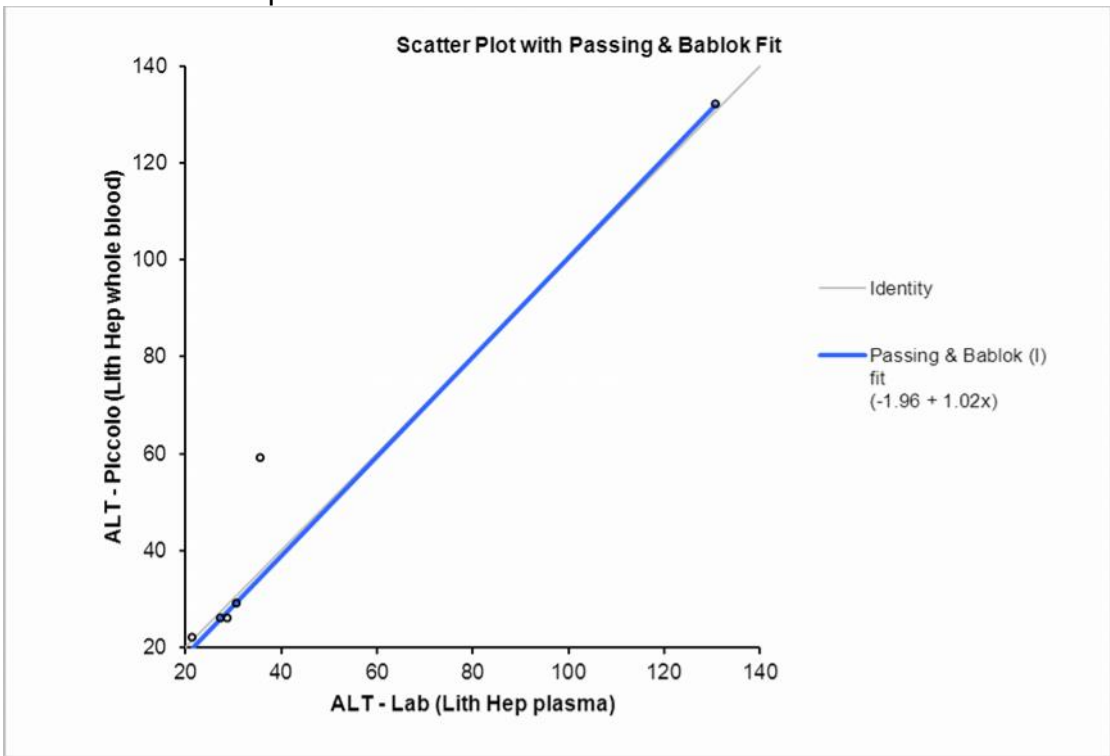


Figure 17: Passing and Bablok regression for Amylase, lithium heparin whole blood vs lithium heparin

