

CO2 calibration failed with DUP flag

IVD International Clinical Application Department

Tim/Van

2024/9/4

CONTENTS

01. Case Background



02. Case Ideas



03. Case Solution



04. Case Summary



Case Background

Hospital name	: Banglen Hospital, General Hospital (First level 60-120 beds)
Distributor support	: Firmer
Model	: BS-800M
Sample	: OPD/IPD ; Heparin blood tube

Problem : CO2 calibration failed; DUP flag. The reagent and new calibrator are not expired.

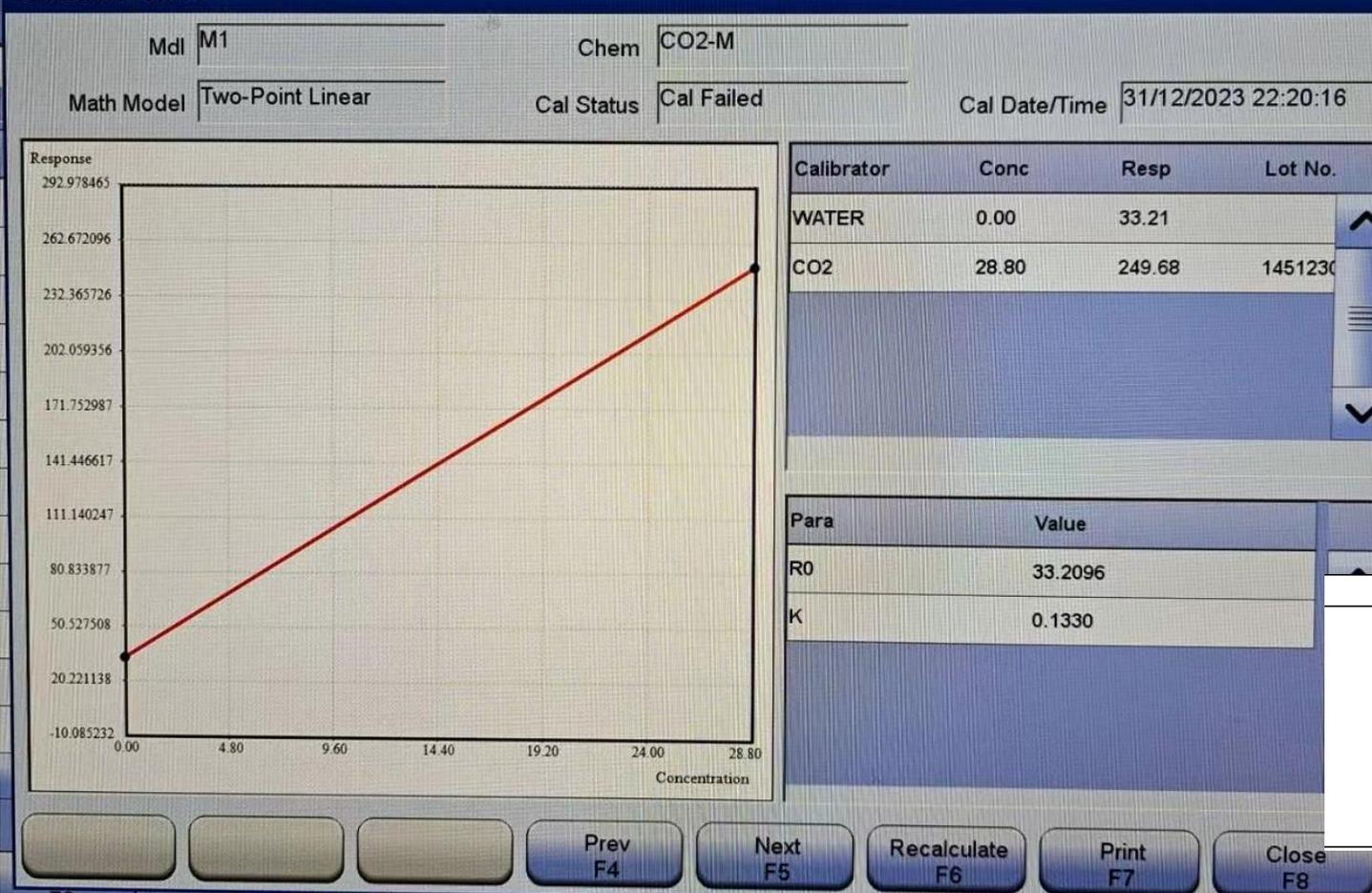
Problem detail :

