CASE SHARING

# CRP II CALIBRATION ISSUE ON BS 240

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# AGENDA

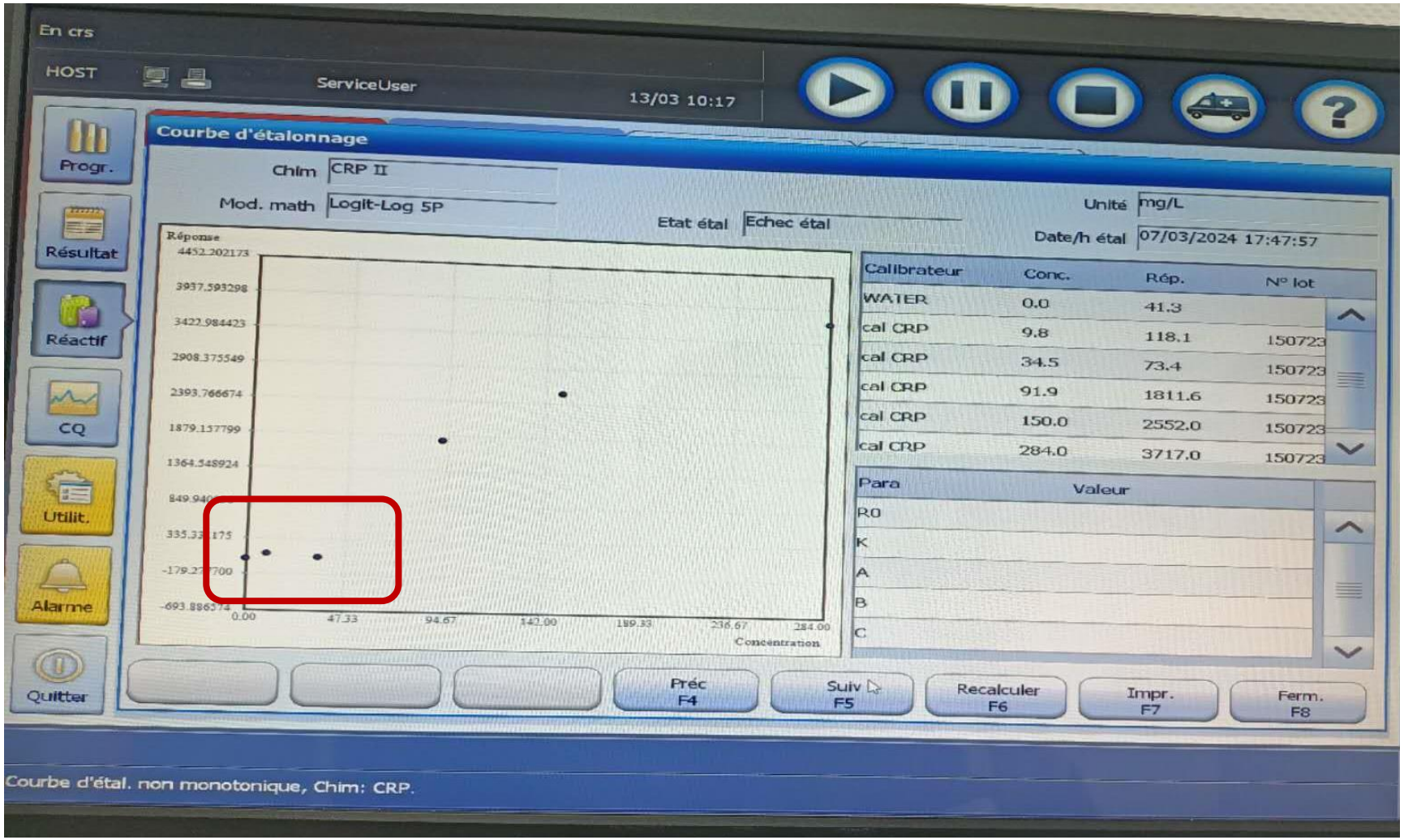
1- ISSUE

2- ESCALATION AND DATA ANALYSIS

3- SOLUTION AND CONCLUSION

4- SUMMARY

# 1- ISSUE




- **Where :** Private laboratory in Algiers
- **Machine model :** BS 240 newly installed

- ISSUE : **CRP II calibration failed**
- Flag : **MON**
- Reagent lot number : 148923007
  Expiration date : 2024-12-04
- Calibrator lot number : 150723001
  Expiration date : 2024-07-31
- QC lot number : no information
- Customer calibrated CRP II 3 times with the same results and flag.

