Design Verification

Calcium liquicolor

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1 Introduction

The performance characteristics of CALCIUM liquicolor multipurpose reagents have been tested and documented in order to verify the clinical usefulness and compliance with the essential requirements of directive 98/79/EC.
March 2022, new performance data for the Triton-free reagent have been included where they differ from the previous performance data for the Triton-containing reagent. In addition, missing performance data were added and obsolete performance data were replaced.
*Triton ban by REACh Regulation No 1907/2006

2 Imprecision

The imprecision (within-run and day-to-day) of the CALCIUM liquicolor method was calculated from six determinations on six consecutive days. Three pooled control sera were employed as sample material.

Analyser: HITACHI 717

Analyte concentration	Intra-assay		Inter-assay	
(mg/dl)	SD (mg/dl)	%CV	SD (mg/dl)	%CV
4.2	0.046	1.09	0.135	3.21
8.05	0.073	0.91	0.161	1.99
14.7	0.15	1.05	0.254	1.73

3 Linearity and Sensitivity

3.1 Linearity

The linearity of CALCIUM liquicolor multipurpose REF 10011 was controlled by employing a high concentrated linearity pool successively diluted in different steps with a physiological saline. The measurements were carried out on AU 480.
The linearity of the test was evaluated over the difference between best fitting nonlinear polynomial and linear polynomial. In this case difference from the 3rd to 1st order was used. In accordance with the European Society for External Quality Assessment, the specification is based on a deviation of up to 1 mg/dl to 10 mg/dl calcium and up to 10% from a concentration of 10 mg/dl calcium.

Criteria Linearity

Range limit		Acceptance criteria max. Deviation from linearity	
From	To	Value	Unit
0	10	1	mg/dl
10	22	10	%

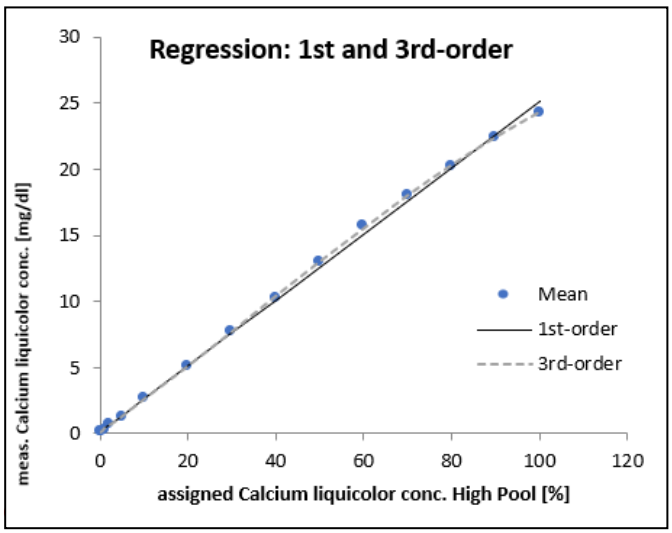
Reagent	Manufacturer	REF	LOT
CALCIUM liquicolor	HUMAN	10011	19008
AUTOCAL	HUMAN	13160	0017
Sample	Linearity pool, LOT ERO122; physiological saline LOT MPE005		

Results

High pool	Mean	Predicted Polynominal		Difference (3rd – 1st)		Specification	
%	mg/dl	1st-order	3rd-order	mg/dl	%	≤	
0	0.2	0.2	0.1	-0.1	-55.6	1 mg/dl	✓
0.5	0.2	0.3	0.2	-0.1	-60.6	1 mg/dl	✓
1	0.3	0.5	0.4	-0.1	-31.3	1 mg/dl	✓
2	0.7	0.7	0.6	-0.1	-15.4	1 mg/dl	✓
5	1.3	1.4	1.3	-0.1	-7.6	1 mg/dl	✓
10	2.7	2.7	2.6	-0.1	-3.8	1 mg/dl	✓
20	5.1	5.2	5.1	-0.1	-1.9	1 mg/dl	✓
30	7.7	7.7	7.7	0	0.0	1 mg/dl	✓
40	10.2	10.1	10.4	0.3	2.9	10 %	✓
50	13	12.6	13	0.4	3.1	10 %	✓
60	15.7	15.1	15.5	0.4	2.6	10 %	✓
70	18	17.6	18	0.4	2.2	10 %	✓
80	20.2	20.1	20.3	0.2	1.0	10 %	✓

90	22.4	22.6	22.4	-0.2	-0.9		>High limit
100	24.3	25.1	24.3	-0.8	-3.3		>High limit

Figure: Regressin 1st and 3rd order



Conclusion: The CALCIUM liquicolor multipurpose reagent on AU 480 is linear from 0 mg/dl to 20 mg/dl.

