Exhaled Breath Alcohol - Quality Assurance in the Field of Legal Metrology

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Abstract: Breath alcohol analyzers are widely accepted as legal measurement instruments used for determination of the mass concentration of alcohol in exhaled breath. The paper focuses on the following issues: configuration of experimental system; the assurance of traceability at the highest standards; calculation of Zeta score and Trueness test - E_n numbers, both for simulator system and CRMs; the influence of CO_2 and on the influence of the exhaled breath temperature when the human body's temperature increases up to 38, 39 or, in extreme conditions, up to 40^0C.

Key Words: *legal metrology, mass concentration, traceability, reference materials, breath analyser*

Introduction

It is well-known that on the one hand alcohol is a stimulant but on the other hand, from a medical point of view, it is a cellular toxin. After drinking, the alcohol diffuses through the stomach and the small intestine walls, passing via the capillaries into the bloodstream. Due to the ethanol property of being volatile a certain quantity of alcohol, proportional with blood alcohol concentration, transfers from blood to lung alveoli (in the same way that CO_2 goes from blood to the lung alveoli) in order to be eliminated from human body. In accordance with Henry's law, a fixed equilibrium is generated between the mass concentration of alcohol in the blood in the lungs (BAC) and the mass concentration of alcohol in the air in the lungs (BrAC), as a result of diffusion compensation process.

I. Experimental system

The experimental system [1], presented in figure 1 [2] consists of:
- CRMs-LNE or CRMs-INM,
- Alcocal Simulator System - a new wet Bath Simulator System with Depletion Compensation and
- Alcotest 9510 breath analyser, which is using a dual IR & EC technology

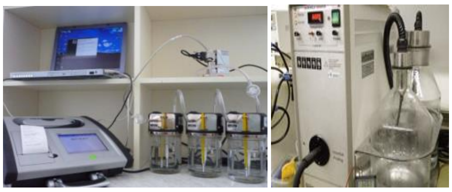

Figure 1. The calibration system used within the INM

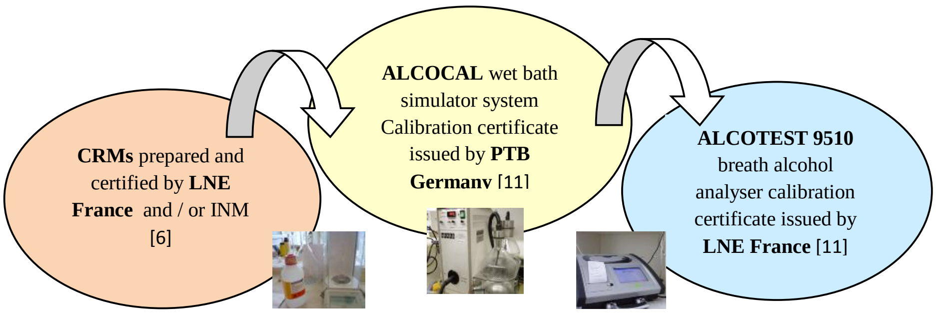

Figure 2. Measurement set-up for mass concentration of alcohol within simulated breath measurements

II. Results and discussions

Table 1. CRM prepared by LNE and used by INM [3], [4], [5]

Mass concentration of alcohol in standard solution	**LNE**	γ_{eth} [g/L]	0.2573	0.5146	0.9005	1.0292	1.8011	2.4444	3.8595
		U_{eth} [g/L]	0.0005	0.0006	0.0011	0.0012	0.0021	0.0028	0.0044
Mass concentration of alcohol in simulated breath		γ_{air} [mg/L]	0.1000	0.1995	0.3500	0.3990	0.6980	0.9500	1.500 0
		U_{air} [mg/L]	0.0033	0.0033	0.0033	0.0033	0.0033	0.0033	0.003 3
Mass concentration of alcohol in standard solution	**INM**	γ_{eth} [g/L]	0.2628	0.5206	0.9073	1.0363	1.8097	2.4543	3.8723
		U_{eth} [g/L]	$4.27\cdot10^{-5}$	$8.46\cdot10^{-4}$	$1.47\cdot10^{-4}$	$1.68\cdot10^{-4}$	$2.94\cdot10^{-4}$	$3.99\cdot10^{-4}$	$6.29\cdot10^{-4}$
Mass concentration of alcohol in simulated breath		γ_{air} [mg/L]	0.102	0.201	0.351	0.401	0.700	0.949	1.497
		U_{air} [mg/L]	$7.05\cdot10^{-6}$	$2.77\cdot10^{-5}$	$8.40\cdot10^{-5}$	$1.10\cdot10^{-4}$	$3.34\cdot10^{-4}$	$6.15\cdot10^{-4}$	$1.53\cdot10^{-4}$

