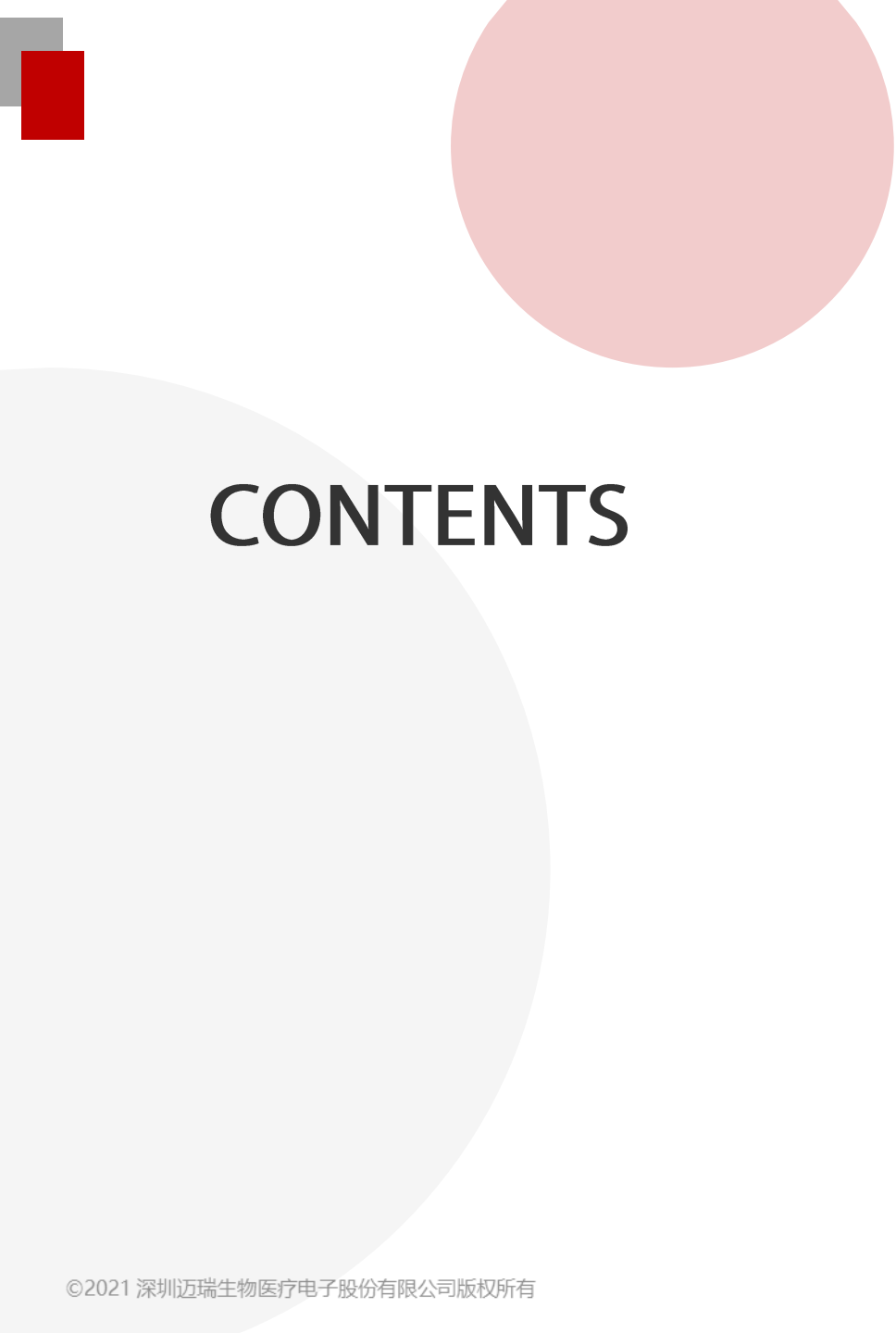


# Critical Carryover Case Study: Resolving Falsely Elevated RF Results

IVD International Clinical Application Department : INDIA

Biswajit Adak

12.05.2025



# CONTENTS

01. Case Background



02. Case Ideas



03. Case Solution



04. Case Summary



# Case Background

Background

Ideas

Solution

Summary

## Issues :

- Customer complains about RF parameter that our RF parameter is not working well & reporting high values randomly.
- When rerun the parameter, values are coming normal.
- Issues escalated

