Fe calibration failure

IVD International Clinical Application Department

Anatoliy Kalinin, Clinical Application Specialist - Russia, Moscow branch

2024/9/11

CONTENTS

mindray 迈瑞

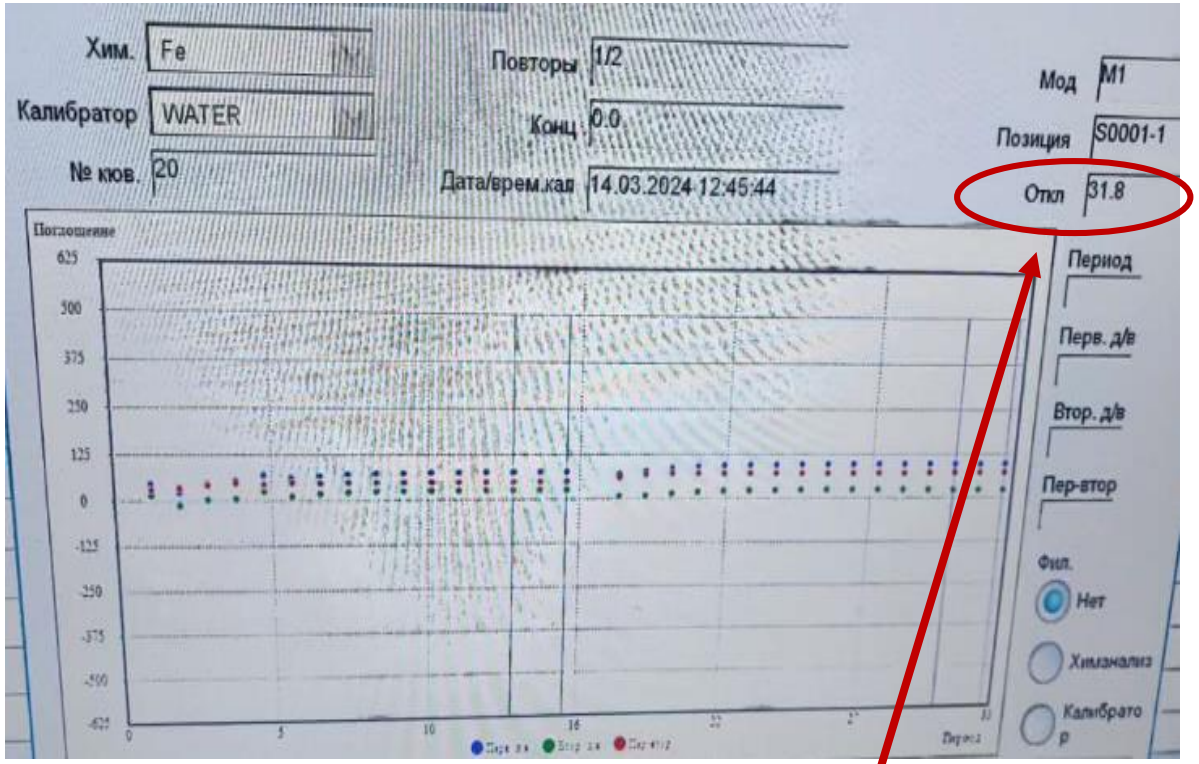
Case Background

Хим.	№ парт	СерНореа	Флаг	Сост.калиб
Fe	3006		DUP	Сбоев кал.
Fe	3006		DUP	Сбоев кал.
Fe	3002		DUP	Сбоев кал.

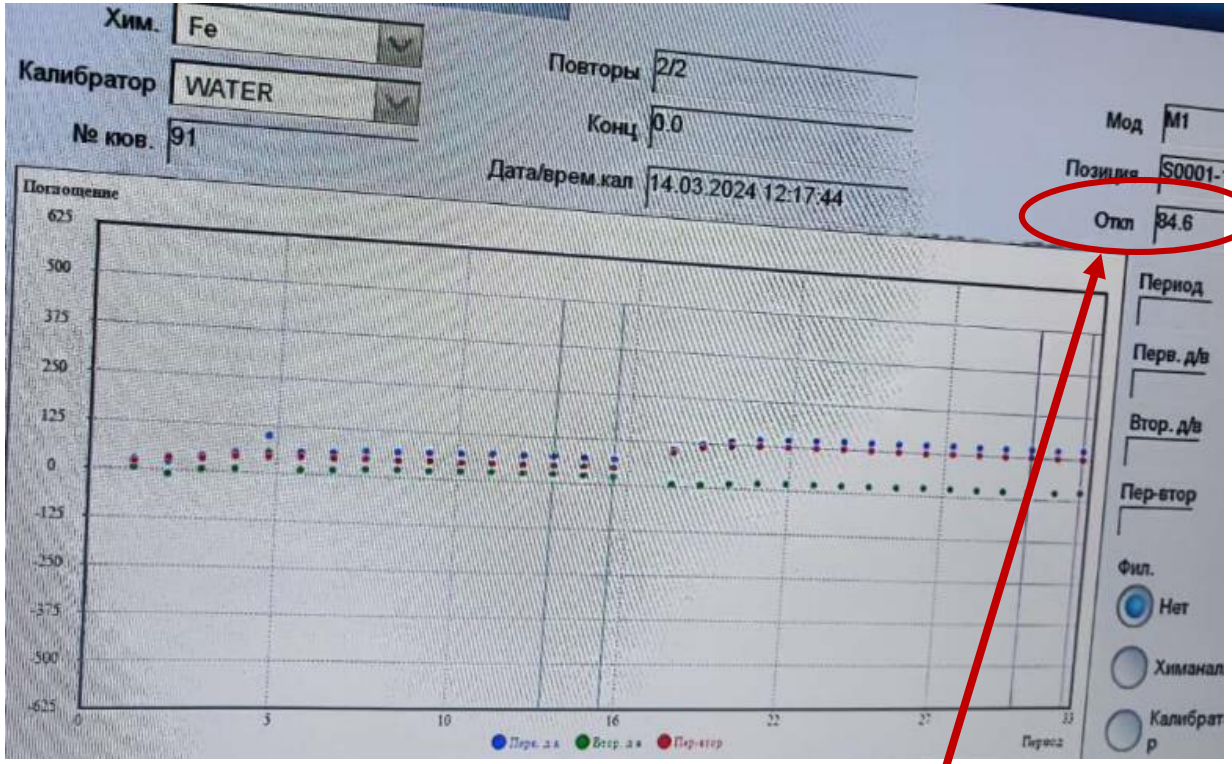
Problem:

- Fe calibration failure with DUP flag.
- The reagent is not expired.
- Reagent opened 3 days ago and stored at 2-8℃ in refrigerator.

Case Background



Response 31,8

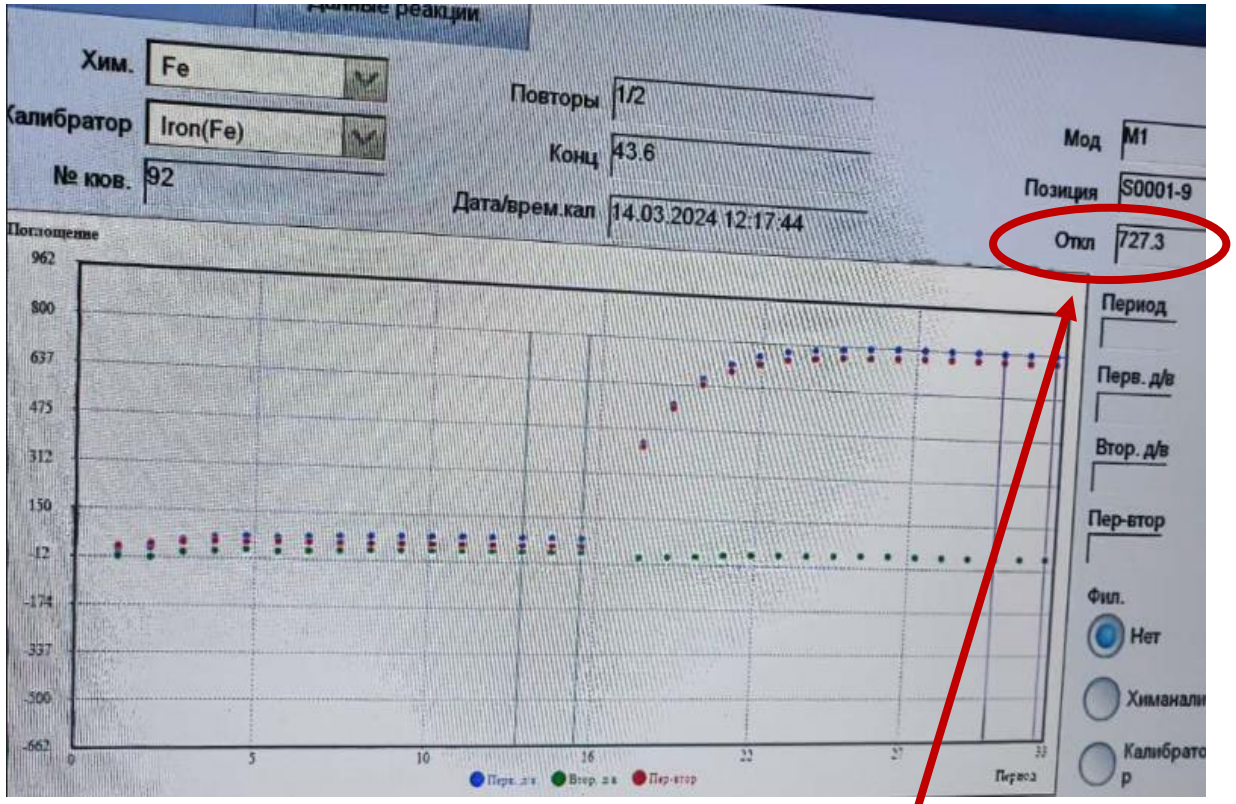


Response 84,6

- Fe calibration failure with DUP flag because of difference between water response in replicates
- Reagent opened 3 days ago and stored at 2-8℃ in refrigerator.

