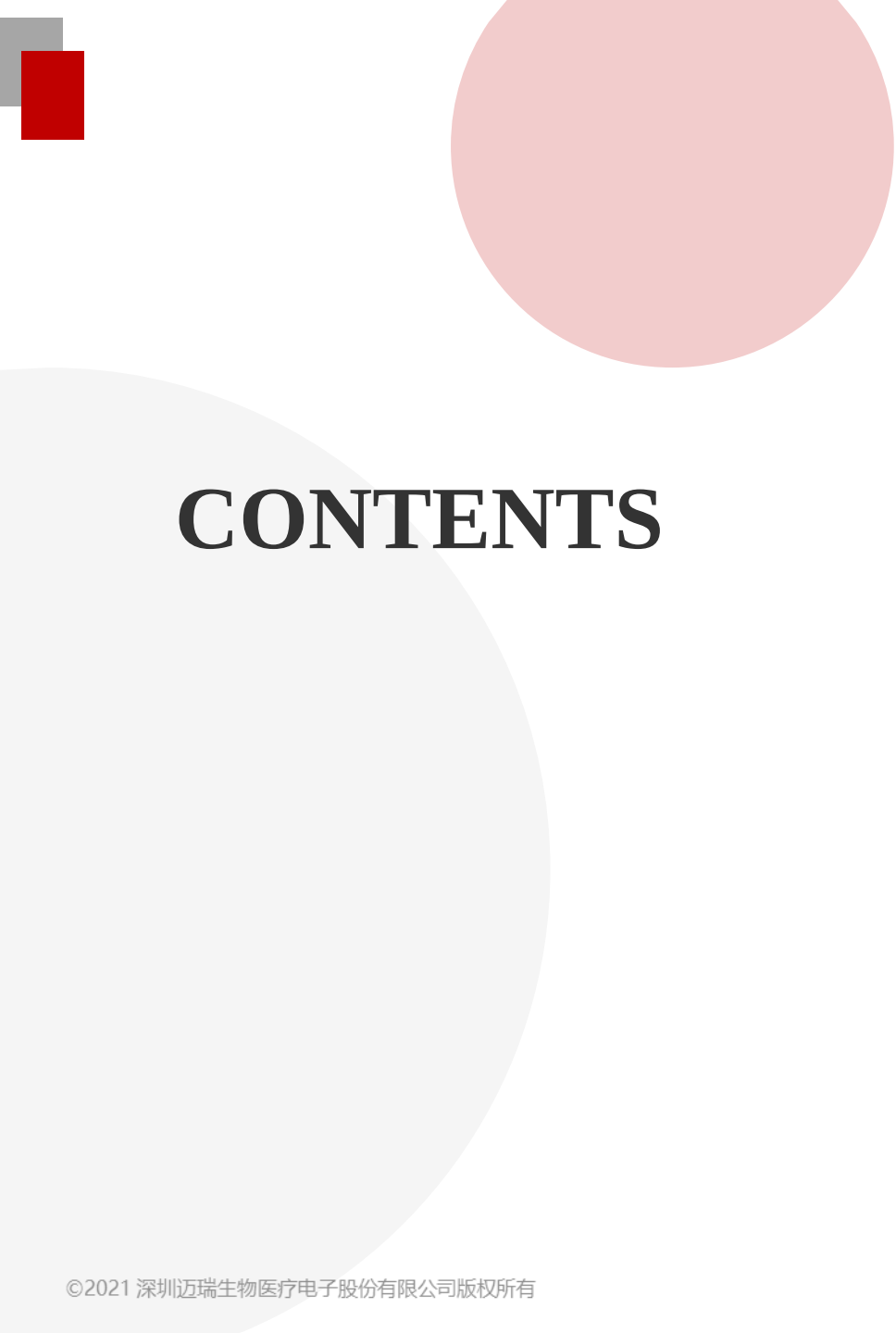


HIV Calibration Failure

IVD Clinical Application Department, Service Division

Ahmed Rabea

2024/10/16