RF PREVIOUS DAY

**Test Report**

|             |          |            |           |
|-------------|----------|------------|-----------|
| First Name: | AKBAR    | Last Name: |           |
| Sex:        | M        | Age:       | 36Year    |
| Patient ID: | 14187814 | Sample ID: | 242096571 |
| Department: |          | Physician: |           |
| Samp Type:  | Others   | Bar Code:  | 242096571 |
| Diagnosis:  |          | Comment:   |           |

| No. | Test Name | Tests             | Result | Unit  | Flag | Ref Range |
|-----|-----------|-------------------|--------|-------|------|-----------|
| 1   | RF        | Rheumatoid Factor | 135.35 | IU/mL |      |           |

First run result 135.35 IU/mL

**Test Report**

|             |       |            |       |
|-------------|-------|------------|-------|
| First Name: |       | Last Name: |       |
| Sex:        |       | Age:       |       |
| Patient ID: |       | Sample ID: | 1     |
| Department: |       | Physician: |       |
| Samp Type:  | Serum | Bar Code:  | akbar |
| Diagnosis:  |       | Comment:   |       |

| No. | Test Name | Tests             | Result | Unit  | Flag | Ref Range |
|-----|-----------|-------------------|--------|-------|------|-----------|
| 1   | RF        | Rheumatoid Factor | 12.43  | IU/mL |      |           |

Rerun value 12.43 IU/mL

## Customer details:

- One of the largest testing laboratory in eastern part of India having more than 25 collection centres.

**Daily sample load is approx. 2000 tubes.**

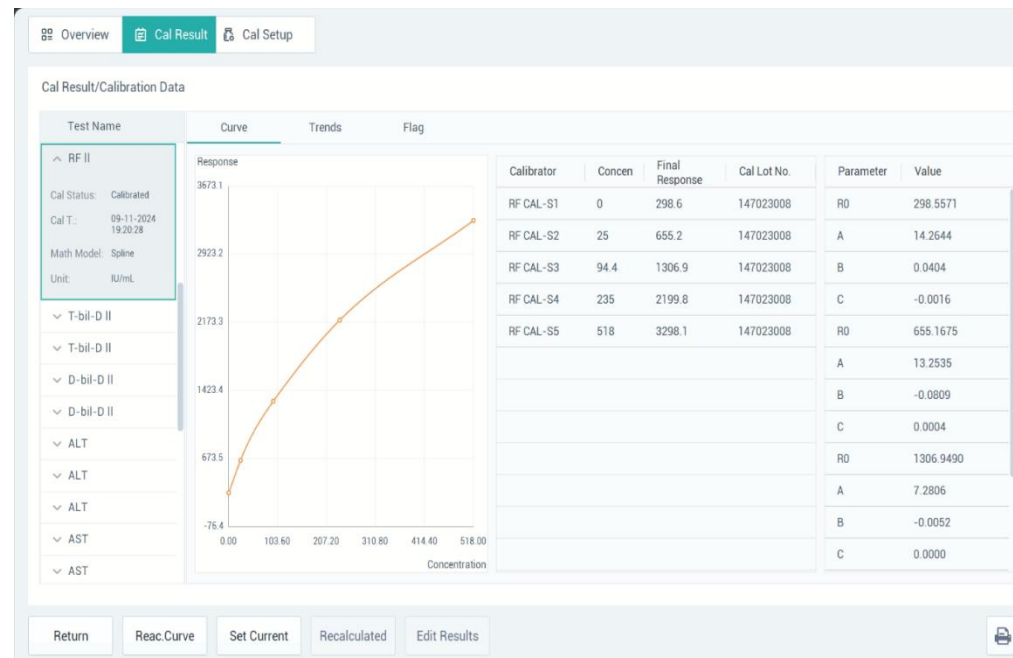
Already user of Roche Cobas 6000 & Mindray BS-380, 2units last 5years.

- We have installed two units of BS-600M (two units) through our national channel partner to meet customer demand with increasing sample load (reduce TAT) & match result quality against competitor.

## Observations :

- Issue happening randomly only with RF II parameter.
- Results are always high with 1<sup>st</sup> run & normal in 2<sup>nd</sup> run.
- Checked the samples but sample quality is fine.
- Checked maintenance, found ok.
- Checked calibration of the parameter.
- Checked reaction curve of the reported results.