**The third level calibration results was lower than the second. It causes MON flag.**

# 2- ESCALATION AND DATAS ANAYSIS

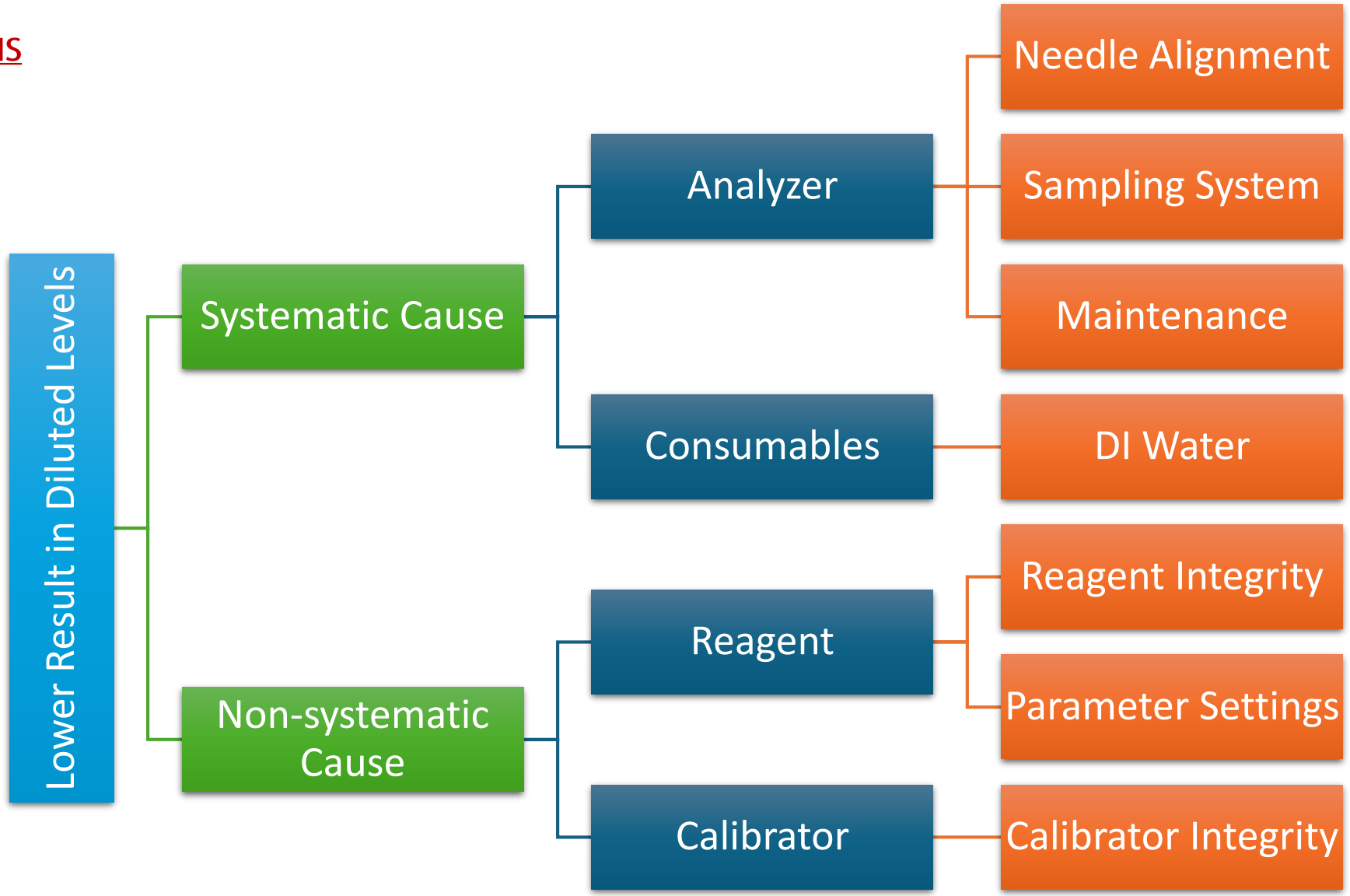
- DATA ANALYSIS

| Calibrators | Standard responses | Calibration failed response | | | | | |
|---|---|---|---|---|---|---|---|
| | | 1st Cal | 1st Bias | 2nd Cal | 2nd Bias | 3rd Cal | 3rd Bias |
| Water | 232.4 | 41.3 | -82.229% | 53.1 | -77.151% | 20.7 | -91.093% |
| CRP cal 2 | 527.1 | 118.1 | -77.594% | 131 | -75.147% | 142.4 | -72.984% |
| CRP cal 3 | 1184.1 | 73.4 | -93.801% | 74.8 | -93.683% | 76.9 | -93.506% |
| CRP cal 4 | 2503 | 1811.6 | -27.623% | 1875 | -25.082% | 1857 | -25.801% |
| CRP cal 5 | 3680.7 | 2552 | -30.665% | 2583 | -29.818% | 2572 | -30.114% |
| CRP cal 6 | 5657.5 | 3717 | -34.300% | 3739 | -33.904% | 3690 | -34.784% |

