

## Evaluation Report

### **Eurolyser NH3 test kit (VT0160) on solo analysers**

---

Location: Eurolyser Diagnostica GmbH  
Operator: Michael Gruber  
Date: June 2012

---

#### **Specimens**

The specimens for sample correlation were taken from a local university from dogs and were fresh EDTA plasma samples. Plasma was aliquoted and tested with the reference method (Axonlab NH3 test kit measured on Pentra) and on Solo analysers.

For all other tests the following controls have been used:

Ammonia Control set Y08330  
Lot: 405806-028

Control low: 41 µmol/l  
Control high: 244 µmol/l

Sample volume: 20 µl

---

#### **Equipment**

- Eurolyser solo analyser: Ar8008, Ar8009, Ar8010
  - Test kits: VT0160: LOT 0312-1
-

## 1. Introduction and Scope

Protein digestion produces ammonia within the intestine by deamination of amino acid. Ammonia reaches the liver by portal blood where it is synthesized into urea (main route of metabolism of intestinal ammonia into urea).

Heavy liver dysfunction (e.g. shunt, cirrhosis) can prevent the liver from synthesizing ammonia into urea. As a result one will receive a lowered urea concentration in relation to creatinine as well as increased blood ammonia. Ammonia and other protein metabolism (aromatic amino acids) that get out of control of the liver metabolites can affect the central nervous system (hepatoencephalic syndrome).

- 1.1 Method comparison  
Testing the correlation between the NH<sub>3</sub> measurement results in the Eurolyser analyser from plasma and the results of the Axonlab Pentra.
- 1.2 Reproducibility  
Characterization of the reproducibility of the Eurolyser NH<sub>3</sub> test at 2 levels
- 1.3 Linearity testing

### Principle:

Enzymatic test. Photometric measurement of the absorbance rate (kinetic) at 340 nm wavelength.

## 2. Comparison Study

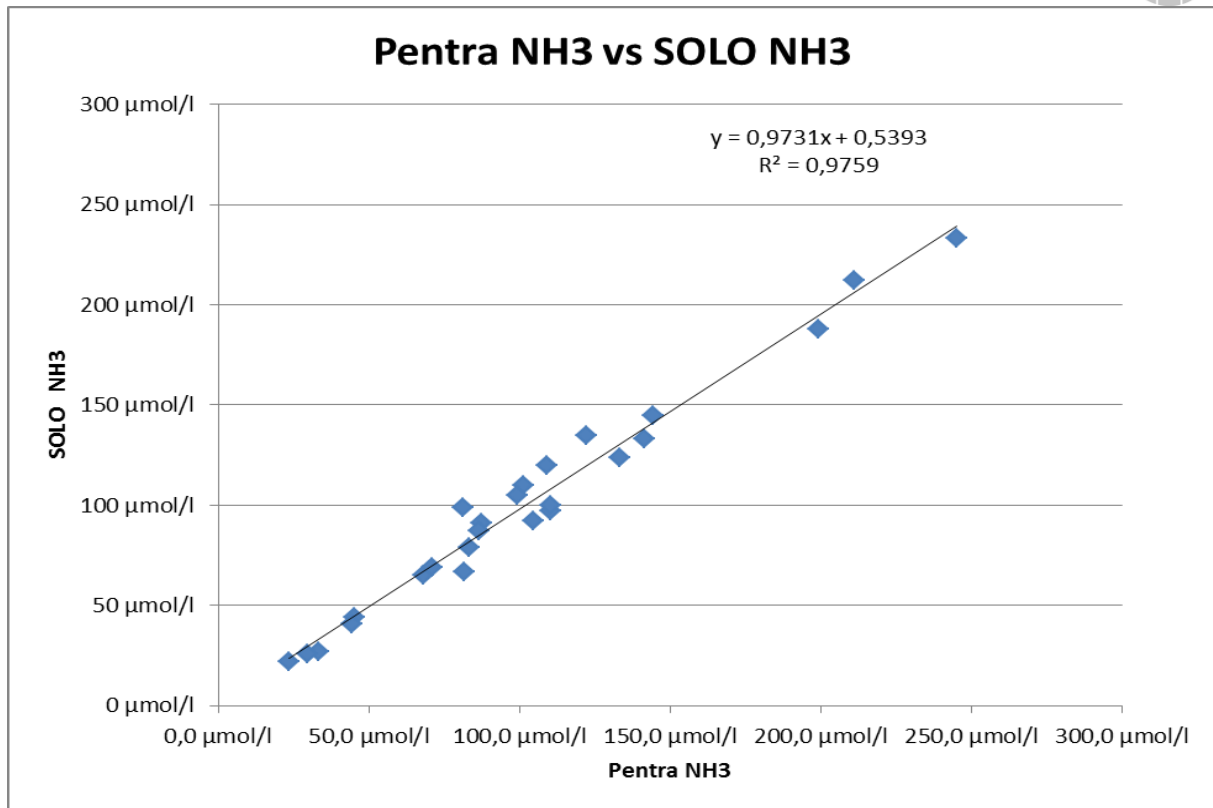
Eurolyser vs Axonlab (Pentra)