3.2 Sensitivity and detection limit

A 20-fold determination of a 0 mg/dl calibrator (phys. saline) on a Hitachi 717 analyser revealed an absolute mean of 0.06 mg/dl and a SD of 0.02 mg/dl.

3.3 Measuring range

The measuring ranges for CALCIUM liquicolor multipurpose reagent were determined taking into account the LoD data and the upper linearity range as follows: 0.1 to 20 mg/dl

4 Traceability

CALCIUM liquicolor multipurpose reagent is calibrated with Kit Standard or AUTOCAL, which are traceable to an in-house master calibrator. The master calibrator is traceable to the reference method (atomic absorption spectometry).

5 Recovery of control sera

A number of commercially available control sera have been employed. The control sera have been reconstituted/prepared according to the manufacturer's instructions. Five-fold determinations of each control serum have been performed with CALCIUM liquicolor reagents of different production lots. The mean values have been calculated and compared with the target values of the respective control sera.

CONTROL SERUM RECOVERY				Reference		HUMAN fresh		10d 45°C	
Control serum	LOT	Target mg/dl	Range mg/dl	Result mg/dl	Deviation (%)	Result mg/dl	Deviation (%)	Result mg/dl	Deviation (%)
Humatrol N	018	9.86	7.54 – 12.8	9.7	-2.07	9.4	-4.50	9.9	0.65
Humatrol P	016	14.7	9.46 – 20.0	13.8	-5.89	13.9	-5.44	13.9	-5.50
Serodos	6868	8.58	7.72 – 9.44	9.0	4.36	8.7	1.93	9.0	4.90
Sero plus	6795	13.8	12.42–15.18	14.1	2.25	14.2	2.65	14.1	2.23
Precinorm	150092	8.7	7.83 – 9.57	9.2	5.52	8.9	2.74	9.5	8.74
Precipath	199459	14.7	13.2 – 16.2	14.6	-0.73	14.8	0.80	14.7	0.27

Conclusion: No significant differences could be observed between fresh and stressed reagents, confirming the stability of the reagents. Controls were all recoverd well within the specified ranges.

6 Comparison of methods

The CALCIUM liquicolor test has been compared against a commercially available calcium method. Control sera as well as patient samples have been employed in the comparison.
The results have been evaluated by a main component analysis. The linear regression obtained could be described as follows:

N =	**52**
Y =	**0.985 X + -0.087**
X_{mean} =	**10.30**
Y_{mean} =	**10.05**

Conclusion: Both methods showed a good agreement and no significant deviation could be observed with any specific sample.

7 Interferences

Interference of CALCIUM liquicolor multipurpose reagent has been studied by adding known amounts of the potentially interfering substance to a known sample. Recoveries have been analyzed according to the method of Glick et al. (Clin.Chem. 1986. 32 470-5).

Results on Hitachi 717

Magnesium			Bilirubin			Ascorbic acid		
Concentration	Analytical Result		Concentration	Analytical Result		Concentration	Analytical Result	
mg/dl	mg/dl	%	mg/dl	mg/dl	%	mg/dl	mg/dl	%
0	7.95	100	0	5.34	100	0	5.36	100
1	8.02	100.9	4	5.33	99.7	2	5.37	100.2
2	8.09	101.7	8	5.30	99.3	4	5.46	101.9
3	8.06	101.4	12	5.32	99.6	6	5.41	100.8
4	7.97	100.2	16	5.35	100.2	8	5.47	102.0
5	7.99	100.4	20	5.29	99.1	10	5.43	101.3
6	7.97	100.2	24	5.33	99.7	12	5.47	102.1
7	7.97	100.2	28	5.30	99.3	14	5.44	101.4
8	7.93	99.7	32	5.31	99.4	16	5.50	102.5
9	7.84	98.6	36	5.25	98.3	18	5.50	102.5
10	7.99	100.5	40	5.29	99.0	20	5.44	101.4
Glick		**1**			**1**			**1**