Table 2. The comparison between the results of measurement data [4], [5], [6], [7], [8]

LNE laboratory data using - LNE-CRMs, LNE-simulator system and breath alcohol analyser Alcotest 9510 type							
$\gamma_{CRM-LNE}$,[mg/L]	-	0.200	-	0.400	0.700	-	1.500
$\gamma_{smallest}$, [mg/L]	-	0.201	-	0.406	0.716	-	1.556
$\gamma_{highest}$, [mg/L]	-	0.204	-	0.410	0.723	-	1.562
$\gamma_{average}$, [mg/L]	-	0.202 8	-	0.407 8	0.718 8	-	1.558 6
s, [mg/L]	-	0.001 0	-	0.003 0	0.002 5	-	0.001 9
RSD, %	-	0.51	-	0.74	0.35	-	0.12
INM laboratory data using -LNE-CRMs, Alcocal-simulator system and breath alcohol analyser Alcotest 9510 type							
$\gamma_{CRM-LNE}$, [mg/L]	0.100 0	0.199 5	0.350 0	0.399 0	0.698 0	0.950 0	1.500 0
$\gamma_{smallest}$, [mg/L]	0.092	0.196	0.354	0.407	0.720	0.981	1.572
$\gamma_{highest}$, [mg/L]	0.094	0.197	0.356	0.410	0.725	0.990	1.586
$\gamma_{average}$, [mg/L]	0.093 4	0.196 2	0.354 8	0.408 4	0.722 5	0.986 4	1.581 1
s, [mg/L]	0.000 7	0.000 4	0.000 8	0.001 3	0.001 4	0.003 5	0.004 7
RSD, %	0.75	0.21	0.22	0.31	0.20	0.36	0.30
Recovery	0.983	0.934	1.014	1.167	1.035	1.413	1.054
$s_{\_Recovery}$	0.007 0	0.002 1	0.002 3	0.003 6	0.002 1	0.005 0	0.003 1
$u_{\_Recovery}$	0.000 22	0.000 13	0.000 25	0.000 40	0.000 45	0.001 11	0.001 49
INM laboratory data using -INM-CRMs, Alcocal-simulator system and breath alcohol analyser Alcotest 9510 type							
$\gamma_{CRM-LNE}$, [mg/L]	0.102	0.201	0.351	0.401	0.700	0.949	1.497
$\gamma_{smallest}$, [mg/L]	0.097	0.198	0.356	0.410	0.715	0.969	1.537
$\gamma_{highest}$, [mg/L]	0.102	0.205	0.364	0.418	0.727	0.985	1.562
$\gamma_{average}$, [mg/L]	0.0991	0.2027	0.3603	0.4136	0.7212	0.9772	1.5505
s, [mg/L]	0.0016	0.0022	0.0025	0.0028	0.0043	0.0050	0.0064
RSD, %	1.61	1.09	0.68	0.68	0.59	0.51	0.41
u_c , mg/L	$9.824\cdot10^{-4}$	$1.096\cdot10^{-3}$	$1.148\cdot10^{-3}$	$1.227\cdot10^{-3}$	$1.625\cdot10^{-3}$	$1.902\cdot10^{-3}$	$2.682\cdot10^{-3}$
U, mg/L (k=2)	$1.96\cdot10^{-3}$	$2.19\cdot10^{-3}$	$2.30\cdot10^{-3}$	$2.45\cdot10^{-3}$	$3.25\cdot10^{-3}$	$3.80\cdot10^{-3}$	$5.36\cdot10^{-3}$

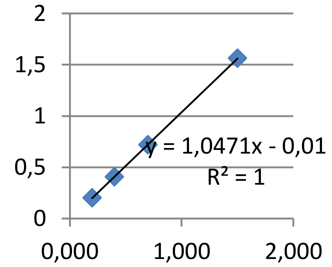

Figure 3. Calibration curve using

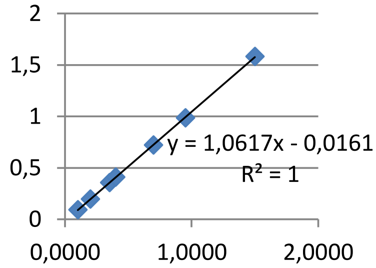

Figure 4. Calibration curve using

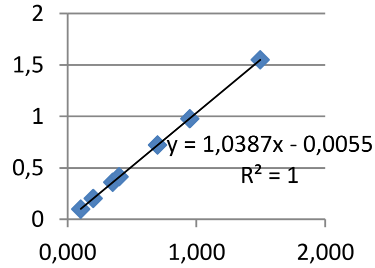

Figure 5. Calibration curve using

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CRMs-LNE & LNE simulator system   CRMs-LNE & INM simulator system   CRMs-INM & INM simulator system