mindray 迈瑞

Case Background



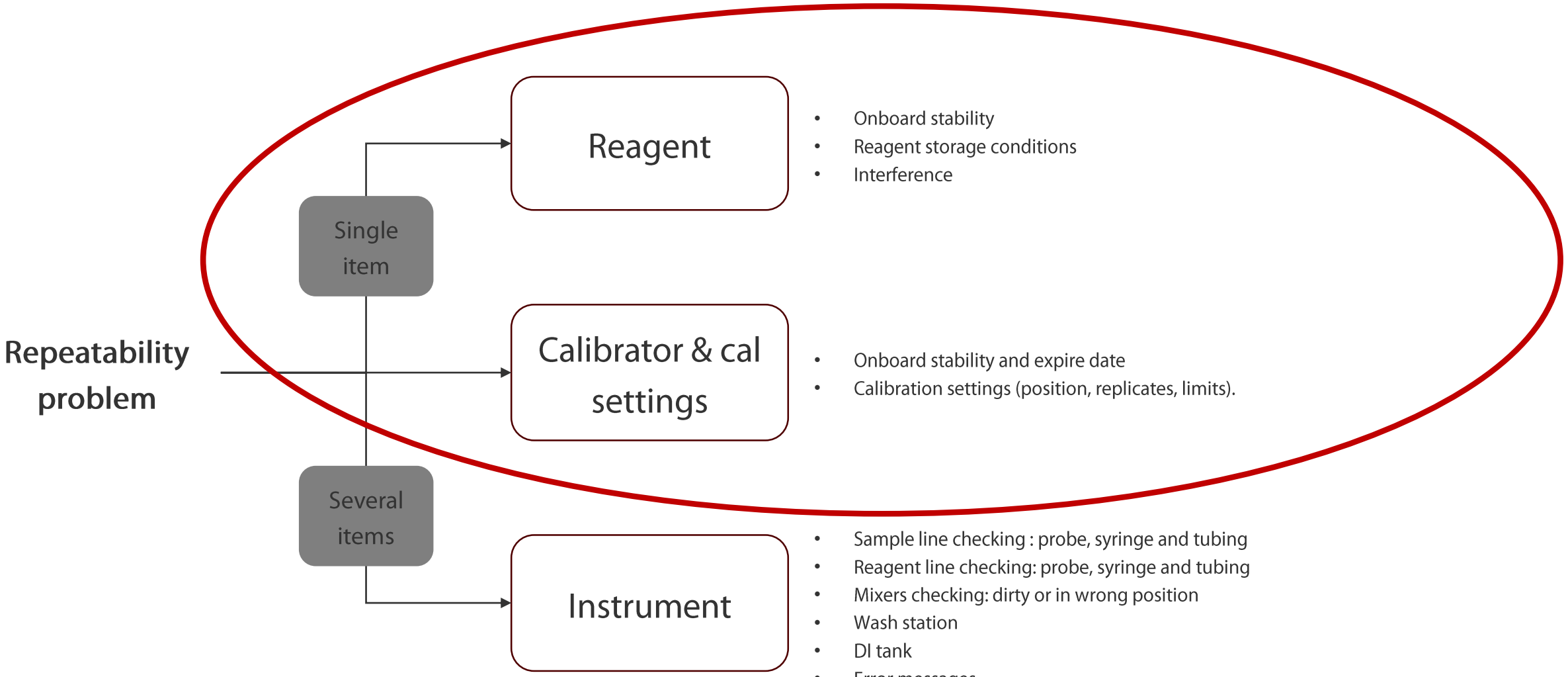
Response 727,3

Response 723,9

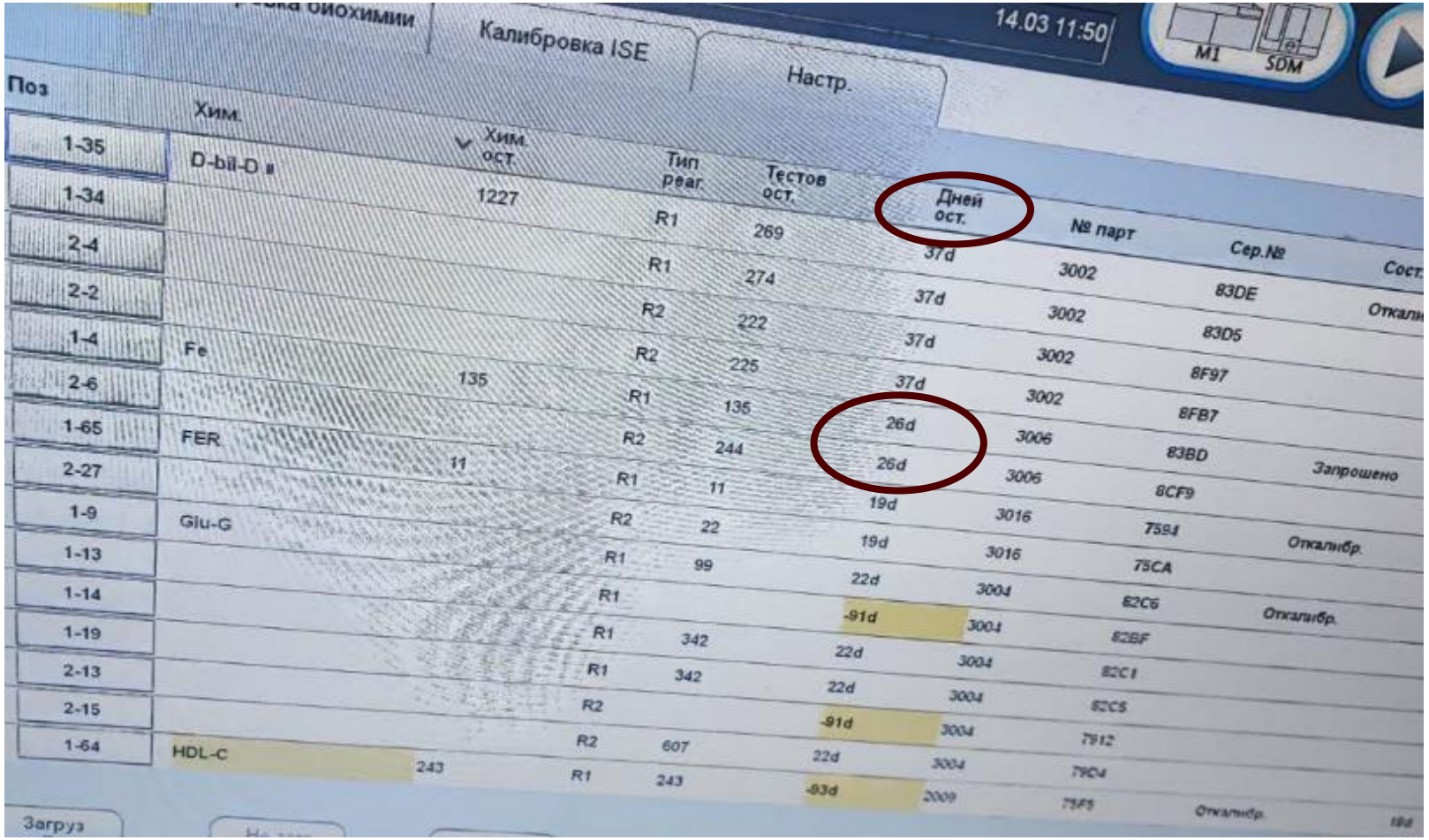
- No difference between cal response in replicates