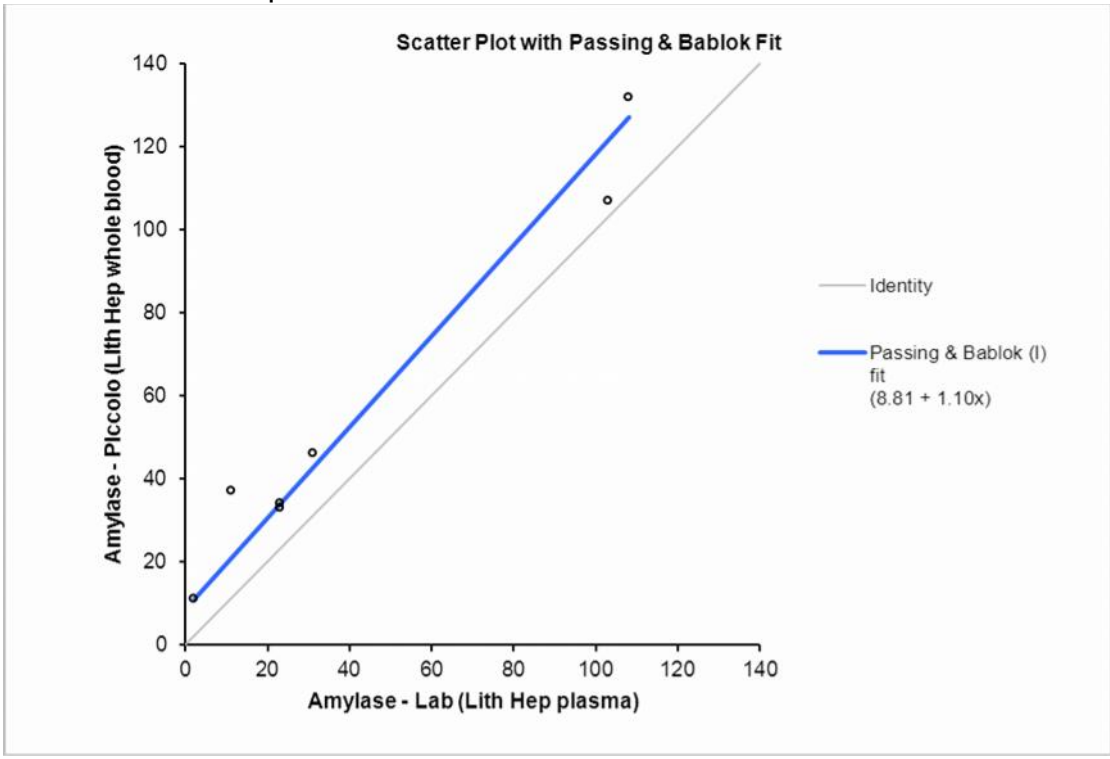


Figure 18: Passing and Bablok regression for AST, lithium heparin whole blood vs lithium heparin

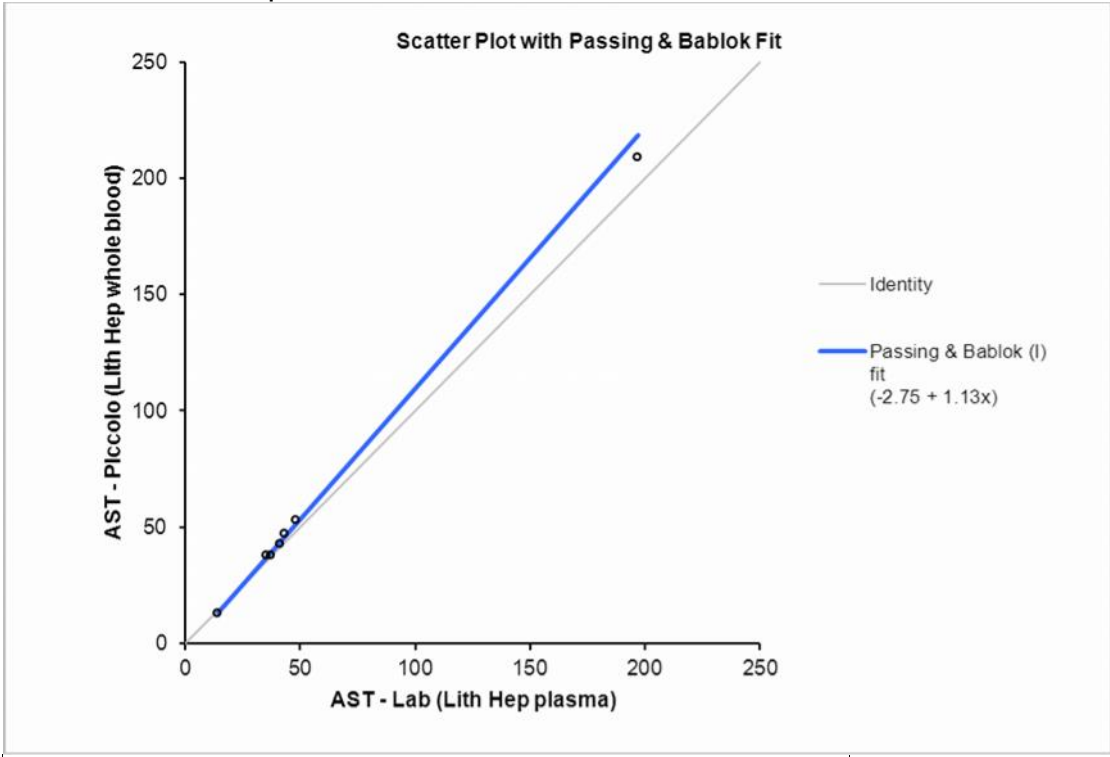


Figure 19: Passing and Bablok regression for Urea, lithium heparin whole blood vs lithium heparin

