Maintaining

Quality in

Laboratory

Medicine

Ammonia
Scheme Guide

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UKAS PROFICIENCY TESTING
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Contents

1. Scheme details and repertoire

Frequency: Monthly *Number of samples: 3*

Analyte	Approx. Range Covered	Units
Ammonia	0 - 1500	µmol/L

For Ammonia - the material is sterile human serum, filtered to 0.2 µm and gentamicin added to maintain sterility. The serum is dispensed and stored at -70°C until dispatched. All human serum is tested at donor levels and found negative for HIV Ab, Hep B surface Ag and Hep C

Although every effort is made to ensure that the material is free from any known infectious agent, the samples should be handled as for clinical specimens.

2. Evaluation of material

During the pilot phase different sample types were evaluated for their suitability.

- Frozen human serum
- Aqueous solution of ammonium sulphate
- Viscosity adjusted aqueous ammonium sulphate

2.1 Distribution 1

For this Distribution, samples 1 and 2 were frozen human serum, whilst samples 3 and 4 were aqueous solutions of ammonium sulphate, with sample 4 having an additional viscosity adjuster. All participants received both samples 1 and 2 and either sample 3 or 4.

Method variability

Samples 3 and 4 had an identical concentration of ammonia of 50 µmol/L, however, the results for both the Ammonia Checker and Vitros were significantly different for the two samples. The viscosity adjusted material performed well on the Ammonia Checker and poorly on the Vitros. Apart from Sample 4, the Vitros results compared well with the GLDH method.

Distribution 1

Sample no.	1	2	3	4
GLDH mean	100	816	35	41
GLDH sd	12.4	72.7	4.7	7.7
n	48	46	24	21
Vitros mean	83	790	30.1	5.9
Vitros sd	10	80.9	4.6	3.4
n	14	14	7	8
Ammonia Checker mean	146	545	72	37
Ammonia Checker sd	15	343.3	9.6	6.4
n	18	8	9	9
Overall mean	104	812	43	35
Overall sd	21.8	75.5	17.1	16.6
n	81	62	40	42
WEQAS sd (prelim)	20.8	162.4	8.6	6.5

2.2 Distribution 2

For this Distribution, samples 3 and 4 were frozen human serum, whilst samples 1 and 2 were aqueous solutions of ammonium sulphate, with sample 2 having an additional viscosity adjuster. All participants received both samples 3 and 4 and either sample 1 or 2.

Method variability

Samples 1 and 2 had an identical concentration of ammonia of 100 µmol/L, however the results for both the Ammonia Checker and Vitros were significantly different for the two samples. The viscosity adjusted material performed well on the Ammonia Checker and poorly on the Vitros.

Distribution 2

Sample no.	1	2	3	4
GLDH mean	101.2	107.4	102.6	447.8
GLDH sd	6.98	9.1	9.24	31.43
n	23	30	63	63
Vitros mean	90.3	61	80.6	425.6
Vitros sd	8.03	0	5.72	28.46
n	17	1	17	17
Ammonia Checker mean	189.8	103.5	146.6	511.8
Ammonia Checker sd	7.08	10.51	11.86	171.9
n	4	13	20	10
Overall mean	98.37	104.1	105.9	437.4
Overall sd	12.17	13.83	21.12	46.53
n	43	45	101	88
WEQAS sd (prelim)	19.67	20.81	21.19	87.48

Conclusions

- Aqueous material performed poorly on Ammonia Checker
- Viscosity adjusted material can not be used for the Vitros analyser.
- Serum matrix is sample of choice