The comparison study is based on the correlation between the results of the Eurolyser NH<sub>3</sub> assay and the Penra NH<sub>3</sub> assay measured on a Pentra.

25 samples have been analysed on Solo analysers.

The acceptance criterion for this comparison study is a coefficient of determination  $R^2 > 0.90$  obtained from linear regression between the Eurolyser NH<sub>3</sub> and the Pentra NH<sub>3</sub>.

Sample N°	Eurolyser instrument	Pentra NHR µmol/l	Solo NH3 µmol/l
1	Ar8008	245,1	233
2	Ar8009	23,6	22
3	Ar8010	68,3	65
4	Ar8008	110,2	97
5	Ar8009	81,5	67
6	Ar8010	104,7	92
7	Ar8008	133,1	124
8	Ar8009	109,2	120
9	Ar8010	45,3	44
10	Ar8008	122,2	135
11	Ar8009	199,1	188
12	Ar8010	87,4	91
13	Ar8008	44,3	41
14	Ar8009	33,2	27
15	Ar8010	81,4l	99
16	Ar8008	141,3	133
17	Ar8009	71,2	69
18	Ar8010	86,4	87
19	Ar8008	144,2	145
20	Ar8009	110,2	100
21	Ar8010	211,2	212
22	Ar8008	29,5	26
23	Ar8008	83,4	79
24	Ar8009	101,2	110
25	Ar8010	99,4	105



Sample correlation:

The result for the correlation between Pentra NH3 and Solo NH3 is the linear regression function:

$$y (\text{Solo NH3}) = 0.9731x (\text{Pentra NH3}) + 0.5393 \text{ and a } R^2 = \mathbf{0.9759}$$

