Quality control charts for internal quality control of forensic blood alcohol analysis

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1. Introduction

Relating to the prosecution of driving under the influence in Germany, forensic alcohol analysis of blood samples must be performed according to the so-called BAC-guidelines [4]. These guidelines have been revised in 2011. Accordingly, internal quality procedures involve control charts for replicate analysis (e.g. 2 determinations by a gas chromatographic (GC) and an enzymatic method (ADH), respectively, Fig.1 and Fig.2). For ethanol concentrations above 1 g/kg blood (1.236 g/l serum) the maximum deviation from the reference value should not exceed 5%. For ethanol concentrations ≤1 g/kg blood, the absolute difference between the analytical results should not exceed 0.05 g/kg blood (0.062 g/l serum). To easily test these demands of the guidelines, a computer program was developed.

2. Material and Methods

Quality control charts are usually designed for only one method. By using methods-combining control charts, the results can be used to estimate the measurement uncertainty (MU) for the forensic ethanol determination according to the Guide to the Expression of Uncertainty in Measurement (GUM) [1]. A practical estimation of the MU can be done by the combination of precision data of reference material in combination with the contributions of the trueness estimated by proficiency tests [5]. As reference material Medidrug S-plus 3.0 g/L (Medichem GmbH, Stuttgart) was determined by the GC- and ADH-method at 31 days in different series according to the BAC-guidelines. The precision data from the combined control charts were combined with accuracy data derived from proficiency tests during 2011 and 2012 (Arvecon GmbH, Walldorf) using target values in the range of 0.29 to 3.69 g/L (0,23 to 2,98 g/kg) [2 – 5]. The new requirements of the current BAC-guidelines were implemented in a computer program developed with Microsoft Excel 2010 using Visual Basic for Applications.

3. Results and Discussion

Within the program following main characteristics are available:

- day to day monitoring of two different analytical methods or their combination
- in addition to systematic (bias), and
- random errors (precision)
- as well as the combined MU according to the GUM.

For the combination of the GC- and the ADH-method, a measurement uncertainty of 2.2% (68.2% significance) and of 6.8% (99.7 %significance) was calculated, Fig. 4. Precision data for both methods and their combination can be easily calculated. Results are shown in Fig. 1-3 and Tab.1-2. Using methods-combining control charts a practical estimation of the MU can also be done easily.