1. The reaction curve is normal.
2. Calibration Resp result is water = 33.21, CO2 =249.68/ Value R0= 33.2096, K =0.1330
3. R0 resp is **25.4, 41.0**
4. CO2 calibration Resp is **146.0, 353.4**
5. Effected to other tests BUN,ALB,TG,TC

DUP flag for CO2 calibration result

Lot No.	R.Serial No.	Flag	Cal Status	Cal Date/Time	R0	K	A	B
			Calibrated	01/01/2024 18:56:52	39.9800	0.0932		
		DUP	Cal Failed	31/12/2023 22:20:16	33.2096	0.1330		
		DUP	Cal Failed	31/12/2023 21:53:00	32.6338	0.1331		

Calibration Curve



Cat. No.

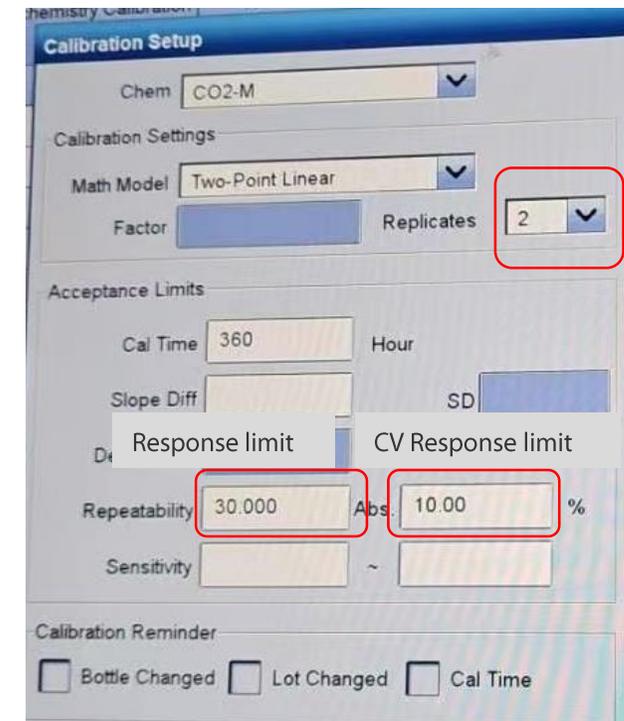
Package size

CO20302	R 2×20 mL+Calibrator 1×1.5 mL
CO21302	R 2×18 mL+Calibrator 1×1.5 mL
CO20303	R 4×20 mL+Calibrator 1×1.5 mL
CO20304	R 6×20 mL+Calibrator 1×1.5 mL
CO20102	R 2×20 mL+Calibrator 1×1.5 mL+Control 1×5 mL
CO21102	R 2×18 mL+Calibrator 1×1.5 mL+Control 1×5 mL
CO20103	R 4×20 mL+Calibrator 1×1.5 mL+Control 1×5 mL
CO20104	R 6×20 mL+Calibrator 1×1.5 mL+Control 1×5 mL