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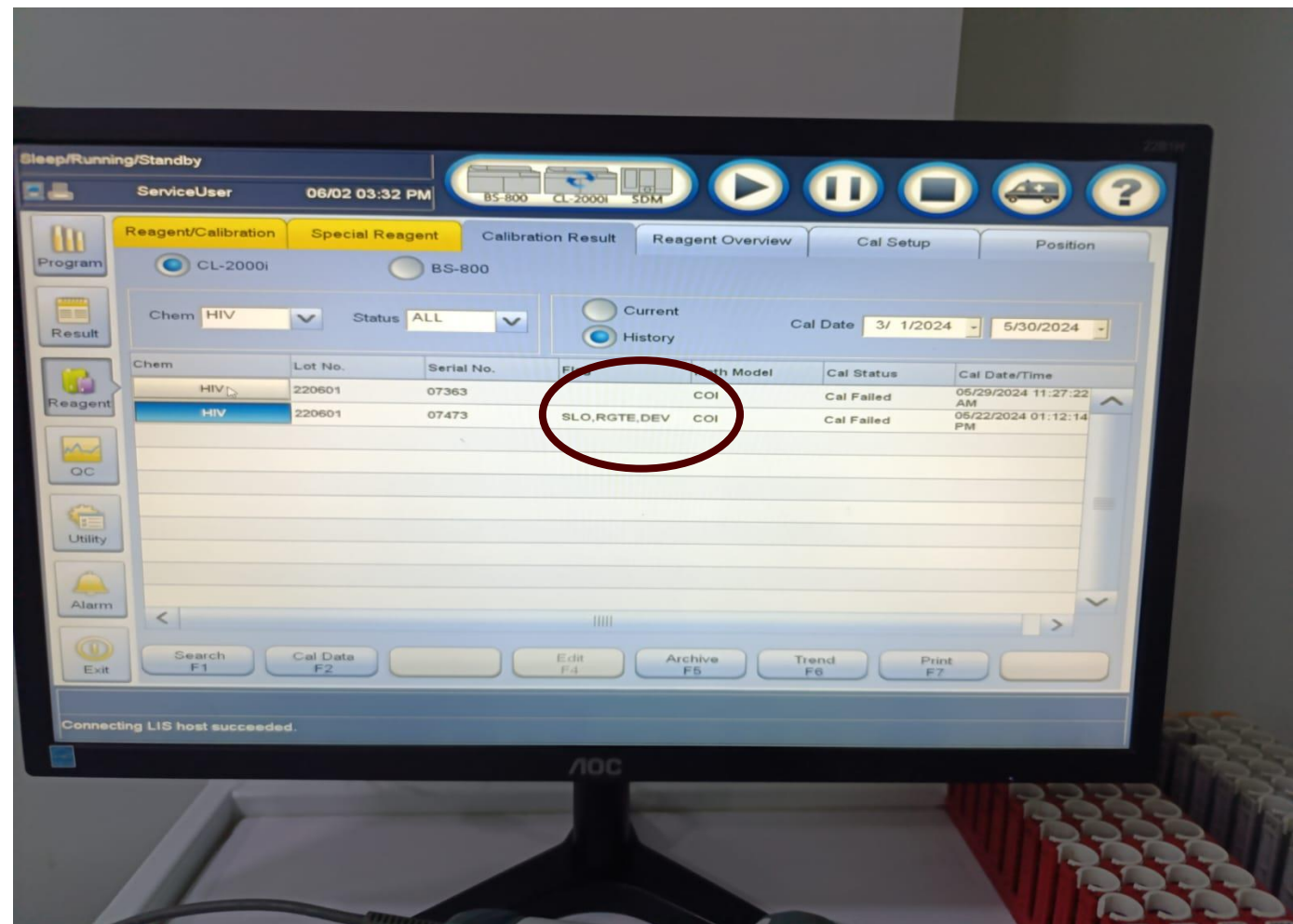
- 01. Case Background
- 02. Case Ideas
- 03. Case Solution
- 04. Case Summary

