

Design Verification

MAGNESIUM liquicolor

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1 Introduction

The performance characteristics of MAGNESIUM liquicolor multipurpose reagent were tested and documented in order to verify the clinical usefulness and compliance with the essential requirements of directive 98/79/EC.

Available kit sizes

Reagent	REF
MAGNESIUM liquicolor	10010

MAGNESIUM liquicolor multipurpose reagents are filled in original HUMAN reagent bottles.

Used Material

Analyzer	Company	REF
AU 480	Beckman Coulter	N3660400
HumaLyzer 4000	HUMAN	18250

2 Imprecision

The imprecision within-run / intra-assay of MAGNESIUM liquicolor multipurpose reagent on AU 480 was calculated from 20 determinations. The imprecision day-to-day / inter-assay was calculated by the means of 2 determinations on 20 consecutive days. 3 patient pools in the concentration ranges low, normal and high were employed as sample material.

Criteria

Imprecision	Acceptance criteria
within-run	CV ≤ 5.0%
day-to-day	CV ≤ 5.0%

Used Material

Reagent	Manufacturer	REF	LOT
MAGNESIUM liquicolor	HUMAN	10010	0087
AUTOCAL	HUMAN	13160	H016
Samples	3 patient pools, LOTs 180517EKO001, 180517EKO002, 180517EKO003		

Results

Imprecision within-run	Measured concentration (mg/dl)		
	Replicates	Low	Medium
1	1.72	3.08	4.26
2	1.74	3.10	4.24
3	1.85	3.15	4.23
4	1.85	3.15	4.29
5	1.83	3.16	4.30
6	1.84	3.16	4.30
7	1.88	3.12	4.27
8	1.86	3.14	4.25
9	1.84	3.17	4.25
10	1.80	3.19	4.26
11	1.84	3.17	4.31
12	1.85	3.16	4.32
13	1.79	3.18	4.32
14	1.82	3.15	4.36
15	1.84	3.15	4.32
16	1.82	3.20	4.30
17	1.85	3.14	4.32
18	1.83	3.10	4.28
19	1.84	3.05	4.34
20	1.86	3.06	4.31
Mean	1.83	3.14	4.29

SD	0.04	0.04	0.04
CV%	2.1	1.3	0.8

Imprecision day-to-day	Measured concentration (mg/dl)								
	Low			Medium			High		
Day	Result 1	Result 2	Mean	Result 1	Result 2	Mean	Result 1	Result 2	Mean
1	1.72	1.74	1.73	3.08	3.10	3.09	4.26	4.24	4.25
2	1.69	1.67	1.68	3.05	2.89	2.97	4.13	4.13	4.13
3	1.61	1.69	1.65	3.15	3.13	3.14	4.34	4.37	4.36
4	1.61	1.60	1.61	3.03	3.00	3.02	4.28	4.33	4.31
5	1.72	1.73	1.73	3.13	3.08	3.11	4.38	4.39	4.39
6	1.63	1.69	1.66	3.09	3.15	3.12	4.33	4.44	4.39
7	1.61	1.62	1.62	3.10	3.07	3.09	4.44	4.43	4.44
8	1.73	1.67	1.70	3.07	3.04	3.06	4.27	4.24	4.26
9	1.57	1.59	1.58	3.06	3.01	3.04	4.24	4.24	4.24
10	1.55	1.66	1.61	2.93	2.88	2.91	4.25	4.20	4.23
11	1.71	1.61	1.66	3.00	2.89	2.95	4.11	4.11	4.11
12	1.67	1.77	1.72	3.10	3.01	3.06	4.21	4.29	4.25
13	1.89	1.99*	1.89	3.48	3.45	3.47	4.81	4.83	4.82
14	1.83	1.81	1.82	3.13	3.05	3.09	4.37	4.31	4.34
15	1.83	1.78	1.81	3.11	3.14	3.13	4.27	5.10	4.69
16	1.64	1.66	1.65	2.98	2.94	2.96	4.13	4.20	4.17
17	1.76	1.72	1.74	2.98	2.90	2.94	4.23	4.15	4.19
18	1.73	1.73	1.73	2.97	2.92	2.95	4.16	4.15	4.16
19	1.75	1.75	1.75	2.96	2.86	2.91	4.09	4.12	4.11
20	1.76	1.76	1.76	2.88	2.85	2.87	4.01	4.00	4.01
Mean			1.70			3.04			4.29
SD			0.08			0.13			0.19
CV%			4.7			4.3			4.5

*outlier, excluded from calculation

Conclusion

MAGNESIUM liquicolor multipurpose reagent on AU 480 fulfilled the within-run / intra-assay and day-to-day / inter-assay precision acceptance criteria in the low (~1.75 mg/dl), medium (~3.00 mg/dl), and high (4.29 mg/dl) concentration range: CV ≤ 5.0 %

3 Linearity and Sensitivity

3.1 Linearity

The linearity of MAGNESIUM liquicolor multipurpose reagent on AU 480 was determined by employing a high concentrated serum pool successively diluted in steps of about 10% with distilled water. The analysed concentrations (n=2) were compared with the calculated concentrations obtained from a linear regression.