mindray 迈瑞

Case ideas



Reagent



Changing reagent bottle and cal didn't solve calibration failed problem.

No cross-contamination with other reagents.

1. Reagent onboard stability

26 day

2. How many reagent bottles are onboard?

1 bottle

3. If there are > 2 bottles, which bottle used for calibration?

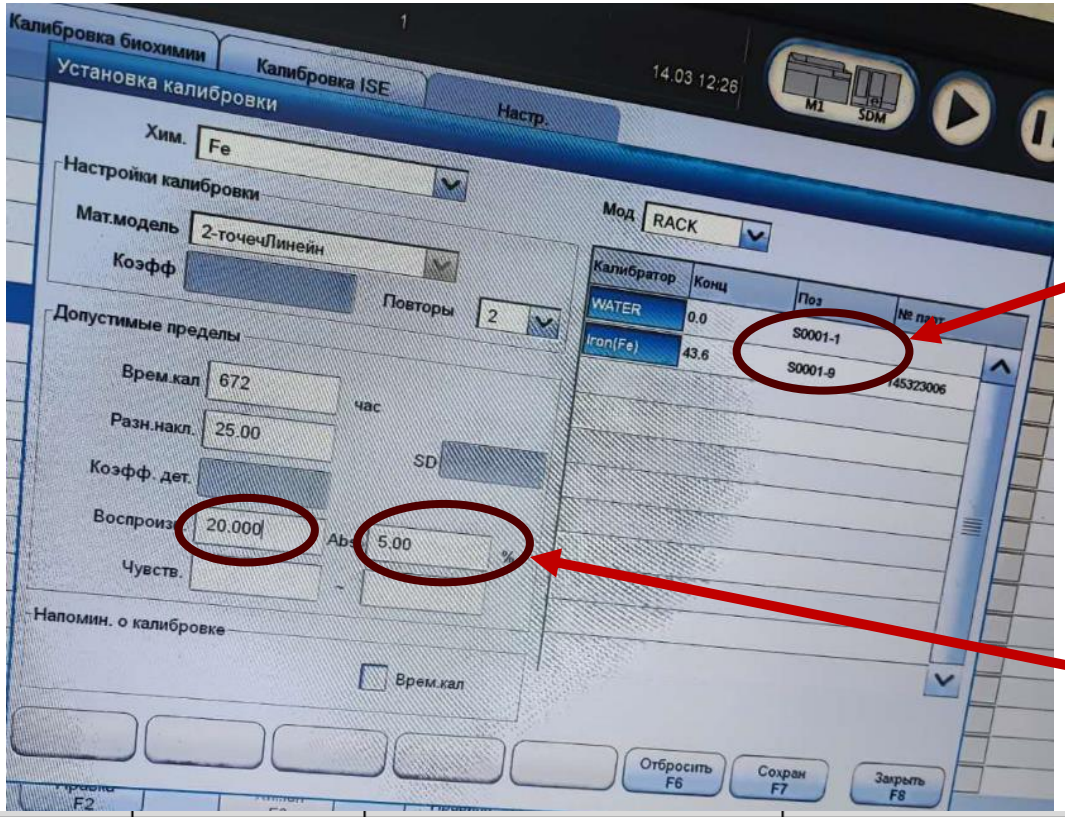
1 bottle

4. Reagent storage temperature

2-8 ℃

mindray 迈瑞

Checking settings



Checking calibrator proper position

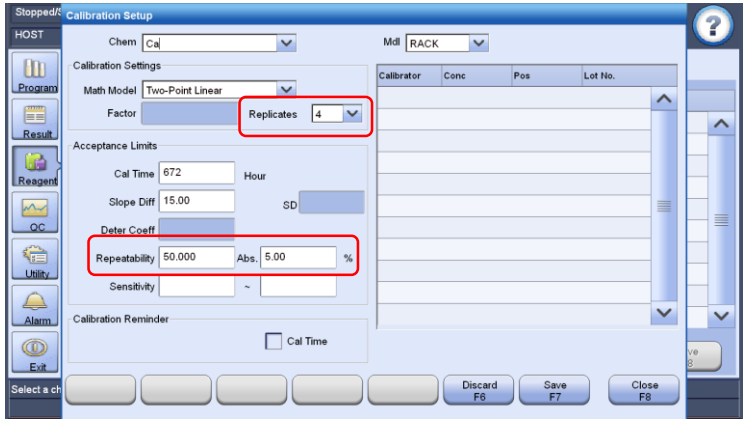
Repeatability	The repeatability is the difference of the maximum and minimum response of each calibrator. If the calculated calibrator response difference is greater than the set limit, the system will give the flag "DUP" and an alarm. The input range must be within 0-34,000. The default is blank, which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

Abs is the meaning of absolute value, and % is the relative deviation. Only when two conditions are met at the same time can DUP flag be triggered.

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.

Checking settings

DUP



Replicates: Calibration test repetitions

Conditions for DUP flag triggering:

- ABS is absolute deviation, % is relative deviation, when both conditions are met, the system triggers DUP alarm。

Common calibration alarms	Cause	Corrective Actions
DUP	Calibration repeatability not satisfied	1. Recalibrate. (whether the repeatability of each calibrator has deviation. if it has been repeated 4 times, use the deviation of the maximum and minimum values, check the mixer, and check if the repeatability is abnormal due to factors such as carryover.) 2. Delete the calibration repeatability limit parameter.

mindray 迈瑞

Checking calibration results

	Water response	Calibrator response
1st replicate	31,8	727,3
2nd replicate	84,6	727,9
Difference between, %	166,04	0,08
Abs difference	52,8	0,06

Too high difference in both Abs and % relative deviation on water responses between two replicates.
Both checking limits out of range, so it is the reason of DUP flag

Possible solutions:
Replace water with physiological saline?...clean mixers?

Case Solution

Maintenance

- Check the reagent probe/ sample probe/mixer exterior: Make sure the shape is normal and there are no stain left
- To check the cuvette: the cuvettes are clean and have been replaced as required;
- To check the syringe: Make sure there are no leakage below each syringe;
- To check the alarm files: pay more attention about the alarm information related to the water quality and lamp;

