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Weqas INR Programme – An Example of Post Market Vigilance

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Background

Weqas have provided an INR EQA programme since 2009 and currently has over 2250 participants.

The EQA data for the May 2018 INR distribution showed a much wider variation of results than expected, with a coefficient of variation (CV) of 11.8% for the Roche CoaguChek meters*.

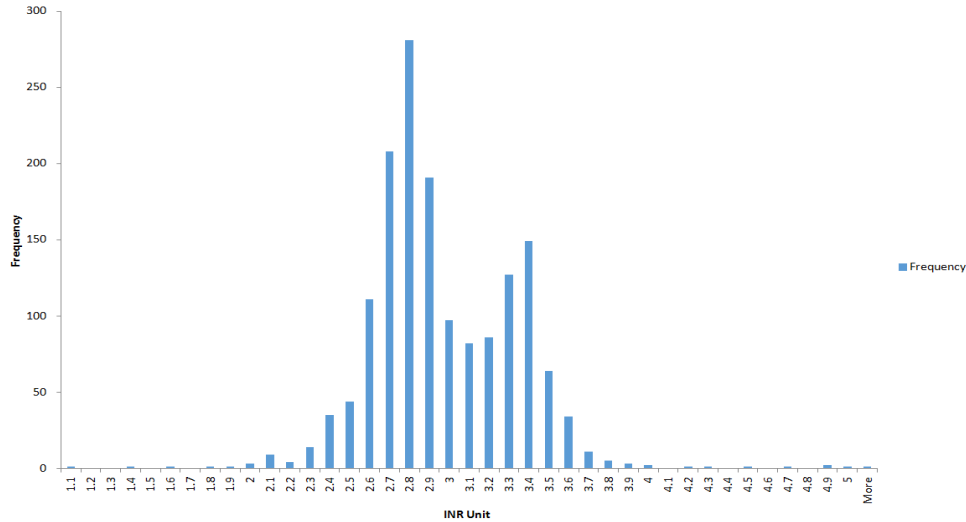
A CV of 2% was observed for the Siemens Xprecia Stride for this same distribution.

A CV of 7.6% was observed for the Roche CoaguChek meters for the same material in May 2017.

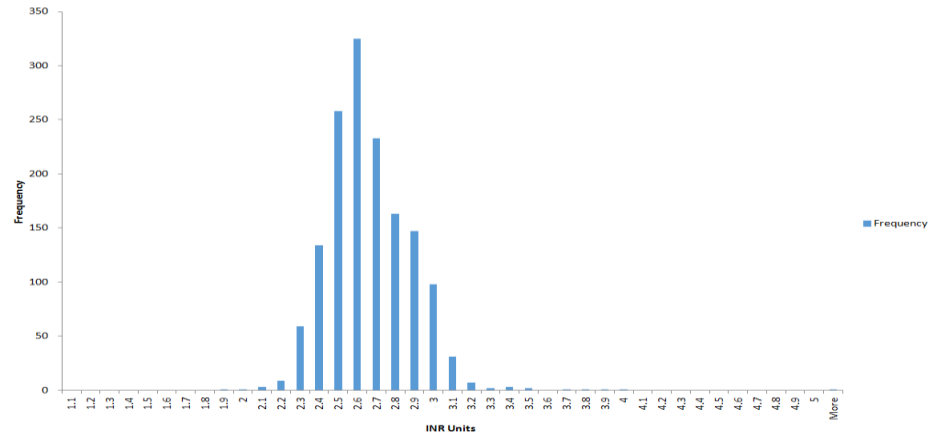
**1430 XS, XS Plus, XSPro. 130 Pro II. 8 Xprecias.*

May 2018 vs May 2017

All Methods / Instrument Histogram Weqas Dist INR 0518



All Methods / Instrument Histogram Weqas Dist INR 0517



Investigation

- The manufacturer was contacted to identify a cause of the bimodal pattern observed for the CoaguChek group.
- Roche confirmed that they had recently issued new strips calibrated to the new WHO International Reference Thromboplastin rTF/16.