Criteria

Linearity	Acceptance criteria
Deviation from regression line	≤ 10 %

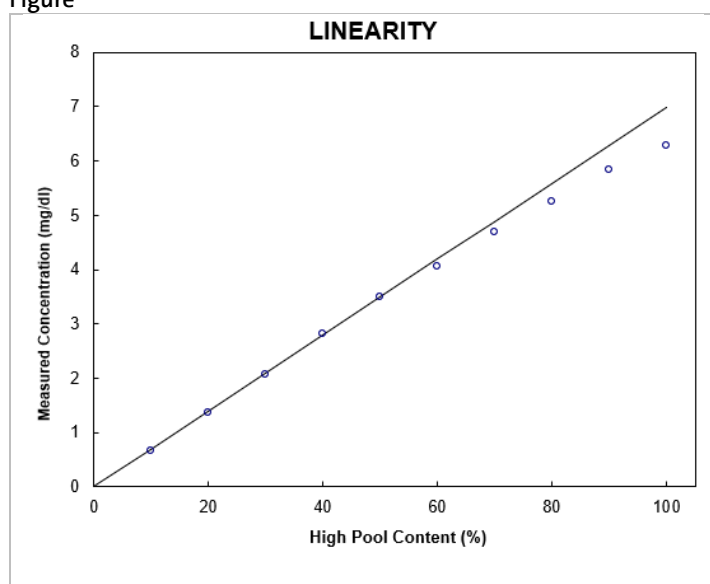
Used Material

Reagent	Manufacturer	REF	LOT
MAGNESIUM liquicolor	HUMAN	10010	0087
AUTOCAL	HUMAN	13160	H016
Sample	Diluted serum pool, LOT BOG243		

Results

High Pool Content (%)	Analytical Data (mg/dl)	Regressed Data (mg/dl)	Deviation from Regression Line	
			(mg/dl)	(%)
0	-0.13	0.00	-0.13	
10	0.68	0.70	-0.02	-3.4
20	1.38	1.40	-0.02	-1.6
30	2.08	2.10	-0.02	-1.0
40	2.82	2.79	0.03	0.9
50	3.50	3.49	0.01	0.2
60	4.07	4.19	-0.12	-2.9
70	4.70	4.89	-0.19	-3.9
80	5.25	5.59	-0.34	-6.1
90	5.85	6.29	-0.44	-7.0
100	6.29	6.99	-0.70	-10.1

Figure



Conclusion

The linearity of MAGNESIUM liquicolor multipurpose reagent on AU 480 is confirmed up to 5.0 mg/dl (or 2.05 mmol/l) at least.

3.2 Sensitivity (LoD)

The limit of detection (LoD) of MAGNESIUM liquicolor on HumaLyzer 4000 was evaluated from a 20-fold determination of physiological saline. The concentrations were manually calculated from the absorbance values. The LoD was calculated as follows: absolute result mean + 3 SD. The values are rounded in the last step.

Material

Reagent	Manufacturer	REF	LOT
Magnesium	HUMAN	10011	16009
Mg Standard	HUMAN	10011	0025
Sample	physiological saline		

Results

Absorbance values 1 (mAbs)	Absorbance values 2 [mAbs]	Delta Absorbance values [mAbs]	Calculated Result mg/dl
866.89	867.07	-0.2	-0.004
865.94	867.07	-1.1	-0.024
865.40	867.07	-1.7	-0.036
865.43	867.07	-1.6	-0.035
865.35	867.07	-1.7	-0.037
865.33	867.07	-1.7	-0.037
865.51	867.07	-1.6	-0.033
865.14	867.07	-1.9	-0.041
865.39	867.07	-1.7	-0.036
865.95	867.07	-1.1	-0.024
865.40	867.07	-1.7	-0.036
865.45	867.07	-1.6	-0.035
865.83	867.07	-1.2	-0.026
865.71	867.07	-1.4	-0.029
866.30	867.07	-0.8	-0.016
865.87	867.07	-1.2	-0.026
865.72	867.07	-1.3	-0.029
865.68	867.07	-1.4	-0.030
866.79	867.07	-0.3	-0.006
867.49	867.07	0.4	0.009
		Mean	-0.03
		SD	0.01
		LoD	0.07

Conclusion

The limit of detection (LoD) of MAGNESIUM liquicolor multipurpose reagent on Humalyzer 4000 was found 0.07 mg/dl.

4 Recovery of Control Sera

A number of commercially available control sera were employed on AU 480. The control sera were reconstituted/prepared according to the manufacturer's instructions. The mean value (n=3) was calculated and compared with the allowable range of the respective control sera.

Criteria

Check	Acceptance criteria
Recovery	within range

Used Material

Reagent	Manufacturer	REF	LOT
MAGNESIUM liquicolor	HUMAN	10010	0087
AUTOCAL	HUMAN	13160	H016
Sample	HUMAN's and commercial controls (Beckman Coulter, Pointe Pointe Scientific)		

Results

Control recovery					
Name	LOT	Target mg/dl	Range mg/dl	Result mg/dl	Within range YES/NO
HumaTrol N	0005	2.02	1.70 – 2.34	2.02	YES
HumaTrol P	0004	3.00	2.52 – 3.48	3.04	YES
SERODOS	0004	2.25	1.89 – 2.61	2.21	YES
SERODOS ^{plus}	0004	3.06	2.57 – 3.55	3.27	YES

Pointe Control L1	724001	1.60	1.20 – 2.00	1.70	YES
Pointe Control L2	717402	3.50	2.60 – 4.40	3.52	YES
Control serum L1	1039	2.58	2.16 – 2.99	2.61	YES
Control serum L2	1040	4.16	3.49 – 4.82	4.07	YES
Mean		2.77		2.81	Dev.%
					1.4

Recovery of control sera using MAGESIUM liquicolor multipurpose reagent yielded a good/acceptable result.