Ammonia Checker

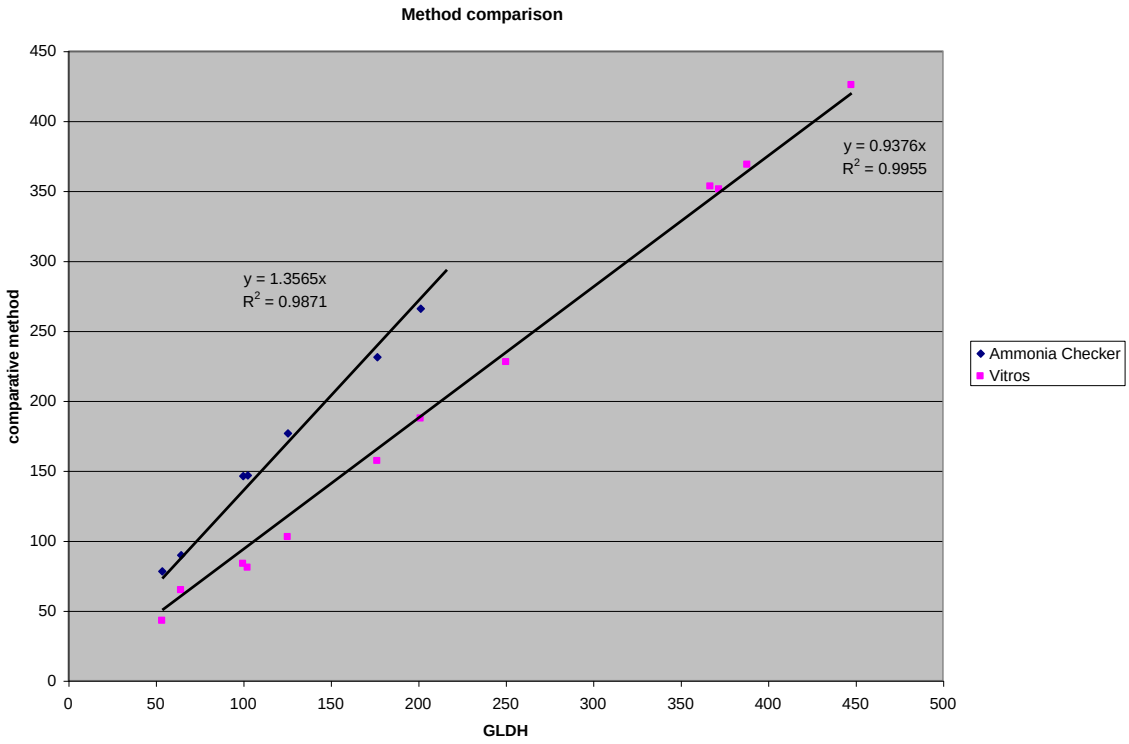
The instrument is designed for whole blood and therefore a matrix/viscosity effect may be produced with alternative material. Our data shows a systematic positive bias for serum.
For Distribution 1 Sample 2 the concentration was greater than the analytical range of the instrument. The majority of users reported >286 µmol/L, however, 6 users reported a value of 286 µmol/L.