Recalibration

- Use fresh physiological saline and DI water

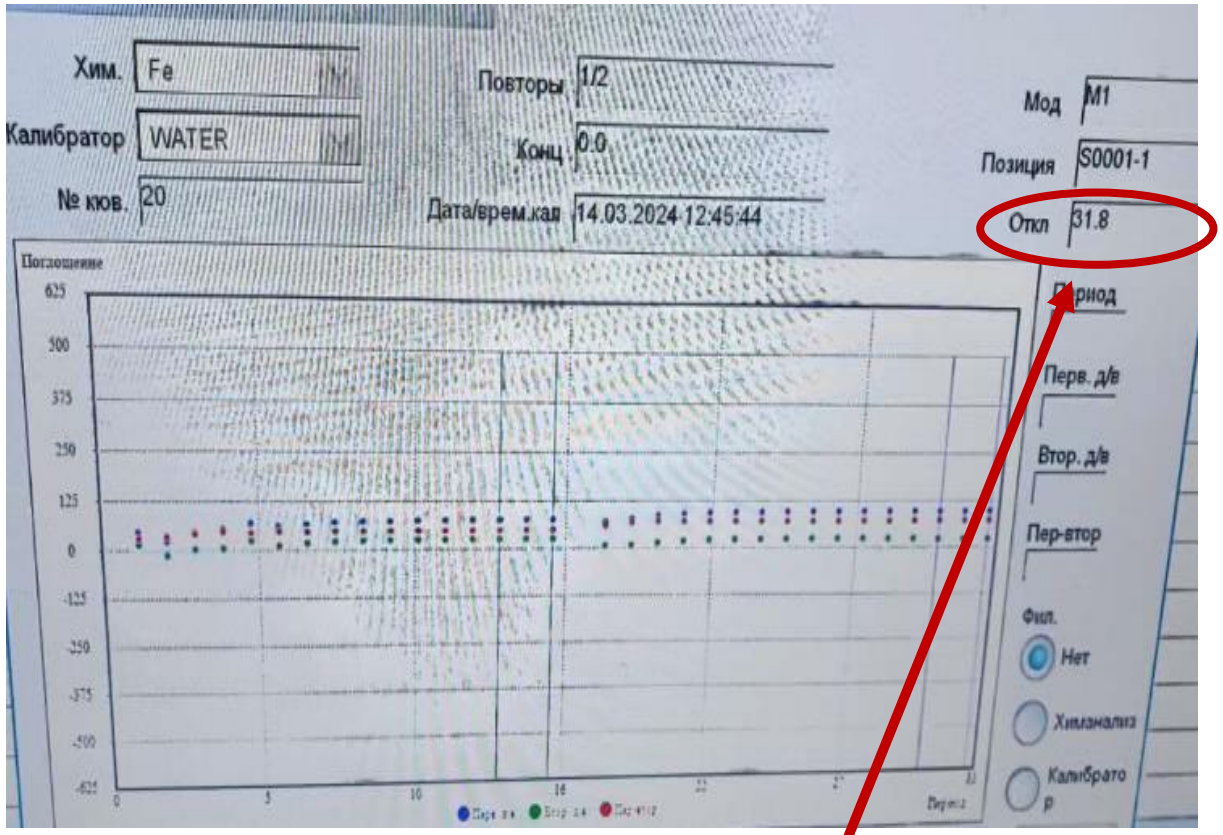
Check response

- Analyze reaction curves and response are good