DUP flag for CO2 calibration result

Operation manual guide explanation

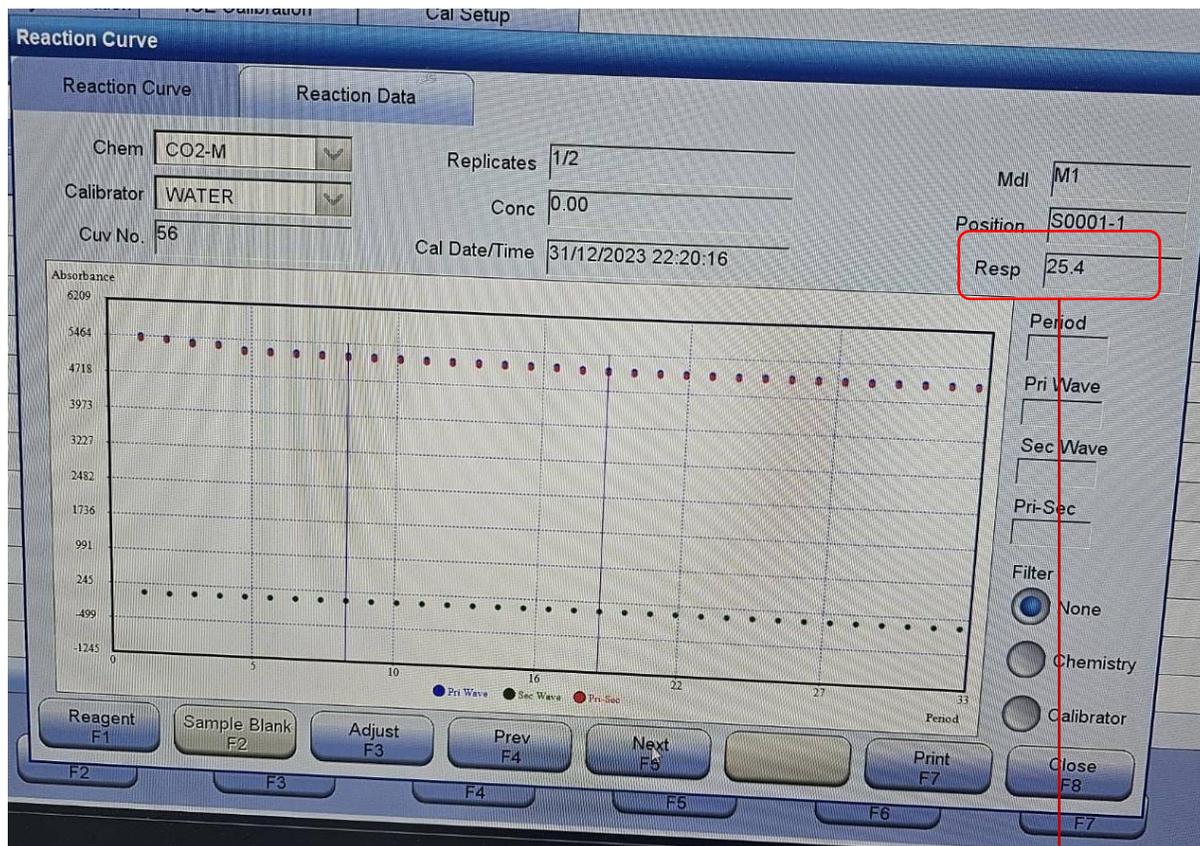
Repeatability	The repeatability is the difference of the maximum and minimum response of each calibrator. If the calculated calibrator response difference is greater than the set limit, the system will give the flag “ DUP ” and an alarm. The input range must be within 0-34,000. The default is blank, which means not performing this check.
---------------	--