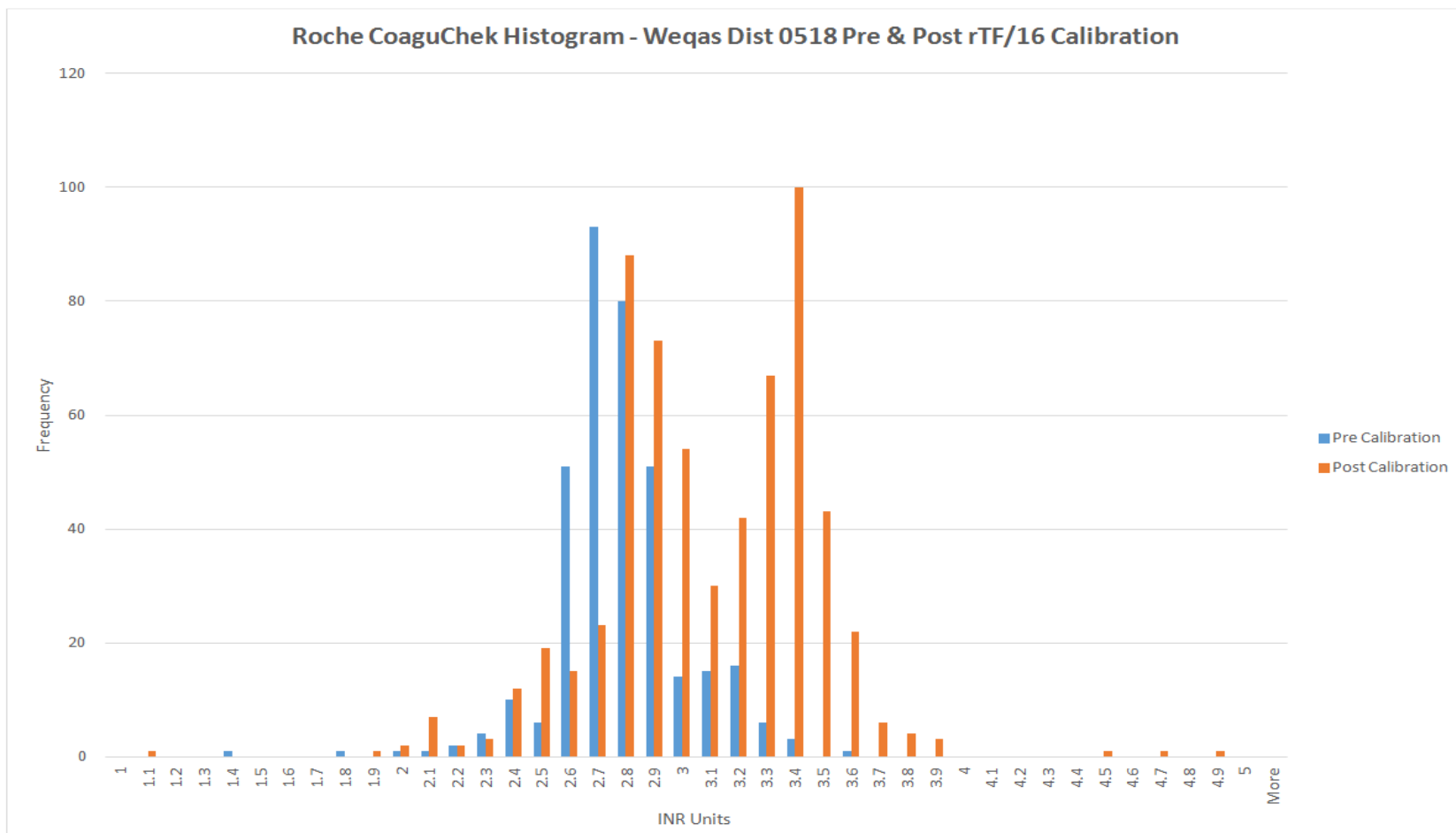
Strips calibrated to WHO reference thromboplastin rTF/09.