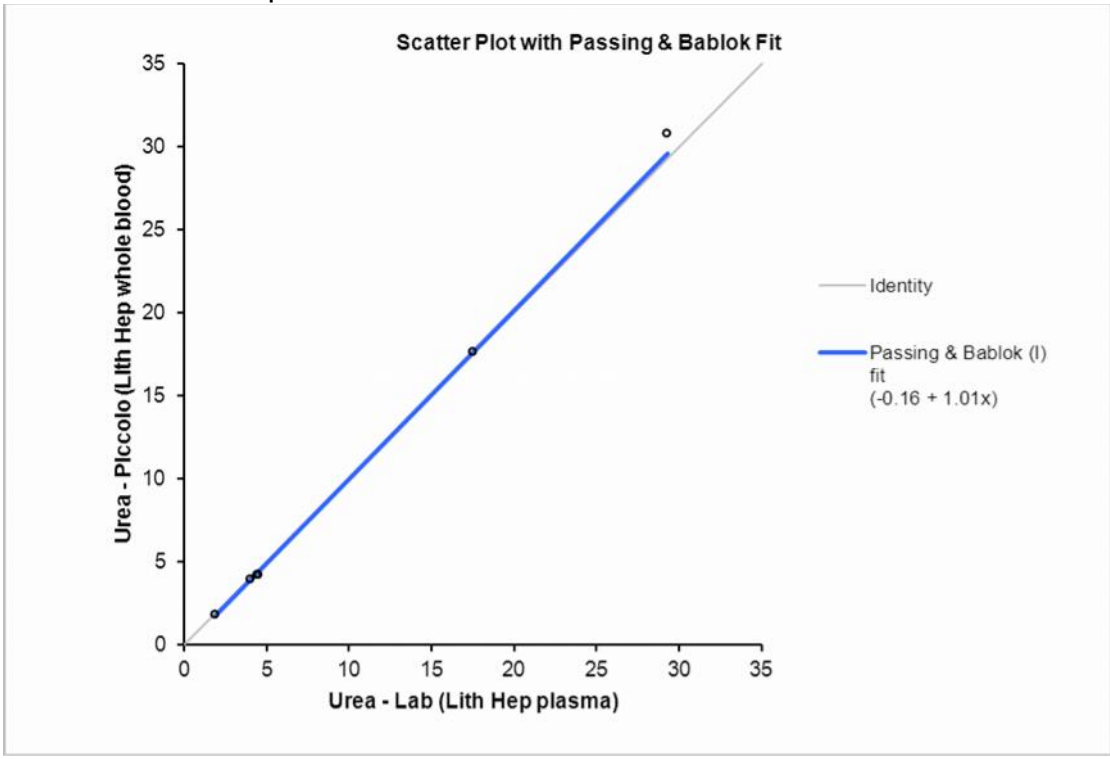


Figure 20: Passing and Bablok regression for Calcium, lithium heparin whole blood vs lithium heparin

