

CRP II CAL FAILED MON FLAG

# 1 The issues description

## CRP II CAL FAILED MON FLAG

Date of the failure CAL : 01-01-2024

Equipment : BS800

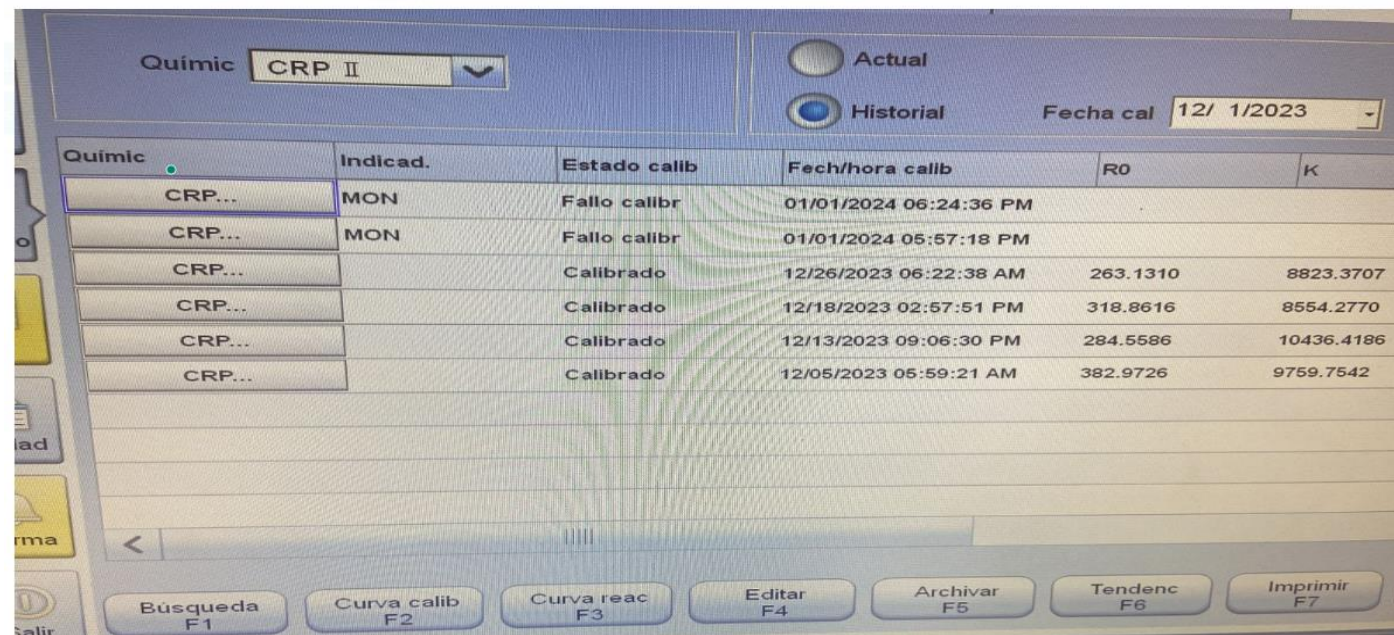
The 3<sup>rd</sup> and 4<sup>th</sup> Points of the CAL do not correspond with the normal response indicating that the problem is in the dilution process of the analyzer.

Information send from customer:

- Only picture from the flag

Information asked from IVD :

- Values and the curve from the CAL, CAL configuration, lot number of the CAL, Last CAL of the item.