- **USERS SHOULD BE AWARE THAT A VALUE OF 286 ON THE AMMONIA CHECKER IS INDICATIVE OF A HIGH, OVER RANGE RESULT.**

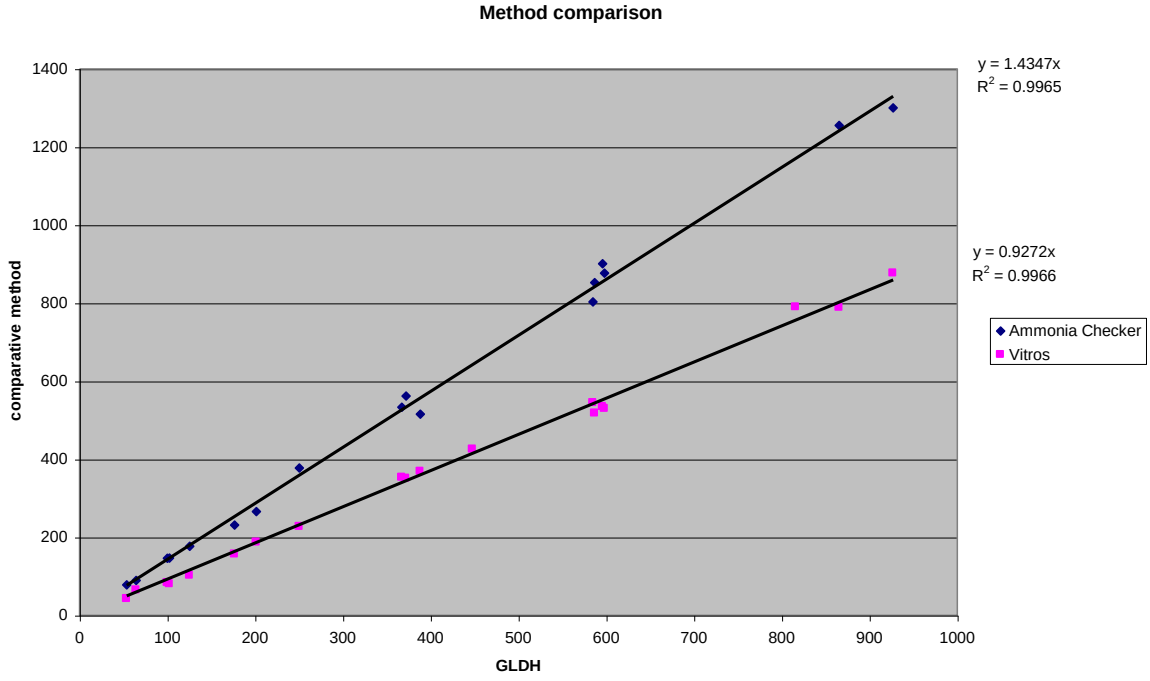
An updated model of the Ammonia Checker is now available, the PocketChem BA, which displays over range results as “Hi”.

3. Calculation of comparability factor (CF)

Only results within the analytical range of the instrument were included for calculation of the CF i.e. < 280 µmol/L for the Ammonia Checker and < 500 µmol/L for the Vitros analyser. A wider variability was observed for the Ammonia Checker at concentrations above this range presumably reflecting the extra dilution step.



For the Ammonia Checker a slope of 1.36 was observed compared with the GLDH method. This relates to a positive systematic proportional bias of +36%. A negative systematic proportional bias of –6% was observed for the Vitros analyser.