### 3. Reproducibility (within-run precision)

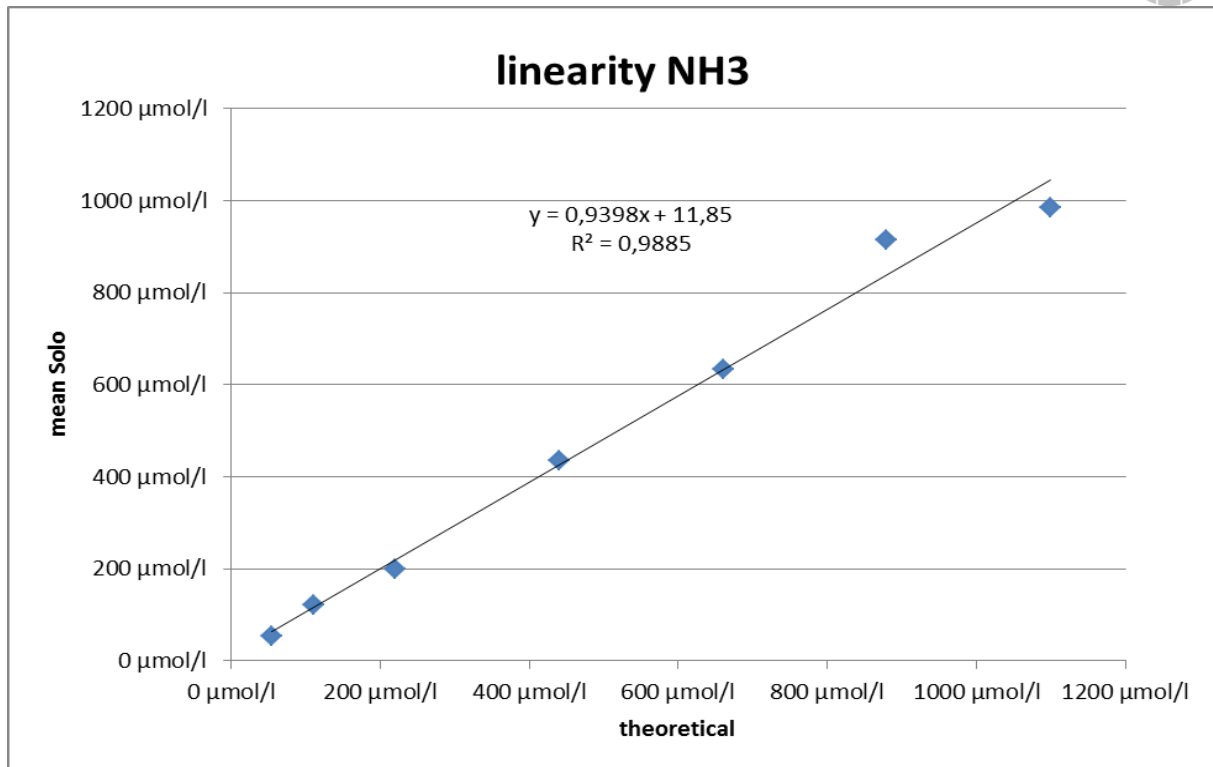
Controls have been tested 20 times and the CV value was calculated (tested with solo analysers):

Sample #	instrument	Control low $\mu\text{mol/l}$	Control high $\mu\text{mol/l}$
1	Ar8008	40	237
2	Ar8009	38	246
3	Ar8010	36	268
4	Ar8008	45	255
5	Ar8009	44	240
6	Ar8010	31	223
7	Ar8008	38	246
8	Ar8009	39	234
9	Ar8010	44	260
10	Ar8008	43	245
11	Ar8009	38	229
12	Ar8010	38	239
13	Ar8008	41	241
14	Ar8008	42	244
15	Ar8009	39	247
16	Ar8010	43	256
17	Ar8008	38	259
18	Ar8008	37	261
19	Ar8009	36	233
20	Ar8010	44	233
<b>Average</b>		<b>39.7</b>	<b>245</b>
<b>Stdev</b>		<b>3.54</b>	<b>11.97</b>
<b>CV</b>		<b>8.92%</b>	<b>4.89%</b>

The CV values are 8.92% for the control low as well as 4.89% for the control high.

### 4. Linearity Test

Spiked Plasma	Ar8008	Ar8009	Ar8010	
Theoretical	meas 1	meas 2	meas 3	mean
1100 $\mu\text{mol/l}$	1050	971	935	985 $\mu\text{mol/l}$
880 $\mu\text{mol/l}$	910	877	955	914 $\mu\text{mol/l}$
660 $\mu\text{mol/l}$	599	666	633	633 $\mu\text{mol/l}$
440 $\mu\text{mol/l}$	433	422	449	435 $\mu\text{mol/l}$
220 $\mu\text{mol/l}$	211	198	188	199 $\mu\text{mol/l}$
110 $\mu\text{mol/l}$	112	123	129	121 $\mu\text{mol/l}$
55 $\mu\text{mol/l}$	49	55	53	52 $\mu\text{mol/l}$



The test kit shows very good linearity.

## 5. Interferences in Plasma

The test system has been analysed for various interferences. Criterion was the recovery within 10% of initial values.

Ascorbic acid	3 mg/dl
Bilirubin	40 mg/dl
Lactate	200 mg/dl
Pyruvate	6.6 mg/l
Triglycerides	200 mg/dl

## 6. Summary

The NH3 test kit designed for solo analysers has a good correlation to the NH3 test from Axonlab measured on a Pentra.

The reproducibility and linearity of the test are good.