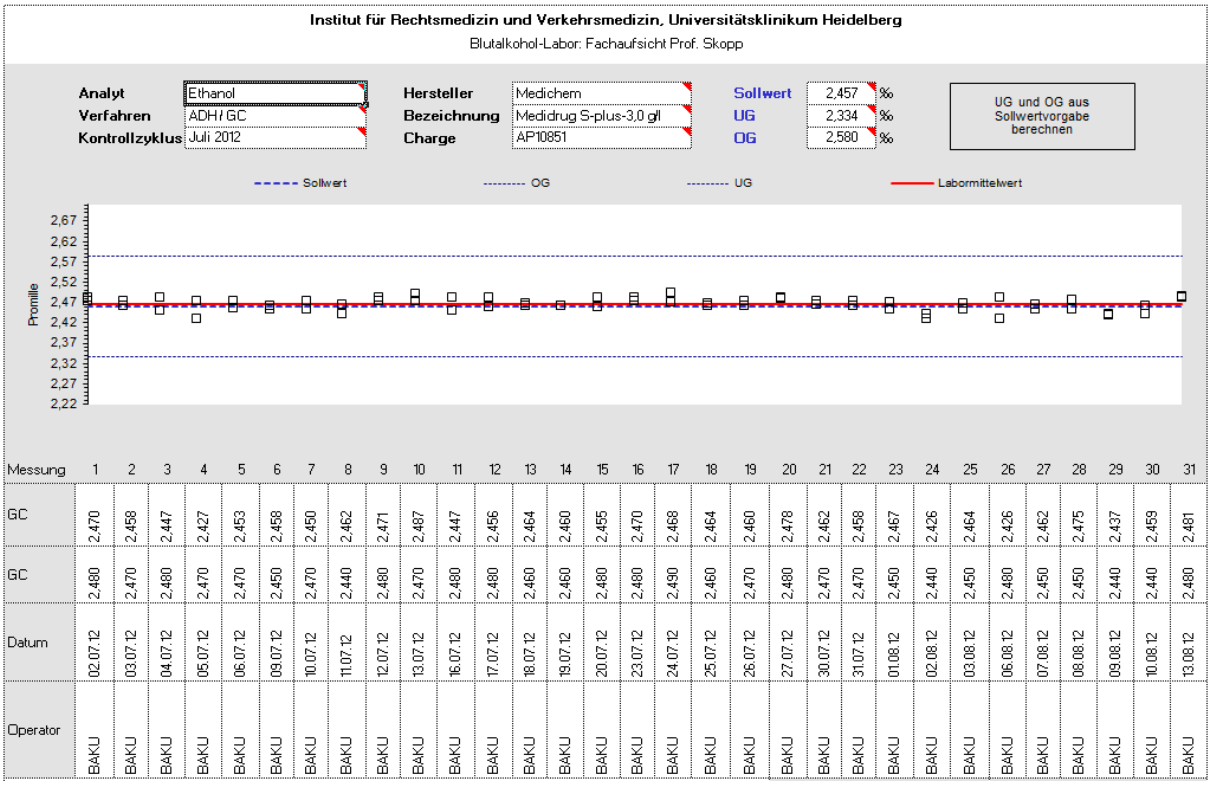

Fig.1. ADH method.

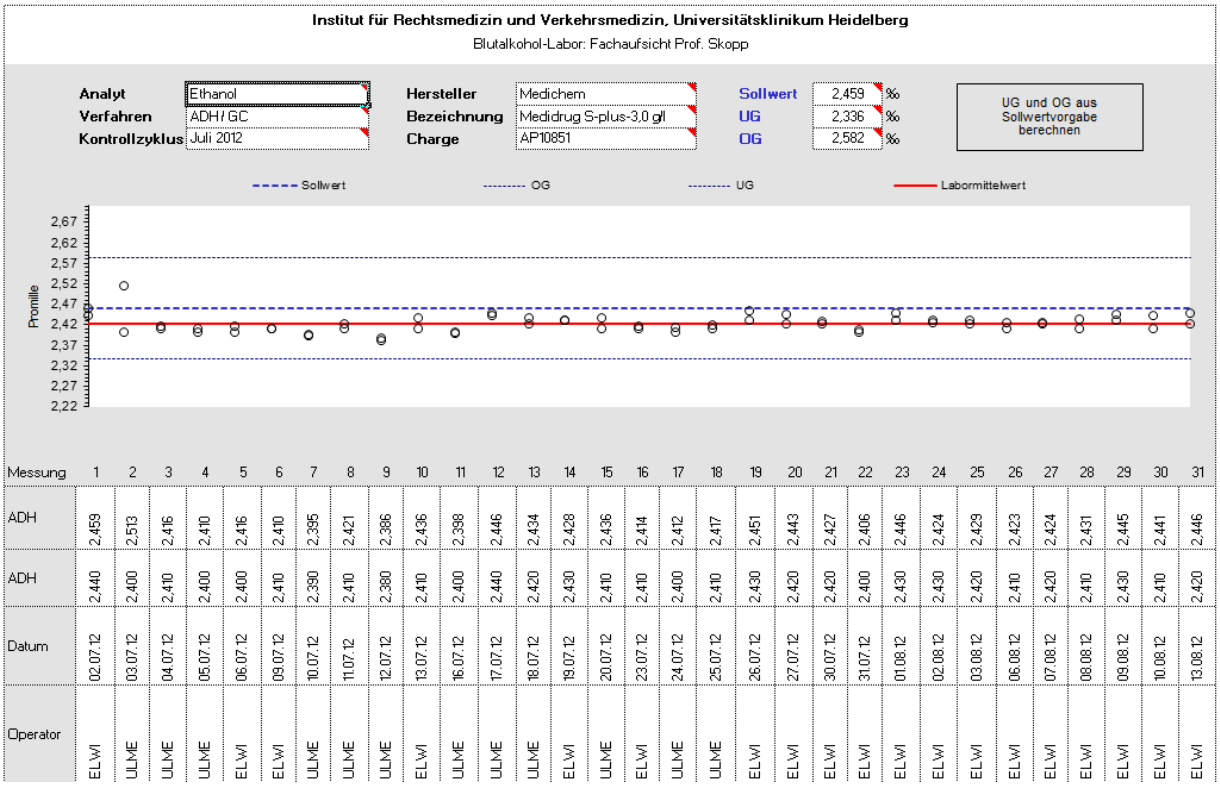

Fig.2. GC method.