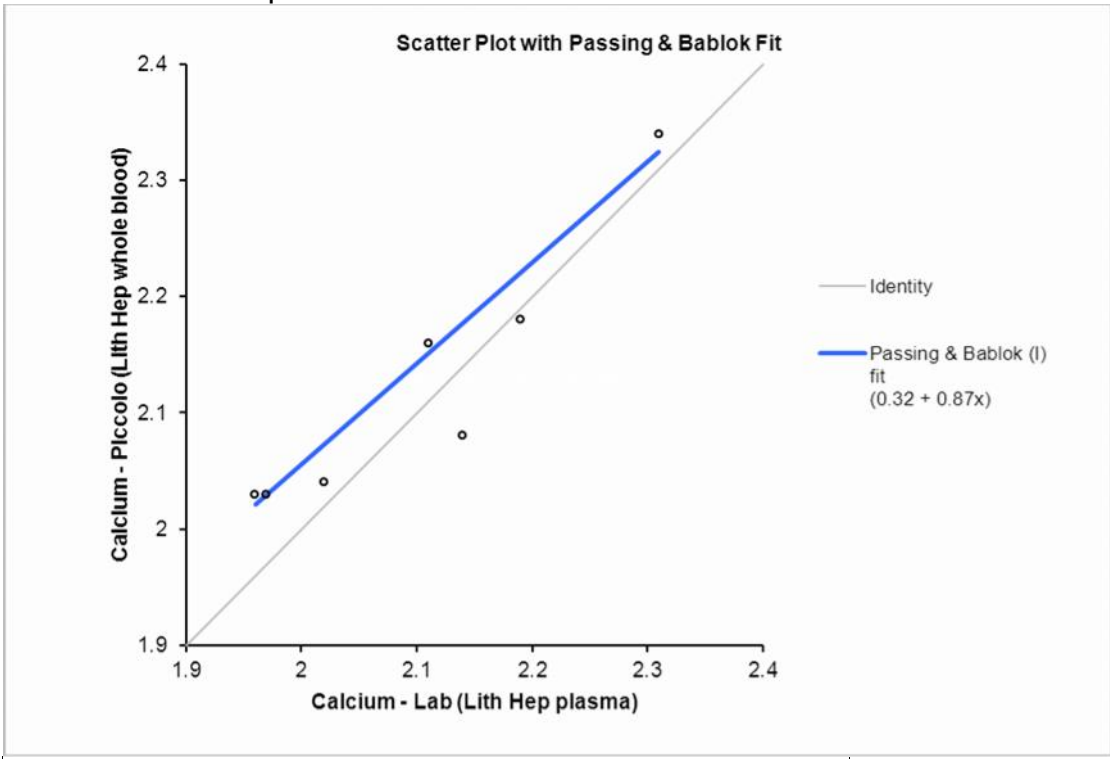


Figure 21: Passing and Bablok regression for Creatinine, lithium heparin whole blood vs lithium heparin

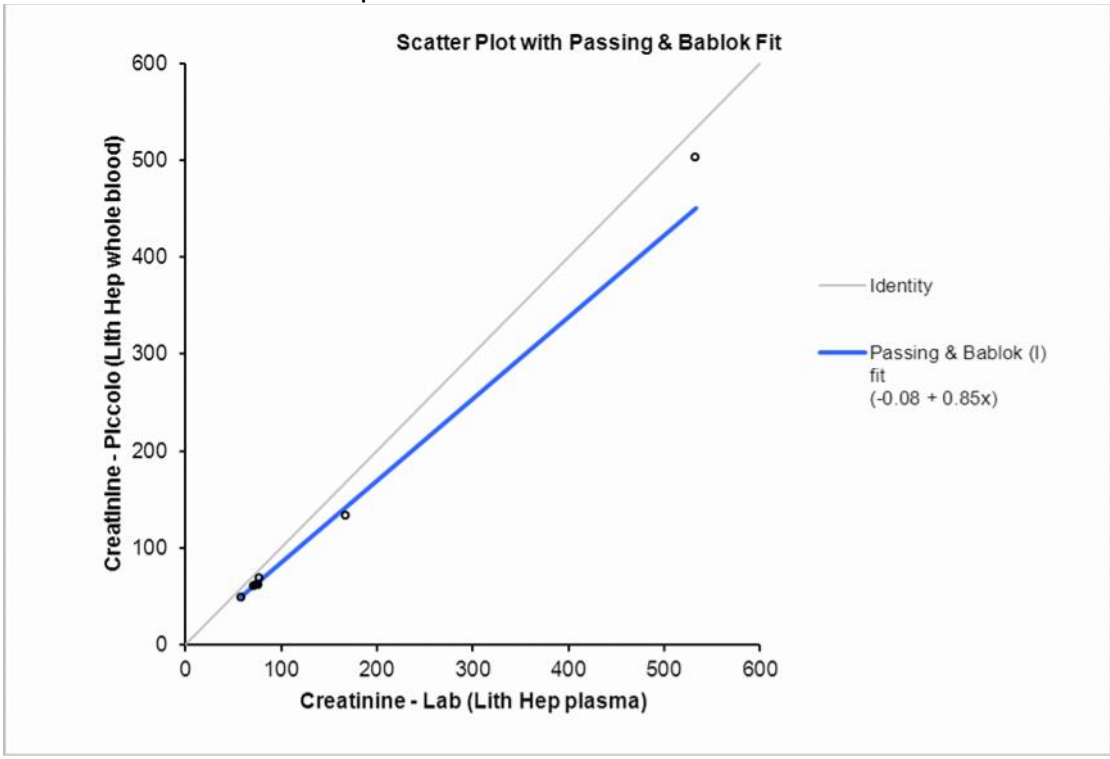


Figure 22: Passing and Bablok regression for GGT, lithium heparin whole blood vs lithium heparin