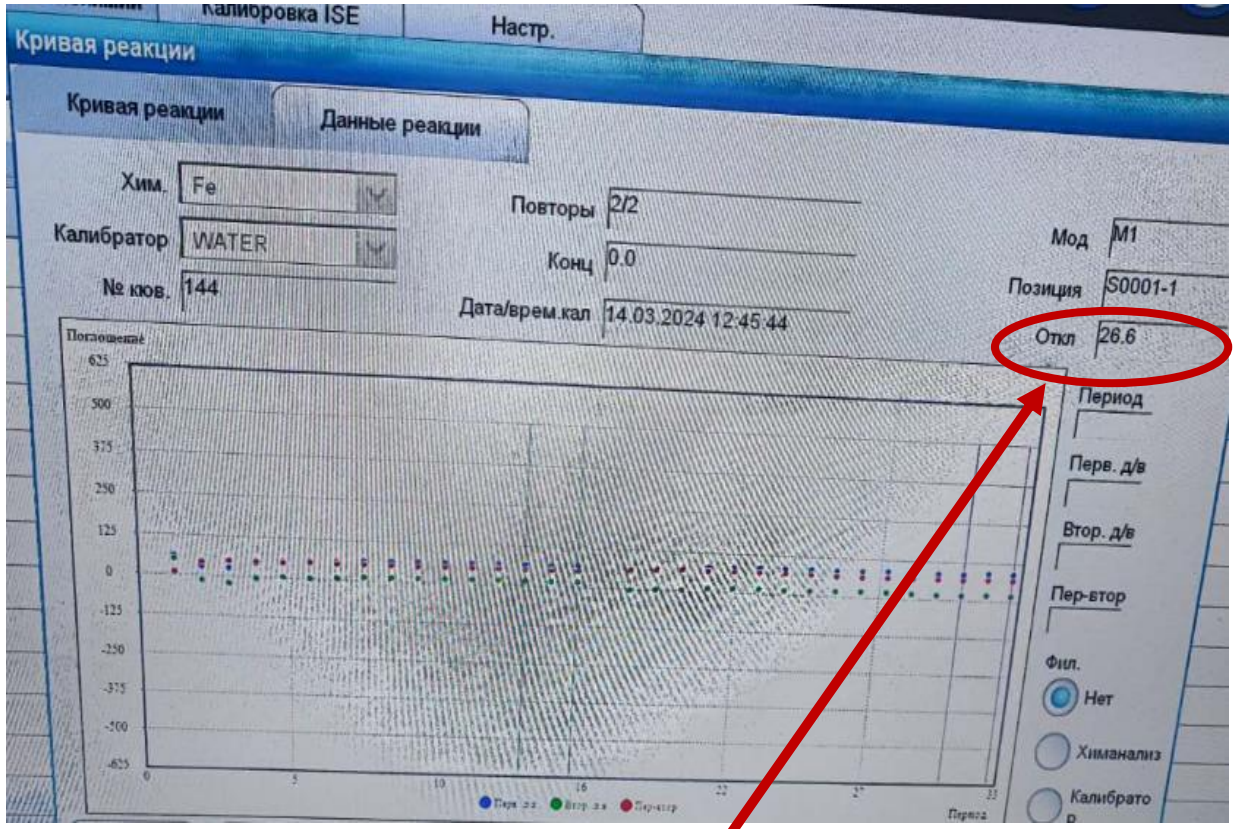
Run QC and samples

- QC pass and sample results are ok

Case Solution



Response 31,8

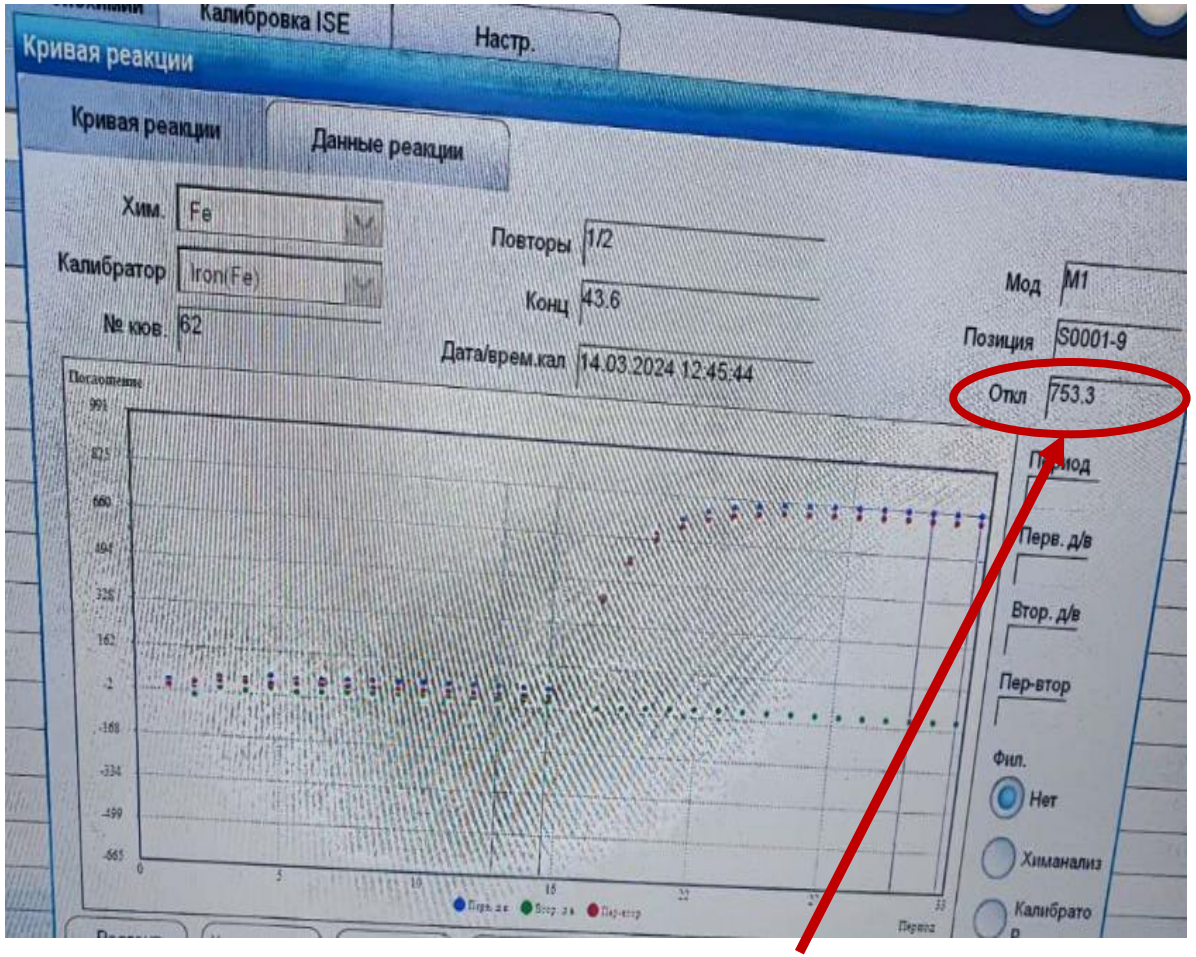