Compared to the factory reference calibration curve, the response of the first 3 levels are significantly lower. Considering these levels are related to water and dilution calibration, it should be the issue of water and dilution calibration.

# 2- ESCALATION AND DATAS ANAYSIS

- HYPOTHESIS



# 2- ESCALATION AND DATAS ANAYSIS

- VERIFICATION - Reagent

## Reagent Integrity

- **no problem reported with this lot** in other laboratories.
- Changed reagent bottle (same lot) ran a new calibration with **the same result**.

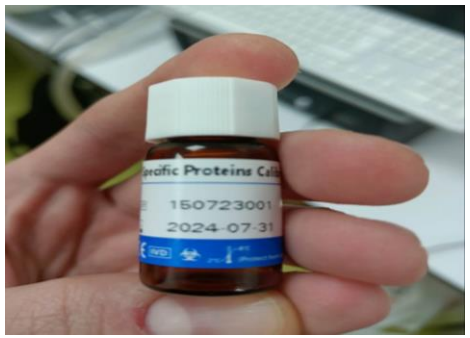
## Reagent Settings

- Parameter  settings are normal.
- Calibration settings are normal.
- Calibration dilution settings are normal.


Unlikely to be caused by reagent.

# 2- ESCALATION AND DATAS ANAYSIS

- VERIFICATION – Analyzer & Calibrator




## Calibrator

- Calibrator was replaced and with the same result.
- Calibrator volume is enough.

## Analyzer

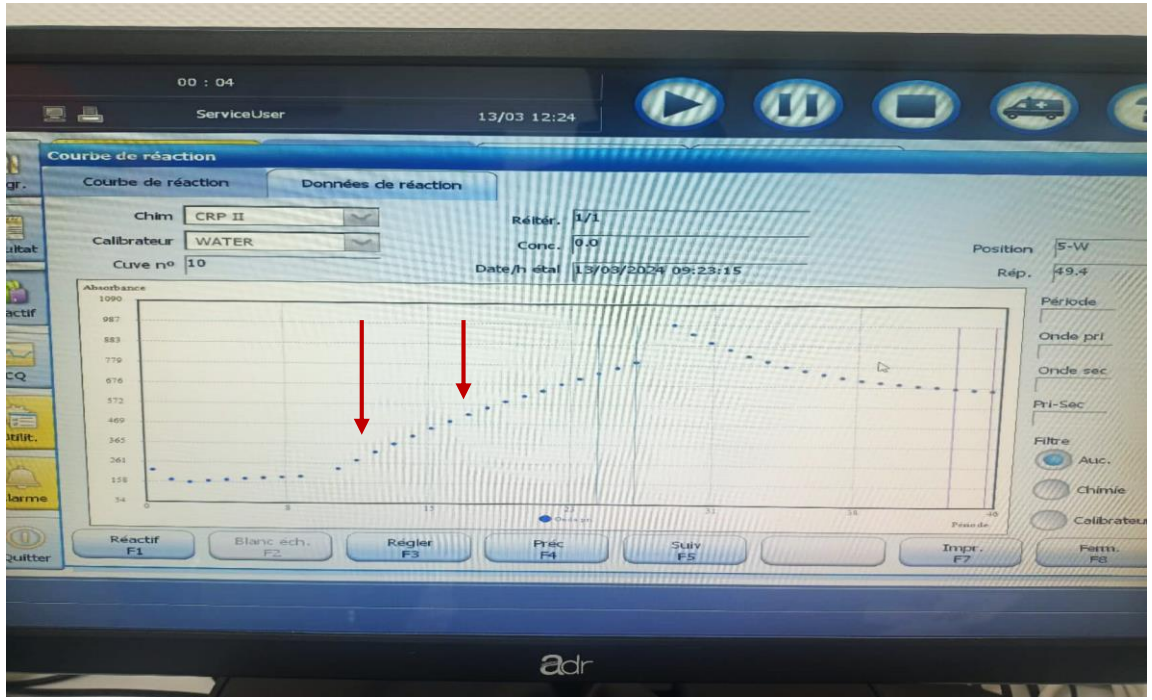
- The analyzer was newly installed.
- Service engineer checked the analyzer and ensured the machine was working normally, but the recalibration failed with the same result.