Fault Description:

The customer complained from HIV Calibration failure

Customer use HIV reagent lot 230505

- Calibrate current lot of reagent with new lot of calibrator (lot number 231201, expiration date 01.05.2025;;
- Calibration failure with flag SLO, DEV



Case Ideas

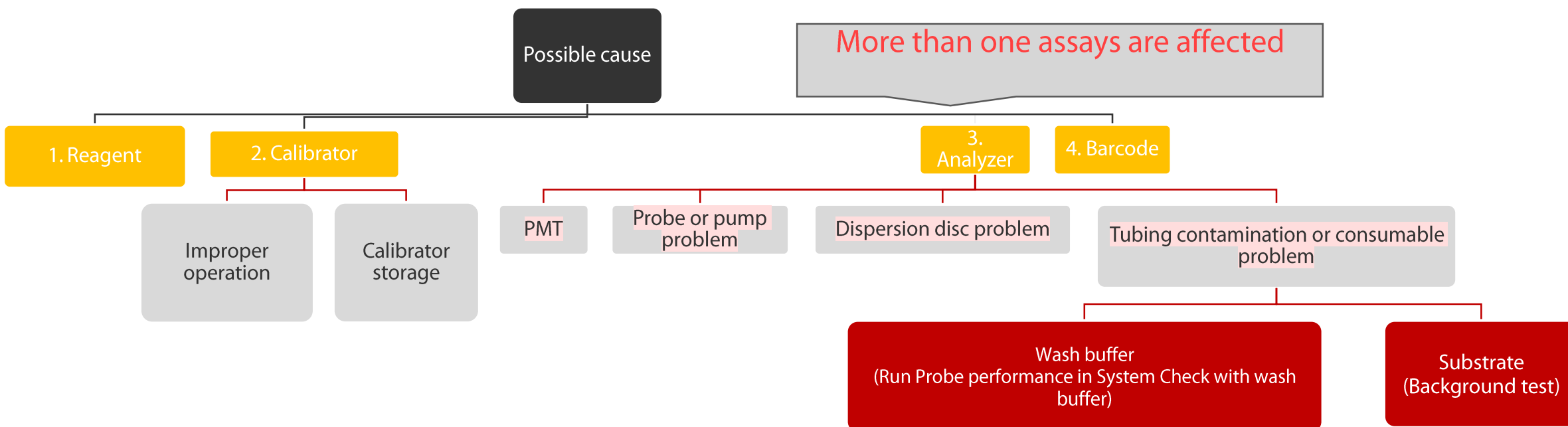
1. Asked about single or multiple Calibration failed
2. If the single calibration failed, so it is not instrument issue.
3. Check LOT Numbers, expiration date and open date of Reagents, Calibrator, Substrate THEN

Check:

1. Effect check, Factor RLU check, wash buffer check
2. Cuvette are new and clean.
3. Reagent magnets mix properly.
4. Calibration setup and positioning
5. Update New software if needed