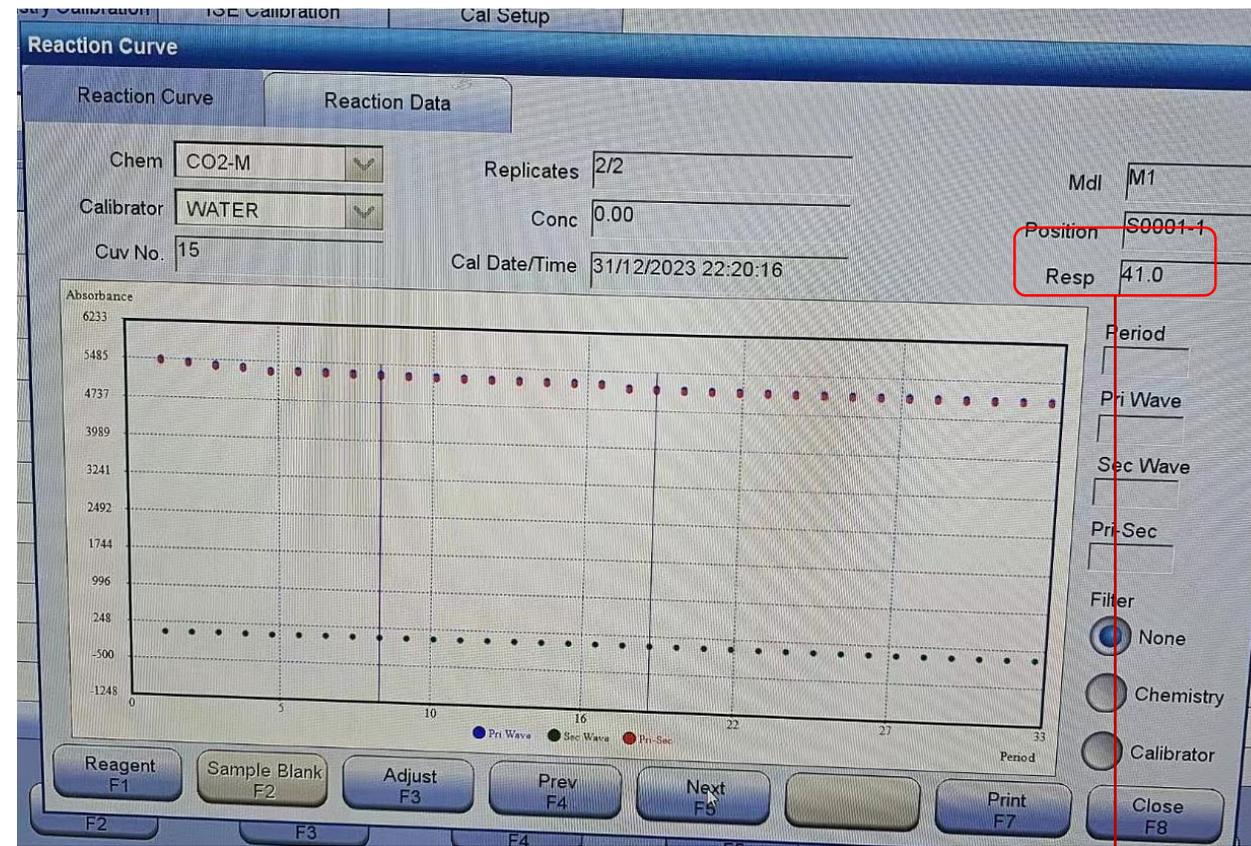
DUP	Calibration related	Calibration repeatability error	The difference between the maximum and minimum response of the calibrator exceeds the specified limit.	Check if the acceptance limit is reasonable, troubleshoot the error, and then recalibrate.
DUP	Calibration related	Potential difference between two calibration replicates out of range	Calibrator of the same concentration level will be run repeatedly on the ISE module. If the difference between two adjacent runs is beyond the set range, this warning will be	If the calibration succeeds, ignore the error; If the calibration fails, take relevant actions according to the alarm.