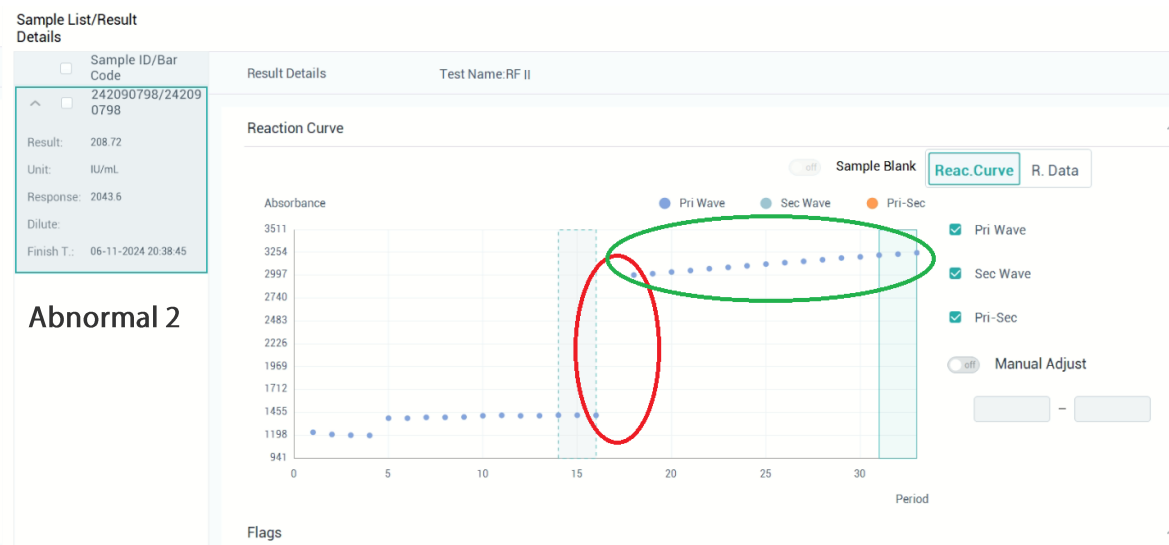
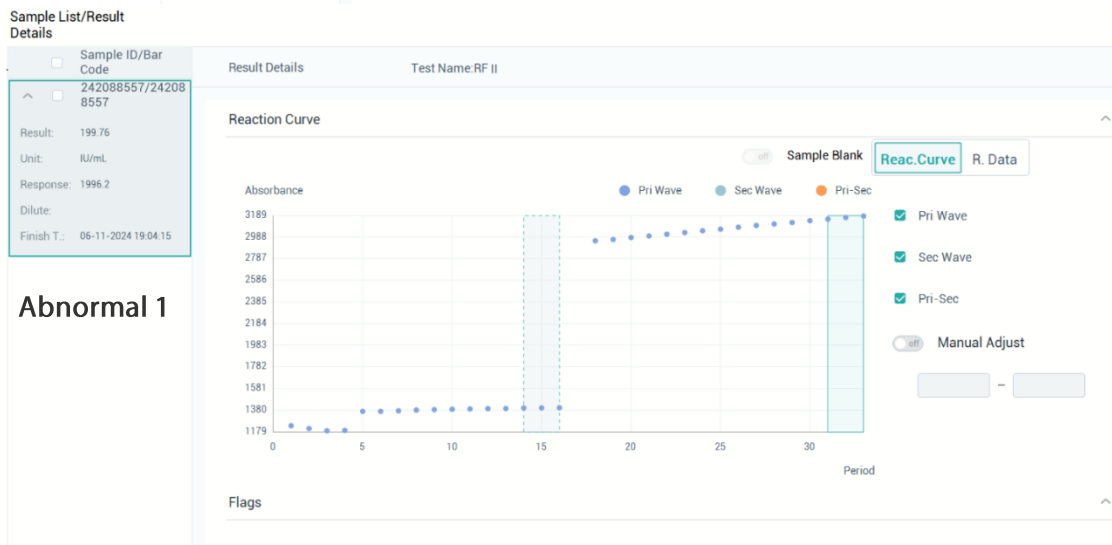