Conclusion

Control findings of MAGNESIUM liquicolor multipurpose reagent met acceptance criteria.

5 Comparison of Methods

MAGNESIUM liquicolor multipurpose reagent on AU 480 (test) were compared against Magnesium, Beckman Coulter, on AU 480 (reference). Patient samples (serum, n = 145) were included to the comparison.

The results were evaluated by a non-parametric regression analysis according to Passing and Bablok.

Criteria

Passing and Bablok	Acceptance criteria
Slope (with CI borders)	0.95 – 1.05
Correlation coefficient	r > 0.95

Used Material

Reagent	Manufacturer	REF	LOT
MAGNESIUM liquicolor (test)	HUMAN	10010	0087
AUTOCAL (test)	HUMAN	13160	H016
Magnesium (reference)	Beckman Coulter	OSR6189	9450XXX
System calibrator (reference)	Beckman Coulter	663000	1120
Sample	Patient samples (serum)		

Results

Sample-no.	UNIT	Mean Reference AU 480	Mean Test AU 480	Difference
1	mg/dl	2.30	2.33	0.025
2	mg/dl	2.13	2.12	-0.010
3	mg/dl	2.08	1.99	-0.090
4	mg/dl	2.01	2.03	0.020
5	mg/dl	1.84	1.85	0.010
6	mg/dl	2.26	2.26	0.005
7	mg/dl	2.13	2.06	-0.070
8	mg/dl	2.20	2.12	-0.080
9	mg/dl	2.15	2.11	-0.035
10	mg/dl	2.04	2.01	-0.030
11	mg/dl	2.05	2.00	-0.050
12	mg/dl	2.17	2.15	-0.025
13	mg/dl	2.31	2.30	-0.005
14	mg/dl	2.09	2.13	0.040
15	mg/dl	2.11	2.13	0.020
16	mg/dl	2.35	2.29	-0.055
17	mg/dl	2.44	2.42	-0.020
18	mg/dl	2.30	2.30	0.000
19	mg/dl	2.43	2.37	-0.060
20	mg/dl	2.21	2.19	-0.020
21	mg/dl	2.24	2.22	-0.020
22	mg/dl	2.11	2.13	0.015
23	mg/dl	2.43	2.19	-0.240
24	mg/dl	2.15	2.16	0.015
25	mg/dl	1.93	1.88	-0.050