Results on HumaStar 100

Reagent	**Manufacturer**	**REF**	**LOT**
CALCIUM liquicolor	HUMAN	10011	19008
AUTOCAL	HUMAN	13160	H016
Samples	Samples spiked with interfering substance		

Hemoglobin			Intralipid		
Concentration	Analytical Result		Concentration	Analytical Result	
mg/dl	mg/dl	%	mg/dl	mg/dl	%
0	8.57	100	0	8.54	100
50	8.75	102.1	100	8.61	100.9
100	8.93	104.3	200	8.78	102.9
150	8.99	105.0	300	8.75	102.5
200	9.13	106.5	400	8.92	104.5
250	9.22	107.6	500	8.92	104.5
300	9.16	106.9	600	9.23	108.1
350	9.38	109.5	700	9.55	111.9
400	9.42	110.0	800	9.79	114.7
450	9.54	111.4	900	9.94	116.5
500	9.68	113.0	1000	10.17	119.2
Glick		**2**			**2**

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

Interfering substance	
Ascorbic acid	up to 20 mg/dl
Bilirubin	up to 40 mg/dl
Hemoglobin	up to 400 mg/dl
Intralipid	up to 600 mg/dl
Magnesium	up to 10 mg/dl

8 Stability

8.1 Accelerated stability testing – Recovery of Control sera

The CALCIUM liquicolor multipurpose reagent was stressed in HUMAN reagent bottles at 45°C for 21 days and then stored at 37°C for 3 days. The recovery fo controls was tested according to the procedure already described in section 5 on AU 480. The mean values (n = 4) obtained with fresh reagent (= reference) and stressed reagent were calculated and compared.

Criteria

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

Used Material

Reagent	Manufacturer	REF	LOT
CALCIUM liquicolor	HUMAN	10011	19008
AUTOCAL	HUMAN	13160	H016
Sample	HUMAN's and commercial controls (Beckman Coulter, INVICON)		

Results

Control recovery				Reference	Test		
				Fresh	21 days at 45°C and 3 days at 37°C		
Name	LOT	Target mg/dl	Range mg/dl	Result mg/dl	Result mg/dl	%Dev	Within range
HumaTrol N	0005	8.91	7.93 – 9.89	9.24	9.71	5.2	YES
HumaTrol P	0004	13.4	11.9 – 14.9	14.0	13.8	-1.4	YES
SERODOS	0004	8.25	7.34 – 9.16	8.36	8.91	6.5	YES
SERODOS^{plus}	0004	12.9	11.5 – 14.3	13.4	13.2	-1.6	YES
Seronorm Human	1512606	9.18	8.63 – 9.73	9.13	9.52	4.3	YES
Seronorm Human High	1506261	13.1	12.3 – 13.9	13.7	13.6	-0.7	YES
Control serum L1	1041	9.00	8.01 – 10.0	9.33	9.53	2.2	YES
Control serum L2	1042	12.5	11.1 – 13.9	13.3	13.1	-1.1	YES
Mean Dev.%						**1.7**	

The accelerated stress data for the CALCIUM liquicolor multipurpose reagent meet the acceptance criteria.

8.2 Accelerated stability testing – Linearity

The linearity of CALCIUM liquicolor multipurpose reagent was determined according to the procedure already described in section 3 using a high concentrated linearity pool successively diluted in different steps with a physiological saline. The measurements were carried out on AU 480. The reagent was stressed in HUMAN reagent bottles at 45°C for 21 days and then stored at 37°C for 3 days.

Criteria lineatity

Max. deviation from linearity	≤ 10%

Used Material

Reagent	Manufacturer	REF	LOT
CALCIUM liquicolor	HUMAN	10011	19008
AUTOCAL	HUMAN	13160	H016
Sample	Diluted high concentrated linearity pool, LOT ERO068, diluted with physiological saline, LOT BOG345		