Table 3 – Zeta score and Trueness test - E_n numbers - Proficiency Testing Eurachem Guide [9]
CRMs-LNE, LNE simulator system or ALCOCAL simulator system, Alcotest 9510 breath analyser

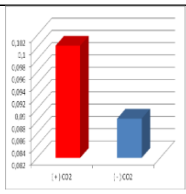
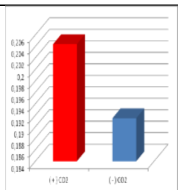
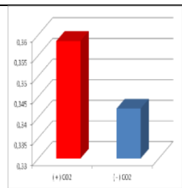
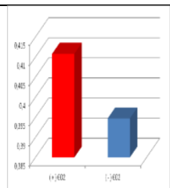
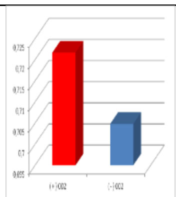
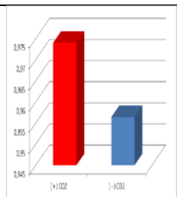
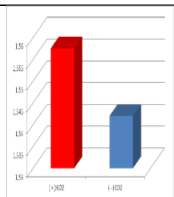
	γ, [mg/L]	**u,** [mg/L]	**RSU,** [%]		**γ,** [mg/L]	**u,** [mg/L]	**RSU,** [%]
$\gamma_{CRM-LNE}$	0.200 1 mg/L			$\gamma_{CRM-LNE}$	0.400 1 mg/L		
γ_{m-LNE}	0.202 80	0.002 50	1.23	γ_{m-LNE}	0.407 80	0.002 50	0.61
$\gamma_{CRM-LNE}$	0.199 5 mg/L			$\gamma_{CRM-LNE}$	0.399 0 mg/L		
γ_m	0.196 20	0.001 93	1.00	γ_m	0.408 40	0.004 79	1.17
Z_{score}	**2.089**			Z_{score}	**0.111**		
E_n	**1.045**			E_n	**0.055**		
$\gamma_{CRM-LNE}$	0.699 8			$\gamma_{CRM-LNE}$	1.555 0		
γ_{m-LNE}	0.719 00	0.004 35	0.61	γ_{m-LNE}	1.558 60	0.004 68	0.30
$\gamma_{CRM-LNE}$	0.698 0			$\gamma_{CRM-LNE}$	1.500 0		
γ_m	0.722 50	0.013 31	1.84	γ_m	1.581 10	0.045 93	2.90
Z_{score}	**0.250**			Z_{score}	**0.487**		
E_n	**0.125**			E_n	**0.244**		

Table 4 – Zeta score and Trueness test - E_n numbers – Proficiency Testing Eurachem Guide [9]
CRMs-LNE or CRMs-INM, ALCOCAL simulator system, Alcotest 9510 breath analyser

	γ, [mg/L]	**u,** [mg/L]	**RSU,** [%]		**γ,** [mg/L]	**u,** [mg/L]	**RSU,** [%]
γ_{CRM},[mg/L]	0.1000	0.001 65	1.65	γ_{CRM},[mg/L]	0.199 5	0.001 65	0.83
γ_m, [mg/L]	0.093 4	0.003 32	3.55	γ_m, [mg/L]	0.196 2	0.001 93	0.98
R	0.934 0	0.015 3	1.64	***R***	0.983 5	0.008 1	0.82
Z_{score}	**1.780**			Z_{score}	**1.299**		
E_n	**0.890**			E_n	**0.650**		
γ_{CRM},[mg/L]	0.350 0	0.0016 5	0.47	γ_{CRM},[mg/L]	0.399 0	0.001 65	0.41
γ_m, [mg/L]	0.354 8	0.002 49	0.70	γ_m, [mg/L]	0.408 4	0.004 79	1.17
R	1.013 7	0.004 8	0.47	***R***	1.023 6	0.004 3	0.42
Z_{score}	**1.609**			Z_{score}	**1.854**		
E_n	**0.805**			E_n	**0.927**		
γ_{CRM},[mg/L]	0.698 0	0.001 65	0.24	γ_{CRM},[mg/L]	0.950 0	0.001 65	0.17
γ_m, [mg/L]	0.722 5	0.013 31	1.84	γ_m, [mg/L]	0.986 4	0.020 16	2.04
R	1.035 1	0.002 5	0.24	***R***	1.038 3	0.002 1	0.21
Z_{score}	**1.827**			Z_{score}	**1.799**		
E_n	**0.914**			E_n	**0.900**		
γ_{CRM},[mg/L]	1.5000	0.001 65	0.11				
γ_m, [mg/L]	1.581 1	0.045 93	2.90				
R	1.054 1	0.001 5	0.14				
Z_{score}	**1.765**						
E_n	**0.882**						