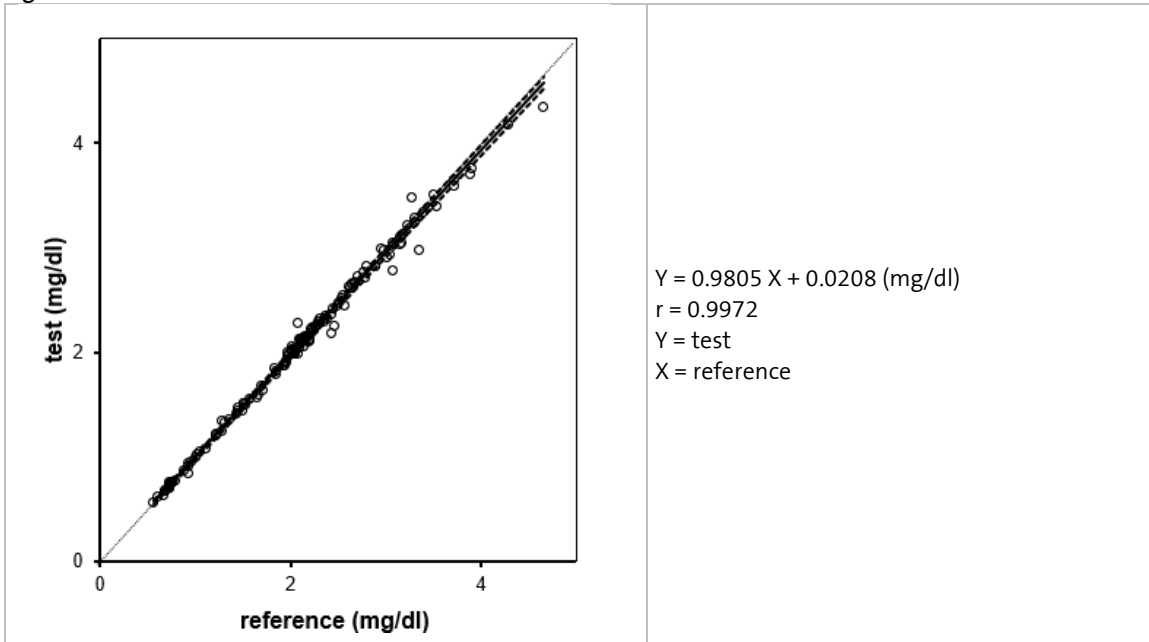


26	mg/dl	2.11	2.11	0.000
27	mg/dl	2.09	2.05	-0.035
28	mg/dl	2.23	2.23	0.000
29	mg/dl	2.01	2.06	0.050
30	mg/dl	2.06	2.04	-0.015
31	mg/dl	2.04	2.05	0.010
32	mg/dl	2.14	2.14	-0.005
33	mg/dl	1.98	1.99	0.010
34	mg/dl	2.21	2.22	0.015
35	mg/dl	2.05	1.99	-0.060
36	mg/dl	2.14	2.15	0.005
37	mg/dl	2.07	2.28	0.205
38	mg/dl	2.20	2.12	-0.075
39	mg/dl	2.20	2.13	-0.065
40	mg/dl	2.02	1.99	-0.030
41	mg/dl	2.38	2.33	-0.050
42	mg/dl	2.18	2.11	-0.070
43	mg/dl	2.29	2.27	-0.020
44	mg/dl	2.11	2.13	0.020
45	mg/dl	2.25	2.24	-0.010
46	mg/dl	2.35	2.32	-0.025
47	mg/dl	2.14	2.14	0.005
48	mg/dl	1.96	1.91	-0.050
49	mg/dl	1.97	2.01	0.035
50	mg/dl	2.37	2.35	-0.020
51	mg/dl	1.69	1.69	-0.005
52	mg/dl	1.44	1.45	0.010
53	mg/dl	1.43	1.42	-0.015
54	mg/dl	1.50	1.51	0.010
55	mg/dl	2.02	2.02	0.000
56	mg/dl	1.97	1.96	-0.010
57	mg/dl	1.93	1.88	-0.050
58	mg/dl	1.95	1.92	-0.030
59	mg/dl	1.65	1.57	-0.080
60	mg/dl	1.49	1.45	-0.040
61	mg/dl	1.70	1.64	-0.060
62	mg/dl	1.85	1.79	-0.060
63	mg/dl	1.66	1.60	-0.060
64	mg/dl	1.52	1.50	-0.020
65	mg/dl	1.57	1.56	-0.010
66	mg/dl	1.28	1.26	-0.025
67	mg/dl	1.85	1.82	-0.025
68	mg/dl	1.45	1.48	0.030
69	mg/dl	1.51	1.52	0.015
70	mg/dl	1.31	1.34	0.025
71	mg/dl	0.67	0.64	-0.025
72	mg/dl	0.73	0.71	-0.020
73	mg/dl	0.92	0.85	-0.070
74	mg/dl	0.76	0.77	0.010
75	mg/dl	0.73	0.71	-0.015
76	mg/dl	0.60	0.62	0.015
77	mg/dl	0.76	0.77	0.005
78	mg/dl	0.68	0.68	-0.005
79	mg/dl	0.73	0.77	0.035
80	mg/dl	0.76	0.77	0.005
81	mg/dl	1.22	1.21	-0.010
82	mg/dl	1.22	1.22	0.000
83	mg/dl	1.01	1.02	0.010
84	mg/dl	0.88	0.87	-0.015
85	mg/dl	0.72	0.72	0.000

86	mg/dl	0.56	0.56	0.000
87	mg/dl	1.27	1.35	0.075
88	mg/dl	1.36	1.37	0.010
89	mg/dl	1.10	1.09	-0.015
90	mg/dl	0.73	0.73	0.000
91	mg/dl	1.05	1.05	-0.002
92	mg/dl	0.96	0.95	-0.010
93	mg/dl	1.01	1.00	-0.005
94	mg/dl	0.92	0.95	0.025
95	mg/dl	0.93	0.92	-0.010
96	mg/dl	0.79	0.78	-0.005
97	mg/dl	0.74	0.75	0.010
98	mg/dl	0.69	0.70	0.010
99	mg/dl	0.68	0.67	-0.005
100	mg/dl	0.73	0.75	0.025
101	mg/dl	2.53	2.53	-0.005
102	mg/dl	2.46	2.25	-0.205
103	mg/dl	2.67	2.67	0.000
104	mg/dl	2.89	2.83	-0.060
105	mg/dl	2.70	2.73	0.035
106	mg/dl	2.88	2.83	-0.050
107	mg/dl	3.17	3.06	-0.110
108	mg/dl	3.39	3.34	-0.045
109	mg/dl	3.53	3.41	-0.120
110	mg/dl	3.71	3.60	-0.115
111	mg/dl	2.50	2.48	-0.020
112	mg/dl	2.64	2.67	0.025
113	mg/dl	2.80	2.83	0.030
114	mg/dl	3.09	3.04	-0.055
115	mg/dl	3.08	3.06	-0.020
116	mg/dl	3.30	3.29	-0.015
117	mg/dl	3.14	3.10	-0.040
118	mg/dl	3.71	3.65	-0.060
119	mg/dl	3.89	3.71	-0.175
120	mg/dl	4.29	4.18	-0.115
121	mg/dl	2.23	2.24	0.005
122	mg/dl	2.63	2.62	-0.010
123	mg/dl	3.07	2.78	-0.285
124	mg/dl	2.95	2.99	0.045
125	mg/dl	2.57	2.45	-0.125
126	mg/dl	3.02	2.92	-0.100
127	mg/dl	3.05	2.94	-0.105
128	mg/dl	3.30	3.24	-0.055
129	mg/dl	3.44	3.39	-0.055
130	mg/dl	3.51	3.51	0.000
131	mg/dl	2.78	2.72	-0.055
132	mg/dl	3.18	3.14	-0.040
133	mg/dl	2.98	2.98	0.000
134	mg/dl	3.23	3.22	-0.015
135	mg/dl	3.14	3.03	-0.110
136	mg/dl	3.16	3.12	-0.040
137	mg/dl	3.27	3.49	0.220
138	mg/dl	3.34	2.99	-0.355
139	mg/dl	3.90	3.76	-0.140
140	mg/dl	4.66	4.36	-0.300
141	mg/dl	2.68	2.66	-0.015
142	mg/dl	2.76	2.77	0.010
143	mg/dl	2.49	2.45	-0.045
144	mg/dl	2.55	2.55	0.000
145	mg/dl	2.61	2.63	0.020