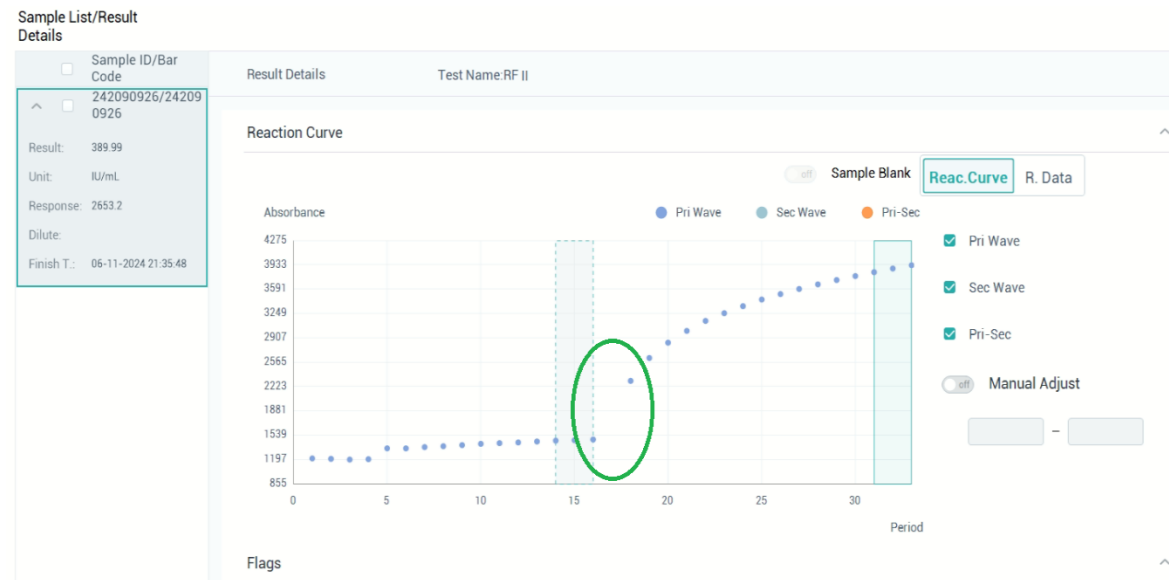
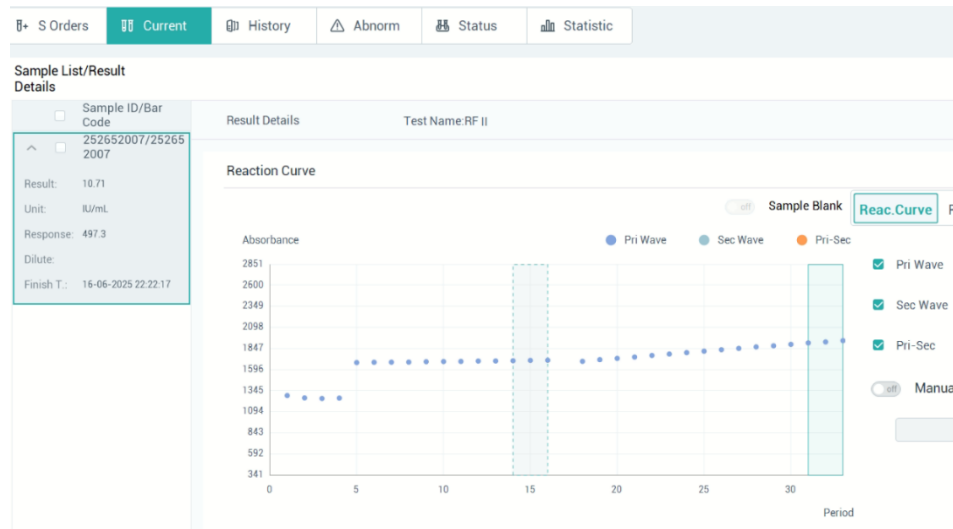
Some thing is not ok.