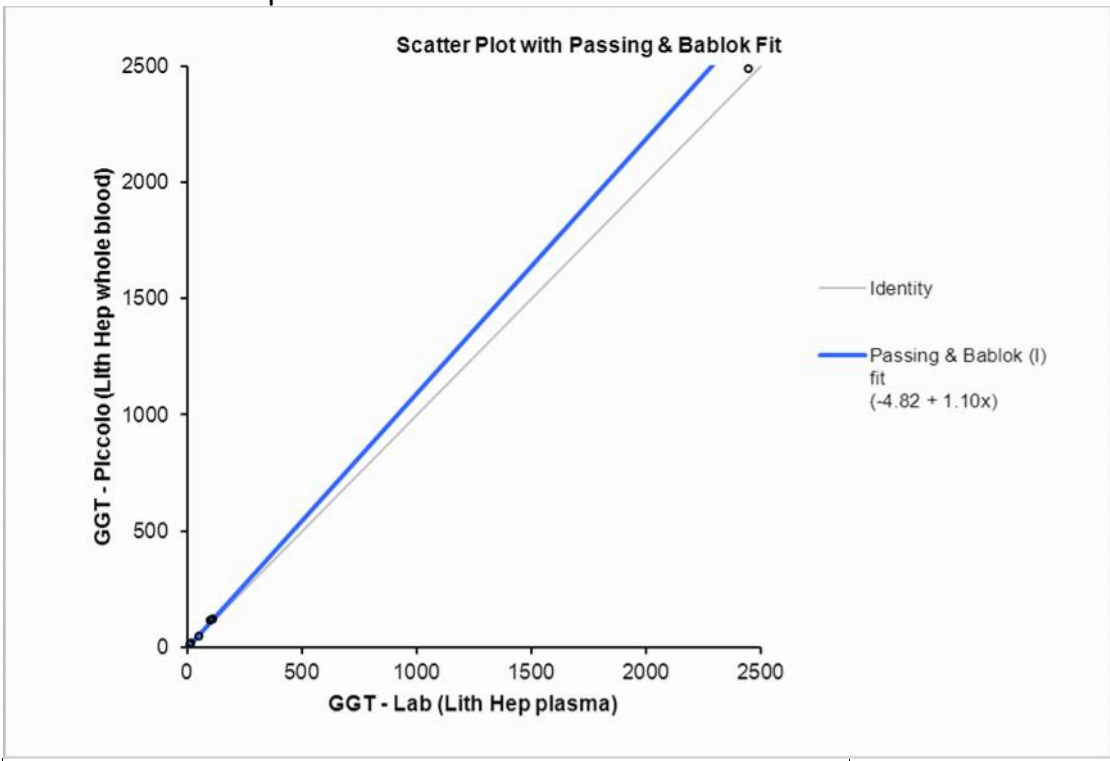


Figure 23: Passing and Bablok regression for Glucose, lithium heparin whole blood vs lithium heparin