Mean	mg/dl	2.10	2.08	
Min	mg/dl	0.56	0.56	
Max	mg/dl	4.66	4.36	

Figure



Conclusion

MAGNESIUM liquicolor multipurpose reagent on AU 480 correlates well with Magensium, Beckman Coulter, on AU 480 ($r = 0.9972$), and no significant deviation could be observed with any specific sample:

$$Y = 0.9805 X + 0.0208 \text{ (mg/dl)}$$

$Y = \text{test}$, $X = \text{reference}$

6 Real-Time Stability

For real-time study, the MAGNESIUM liquicolor multipurpose reagent kit size was used. The reagent was stored at 2...25°C. The real-time stability was tested up to 125% of the shelf life at several intervals.

6.1 Recovery of Control sera

A number of commercially available control sera have been employed according to the procedure already described in section 4 on AU 480 or AU 400 analyzers. The mean values ($n=2$) obtained with fresh reagent (=reference) and 3 different reagent LOT/s have been calculated and compared.

Criteria

Check	Acceptance criteria
Recovery	within range
Difference of LOT to reference (mean), Dev%	$\leq 10\%$

Outliers are marked in grey

Material

Reagent	Manufacturer	REF	LOT
MAGNESIUM liquicolor	HUMAN	10010	15005, 15007, 19008
AUTOCAL	HUMAN	13160	H015, H016, 0018
Sample	HUMAN's and commercial controls (Beckman Coulter, INVICON, Pointe Scientific)		

Results

LOT 15005 / 0 months							
Name	LOT	Target mg/dl	Range mg/dl	Reference		0 months 2-25°C	
				Result mg/dl	Within range YES/NO	Result mg/dl	Within range YES/NO
HumaTrol N	0004	2.16	1.81 - 2.51	2.09	YES	2.05	YES
HumaTrol P	0003	3.39	2.85 - 3.93	3.22	YES	3.19	YES
SERODOS	0003	2.33	1.96 - 2.70	2.15	YES	2.15	YES
SERODOSplus	0003	3.20	2.69 - 3.71	3.07	YES	3.06	YES
Precinorm	176982	1.92	1.71 - 2.19	1.94	YES	1.94	YES
Precipath	174288	3.40	2.98 - 3.82	3.30	YES	3.27	YES
Control serum L1	0035	2.38	2.00 - 2.76	2.32	YES	2.32	YES
Control serum L2	0036	4.01	3.37 - 4.65	3.75	YES	3.78	YES
							Dev.%
Mean		2.85		2.73		2.72	-0.3

LOT 15005 / 30 months							
Name	LOT	Target mg/dl	Range mg/dl	Reference		30 months 2-25°C	
				Result mg/dl	Within range YES/NO	Result mg/dl	Within range YES/NO
HumaTrol N	0005	2.02	1.70 - 2.34	2.18	YES	2.15	YES
HumaTrol P	0004	3.00	2.52 - 3.48	3.18	YES	3.06	YES
SERODOS	0004	2.25	1.89 - 2.61	2.23	YES	2.21	YES
SERODOSplus	0004	3.06	2.57 - 3.55	3.23	YES	3.28	YES
Precinorm	186436	1.96	1.72 - 2.20	2.10	YES	2.09	YES
Precipath	186443	3.43	3.01 - 3.85	3.51	YES	3.48	YES
Control serum L1	0037	2.41	2.02 - 2.79	2.52	YES	2.50	YES
Control serum L2	0038	4.16	3.49 - 4.82	4.11	YES	4.44	YES
							Dev.%
Mean		2.79		2.88		2.90	0.3

LOT 15007 / 0 months							
Name	LOT	Target mg/dl	Range mg/dl	Reference		0 months 2-25°C	
				Result mg/dl	Within range YES/NO	Result mg/dl	Within range YES/NO
HumaTrol N	0004	2.16	1.81 - 2.51	1.93	YES	1.91	YES
HumaTrol P	0003	3.39	2.85 - 3.93	3.22	YES	3.14	YES
SERODOS	0003	2.33	1.96 - 2.70	2.17	YES	2.15	YES
SERODOSplus	0003	3.20	2.69 - 3.71	2.93	YES	2.94	YES
Precinorm	176367	1.95	1.71 - 2.19	1.93	YES	1.90	YES
Precipath	176371	3.35	2.96 - 3.74	3.15	YES	3.20	YES
Control serum L1	0035	2.38	2.00 - 2.76	2.24	YES	2.22	YES
Control serum L2	0036	4.01	3.37 - 4.65	3.65	YES	3.68	YES
							Dev.%
Mean		2.85		2.65		2.64	-0.5