# Case Solution

## Troubleshooting :

Good reaction graph of a high sample



# Case Solution

Background

Ideas

Solution

Summary

## Troubleshooting :

- What cause sudden jump of reaction graph after the addition of R2?
- Carryover? From where?
- Customer using two open channel for Creatinine- Jaffe & Total bile acid
- Checked both the open parameters.

Creatinine- Jaffe: PW 505 & SW 570; Total bile acid: PW 412 & RF II: PW 340

- Checked test sequence in sample result view screen according to finish time

Tests/Test View and Setup/CREAT MEDICON

Test: CREAT MEDICON

Measuring Method: Reaction Parameters

Reac Type: Fixed-time Direction: Positive Pri Wave: 505nm Sec Wave: 570nm Rgt Onboard-Day: 14

Tests/Test View and Setup/TOTAL BILE

Test: TOTAL BILE

Measuring Method: Reaction Parameters

Reac Type: Fixed-time Direction: Positive Pri Wave: 412nm Sec Wave: Rgt Onboard-Day: 28

Tests/Test View and Setup/RF II

Test: RF II

Measuring Method: Reaction Parameters

Reac Type: Endpoint Direction: Positive Pri Wave: 340nm Sec Wave: Rgt Onboard-Day: 28

Time Parameter: Blank T: 14 - 16 Read Time: 31 - 33

Sample Parameters: Sample Blank: Standard: 6 μL Decreased: 6 μL Increased: μL Aspirated: 25 μL Diluent: 100 μL

Reagent Parameters: R1 R2 R3 R4

| Type   | Sample ID | Bar Code  | Position | Sample Status | Finish T.        | Host | Test  | Result | Dilute | Flag | Unit  |
|--------|-----------|-----------|----------|---------------|------------------|------|-------|--------|--------|------|-------|
| Rou... |           | 242090848 | N0022-1  | Complete      | 06-11-2024 20:36 | Y    | RF II | 208.72 |        |      | IU/mL |
| Rou... | 242090810 | 242090810 | N0022-2  | Complete      | 06-11-2024 20:36 | Y    |       |        |        |      |       |
| Rou... | 242090656 | 242090656 | N0022-4  | Complete      | 06-11-2024 20:36 | Y    |       |        |        |      |       |
| Rou... | 242089355 | 242089355 | N0022-5  | Complete      | 06-11-2024 20:36 | Y    |       |        |        |      |       |
| Rou... | 242089383 | 242089383 | N0022-6  | Complete      | 06-11-2024 20:36 | Y    |       |        |        |      |       |
| Rou... | 242090428 | 242090428 | N0022-7  | Complete      | 06-11-2024 20:36 | Y    |       |        |        |      |       |
| Rou... | 242090642 | 242090642 | N0022-8  | Complete      | 06-11-2024 20:37 | Y    |       |        |        |      |       |
| Rou... | 242089382 | 242089382 | N0022-9  | Complete      | 06-11-2024 20:37 | Y    |       |        |        |      |       |
| Rou... | 242090614 | 242090614 | N0022-10 | Complete      | 06-11-2024 20:37 | Y    |       |        |        |      |       |
| Rou... | 242090343 | 242090343 | N0027-1  | Complete      | 06-11-2024 20:38 | N    |       |        |        |      |       |
| Rou... | 242090798 | 242090798 | N0027-2  | Complete      | 06-11-2024 20:38 | Y    |       |        |        |      |       |
| Rou... | 242090845 | 242090845 | N0020-1  | Complete      | 06-11-2024 20:41 | Y    |       |        |        |      |       |
| Rou... | 242089371 | 242089371 | N0020-3  | Complete      | 06-11-2024 20:41 | Y    |       |        |        |      |       |

Falsely high RF result from this sample

| Type   | Sample ID | Bar Code  | Position | Sample Status | Finish T.        | Host | Test          | Result | Dilute | Flag      |
|--------|-----------|-----------|----------|---------------|------------------|------|---------------|--------|--------|-----------|
| Rou... |           | 242090848 | N0022-1  | Complete      | 06-11-2024 20:36 | Y    | TC            | 155.8  |        | CAL EX... |
| Rou... | 242090810 | 242090810 | N0022-2  | Complete      | 06-11-2024 20:36 | Y    | TG            | 156.5  |        | SLP       |
| Rou... | 242090656 | 242090656 | N0022-4  | Complete      | 06-11-2024 20:36 | Y    | T-bil-D II    | 0.14   |        | SLP       |
| Rou... | 242089355 | 242089355 | N0022-5  | Complete      | 06-11-2024 20:36 | Y    | D-bil-D II    | 0.11   |        |           |
| Rou... | 242089383 | 242089383 | N0022-6  | Complete      | 06-11-2024 20:36 | Y    | ALT           | 18.3   |        | SLP       |
| Rou... | 242090428 | 242090428 | N0022-7  | Complete      | 06-11-2024 20:36 | Y    | AST           | 19.6   |        | SLP       |
| Rou... | 242090642 | 242090642 | N0022-8  | Complete      | 06-11-2024 20:37 | Y    | ALP           | 65.8   |        | CAL EX... |
| Rou... | 242089382 | 242089382 | N0022-9  | Complete      | 06-11-2024 20:37 | Y    | TP            | 6.93   |        | SLP       |
| Rou... | 242090614 | 242090614 | N0022-10 | Complete      | 06-11-2024 20:37 | Y    | ALB II        | 4.3    |        |           |
| Rou... | 242090343 | 242090343 | N0027-1  | Complete      | 06-11-2024 20:38 | N    | CRP II        | <2.00  |        | <         |
| Rou... | 242090798 | 242090798 | N0027-2  | Complete      | 06-11-2024 20:38 | Y    | AST/ALT       | 1.1    |        |           |
| Rou... | 242090845 | 242090845 | N0020-1  | Complete      | 06-11-2024 20:41 | Y    | IBIL-D        | 0.03   |        |           |
| Rou... | 242089371 | 242089371 | N0020-3  | Complete      | 06-11-2024 20:41 | Y    | CREAT MEDICON | 0.87   |        | R Exp.SLP |