Response 26,6

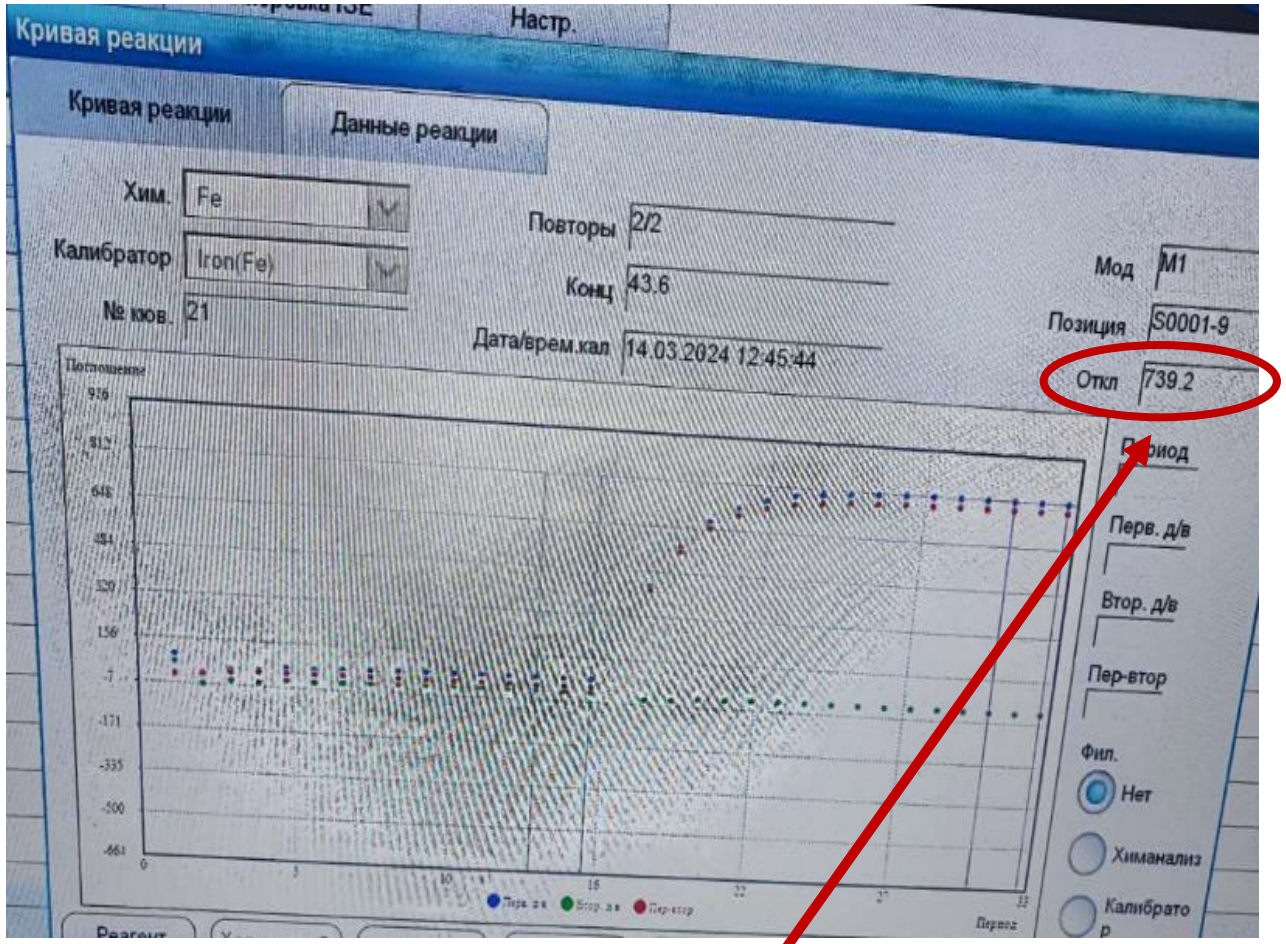
After replace physiological saline instead water in rack and cleaning mixers we passed DUP flag checking