Results

High pool	Mean	Predicted polynomial			Deviation %	
%	mg/dl	1st order	2nd order	3rd order	2nd - 1st	3rd – 1st
0.5	0.18	0.46	0.17	0.19	-161.1	-150
1	0.34	0.59	0.32	0.34	-79.4	-73.5
2	0.65	0.85	0.62	0.63	-35.4	-33.8
5	1.51	1.64	1.52	1.51	-7.9	-8.6
10	3.1	2.95	2.99	2.97	1.3	0.6
20	5.62	5.57	5.86	5.82	5.2	4.4
30	8.62	8.19	8.61	8.59	4.9	4.6
40	11.28	10.81	11.25	11.25	3.9	3.9
50	13.96	13.44	13.78	13.8	2.4	2.6
60	16.2	16.06	16.2	16.23	0.9	1
70	18.36	18.68	18.5	18.52	-1	-0.9
80	20.75	21.3	20.7	20.66	-2.9	-3.1

Accelerated stress data for CALCIUM liquicolor multipurpose reagent confirms the linear range on AU 480 as indicated in section 3: up to 20 mg/dl

Conclusion: For CALCIUM liquicolor multipurpose reagent, REF 10011, all accelerated stress data above are indicative for a real-time stability of: 24 months at 2-25°.

8.3 Real time stability for Triton-free reagent – Recovery of Control sera

The CALCIUM liquicolor multipurpose reagent was stored in original HUMAN reagent bottles at 15-25°C. The real-time stability was tested up to 125% of the shelf life at several intervals.
A number of commercially available control sera have been employed according to the procedure already described in section 5 on AU 400. The mean values (n = 2) obtained with fresh reagent (=reference) and stored reagent LOT has been calculated and compared with the fresh mean of the respective control sera.

The real-time stability studies for REF 10011 are ongoing.

Criteria

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

Used Material

Reagent	Manufacturer	REF	LOT
CALCIUM liquicolor	HUMAN	10011	21001 / reference
CALCIUM liquicolor	HUMAN	10011	19008 /30 months
AUTOCAL	HUMAN	13160	0018
Sample	HUMAN's and commercial controls (Beckman Coulter, INVICON)		

Results

Control recovery	Reference	Test
	LOT 21001	LOT 19008
	Fresh	30 months

Name	LOT	Target mg/dl	Range mg/dl	Result mg/dl	Result mg/dl	%Dev	Within range
HumaTrol N	0006	8.60	7.65 - 9.55	8.59	8.89	3.4	Yes
HumaTrol P	0005	12.9	11.5 - 14.3	13.4	13.1	-2.3	Yes
SERODOS	0005	8.19	7.29 - 9.09	8.01	8.24	2.8	Yes
SERODOS^{plus}	0007	12.1	11.4 - 12.9	12.3	12.2	-0.3	Yes
Seronorm Human	1806848	8.82	8.29 - 9.35	8.64	8.94	3.5	Yes
Seronorm Human High	1801801	12.8	12.1 - 13.6	12.9	12.8	-0.9	Yes
Control serum L1	1043	8.92	7.94 - 9.9	8.76	9.10	3.9	Yes
Control serum L2	1044	12.5	11.1 - 13.9	12.7	12.4	-1.7	Yes
Mean Dev.%						**1.0**	

The control recovery met acceptance criteria and confirmed the shelf life of 24 months at 2 – 25°C for CALCIUM liquicolor multipurpose reagent, REF 10011.

8.4 Real time stability for Triton-free reagent – Linearity

The linearity of CALCIUM liquicolor multipurpose reagent, REF 10011, was controlled according to the procedure already described in section 3 using a high concentrated linearity pool successively diluted in different steps with a physiological saline. The measurements were carried out on AU 400.

The real-time stability studies for REF 10011 are ongoing.

Criteria Linearity

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

Reagent	Manufacturer	REF	LOT
CALCIUM liquicolor	HUMAN	10011	19008
AUTOCAL	HUMAN	13160	0018
Sample	Linearity pool, LOT ERO122; physiological saline LOT MZM122		