Last test of previous sample

# Case Solution

## Conformed carryover effect from Creatinine- Jaffe (open channel parameter)

|                          |                |    |       |    |   |   |
|--------------------------|----------------|----|-------|----|---|---|
| <input type="checkbox"/> | CREAT MEDIC... | R2 | RF II | DB | 1 | Y |
|--------------------------|----------------|----|-------|----|---|---|

New carryover pair applied for RF II parameter & kept under observation for few days.

After two days customer complained that few other parameters (MLB, CRP II, ASO II) results also not ok.

Advised to apply carryover for those parameters similarly like RF II.

Again, customer suspected & complained about other routine parameters also not ok.

Visited at customer site checked few results & found similar effect coming from Creatinine- Jaffe para.

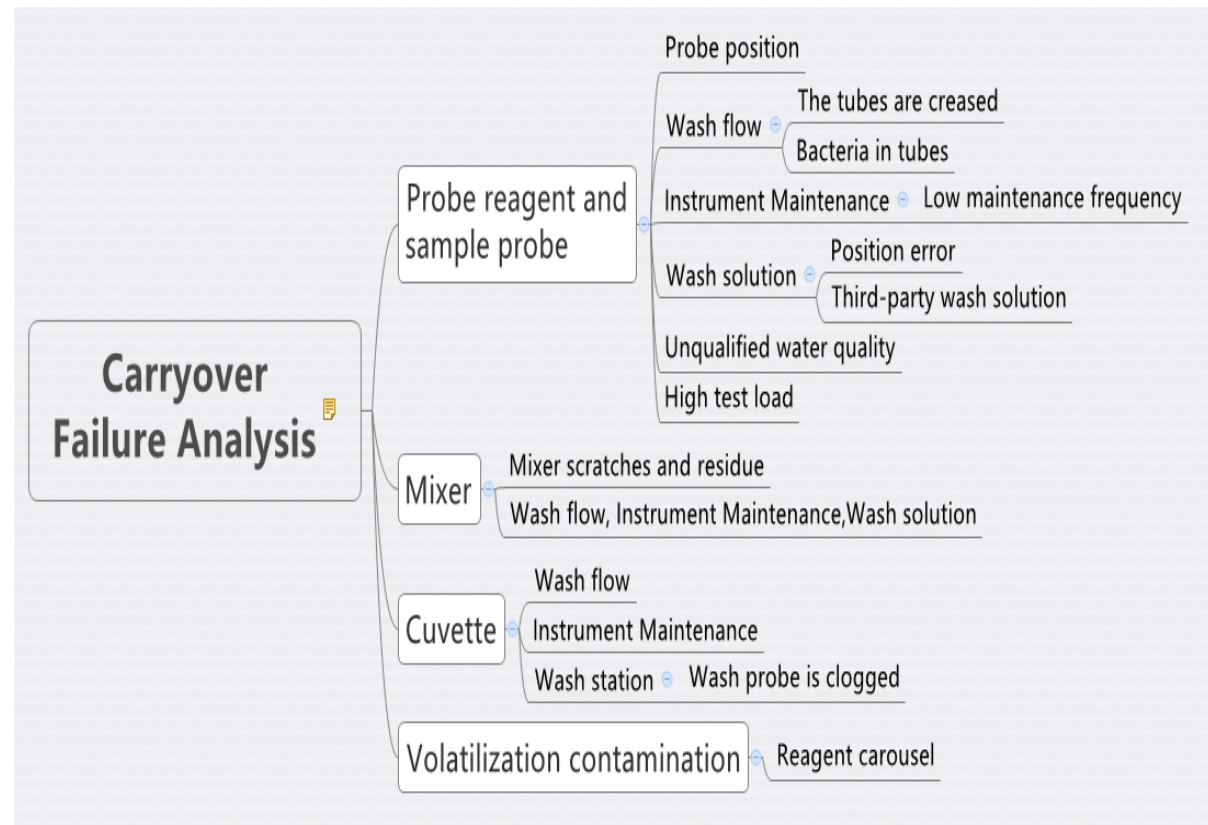
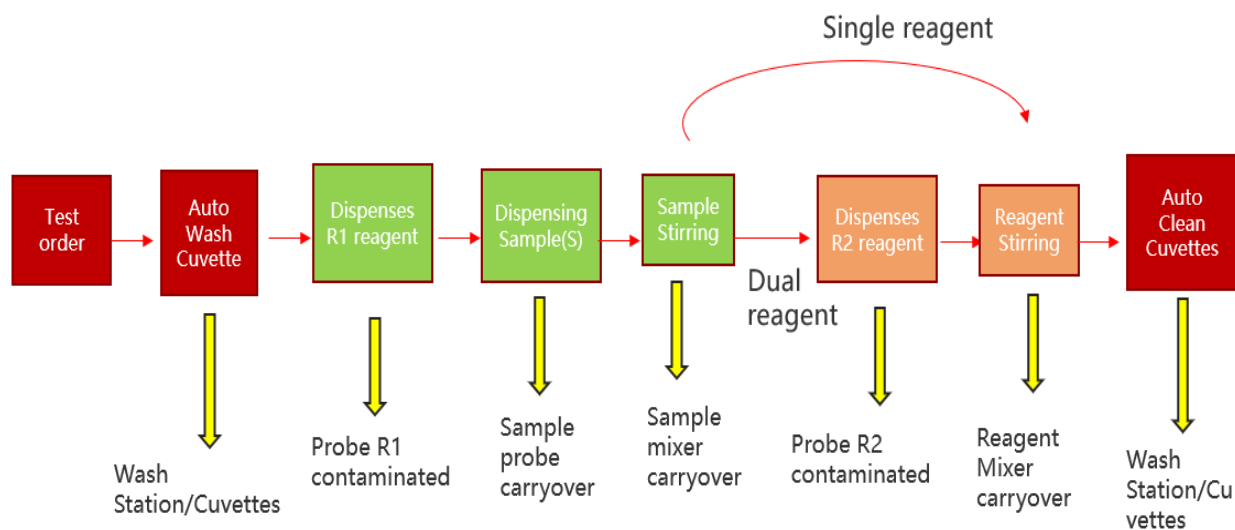
| Carryover                               |                  |                   |           |            |                     |
|-----------------------------------------|------------------|-------------------|-----------|------------|---------------------|
| <div>ReagentSampleCuvette</div>         |                  |                   |           |            |                     |
| Contaminator Test                       | Contaminator Rpt | Contaminated Test | Wash Type | Wash Count | Forced special wash |