Table 5. The influence of CO_2 at different mass concentrations of alcohol in exhaled breath [10]

γ_{CRM} [mg/L]	0.1000	0.1995	0.3500	0.3990
γ_m (- CO_2) [mg/L]	0.0884	0.1915	0.3421	0.3947
γ_m (+ CO_2) [mg/L]	0.1003	0.2044	0.3585	0.4108
RSD [%]	**11.90**	**6.47**	**4.69**	**4.04**

Graphical representation				
γ_{CRM} [mg/L]	0.6980	0.9500	1.5000	
γ_m (- CO_2) [mg/L]	0.7048	0.9564	1.5420	
γ_m (+ CO_2) [mg/L]	0.7217	0.9740	1.5575	
RSD [%]	**2.42**	**1.85**	**1.03**	
Graphical representation				

The temperature of a healthy human being is about 37 degrees Celsius while the exhaled breath temperature varies around 34 degrees Celsius. Taking into consideration that the body's temperature can have in extreme conditions about 40 degrees Celsius which means that a difference of about 3 degrees Celsius was found between the air temperature from alveoli and the breath exhaled temperature.

Table 6. The mass concentration of alcohol with 1 ^{0}C & 2 ^{0}C variation of breath temperature. Prediction for 3 ^{0}C [3]

CRM	[g/L]	**0.257 3**	**0.514 6**	**0.900 5**	**1.029 2**	**1.801 1**	**2.444 4**
$\mathbf{T_{34}}$	[^{0}C]	33.94	34.08	34.04	34.01	33.92	33.99
γ_{34}	[mg/L]	0.086 5	0.191 3	0.344 1	0.393 6	0.699 0	0.955 8
$\mathbf{T_{35}}$	[^{0}C]	34.98	35.02	35.30	34.97	35.08	35.12
γ_{35}	[mg/L]	0.094 3	0.205 4	0.374 9	0.422 2	0.756 3	1.031 8
$\mathbf{T_{36}}$	[^{0}C]	36.21	36.06	36.06	36.03	36.46	36.23
γ_{36}	[mg/L]	0.098 6	0.220 1	0.394 9	0.451 3	0.828 9	1.096 7
$\mathbf{T_{35}\text{-}T_{34}}$	[^{0}C]	1.04	0.95	1.26	0.96	1.16	1.13
$\gamma_{35}\text{-}\gamma_{34}$	[mg/L]	0.0078	0.014 1	0.030 8	0.028 6	0.055 3	0.076 1
$\Delta\gamma$, 1 ^{0}C more	[%]	**0.75**	**1.48**	**2.44**	**2.99**	**4.76**	**6.75**
$\mathbf{T_{36}\text{-}T_{34}}$	[^{0}C]	2,27	2.02	2.02	1.90	2.54	2.24
$\gamma_{36}\text{-}\gamma_{34}$	[mg/L]	0.012 1	0.028 8	0.050 8	0.057 8	0.129 9	0.141 0
$\Delta\gamma$, 2 ^{0}C more	[%]	**1.07**	**2.86**	**5.01**	**6.08**	**10.21**	**12.57**
Prediction γ_{37}	[mg/L]	0.1049	0.2293	0.4182	0.4758	0.8739	1.1671
$\Delta\gamma$, 3 ^{0}C more	[%]	**1.84**	**3.80**	**7.41**	**8.22**	**17.49**	**21.14**

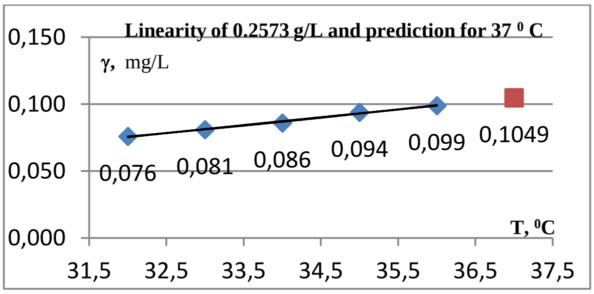


Figure 6 - Prediction of 0.2573 g/L for 37 ^{0} C [3]