Results

High pool	Mean	Predicted Polynominal		Difference (3rd – 1st)		Specification	
%	mg/dl	1st-order	3rd-order	mg/dl	%	≤	
0	0.03	0.29	0.03	-0.26	-866.7	1 mg/dl	✓
0,5	0.18	0.41	0.16	-0.25	-138.9	1 mg/dl	✓
1	0.3	0.54	0.3	-0.24	-80.0	1 mg/dl	✓
2	0.6	0.78	0.57	-0.21	-35.3	1 mg/dl	✓
5	1.36	1.52	1.37	-0.15	-11.1	1 mg/dl	✓
10	2.63	2.75	2.71	-0.04	-1.5	1 mg/dl	✓
20	5.45	5.2	5.37	0.17	3.1	1 mg/dl	✓
30	7.86	7.66	7.99	0.33	4.2	1 mg/dl	✓
40	10.84	10.12	10.56	0.44	4.1	10 %	✓
50	12.93	12.57	13.06	0.49	3.8	10 %	✓
60	15.41	15.03	15.48	0.45	2.9	10 %	✓
70	17.82	17.49	17.8	0.31	1.7	10 %	✓
80	20.03	19.94	20.01	0.07	0.3	10 %	✓
90	22.13	22.4	22.1	-0.3	-1.4	10 %	✓
100	24.03	24.85	24.05	-0.8	-3.3	10 %	✓

CALCIUM liquicolor multipurpose reagent is specified to cover a linear range as indicated in section 3: up to 20.0 mg/dl

Conclusion: All real time stability data for CALCIUM liquicolor multipurpose reagent, REF 10011, confirm the shelf life of 24 months at 2-25°C.

8.5 Recovery of control sera for Triton-containing reagent

Commercially available control sera have been employed. The control sera have been reconstituted/prepared according to the manufacturer's instructions. Five-fold determinations of each control serum have been performed with the CALCIUM liquicolor test method. The means of the fivefold determinations have been calculated and compared with the target values.

CONTROL SERUM RECOVERY				reference		26 months		27 months		28 months	
Control serum	LOT	Target mg/dl	Range mg/dl	Result mg/dl	Dev. (%)	Result mg/dl	Dev. (%)	Result mg/dl	Dev. (%)	Result mg/dl	Dev. (%)
HUMATROL N	# 019	10	9 – 11	10.16	0.98	10.37	0.96	10.6	0.94	10.29	0.97
HUMATROL P	# 017	14.4	12.9 – 15.8	14.3	1.01	14-36	1.01	14.6	0.99	14.54	0.99
SERODOS	# 6868	9.32	8.39 – 10.3	9.4	0.99	9.82	0.95	9.9	0.94	9.70	0.96
SERODOS	# 6869	8.84	7.87 – 9.8	9.8	0.90	10.22	0.86	10.32	0.94	10.10	0.87
SERODOS.Plus	# 6796	13.3	11.8 – 14.8	14.07	0.94	14.03	0.94	14.26	0.89	14.27	0.93
Precinorm	#162576	9.28	8.17 – 10.4	10.07	0.92	10.39	0.89	10.39	0.94	10.22	0.91
Precipath	#151348	13.2	12 – 14.4	13.7	0.96	13.66	0.77	13.93	0.83	13.81	0.95

Conclusion: The above results clearly demonstrate the stability of the test for more than 24 months after production. In addition to the real-time stability studies, temperature stress tests are routinely performed on each production batch as part of the end control of the product.

8.6 Linearity for Triton-containing reagent

Three independent lots have been stored under the recommended conditions for up to 28 months. A high concentration pool serum was employed and dilutions with phys. saline were made. The analysed concentrations were calculated vs. the regression line. Deviation from the regression line are expressed in absolute and relative values.

	26 months		27 months		28 months	
High pool Content (%)	Analytical Data mg/dl	Regression Line (%)	Analytical Data mg/dl	Regression Line (%)	Analytical Data mg/dl	Regression Line (%)
0	0.04	-85.21	-0.01	-101.39	-0.03	-109.49
10	2.50	-1.11	2.53	-3.42	2.46	-2.70
20	4.97	3.13	5.12	4.84	4.99	4.11
30	7.21	1.40	7.37	3.24	7.13	1.02
40	9.44	0.41	9.57	1.83	9.47	1.52
50	11.82	1.08	11.81	1.31	11.84	2.17
60	14.05	0.43	14.08	1.17	14.08	1.64
70	16.03	-1.51	15.68	-3.10	15.59	-3.31
80	16.74	-9.87	16.86	-8.55	17.15	-6.71
90	17.06	-18.23	17.12	-17.30	18.72	-9.34
100	17.90	-22.70	17.86	-22.19	18.91	-17.47

Conclusion: The results obtained with reagents stored for even 28 months under real-time conditions. From the above results the stability claim of 24 months from the date of manufacture has been confirmed.