Strip Type	Lot Number	Code Number	Expiry Date
CoaguChek XS PT, XS PT PST	272166 (up to & including)	S_302 (up to & including)	31.05.2019
CoaguChek PT	250325 (up to & including)	S_053 (up to & including)	28.02.2019

Strips calibrated to WHO reference thromboplastin rTF/16

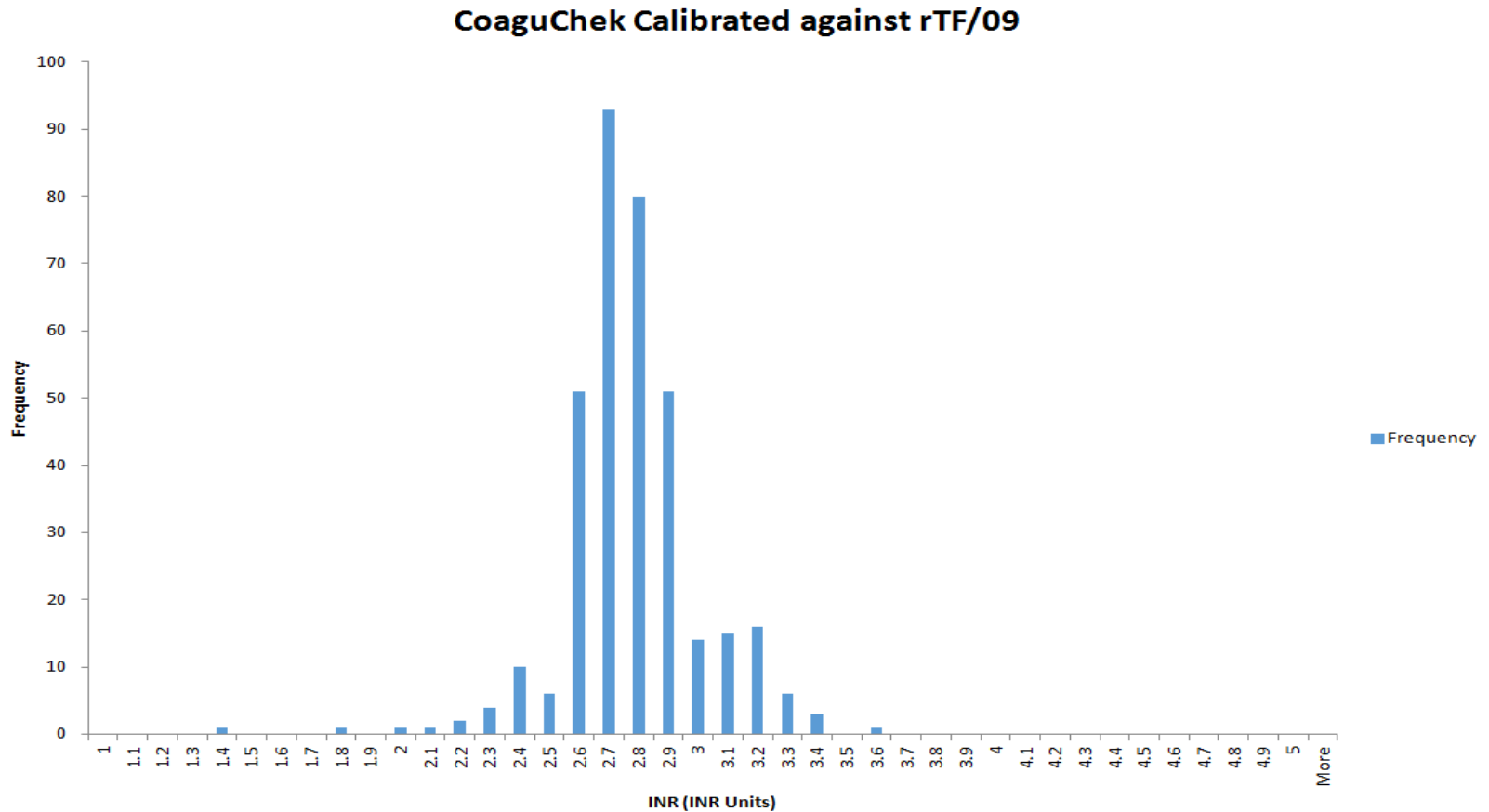
Strip Type	Lot Number	Code Number	Expiry Date
CoaguChek XS PT, XS PT PST	272167 (or higher)	S_303 (or higher)	30.06.2019
CoaguChek PT	272170 (or higher)	S_054 (or higher)	30.09.2019

Participants' results were further classified based on strip lot numbers and reviewed in light of the recalibration process, identifying the strips relating to pre and post recalibration results.