DUP flag for CO2 calibration result

R0



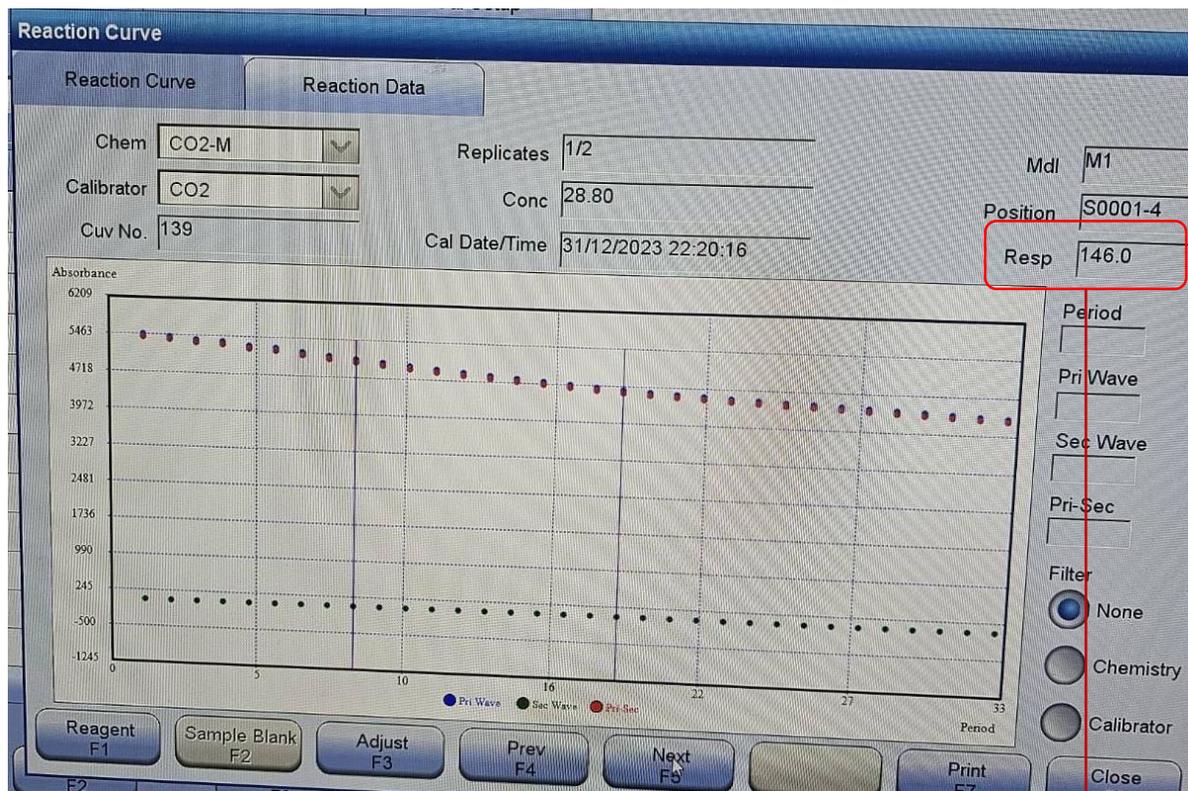
Water : Rep1 = 25.4



Water : Rep2 = 41.0

DUP flag for CO2 calibration result

CO2 Calibration result

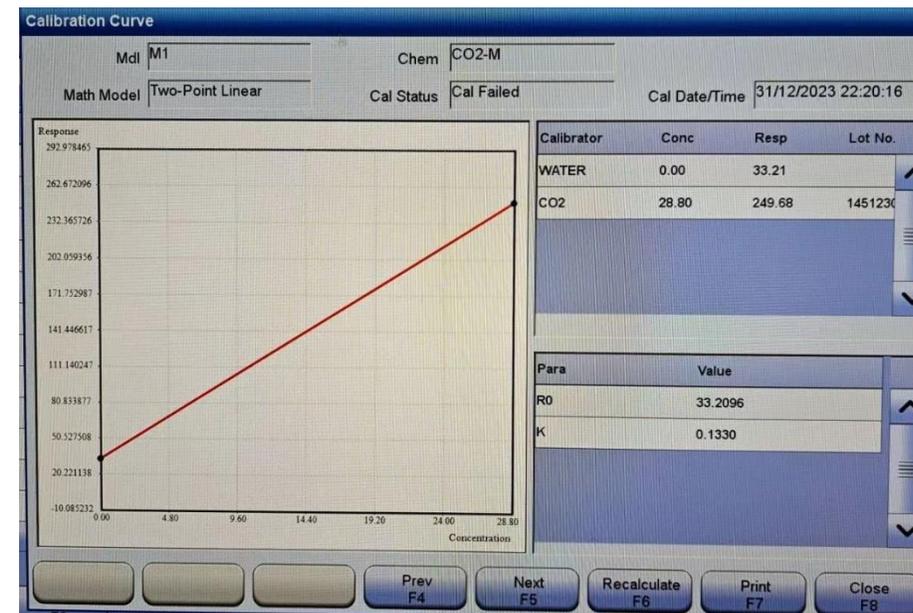