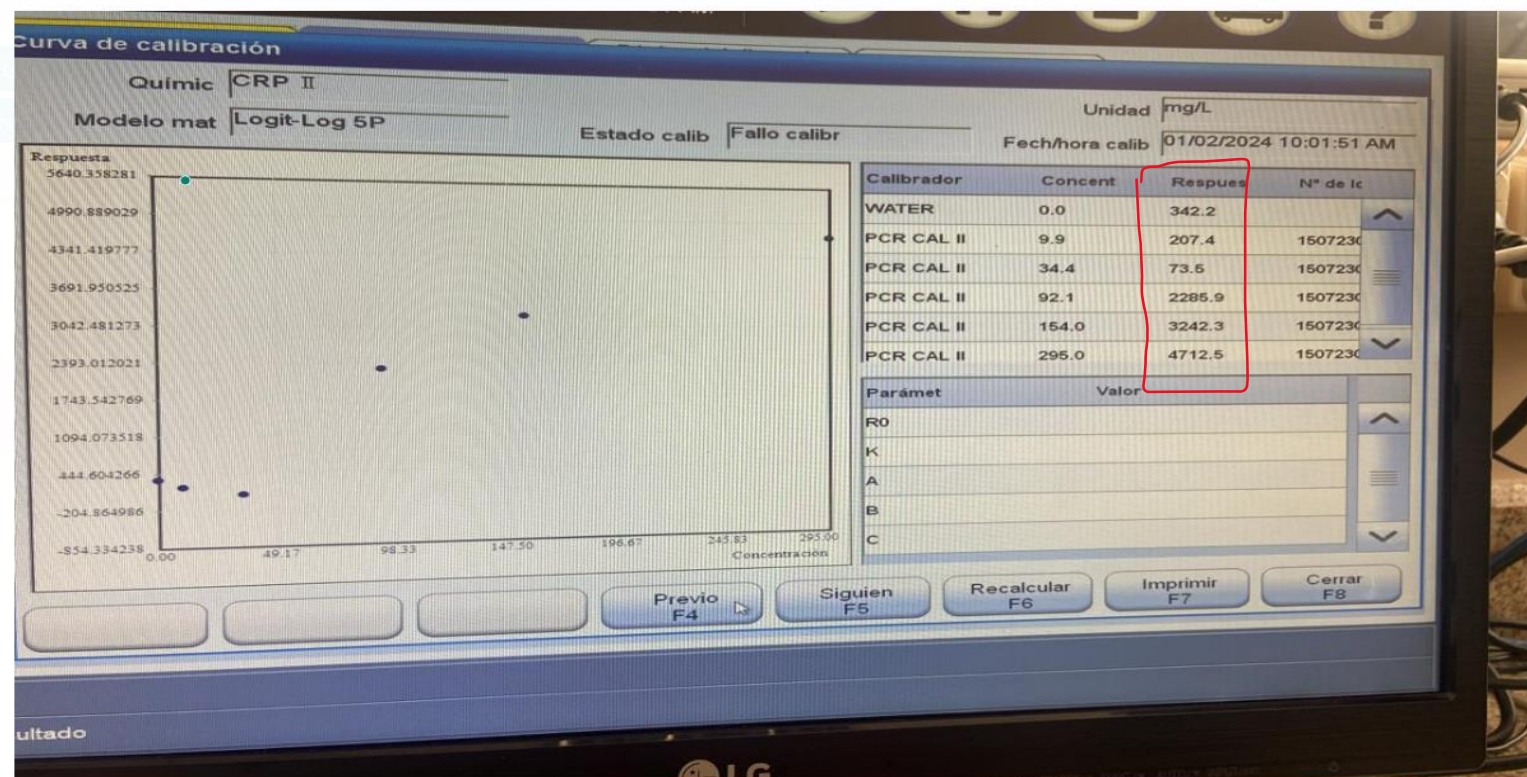


Químico: CRP II

Actual ☐ Historial ☒ Fecha cal: 12/ 1/2023

Químico	Indicad.	Estado calib	Fecha/hora calib	R0	K
CRP...	MON	Fallo calibr	01/01/2024 06:24:36 PM		
CRP...	MON	Fallo calibr	01/01/2024 05:57:18 PM		
CRP...		Calibrado	12/26/2023 06:22:38 AM	263.1310	8823.3707
CRP...		Calibrado	12/18/2023 02:57:51 PM	318.8616	8554.2770
CRP...		Calibrado	12/13/2023 09:06:30 PM	284.5586	10436.4186
CRP...		Calibrado	12/05/2023 05:59:21 AM	382.9726	9759.7542

Buttons: Búsqueda F1, Curva calib F2, Curva reac F3, Editar F4, Archivar F5, Tendenc F6, Imprimir F7





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The configuration of the Dilution is correct, and the configuration of the parameter is also correct.