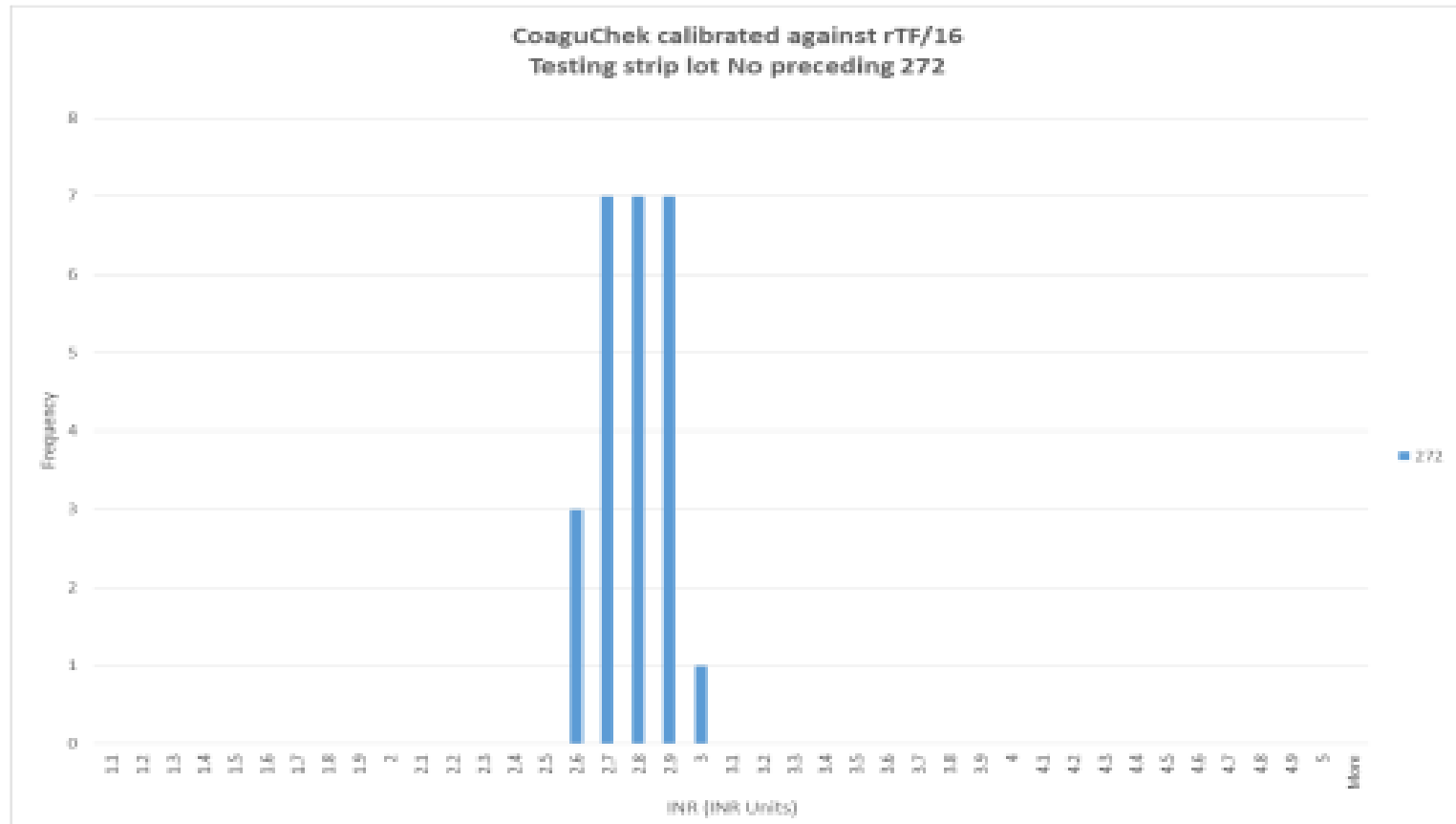


Results

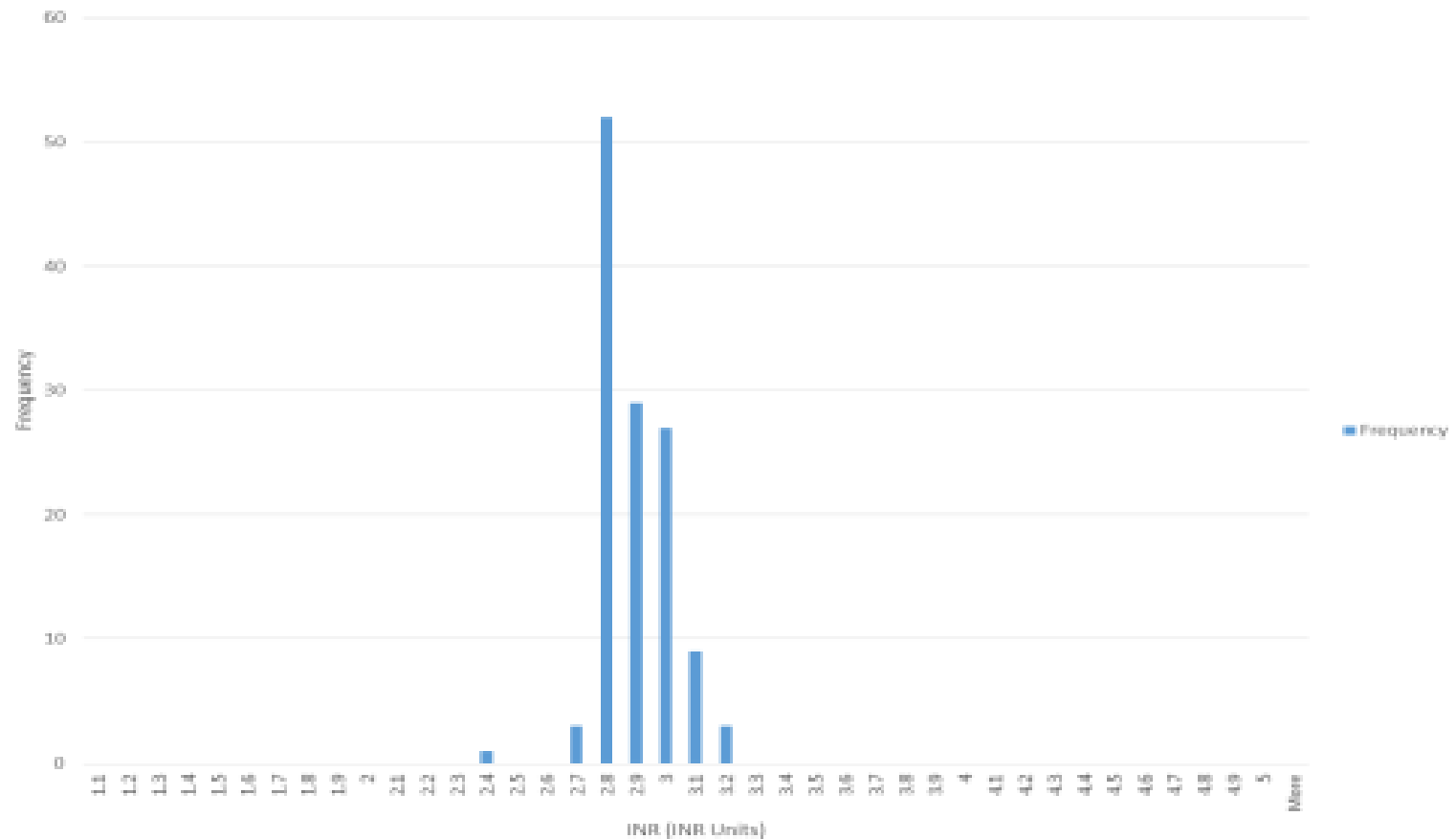
Strips calibrated to WHO reference thromboplastin rTF/09 gave a median of 2.8, which compared well with the results from Distribution 0517 (median 2.8)