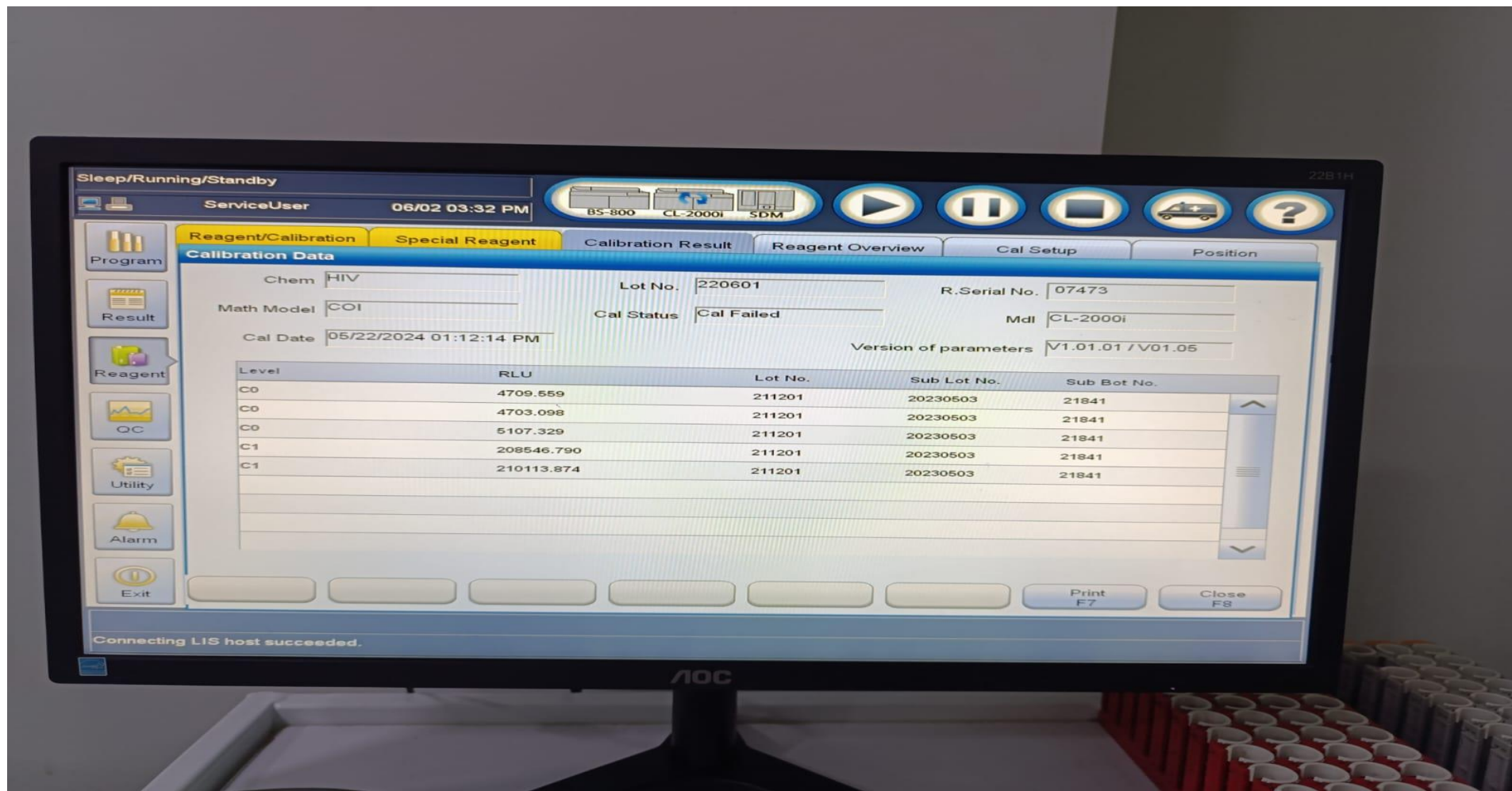
Analyze and find root cause:

1. Recalibrate
If calibration failed, try to calibrate with New LOT of Reagent.
To check if it is Reagent issue or not, try .
If calibration passed successfully Run QC
2. Run QC