LOT 15007 / 30 months							
Name	LOT	Target mg/dl	Range mg/dl	Fresh		30 months 2-25°C	
				Result mg/dl	Within range YES/NO	Result mg/dl	Within range YES/NO
HumaTrol N	0005	2.02	1.70 - 2.34	2.04	YES	2.10	YES
HumaTrol P	0004	3.00	2.52 - 3.48	2.99	YES	3.04	YES
SERODOS	0004	2.25	1.89 - 2.61	2.21	YES	2.20	YES
SERODOSplus	0004	3.06	2.57 - 3.55	3.26	YES	3.26	YES

Control serum L1	1039	2.41	2.02 - 2.79	2.66	YES	2.66	YES
Control serum L2	1040	4.16	3.49 - 4.82	4.16	YES	4.03	YES
Pointe Level 1	724001	1.60	1.20 - 2.00	1.47	YES	1.48	YES
Pointe Level 2	717402	3.50	2.60 - 4.40	3.45	YES	3.47	YES
							Dev.%
Mean		2.75		2.78		2.78	0.3

LOT 19008 / 6 months							
Name	LOT	Target mg/dl	Range mg/dl	Reference		6 months 2-25°C	
				Result mg/dl	Within range YES/NO	Result mg/dl	Within range YES/NO
HumaTrol N	0006	8.60	7.65 - 9.55	8.58	YES	8.57	YES
HumaTrol P	0005	12.9	11.5 - 14.3	13.5	YES	13.5	YES
SERODOS	0005	8.19	7.29 - 9.09	8.23	YES	8.24	YES
SERODOSplus	0007	12.1	11.4 - 12.9	13.4	YES	13.3	YES
Seronorm	1512606	9.18	8.63 - 9.73	8.83	YES	8.88	YES
Seronorm high	1801801	12.8	12.1 - 13.6	12.6	YES	12.7	YES
Control serum L1	1043	8.92	7.94 - 9.9	8.89	YES	8.81	YES
Control serum L2	1044	12.5	11.1 - 13.9	12.6	YES	12.7	YES
							Dev.%
Mean		10.9		10.8		10.8	0.1

LOT 19008 / 30 months							
Name	LOT	Target mg/dl	Range mg/dl	Fresh		30 months 2-25°C	
				Result mg/dl	Within range YES/NO	Result mg/dl	Within range YES/NO
HumaTrol N	0006	8.60	7.65 - 9.55	8.59	YES	2.10	YES
HumaTrol P	0005	12.9	11.5 - 14.3	13.4	YES	3.04	YES
SERODOS	0005	8.19	7.29 - 9.09	8.01	YES	2.20	YES
SERODOSplus	0007	12.1	11.4 - 12.9	12.3	YES	3.26	YES
Seronorm	1806848	8.82	8.29 - 9.35	8.64	YES	2.66	YES
Seronorm high	1801801	12.8	12.1 - 13.6	12.9	YES	4.03	YES
Control serum L1	1043	8.92	7.94 - 9.9	8.76	YES	1.48	YES
Control serum L2	1044	12.5	11.1 - 13.9	12.7	YES	3.47	YES
							Dev.%
Mean		10.6		10.7		10.71	-0.01

The data was accepted. A few data points for the reference were out of specifications, but all data for the reagent LOTs met the acceptance criteria of a control recovery within range, plus the difference of the means $\leq 10\%$.

Conclusion

The real-time stability data demonstrates a shelf life of MAGNESIUM liquicolor multipurpose reagent (REF 10010) of 24 months at 2...25°C.

6.2 Linearity

The MAGNESIUM liquicolor multipurpose reagent was stored at 2 - 25°C. The real-time stability was tested at several time points, covering a range of 0% to 125% of the shelf life.

Linearity was tested with a dilution series of a high-concentration analyte pool. The analytical results and the calculated results (linear regression) were compared. Tests were run with 3 different reagent LOTs on an AU480 or AU 400 analyzer.

Criteria

Linearity	Acceptance criteria
Range	0 to 5 mg/dl
Deviation from regression line	≤ 10%

Outliers are marked in grey

Used Material

Reagent	Manufacturer	REF	LOT
MAGNESIUM liquicolor	HUMAN	10010	15003
MAGNESIUM liquicolor	HUMAN	10010	15005
MAGNESIUM liquicolor	HUMAN	10010	15007
MAGNESIUM liquicolor	HUMAN	10010	19008
AUTOCAL	HUMAN	13160	H015, H016, 0018
Sample	High pool, LOT ERO122, physiological saline, LOT MZM122		

Results

LOT 15005/0 months				
High Pool Content (%)	Analytical Data mg/dl	Regressed Data mg/dl	Deviation from Regression Line	
			mg/dl	(%)
0	-0.04	0.00	-0.04	
10	0.71	0.67	0.04	6.2
20	1.37	1.34	0.03	2.1
30	2.02	2.01	0.01	0.5
40	2.74	2.67	0.06	2.3
50	3.41	3.34	0.07	2.0
60	4.00	4.01	-0.02	-0.4
70	4.59	4.68	-0.09	-1.9
80	5.19	5.35	-0.16	-3.0
90	5.66	6.02	-0.36	-6.0
100	6.26	6.68	-0.43	-6.4

LOT 15005/30 months				
High Pool Content (%)	Analytical Data mg/dl	Regressed Data mg/dl	Deviation from Regression Line	
			mg/dl	(%)
0	0.01	0.17	-0.17	
10	0.87	0.86	0.01	0.7
20	1.65	1.54	0.10	6.5
30	2.22	2.23	-0.01	-0.6
40	2.94	2.91	0.03	0.9
50	3.95	3.60	0.35	9.7
60	4.20	4.29	-0.09	-2.0
70	4.76	4.97	-0.22	-4.3
80	5.25	5.66	-0.41	-7.3
90	5.79	6.34	-0.56	-8.8
100	6.26	7.03	-0.77	-11.0

The linearity for LOT 15005 in these test series is within specifications for 0 - 5 mg/dl magnesium.