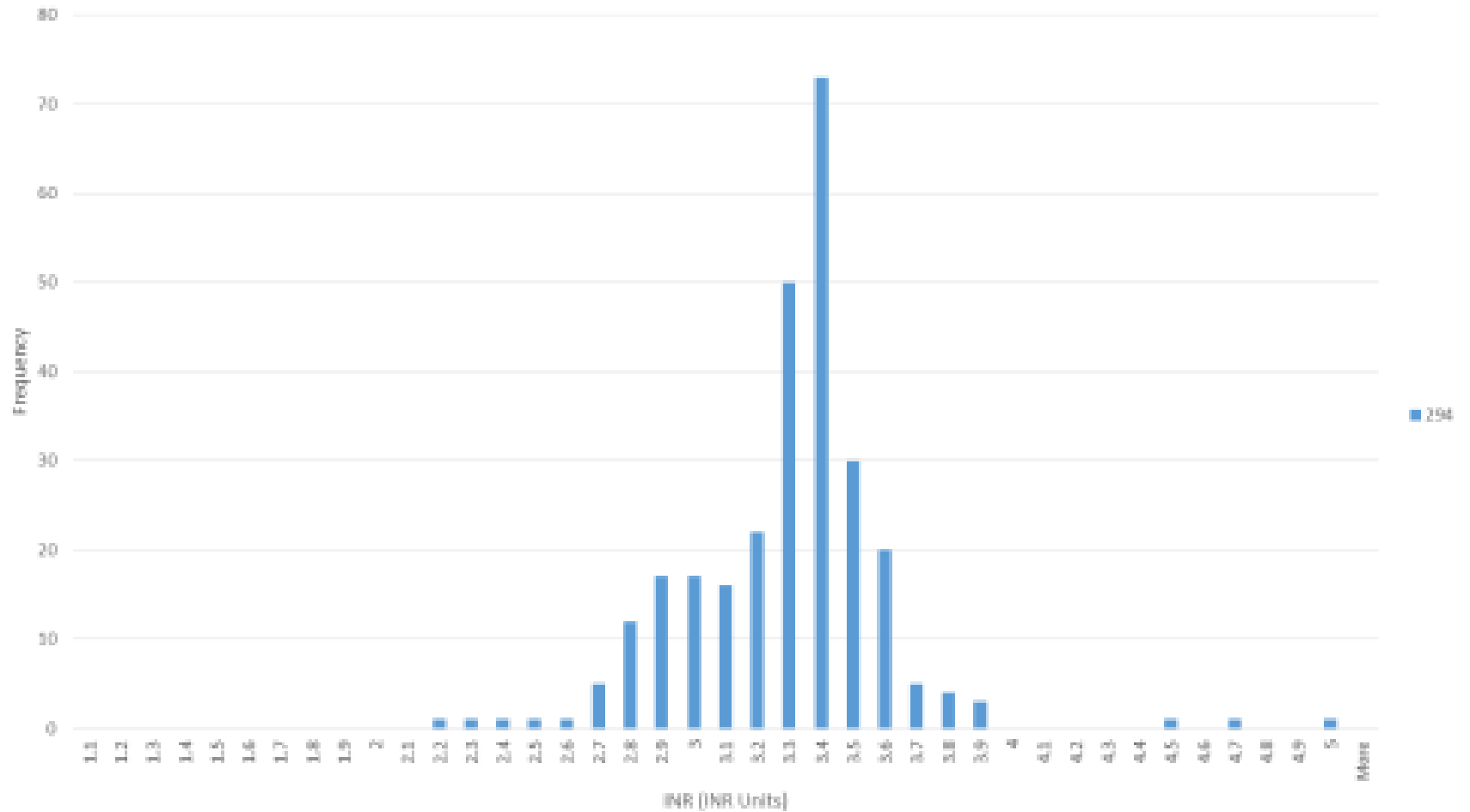
However, much higher results and a wider distribution was observed for the rTF/16 calibrated strips. A lot specific bias was also observed, median 2.8 for strip lot numbers prefixed with 272 and 286, and median 3.4 for prefix 294.