9 Use of Wavelengths

Spectral analysis indicates that the major peak of CALCIUM liquicolor occurs at 574 nm, which is the wavelength recommended by HUMAN. Alternatively, 546 nm may be used with a corresponding loss of signal of about 40%. This was demonstrated by measuring the same sample in a spectrum between 530 and 580 nm and comparing the respective absorptive values, as indicated in the table below.

Wavelength	OD aq. dest.	OD sample (8 mg/dl)	Wavelength	OD aq. dest.	OD sample (8 mg/dl)
530	0.011	0.318	556	0.011	0.552
531	0.011	0.324	557	0.011	0.567

532	0.011	0.33	558	0.011	0.581
533	0.011	0.337	559	0.011	0.596
534	0.011	0.344	560	0.011	0.611
535	0.011	0.351	561	0.011	0.626
536	0.011	0.358	562	0.011	0.641
537	0.011	0.364	563	0.011	0.657
538	0.011	0.371	564	0.011	0.672
539	0.011	0.378	565	0.011	0.686
540	0.011	0.386	566	0.011	0.699
541	0.011	0.394	567	0.011	0.712
542	0.011	0.401	568	0.011	0.723
543	0.011	0.41	569	0.011	0.732
544	0.011	0.417	570	0.011	0.74
545	0.011	0.426	571	0.011	0.746
546	**0.011**	**0.436**	572	0.011	0.751
547	0.011	0.445	573	0.011	0.753
548	0.011	0.455	**574**	**0.011**	**0.753**
549	0.011	0.466	575	0.01	0.752
550	0.011	0.477	576	0.01	0.748
551	0.011	0.488	577	0.01	0.742
552	0.011	0.5	578	0.011	0.734
553	0.011	0.512	579	0.011	0.724
554	0.011	0.525	580	0.011	0.712
555	0.011	0.538	581	0.011	0.698

10 Open vial stability

To examine the open vial stability of the reagent after 1st opening, the control recovery was tested at different time intervals. After each use, the reagent was closed properly and stored at room temperature (15 - 25°C). The measurements were carried out on an AU 480 according to the procedure already described in section 5.
The mean values (n=3) obtained with fresh reagent (=reference) and opened reagent were calculated and compared with the target mean of the respective control sera.

Criteria

Check	**Acceptance criteria**
Recovery	within range

Used Material

Reagent	**Manufacturer**	**REF**	**LOT**
CALCIUM liquicolor	HUMAN	10011	19008
AUTOCAL	HUMAN	13160	0017
Sample	HUMAN's and commercial controls (Audit, Beckman Coulter)		

Results

Control recovery						**%Recovery**	
Name	**LOT**	**Target [mg/dl]**	**Range [mg/dl]**	**Fresh [mg/dl]**	**After 182 days [mg/dl]**	**Fresh [mg/dl]**	**After 182 days [mg/dl]**
HumaTrol N	0006	8.60	7.65 – 9.55	8.46	8.51	98	99
				8.60	8.43	100	98
				7.71	8.50	90	99
HumaTrol P	0004	13.4	11.9 – 14.9	13.2	13.2	99	98
				13.2	13.0	99	97
				13.2	13.0	98	97
SERODOS	0005	8.19	7.29 – 9.09	8.01	7.89	98	96
				7.91	7.77	97	95
				7.81	7.82	95	95
SERODOSplus	0005	13.5	12.0 – 15.0	13.2	13.1	97	97
				13.2	13.1	98	97
				13.3	13.0	98	96

FD Assayed Chemistry Level 1	06537D	8.70	7.00 – 10.4	8.36	8.53	96	98
				8.32	8.47	96	97
				9.77	9.83	112	113
FD Assayed Chemistry Level 2	05638D	10.2	8.20 -.12.2	9.87	10.0	97	98
				8.49	8.40	83	82
				9.88	9.79	97	96
Control serum 1	1043	8.92	7.94 – 9.90	8.72	8.60	98	96
				8.86	8.58	99	96
				8.63	8.61	97	97
Control serum 2	1044	12.5	11.1 - 13.9	12.3	12.3	99	99
				12.4	12.4	99	99
				12.3	12.3	99	98

Open-vial stability data for control findings of CALCIUM liquicolor multipurpose reagent met acceptance criteria.

Conclusion All results above confirm the open-vial stability of at least 180 days or 6 months for CALCIUM liquicolor multipurpose reagent on AU 480.