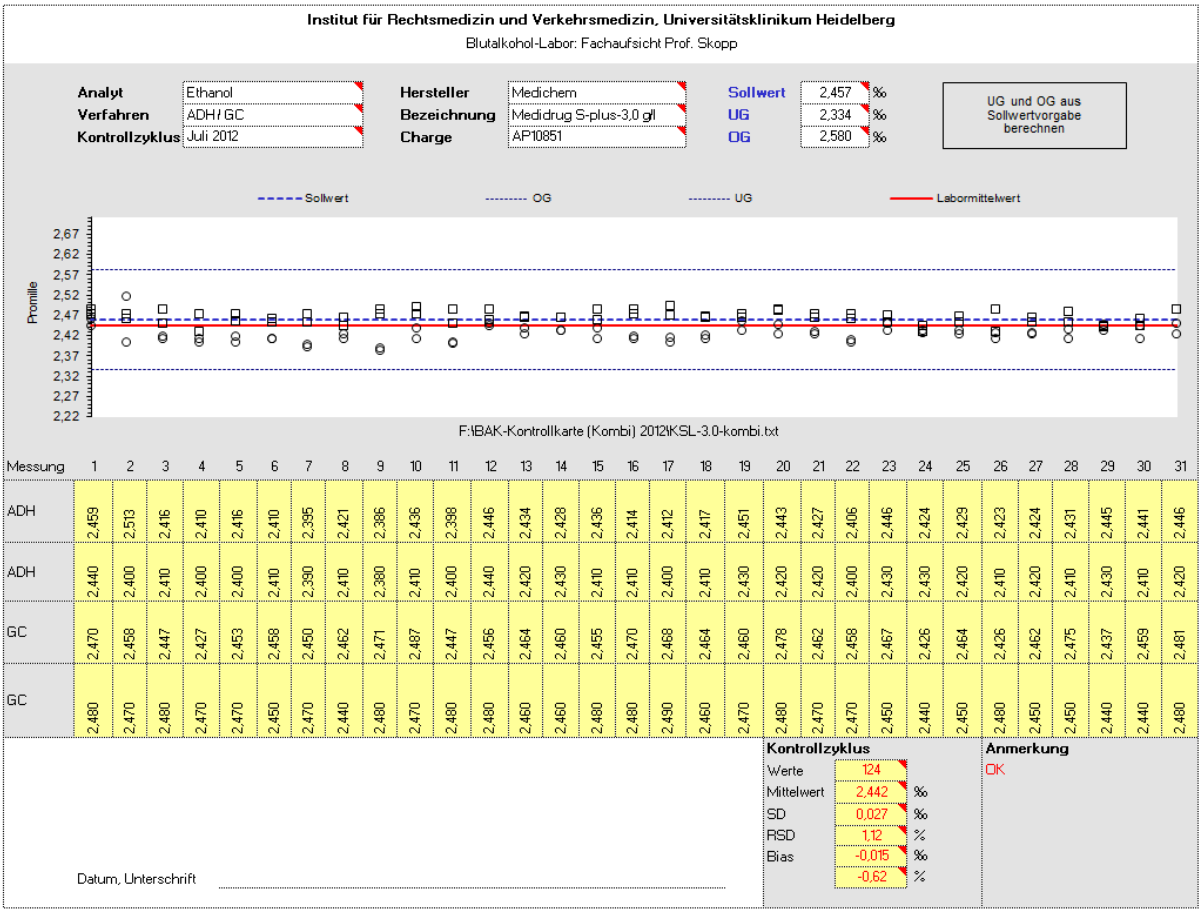

Fig.3. Combined methods.