mindray 迈瑞

Case Solution



Response 753,3



Response 739,2

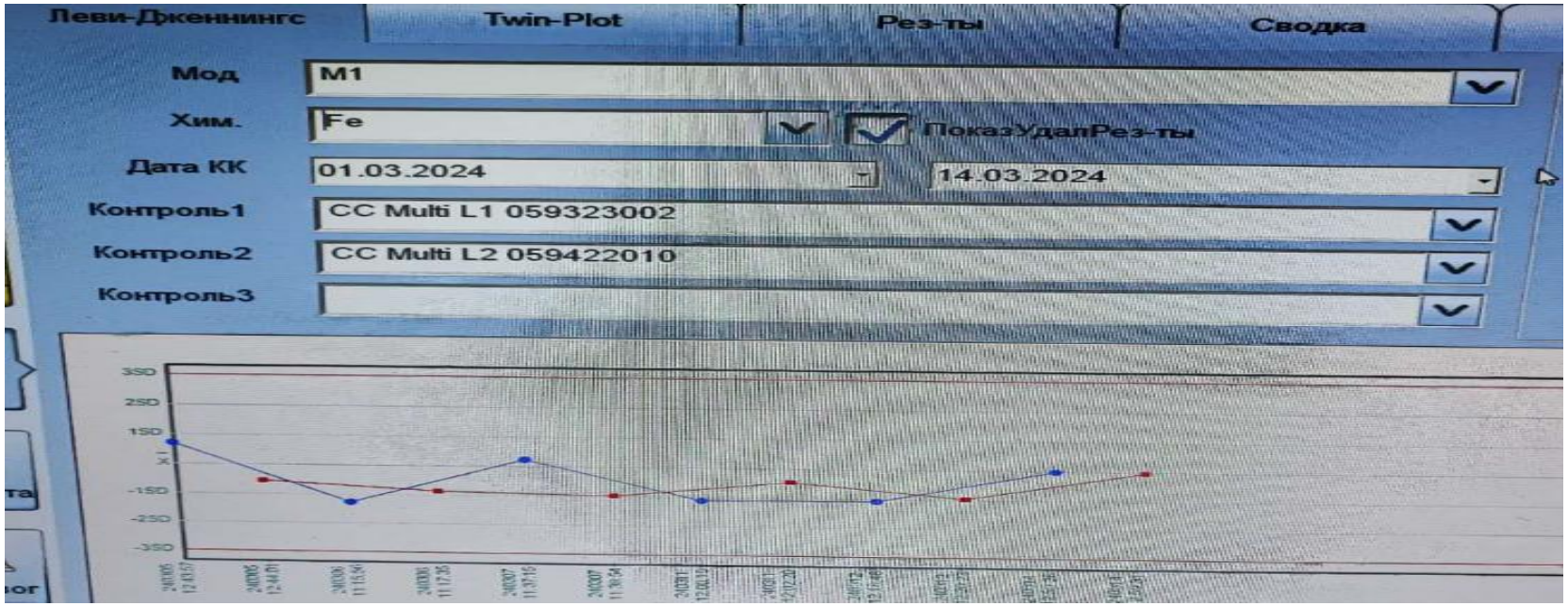
mindray 迈瑞

Checking calibration results

	Water response	Calibrator response
1st replicate	31,8	727,3
2nd replicate	26,6	727,9
Difference between, %	16,35	0,08
Abs difference	5,2	0,06

Too high difference in % relative deviation but we pass Abs checking on water responses between two replicates.
So we passed DUP flag checking

Case Summary



- **Replace water before each Fe calibration!** Water quality can influence Fe item greatly. Place physiological saline instead water in sample carousel or sample rack corresponding position.
- **Provide periodical maintenance.**

Contamination

- Iron chips from mixer or probe could interfere Fe test result, maintenance to the instrument is very important to the Fe test.

mindray 迈瑞

Thanks!

mindray 迈瑞