Volume and positions are correct



Config dilución calibrador

Calibrador: PCR CAL II

P. bioquí: CRP II

Unidad: mg/L

	Concent	Vol aspirado	Vol neto	Vol diluyente
1	9.9	8.0	11.0	99.0
2	34.4	16.0	25.0	100.0
3	92.1	8.0		
4	154.0	14.0		
5	295.0	28.0		
6				

ServiceUser 01/02 09:21 AM

Configuración

Químico: CRP II

Config calibr

Modelo mat: Logit-Log 5P

Factor: [ ] Réplicas: 1

Límites aceptación

Tiempo cal: 672 Hora: [ ]

Difer pend: [ ] SD: 999.000

Sensibilidad: [ ] Repetibilidad: 33000.000

Coef determ: 0.950

Calibración autom

☐ Botella camb. ☒ Lote camb. ☐ Tiempo cal

Calibrador	Concent	Posic	Nº de lote
WATER	0.0	W	
PCR CAL II	9.9	10-S5	150723009
PCR CAL II	34.4	10-S5	150723009
PCR CAL II	92.1	10-S5	150723009
PCR CAL II	154.0	10-S5	150723009
PCR CAL II	295.0	10-S5	150723009

Previo F4 Siguien F5 Anular F6 Guardar F7 Cerrar F8

# The troubleshooting process

1

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After getting accurate information from the customer, we proceed to analyze the problem, The calibrator used is Specific proteins CAL

. We check stability and dates of the reagents and consumibles. DW wasnt changed in long time

Checking the conditions of the analyzer and environment, values, storage, reconstitution etc.

Configuration of the parameter and dilute calibrator settings is good

No specific action or problem was found, we decide to perform a Cal after specific actions : Considering the CAL point failed in the dilutions process

Perform cleaning and mantainance of probes and mixers. (there is a posibility that the probe is dirty or DW contaminated)