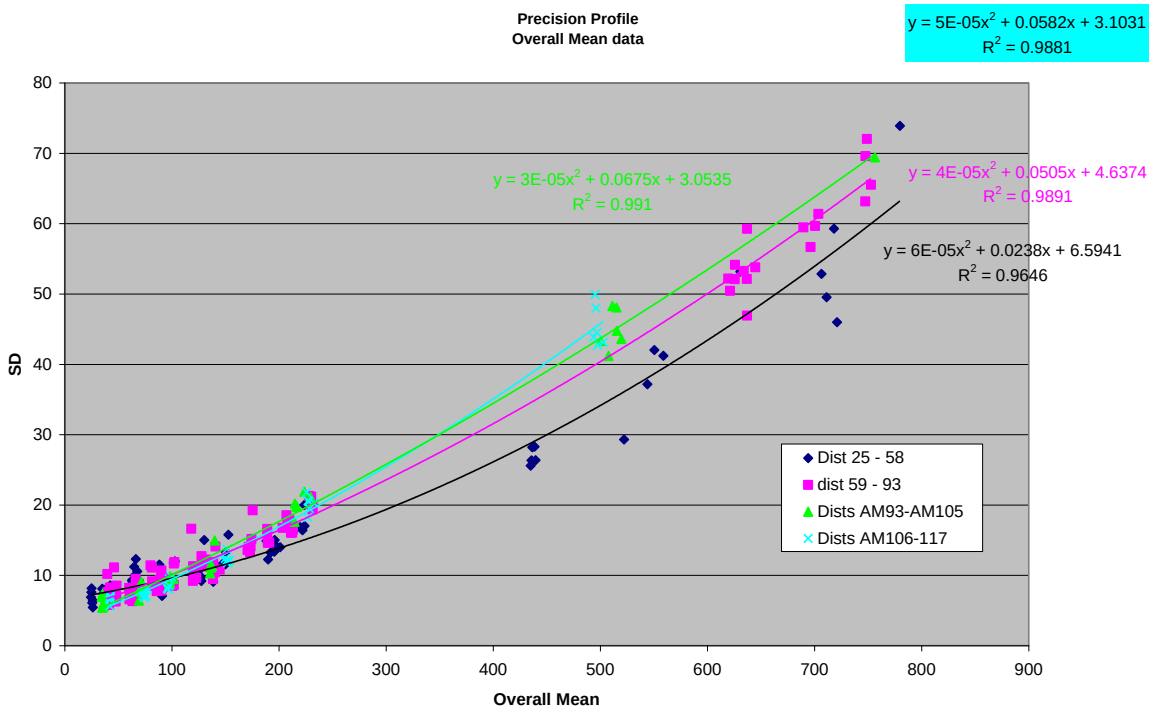


When all the results were included, the bias for the ammonia checker increased to +43%.

4. Performance Criteria

Standard deviation limits used in the report are based on precision profiles calculated over several batches and are fixed for a given level of analyte. They are reviewed yearly and reflect the state of the art of the methods used.

The Ammonia Checker shows a wider interlaboratory variation than the GLDH and Vitros methods. For this reason the data for the GLDH method is used to establish performance criteria.



5. Instructions for use

Samples should be stored at 4°C prior to analysis. The samples should be mixed well and analysed within 48 hours of the dispatch date. Please store at -20°C if there is a delay in analysing the samples.

Please follow the manufacturers' instructions for processing samples that indicate a concentration greater than the analytical range.

Although every effort is made to ensure that the material is free from any known infectious agent, the samples should be handled as for clinical specimens.

6. Statistical Analysis

Please refer to the Participants Manual for full details on statistical analysis and interpretation of results.

An overview of Ammonia Checker results is distributed quarterly. An excerpt of this report is given below.

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Ammonia Checker / Pocket Chem Results

March 2014 – May 2014

Dear Colleague,

Please find below results for the Ammonia Scheme Distributions AM137, AM138 and AM139.

Material

The material used in the Ammonia Scheme is sterile human serum. This is filtered to 0.2µm with gentamicin added to maintain sterility. Following preparation, the serum is dispensed and then stored at -70°C until dispatch.

Method variability

Distribution AM137

Sample no.	1	2	3
GLDH mean	95.48	72.40	643.66
GLDH Std. Dev.	7.92	8.05	59.22
n	189	191	184
Ammonia Checker / Pocket Chem mean	130.80	98.92	N/A
Ammonia Checker / Pocket Chem Std. Dev.	9.77	6.81	N/A
n	25	26	29
Overall mean	95.92	72.95	648.64
Overall Std. Dev.	8.05	9.43	59.96
n	235	238	202
WEQAS S.D.	9.15	7.61	61.89

Sample 1 had a concentration of 95.48 µmol/L (GLDH method mean). The reported Ammonia Checker / Pocket Chem values ranged from 75 – 157 µmol/L.

Sample 2 had a concentration of 72.40 µmol/L (GLDH method mean). The reported Ammonia Checker / Pocket Chem values ranged from 74 – 122 µmol/L.

Sample 3 had a concentration of 643.66 µmol/L (GLDH method mean). Of the 29 labs that reported results for the Ammonia Checker / Pocket Chem; 27 labs reported >286 and 1 reported >285. **Of some concern is the 1 laboratory reporting a result of 286µmol/L. Users should be aware that a value of 286 on the Ammonia Checker is indicative of a high, over range result and not an ammonia result of 286 µmol/L**