LOT 15007/0 months				
High Pool Content (%)	Analytical Data mg/dl	Regressed Data mg/dl	Deviation from Regression Line	
			mg/dl	(%)
0	-0.01	0.00	-0.01	

10	0.70	0.67	0.03	3.7
20	1.40	1.34	0.05	4.1
30	2.03	2.01	0.01	0.7
40	2.72	2.68	0.04	1.5
50	3.32	3.35	-0.04	-1.0
60	3.97	4.02	-0.05	-1.2
70	4.46	4.69	-0.23	-4.9
80	5.02	5.36	-0.35	-6.4
90	5,50	6,03	-0,54	-8,9
100	6,17	6,70	-0,54	-8,0

LOT 15007/30 months				
High Pool Content	Analytical Data	Regressed Data	Deviation from Regression Line	
(%)	mg/dl	mg/dl	mg/dl	(%)
0	0.01	0.08	-0.08	
10	0.81	0.78	0.03	4.3
20	1.49	1.47	0.01	0.8
30	2.25	2.17	0.07	3.5
40	2.87	2.87	0.00	-0.1
50	3.58	3.56	0.02	0.5
60	4.20	4.26	-0.06	-1.4
70	4.78	4.96	-0.18	-3.7
80	5.34	5.65	-0.32	-5.6
90	5.83	6.35	-0.52	-8.2
100	6.29	7.05	-0.76	-10.8

The linearity for LOT 15007 in these test series is within specifications for 0 - 5 mg/dl magnesium.

Results LOT 19008, 30 months

Range limit		Acceptance criteria max. Deviation from linearity	
From	To	Value	Unit
0	10	1	mg/dl
10	25	10	%

High pool [%]	Mean mg/dl	Predicted Polynomial		Difference (3 rd – 1 st)		Specification	
		1 st order	3 rd order	mg/dl	%	≤	✓
0	0.03	0.29	0.03	-0.26		1 mg/dl	✓
0.5	0.18	0.41	0.16	-0.25		1 mg/dl	✓
1	0.3	0.54	0.3	-0.24		1 mg/dl	✓
2	0.6	0.78	0.57	-0.21		1 mg/dl	✓
5	1.36	1.52	1.37	-0.15		1 mg/dl	✓
10	2.63	2.75	2.71	-0.04		1 mg/dl	✓
20	5.45	5.2	5.37	0.17		1 mg/dl	✓
30	7.86	7.66	7.99	0.33		1 mg/dl	✓
40	10.84	10.12	10.56		4.1	10 %	✓
50	12.93	12.57	13.06		3.8	10 %	✓
60	15.41	15.03	15.48		2.9	10 %	✓
70	17.82	17.49	17.8		1.7	10 %	✓
80	20.03	19.94	20.01		0.3	10 %	✓
90	22.13	22.4	22.1		-1.4	10 %	✓
100	24.03	24.85	24.05		-3.3	10 %	✓

MAGNESIUM liquicolor HumaStar system reagent is specified to cover a linear range on AU 480 as indicated in section 3: up to 5 mg/dl

The data was accepted. All data met acceptance criteria for the linear range of 0 - 5 mg/dl, with some outliers out of specifications for higher concentrations. The linear range of 0 - 5 mg/dl for 24 months at 2 – 25°C was confirmed.

Conclusion

The real-time stability data demonstrated a shelf life of MAGNESIUM liquicolor multipurpose reagent (REF 10010) of 24 months at 2 – 25°C.

7 Open-Vial Stability

For open-vial study, the MAGNESIUM liquicolor multipurpose reagent (REF 10010) was used. To examine the open-vial and calibration stability, the reagent was measured on several days. After usage, the reagent was closed properly and stored at.

The recovery of control sera of MAGNESIUM liquicolor multipurpose reagent, REF 10010 was checked according to the procedure already described in section 3 on AU 480. The mean values (n=2) obtained with fresh reagent (= reference) and opened reagent were calculated and compared with the fresh mean of the respective control sera.