Rerun  
CAL



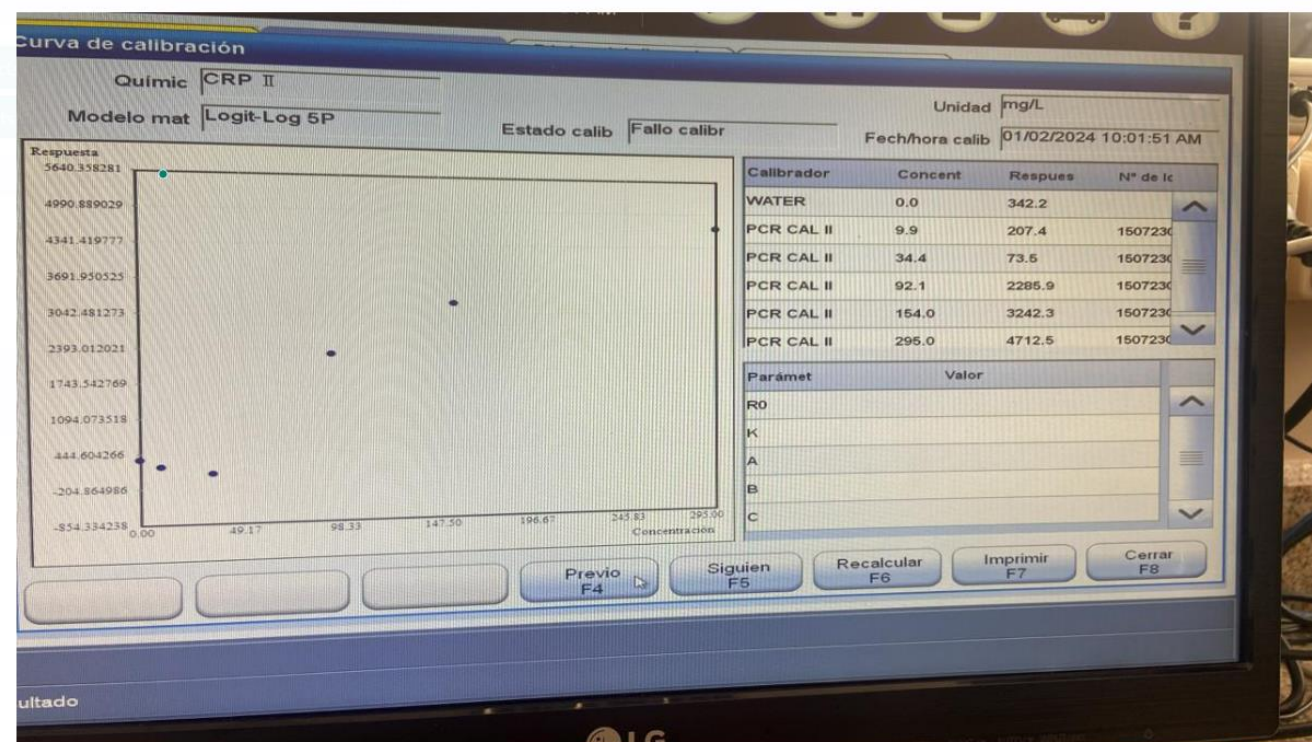
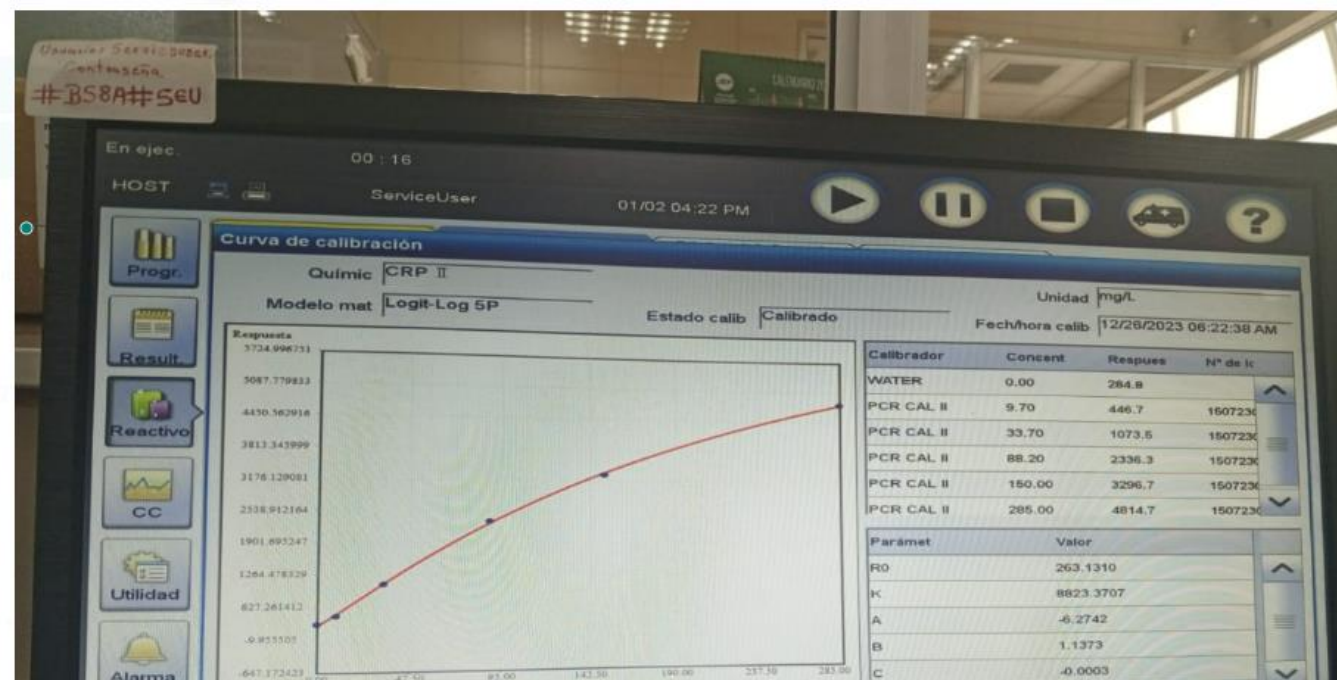
# 1 The verification process