Unlikely to be caused by calibrator or analyzer.

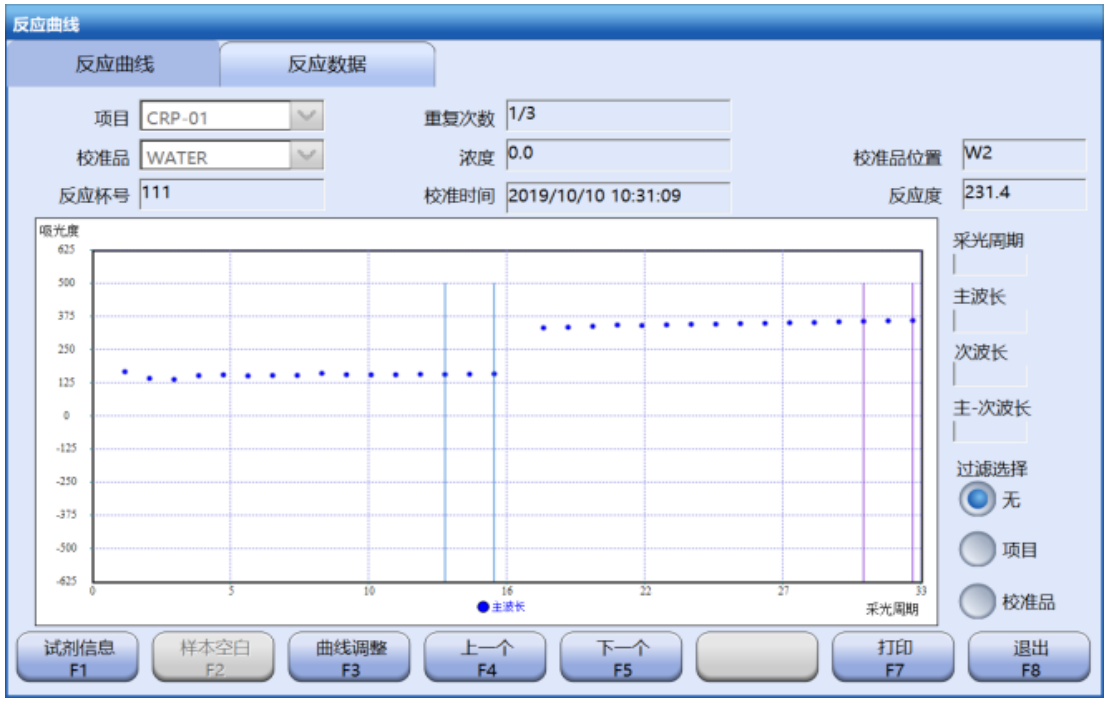
# 2- ESCALATION AND DATAS ANAYSIS

## - VERIFICATION - Consumables

Considering the responses of the first 3 levels are significantly lower, the water quality should be questioned, so reaction curve of DI water was checked.




Reaction curve of DI water level

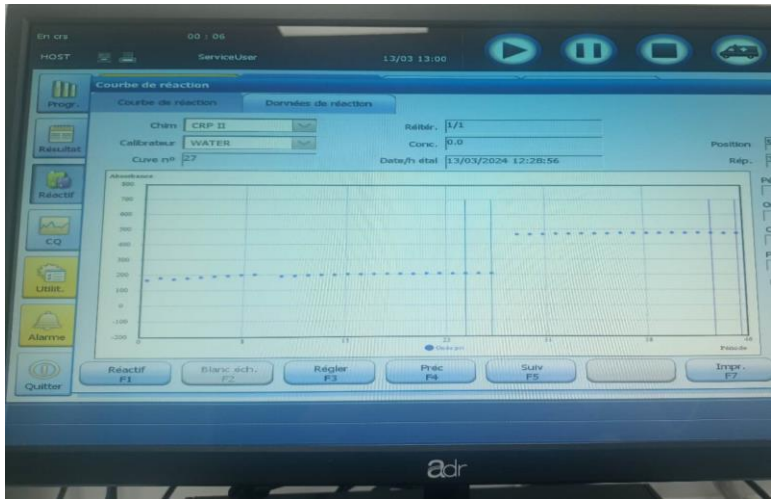



Standard water reaction curve

The reaction curve of DI water level was increasing during incubation period, which indicates interference from water. It tells us that the water quality was not good, causing lower results in the calibration levels related to DI water.