Criteria

Check	Acceptance criteria
Recovery	within range
Deviation result mean from fresh mean	≤ 10%

Used Material

Reagent	Manufacturer	REF	LOT
MAGNESIUM liquicolor	HUMAN	10010	0070314
AUTOCAL	HUMAN	13160	H016
Sample	HUMAN's and commercial controls (Beckman Coulter, Pointe Scientific)		

Results

Control recovery				MAGNESIUM liquicolor, REF 10010		
				Fresh	1 day after opening	
Name	LOT	Target mg/dl	Range mg/dl	Result mg/dl	Result mg/dl	Within range YES/NO
HumaTrol N	0005	2.02	1.70 - 2.34	2.04	2.02	YES
HumaTrol P	0004	3.00	2.52 - 3.48	3.02	3.03	YES
SERODOS	0004	2.25	1.89 - 2.61	2.29	2.39	YES
SERODOS ^{plus}	0004	3.06	2.57 - 3.55	3.36	3.40	YES
Pointe Control 1	724001	1.60	1.20 – 2.00	1.51	1.41	YES
Pointe Control 2	717402	3.50	2.60 - 4.40	3.48	3.57	YES
Control Serum 1	1037	2.58	2.16 - 2.99	2.65	2.54	YES
Control Serum 2	1040	4.16	3.49 - 4.82	4.37	4.07	YES
						Dev.%
Mean		2.77		2.84	2.80	-1.2

Control recovery				MAGNESIUM liquicolor, REF 10010		
				Fresh	7 days after opening	
Name	LOT	Target mg/dl	Range mg/dl	Result mg/dl	Result mg/dl	Within range YES/NO
HumaTrol N	0005	2.02	1.70 - 2.34	2.04	2.11	YES
HumaTrol P	0004	3.00	2.52 - 3.48	3.02	3.07	YES
SERODOS	0004	2.25	1.89 - 2.61	2.29	2.32	YES
SERODOS ^{plus}	0004	3.06	2.57 - 3.55	3.36	3.32	YES

Pointe Control 1	724001	1.60	1.20 – 2.00	1.51	1.56	YES
Pointe Control 2	717402	3.50	2.60 - 4.40	3.48	3.53	YES
Control Serum 1	1037	2.58	2.16 - 2.99	2.65	2.68	YES
Control Serum 2	1040	4.16	3.49 - 4.82	4.37	4.18	YES
						Dev.%
Mean		2.77		2.84	2.80	0.2

The data were found within acceptance criteria.

Conclusion

The open-vial stability data for MAGNESIUM liquicolor multipurpose reagent (REF 10010) demonstrates an open-vial stability of 7 days at 2 – 25°C.

8 Interferences

Interference of MAGNESIUM liquicolor multipurpose reagent was studied by adding known amounts of the potentially interfering substance to a known sample. The deviation in recovery of spiked and unspiked samples was calculated and compared.

Criteria

Glick	Acceptance criteria
Glick number	≤ 2
Recovery spiked sample results vs unspiked result	90 – 110 %

Material

Reagent	Manufacturer	REF	LOT
MAGNESIUM liquicolor	HUMAN	10010	0087
AUTOCAL	HUMAN	13160	H016
Sample	Samples spiked with interfering substance		

Instrument	Manufacturer	REF
AU 480	Beckman Coulter	N3660400

Results

Ascorbic acid			Bilirubin			Hemoglobin		
Concentration	Analytical Results		Concentration	Analytical Result		Concentration	Analytical Result	
mg/dl	mg/dl	%	mg/dl	mg/dl	%	mg/dl	UNIT	%
0	1.64	100	0	1.61	100	0	1.53	100
2	1.62	98.8	4	1.61	100.3	50	1.57	102.6
4	1.62	98.8	8	1.63	101.2	100	1.60	104.9
6	1.62	99.1	12	1.65	102.5	150	1.64	107.5
8	1.62	99.1	16	1.67	103.7	200	1.67	109.2
10	1.60	97.9	20	1.67	104.0	250	1.72	112.8
12	1.61	98.2	24	1.70	105.6	300	1.76	115.1
14	1.62	99.1	28	1.69	105.3	350	1.77	115.7
16	1.61	98.2	32	1.72	106.9	400	1.82	119.0
18	1.61	98.5	36	1.75	108.7	450	1.84	120.3
20	1.62	99.1	40	1.75	109.0	500	1.89	123.6
Glick		1			2			3

Intralipid			Triglycerides			Calcium		
Concentration	Analytical Results		Concentration	Analytical Result		Concentration	Analytical Result	
mg/dl	mg/dl	%	mg/dl	mg/dl	%	mg/dl	mg/dl	%
0	1.53	100	0	1.38	100	0	1.55	100

100	1.53	100.0	250	1.38	100.0	3	1.57	101.6
200	1.57	103.0	500	1.40	101.4	6	1.56	101.0
300	1.57	103.0	750	1.39	100.4	9	1.57	101.6
400	1.55	101.6	1000	1.42	102.5	12	1.57	101.6
500	1.57	103.0	1250	1.39	100.7	15	1.56	101.0
600	1.59	104.3	1500	1.38	100.0	18	1.59	102.9
700	1.59	103.9	1750	1.40	101.1	21	1.59	102.9
800	1.60	104.6	2000	1.41	101.8	24	1.58	101.9
900	1.59	104.3	2250	1.38	100.0	27	1.61	103.9
1000	1.60	104.9	2500	1.40	101.1	30	1.61	104.2
Glick		2			1			2

Conclusion

No interference of MAGNESIUM liquicolor multipurpose reagent was detected up to following concentrations:

Interfering substance	AU 480
Ascorbic acid	up to 20 mg/dl
Bilirubin	up to 40 mg/dl
Hemoglobin	up to 200 mg/dl
Intralipid	up to 1000 mg/dl
Triglycerides	up to 2500 mg/dl
Calcium	up to 30 mg/dl

9 Traceability

MAGNESIUM liquicolor multipurpose reagent is calibrated with the kit standard or with AUTOCAL, which are traceable to the reference method AAS (atomic absorption spectrometry).