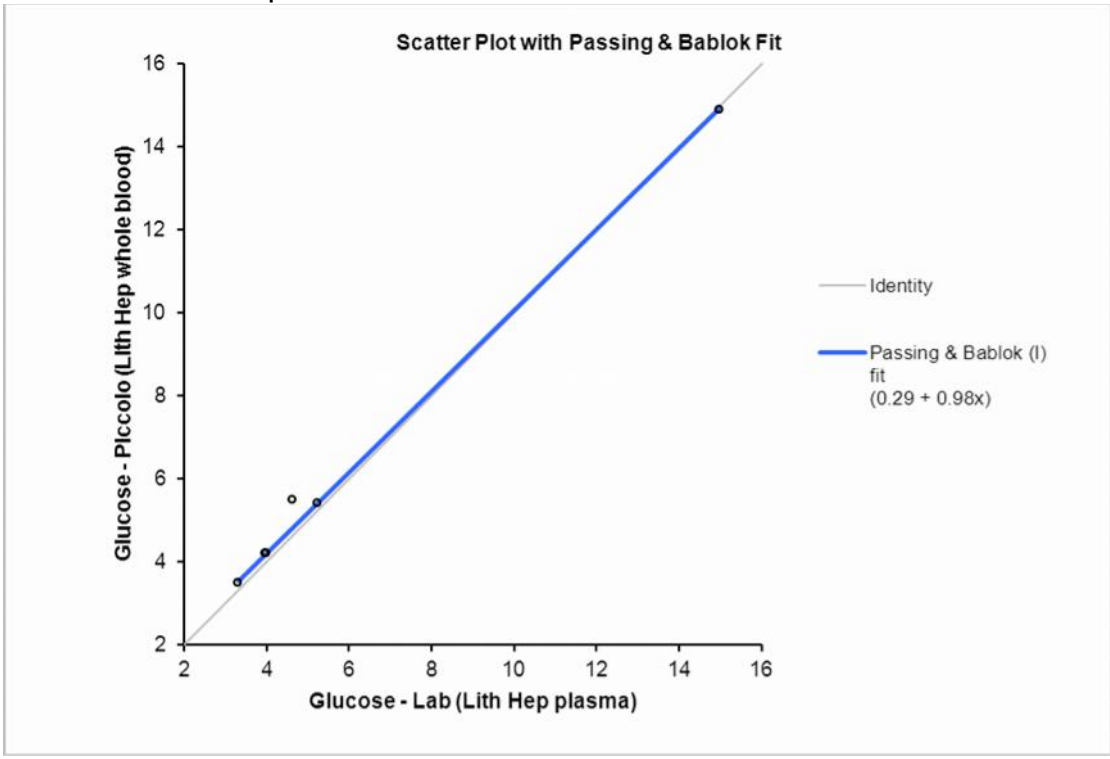


Figure 24: Passing and Bablok regression for Total Bilirubin, lithium heparin whole blood vs lithium heparin

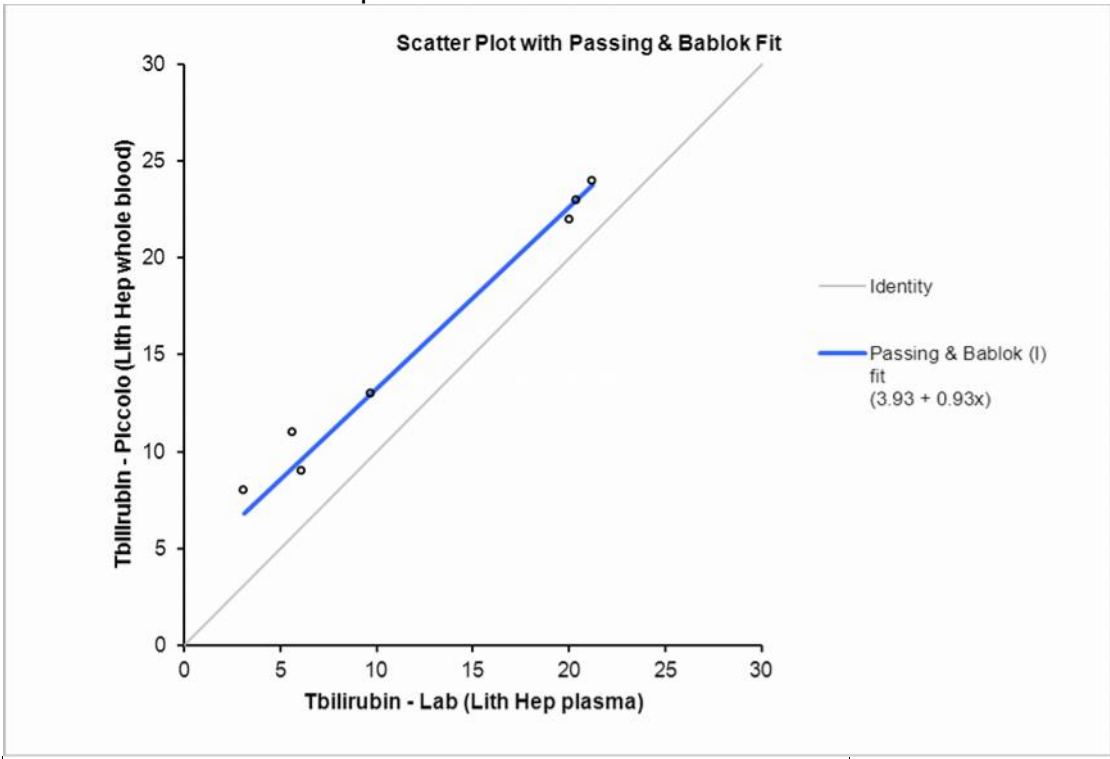


Figure 25: Passing and Bablok regression for Total protein, lithium heparin whole blood vs lithium heparin