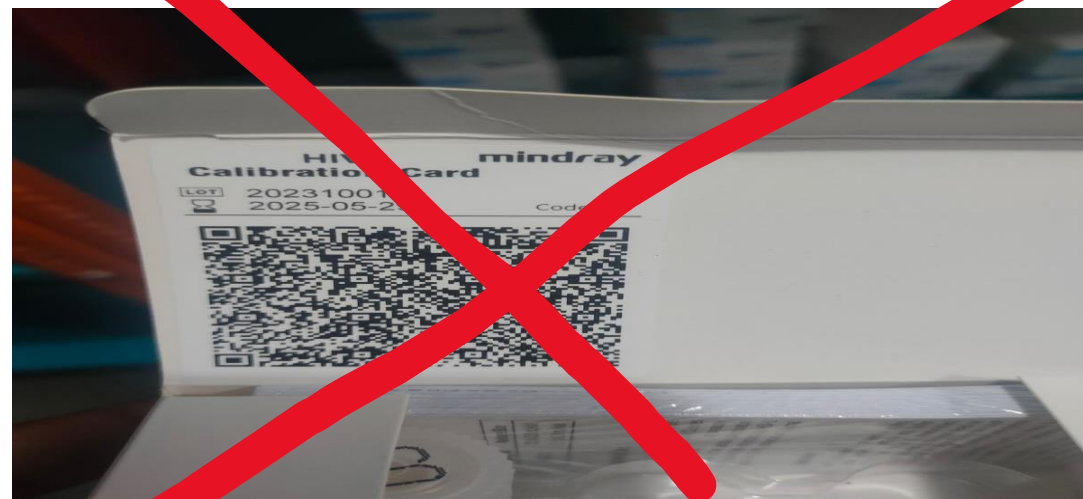
In our case **single** calibration failed, so it is not instrument issue.

Calibration result



Case analysis:

- No problem with other tests;
- System status of analyzer is ok: no error message, no alarms;
- Effect check is ok;
- Expiration date of reagent is expired but was no issue the same kit before using the new calibrator ;
- Consumables status is Ok;
- Ask the customer to give me the calibrator Card to review the calibration setup, said that we receive the calibrator aliquot without any card and run it, thought that it was the same calibrator lot.



- Contact the distributor to send the calibrator
- Review the RLU (Factory)

HIV		Catalog							
Calibrator	Cal point	Lot210801	Lot211201	Lot220501	Lot220502	Lot220901	Lot230201	Lot230601	Lot231001
Reagent Lot20220601	Cutoff	123812	123866	123871	123871	108426	73743	68538	63230
	C0-RLU	8629	8528	8463	8463	7301	5780	5479	4698
	C1-RLU	625242	668735	704951	704951	543182	360160	351767	295181
	C0-COI	0.07	0.07	0.07	0.07	0.07	0.08	0.08	0.07
	C1-COI	5.05	5.40	5.69	5.69	5.01	4.88	5.13	4.67
	Cal factor 2	0.1868	0.1747	0.1657	0.1657	0.1887	0.1918	0.1821	0.2015
	Cal factor 1	0.8132	0.8253	0.8343	0.8343	0.8113	0.8082	0.8179	0.7985

Recalibrate

Background

Ideas

Solution

Summary

Calibration (Calibrated)

Sleep/Standby/Standby

ServiceUser 06/02 04:57 PM

BS-800 CL-2000i SDM

Reagent/Calibration Special Reagent Calibration Result Reagent Overview Cal Setup Position

Calibration Data

Chem HIV Lot No. 220601 R.Serial No. 07363

Math Model COI Cal Status Calibrated Mdl CL-2000i

Cal Date 06/02/2024 04:01:17 PM Version of parameters V1.01.01 / V01.05

Level	RLU	Lot No.	Sub Lot No.	Sub Bot No.
C0	5249.165	231001	20230503	21842
C0	5915.946	231001	20230503	21842
C0	4877.395	231001	20230503	21842
C1	206246.122	231001	20230503	21842
C1	210758.872	231001	20230503	21842

Program Result Reagent QC Utility Alarm Exit

Print F7 Close F8

Conclusion

Check effect check,
Calibrator, Reagent, substrate
open date, On board stability
of consumables.

Check the Setup and
operation carefully

Not recommended to
sent the calibrator
without calibration card .

Not recommended to aliquot
the calibrator in the
warehouse and send it to the
customers .

Thanks

mindray迈瑞