# 3- SOLUTION AND CONCLUSION


CRP II calibration curve result with good DI water



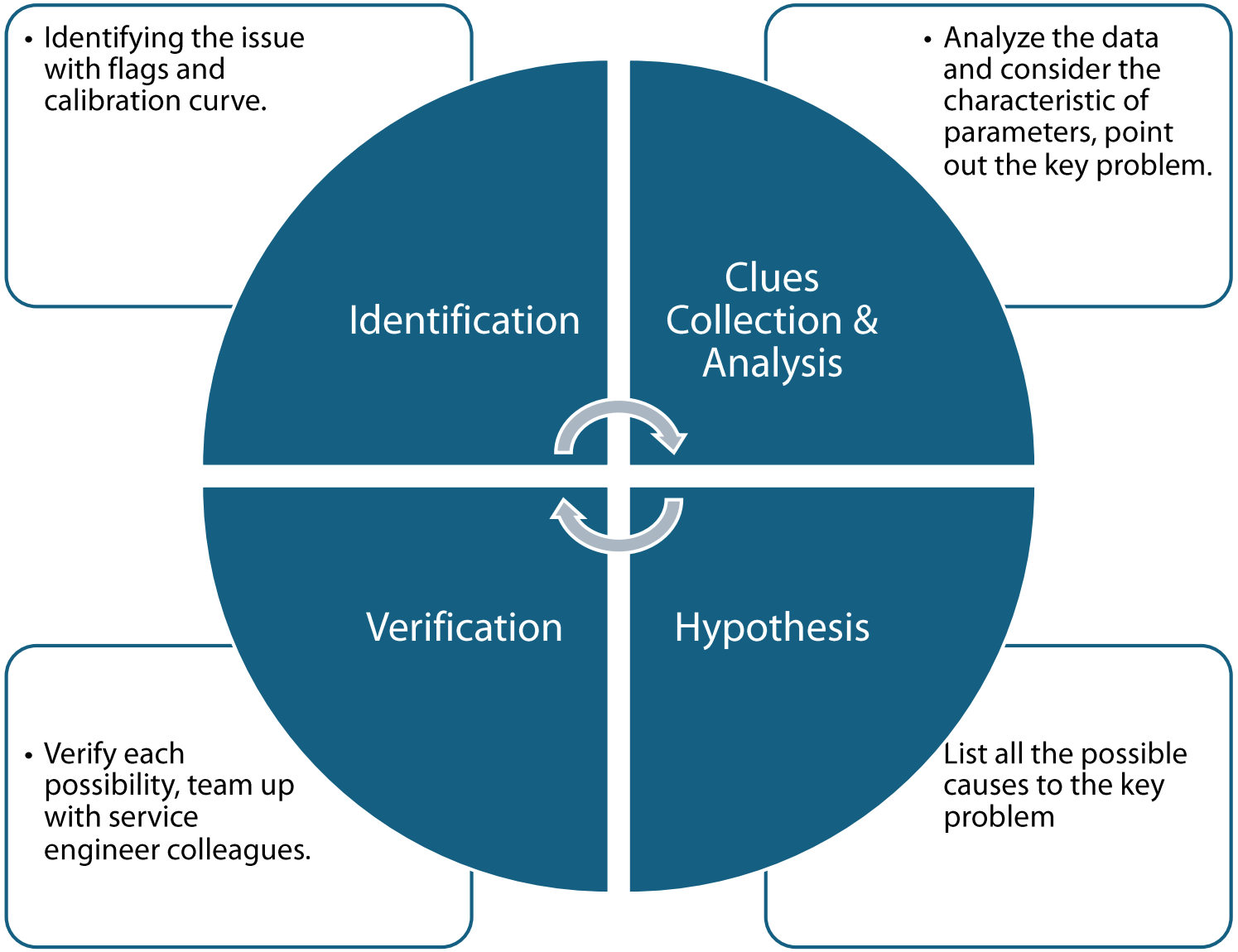

CRP II water reaction curve with the new DI water

QC level 1 and 2 near to the targuet value

**DI water was changed** and a new calibration was run

- The calibration **passed**
- QC on the **target value.**

# 4- SUMMARY


• Identifying the issue with flags and calibration curve.
• Analyze the data and consider the characteristic of parameters, point out the key problem.
Identification
Clues Collection & Analysis
Verification
Hypothesis
• Verify each possibility, team up with service engineer colleagues.
List all the possible causes to the key problem

Thank **you!**