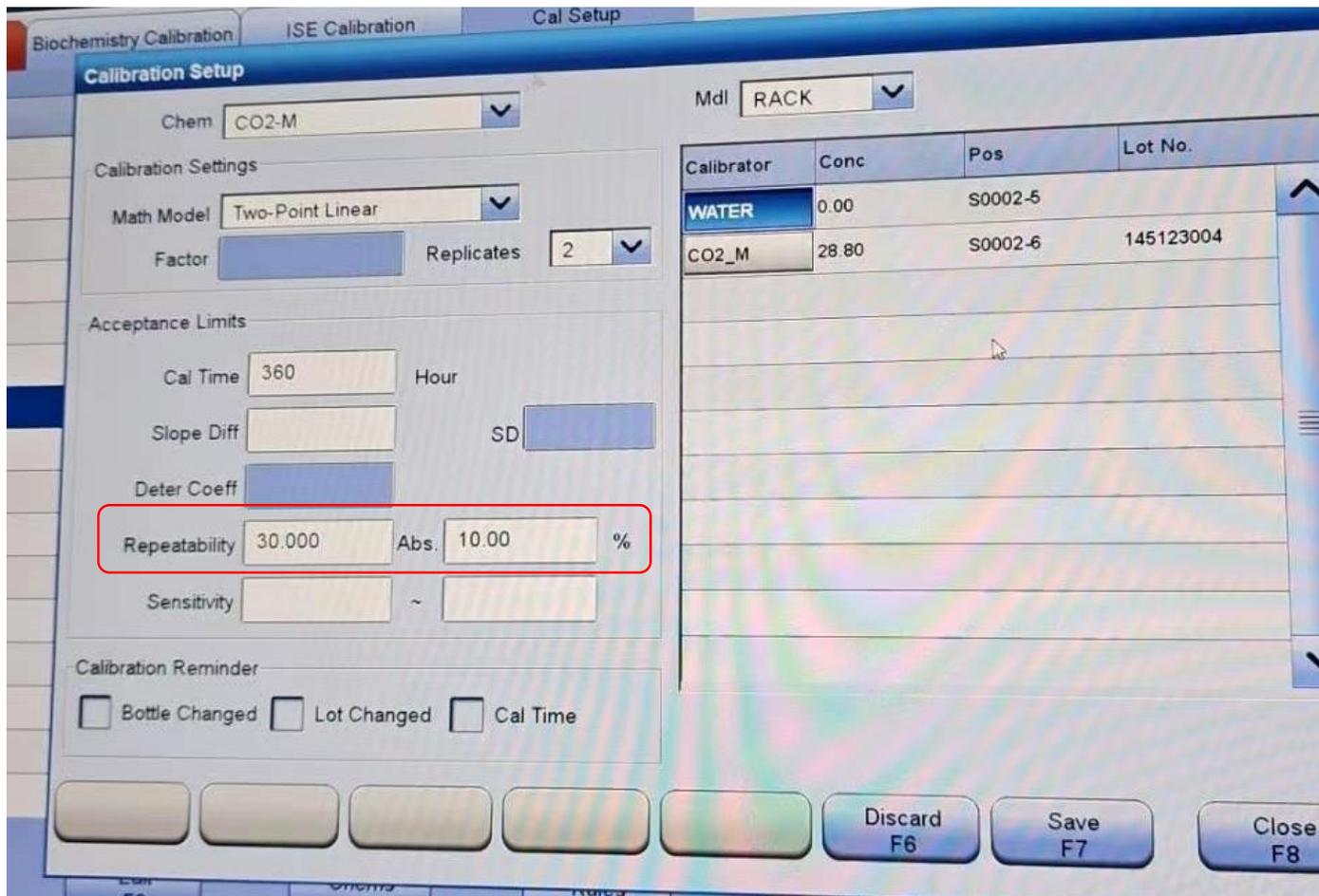


CO2 cal Rep1 = 146.0



CO2 cal Rep2 = 353.4

DUP flag for CO2 calibration result



	Water	CO2
Rep1	25.4	146.0
Rep2	41.0	353.4
AVG	33.2	249.7
SD	11.0	146.7
CV	33%	59%