| <input type="checkbox"/> ALB II         | R1               | CREAT             | DB        | 1          | N                   |
| <input type="checkbox"/> TP II          | R2               | CREAT             | DA        | 1          | Y                   |
| <input type="checkbox"/> TPUC           | R1               | CREAT             | DB        | 1          | Y                   |
| <input type="checkbox"/> CREAT MEDIC... | R2               | ALL               | DB        | 1          | Y                   |
| <input type="checkbox"/> CREAT MEDIC... | R2               | MALB              | DB        | 1          | Y                   |
| <input type="checkbox"/> CREAT MEDIC... | R2               | CRP II            | DB        | 1          | Y                   |
| <input type="checkbox"/> CREAT MEDIC... | R2               | ASO II            | DB        | 1          | Y                   |
| <input type="checkbox"/> CREAT MEDIC... | R2               | RF II             | DB        | 1          | Y                   |
| <div>EditDeleteReturn</div>             |                  |                   |           |            |                     |

**Final solution: Mindray CREA (SOX)**

(After a long discussion with doctor-Biochemist & owner of laboratory.)

## Conclusion :

➤ CARRYOVER definition: **Something that comes from or continues from an earlier period**



**Carryover is a tough situation to identify, proof, convince & solve.**

# Thanks!

**mindray**迈瑞