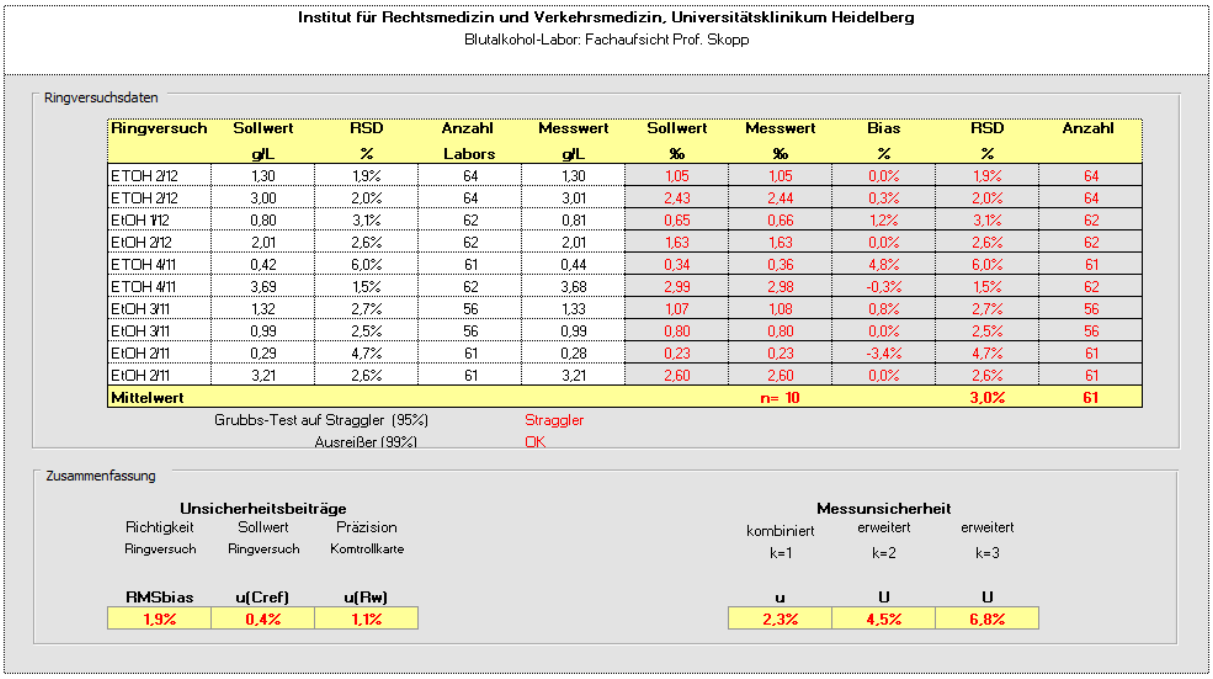

Fig.4. Combined measurement uncertainty.

Tab. 1. Precision data of reference material with 3 g/L.

	RSD, %
GC-method	0,62
ADH-method	0,85
combined methods	1,12

Tab. 2. Trueness estimated by proficiency tests according to the guidelines of the GTFCH [4].

Proficiency test	Target value, g/L	RSD, %	Labs	Own value, g/L
EtOH 2/12	1,30	1,9%	64	1,30
EtOH 2/12	3,00	2,0%	64	3,01
EtOH 1/12	0,80	3,1%	62	0,81
EtOH 2/12	2,01	2,6%	62	2,01
EtOH 4/11	0,42	6,0%	61	0,44
EtOH 4/11	3,69	1,5%	62	3,68
EtOH 3/11	1,32	2,7%	56	1,33
EtOH 3/11	0,99	2,5%	56	0,99
EtOH 2/11	0,29	4,7%	61	0,28
EtOH 2/11	3,21	2,6%	61	3,21

The handling of the program was demonstrated at the GTFCh-symposium in Mosbach. For GTFCh-members a download is available on the GTFCh-Homepage (www.gtfch.org).

4. Conclusion

The software complies with the current version of the BAC-guidelines and can easily be applied.

5. References

[1] Guide to the Expression of Uncertainty in Measurement (Geneva, Switzerland: International Organisation for Standardisation). ISBN 92-67-10188-9, 1995.

[2] Nordtest Technical Report 537. Handbook for Calculation of Measurement Uncertainty in Environmental Laboratories, 2003.

[3] Forensic blood alcohol determination: Monitoring of precision and accuracy using control charts combining results of the two stipulated methods (2008). Blutalkohol 45, 221-231.

[4] Richtlinien zur Bestimmung der Blutalkoholkonzentration im Blut (BAK) für forensische Zwecke: BAK-Richtlinien. Herausgegeben von der Deutschen Gesellschaft für Rechtsmedizin, der Deutschen Gesellschaft für Verkehrsmedizin und der Deutschen Gesellschaft für Toxikologie und Forensische Chemie. Blutalkohol 2011;48:137-143.

[5] Richtlinien der GTFCh zur Qualitätssicherung bei forensisch-toxikologischen Untersuchungen. Toxichem Krimtech 2009;76:42-176.