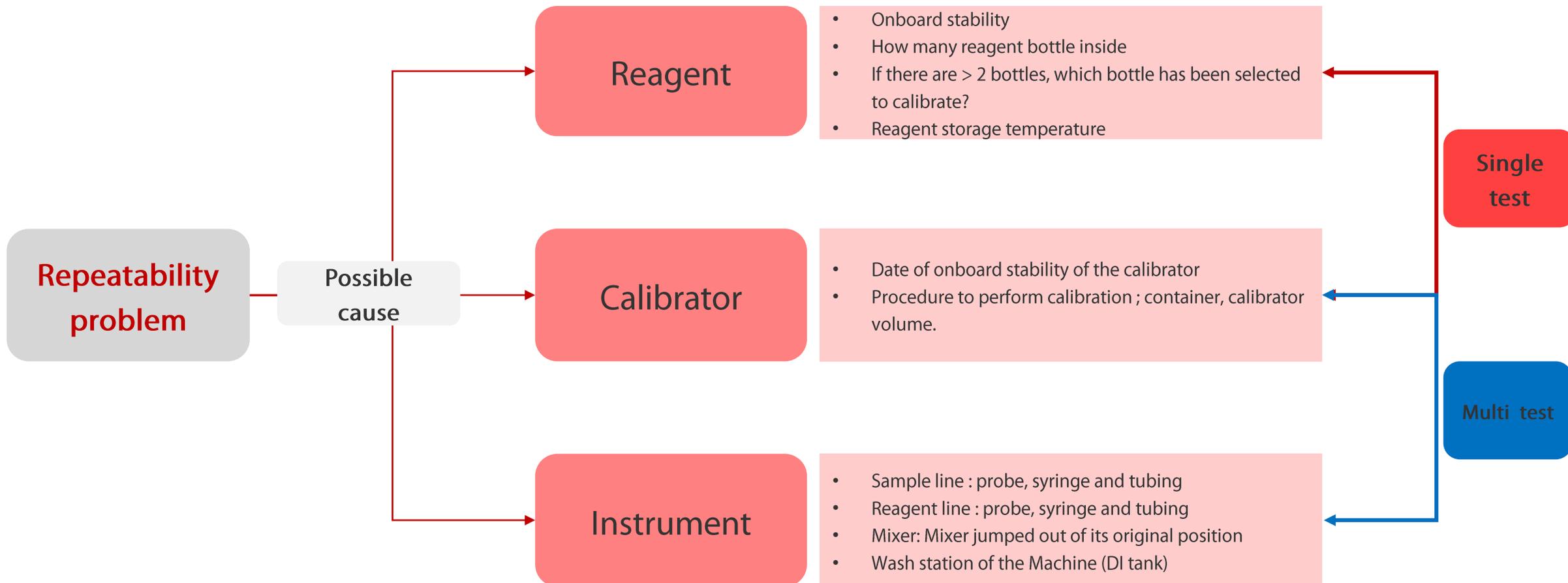
$$\text{Conc} = K * (R - R_0)$$

$$K = \text{Conc} / (R - R_0)$$

$$K = 28.8 / (249.7 - 33.2)$$

$$K = 0.1330$$

Case Ideas



Reagent

Standby/Standby
HOST ServiceUser 01/01 15:59

Reagent/Calibration Biochemistry Calibration ISE Calibration Cal Setup

Mdl	Pos	Chem	Chems Left	Rgt Type	Tests Left	Days Left	Lot No.	Serial No.	Cal Status	Time Left
M1	1-27	ALB II	72	R1	72	17d	3003	FB8B	Calibrated	26d
M1	1-22	ALP	106	R1	265	6d	3010	8F37	Calibrated	5d
M1	2-23			R2	106	-15d	2010	7586		
M1	1-23	ALT	171	R1	271	25d	3011	7E3B	Calibrated	26d
M1	2-24			R2	171	8d	3011	9293		
M1	1-21	AST	116	R1	116	19d	3010	7A38	Calibrated	25d
M1	2-21			R2	490	21d	3010	8129		
M1	1-30	Ca	39	R1	39	5d	3007	7901	Calibrated	26d
M1	1-40 M	CO2-M	48	R1	48	<-99d	3004	7D97	Cal Failed	
M1	1-44	CREA-S	31	R1	31	22d	3026	7E82	Calibrated	25d
M1	2-43			R2	114	17d	3026	843E		
M1	1-16	D-BII-V	120	R1	120	19d	3003	8D71	Calibrated	25d
M1	2-17			R2	212	9d	3003	8473		
M1	1-2	Glu-H	30	R1	147	22d	3002	C3F6	Calibrated	25d
M1	2-2			R2	30	17d	3002	BB17		