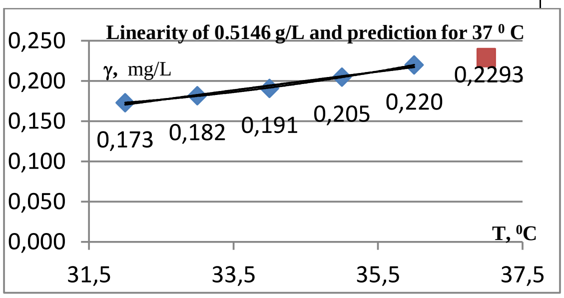


Figure 7- Prediction of 0.5146 g/L for 37 ^{0} C [3]

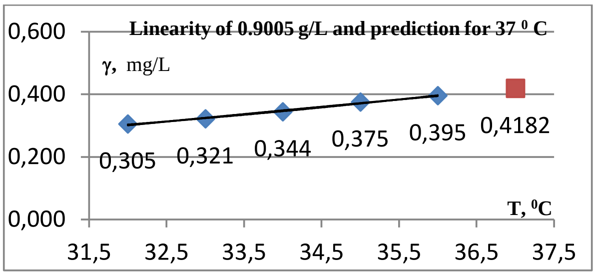


Figure 8 - Prediction of 0.9005 g/L for 37 ^{0} C [3]

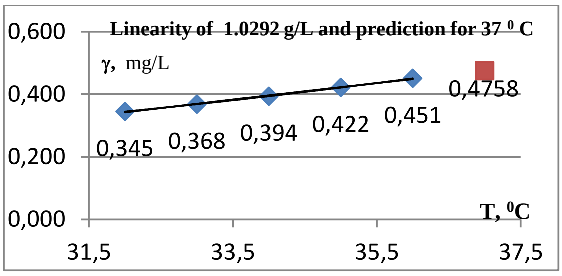


Figure 9 - Prediction of 1.0292 g/L for 37 ^{0} C [3]

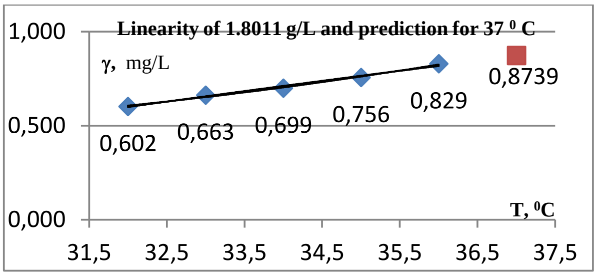


Figure 10 - Prediction of 1.8011 g/L for 37 ^{0} C, [3]

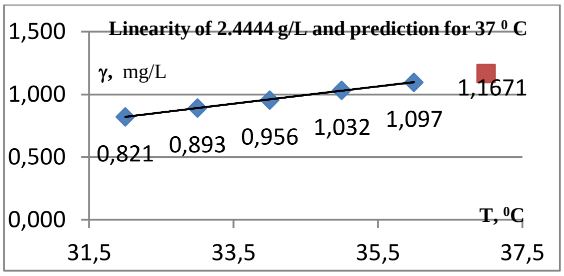


Figure 11 - Prediction of 2.444 4 g/L for 37 ^{0} C, [3]

III. Conclusions

Taking into account the measurements results, presented in tables 2-4 and figures 3-5, it is obvious the following: CRMs prepared by gravimetric method, AlcoCal wet simulator system and Alcotest 9510 configured with a dual IR & EC technology, demonstrated our good capabilities in the field of mass concentration of alcohol in exhaled breath. The tables 3 and 4 presents the results obtained during comparison of laboratories, and they are shown that the different simulator systems used involve a greater deviation of measurements results than the deviation due to the preparation process of standards (CRM's). Table 5 proves the fact that is mandatory to use the CO_2 in simulator system or to take into consideration its contribution to the final result of measurements. The temperature of a healthy human being is about 37 degrees Celsius while the exhaled breath temperature varies around 34 degrees Celsius. Taking into consideration a difference of about 3 degrees Celsius in mass concentration of alcohol, the table 6 and figures 6-11 are focused on the influence of the exhaled breath temperature when the human body's temperature increases up to 38, 39 or, in extreme conditions, up to 40 degrees Celsius.

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