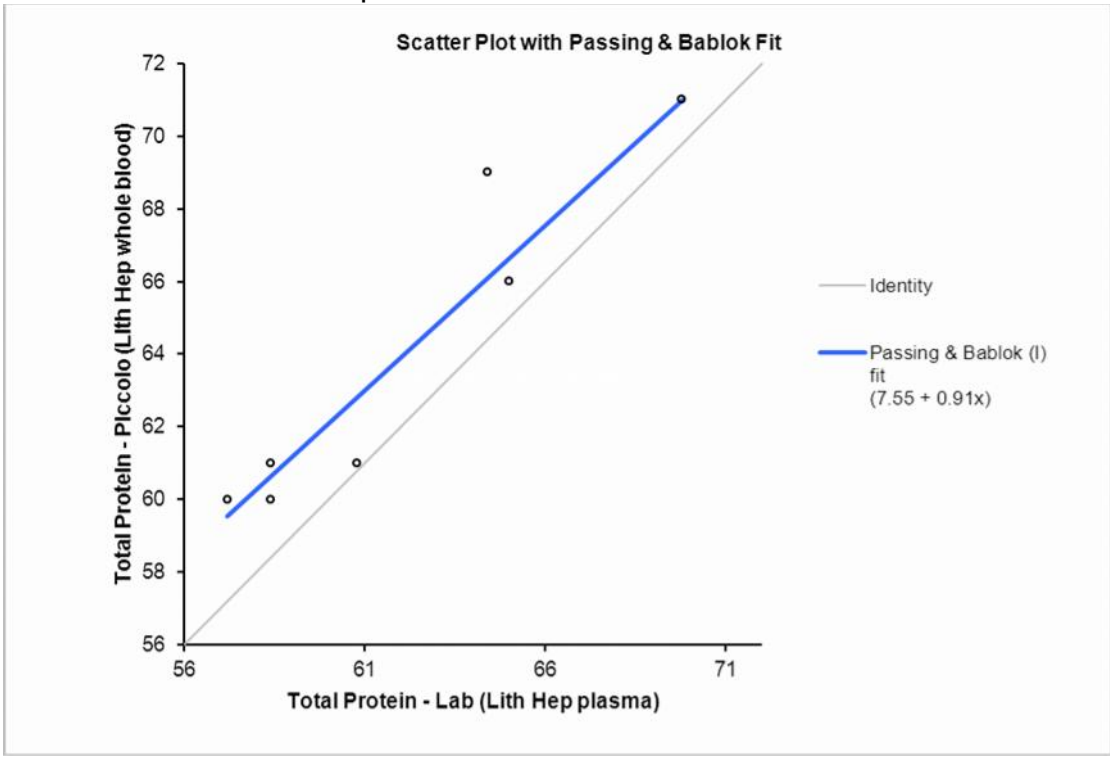
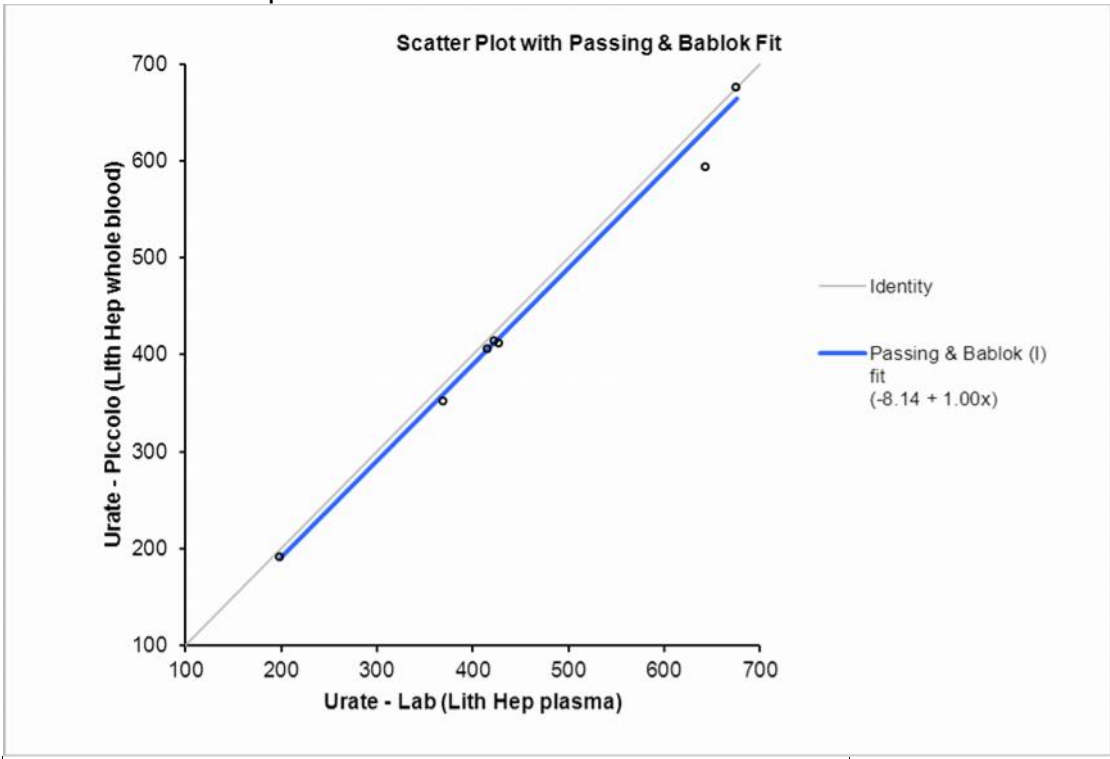