Load F1 No Load F2 Inventory F3 Load List F4 Cal F5 No Cal F6 Print F7 Cal Options F8

M1 : The reagent is about to expire. Check its expiration date on the Rgt box or on the bottle label. Chem:UA Lot No: 3003

1. Onboard stability

1 day ago

2. How many reagent bottles are inside?

1 bottle

3. If there are > 2 bottles, which bottle has been selected to calibrate?

Lot.3004 SN.7D97 (1 bottle)

4. Reagent storage temperature

2-8 °C

Try to change the new bottle reagent, but still, calibration failed.

Calibrator material

				New Reagent/ New Calibrator (new lot)	
DUP	Cal Failed	31/12/2023 22:20:16	33.2096	0.1330	
DUP	Cal Failed	31/12/2023 21:53:00	32.6338	0.1331	
DUP	Cal Failed	31/12/2023 21:16:13	26.9472	0.1300	
DUP	Cal Failed	31/12/2023 21:04:23	14.4485	0.0912	
DUP	Cal Failed	31/12/2023 20:57:02	17.5869	0.0746	

3 days usage reagent/
New calibrator (new lot)

3 days usage reagent/
calibrator opened more than 2 wks.



Special position

W1 (No.69): physiological saline (sample dilution)

D1 (No.70): wash solution (R1 probe)

D2 (No.50): wash solution (R2 probe)



Replace detergent : W1, D1 and D2: **No issues**

Mixer is **in the original position**



Check syringe : sample/reagent: **no issue**

Check DI tank and filter: **DI water tank and filter is dirty, clean the tank and change filter, run calibration again**

Calibration result after cleaning the DI water tank and changing the filter

ServiceUser 01/01 19:48

Reagent/Calibration Biochemistry Calibration ISE Calibration Cal Setup

Chem ALL

Current History

Cal Date 1/1/2567

Chem	Lot No.	R.Serial No.	Flag	Cal Status	Cal Date/Time	R0	K	A
CO2	3011	852D		Calibrated (B)	01/01/2024 19:34:25	36.3631	0.0956	
CO2-M				Calibrated	01/01/2024 18:56:52	39.9800	0.0932	

Calibration pass
QC pass

Sample By Chemistry

Sample ID	Bar Code	Position	Patient Name	Status	Completion Time	Patien	Chemistry	Result	Flag
CO2-N	145122009	C0001-5		Complete	19:45		CO2-M	13.77	
CO2-N	145122009	C0001-5		Complete	20:49				
CO2-N	145123011	C0001-5		Complete	21:44				
CC Multi L1	059323006	C0001-1		Complete	09:22				
CC Multi L2	059423005	C0001-2		Complete	09:23				
9	0103342403	N0006-9		Complete	09:42				
13	0103341403			Complete	09:43				
19	123	N0004-1		Complete	20:53				
20	0103351203	N0003-2		Complete	21:18				
21	124	N0005-1		Complete	21:21				
22	125	N0002-1		Complete	21:46				
1	0103343303	N0006-1		Incomplete	09:40				
2	0103340403	N0006-2		Incomplete	09:40				
3	0103341903	N0006-3		Incomplete	09:41				
4	0103340703	N0006-4		Incomplete	09:41				



Summary:

In conclusion, CO2 test item: if the reagent and calibrator are new, please focus the instrument, especially the water quality for washing; it will affect CO2 results.

When we received issue calibration failed, we need to pay attention to:

1. Flag and error alarm message
2. Single test or multi test
3. Analyze the possible cause according to the flag and test items.
4. DUP, repeatability are not acceptable.
 1. Check the reagent and test.
 2. Check the calibrator material and test.
 3. Instrument > which part affect to this test? DI water/washing part/ S.probe /R.probe/Mixer....
5. After testing for all, please rerun the calibration and QC check.

*** Test items will be sensitive to **Water Quality** : Mg, Ca, Fe, Phos, CO2, UA, TG

Thanks!

mindray 迈瑞