## CRP II CAL FAILED MON FLAG

### Comments

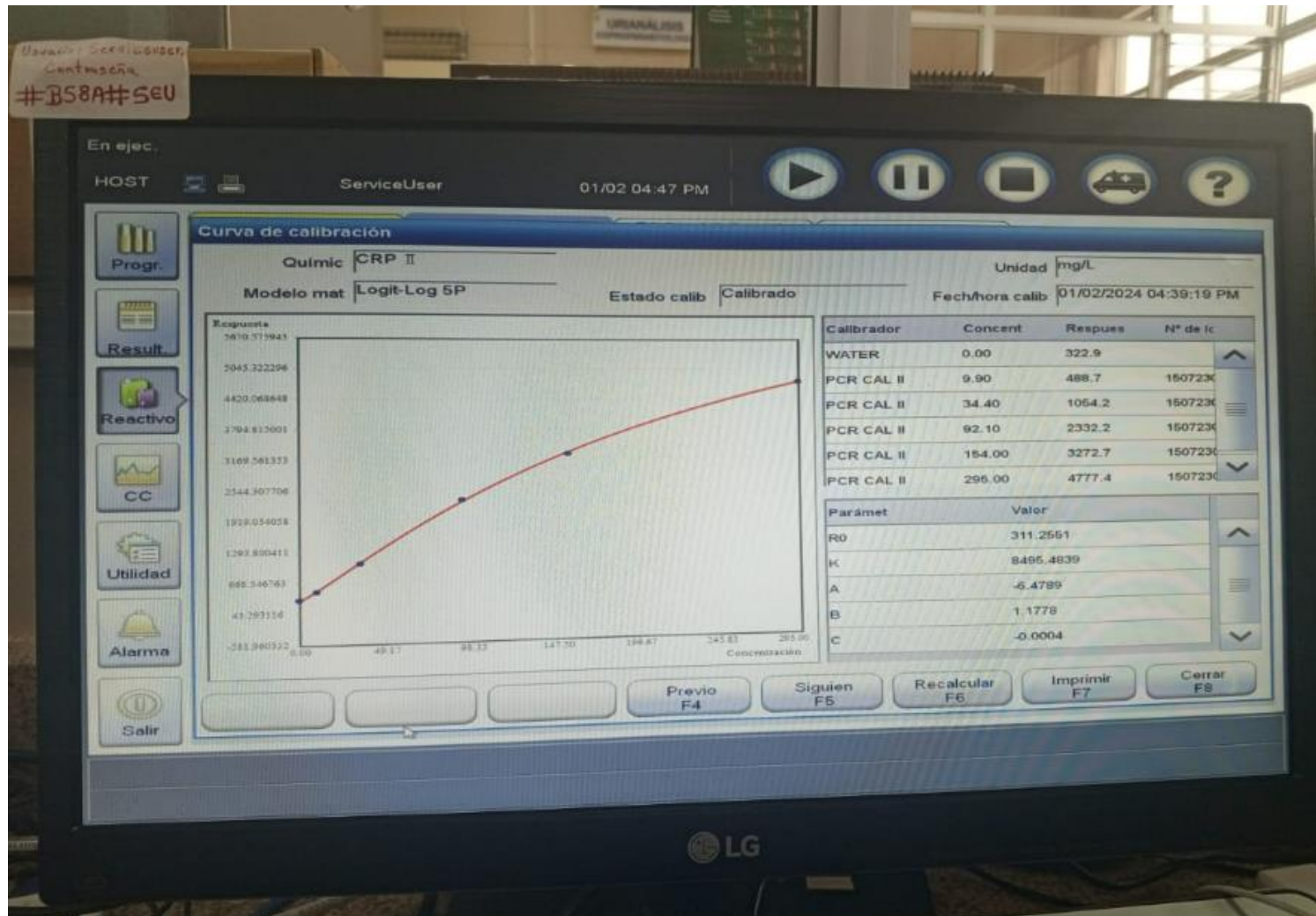
Comparing abnormal curve calibration(down)  
vs new one Normal (up )

Because the calibration the first points had a low response, the dilution process was affecting the results, in this case the sample probe probably was clogged. After doing the maintainance we rerun calibration and CRP was calibrated.



# 1 The verification process

## CRP II CAL FAILED MON FLAG



### Cal succeed

The problem was that the sample probe probably was dirty.

Actions:

- 1) Cleaning and mantainance of probes and mixers
- 2) Dw change

Recomendation:

Cleaning and mantainance should be a priority action even if the customer said that it was done

# Thanks!

**mindray**迈瑞