Figure 26: Passing and Bablok regression for Urate, lithium heparin whole blood vs lithium heparin



- *EQA comparison*

Due to the number of reagent discs available, EQA performance was not assessed.

- *Dilution check*

Samples with results outside of the measuring range should not be diluted.

- *Imprecision*
  - *Within run* – see between run
  - *Between run*

Precision was found to be acceptable for all analytes (<5 %CV) except creatinine and ALT - see table 1 for data.

The level 1 QC for creatinine had a mean concentration of 42.8µmol/L and gave a %CV of 16.12. This is higher than is desirable even for a point of care instrument and has been fed back to the manufacturer.

The level 1 QC for ALT had a mean concentration of 26.8 U/L and gave a %CV of 5.95. This is probably acceptable precision for a point of care device.

- *Measurement uncertainty*

Measurement uncertainty is estimated as being the intermediate imprecision expressed as 1 SD. The intermediate imprecision is the imprecision of the analytical method over a period of time, taking into account changes in reagent lots and calibration lots. Cannot be determined at this time and to be determined at a later date.

- *Other (if applicable, e.g. non-CE marked method, or change of use of CE marked method)* – Not applicable.
  - *Limit of detection*
  - *Limit of quantitation*
  - *Linear range*
  - *Recovery*
  - *Interference*
  - *Analyte stability*

Table 1: Precision data for all analytes in the chemistry 13 panel.

	Level 1			Level 2		
	Within Day		Between Day	Within Day		Between Day
	Mean	%CV	%CV	Mean	%CV	%CV
Albumin	32.80	2.55	2.35	45.00	0.00	3.07
ALP	79.00	4.56	4.83	367.20	1.53	3.28
ALT	26.80	8.09	5.95	158.00	0.45	1.83
Amylase	36.80	1.22	1.71	333.80	2.13	1.50
AST	31.60	1.73	3.54	180.60	0.50	0.84
Urea	4.62	3.56	2.33	23.52	1.02	0.82
Calcium	1.65	2.03	1.68	2.83	2.05	1.39
Creatinine	42.80	13.26	16.12	432.00	1.00	2.27
GGT	25.40	4.49	5.54	139.80	0.93	0.79
Glucose	3.00	0.00	0.00	15.06	0.36	0.35
Total bilirubin	18.20	2.46	3.71	85.20	0.52	1.44
Total Protein	44.60	1.23	1.20	77.40	1.16	1.02
Urate	165.60	1.01	2.66	497.20	1.44	1.62

Cost implications

Instrumentation & IT connectivity

The capital cost of each instrument does not include interfacing of the Piccolo Xpress to the LIMS.

Quality Control

Randox Chemistry QC material which is currently used by the laboratory is suitable for use on the Piccolo Xpress. The cost of the QC material is QC costs are included in the laboratory cost per test.

Turn around times

This assay is intended to be performed in the A&E department. It is therefore expected for the turnaround time to improve. This does rely on suitably trained staff being available to perform the analysis as well as machine availability. The chemistry 12 panel takes approx. 12 minutes.

Conclusion

The Piccolo Xpress chemistry analyser and chemistry 13 reagent disk have been evaluated by the Point of Care department. The evaluation has shown that the assays are suitable, in terms of performance for use in the A&E department. Further work to be carried out include

1) Analysis of EQA material
2) Repeat comparison of calcium on the Piccolo versus the laboratory assay, particularly if a more stable calcium assay is introduced into the laboratory.
3) Repeat precision for creatinine and ALT.

Funding to cover the costs of purchase, reagents, QC and maintenance needs to be identified.

Gateshead Health NHS
NHS Foundation Trust

Confirmation Method Evaluation Date of Introduction:	Date	Signature
Staff Name (print):		
Departmental BMS 4 Name (print):		
Head of Department Name (print)		