CoaguChek calibrated against rTF/16
Testing strip lot No preceding 268



CoaguChek calibrated against rTF/16
Testing strip lot No preceding 294



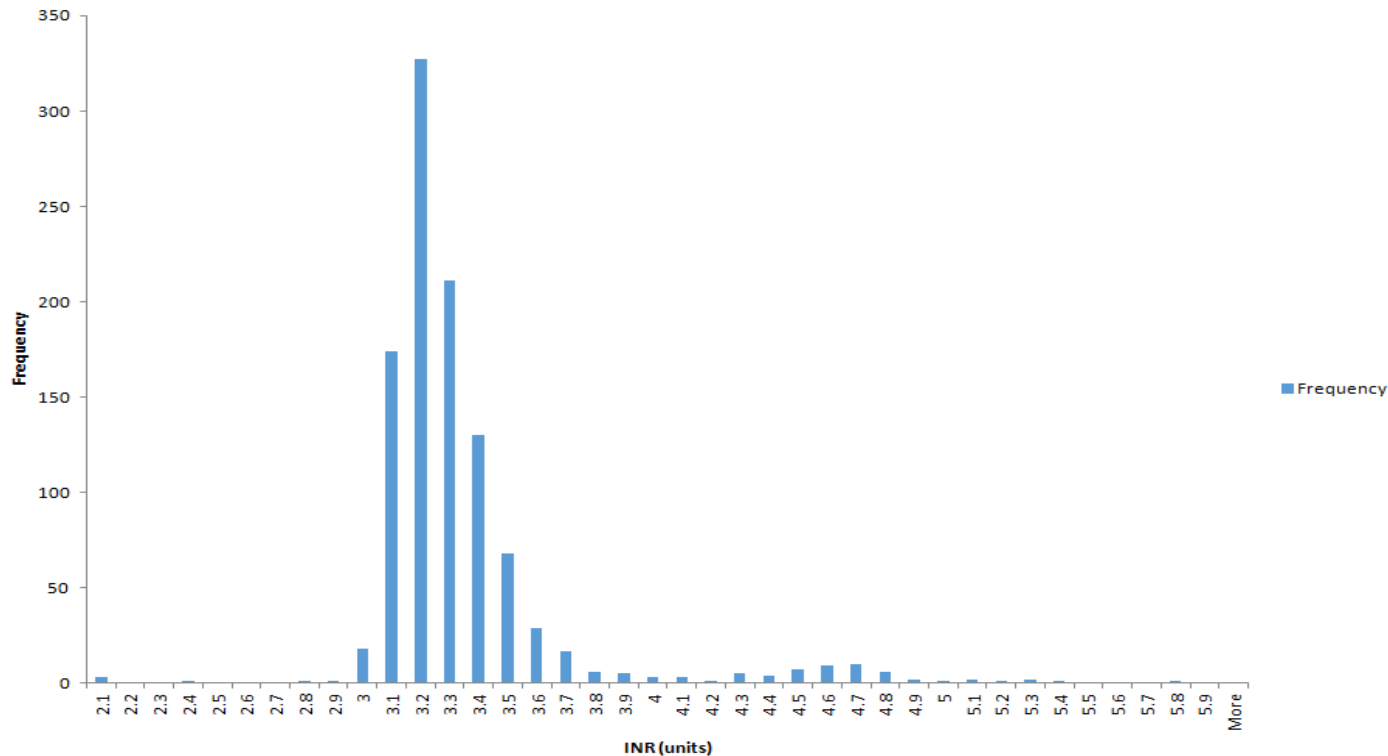
Discussion

- The wider interlaboratory variation was attributed to a change in calibration with a large positive bias observed for lot numbers prefixed 294.
- Data was supplied to Roche and the MHRA.
- Roche subsequently issued a field safety notice which stated that the rTF/16 calibration process had resulted in a positive bias and results > 4.5 should be verified with a laboratory. However, our data suggests that for some lot numbers the bias was apparent at a much lower concentration.
- Still continue to see bimodal patterns within EQA data.

Current Status – EQA data

In July 2019, this same sample was distributed once again. A bimodal distribution was again observed for the CoaguChek XS systems, however the number of results submitted from participants using strips calibrated against rTF/16 was significantly reduced.

CoaguChek XS Systems Method Histogram Weqas Dist IN0719



- 994 XS systems.
- 664 Pro II.

Current Status - Roche

- Roche have reverted to rTF/09 calibration, with the first of these new strips being available from November 2018.

Roche stated in Sept 2019:

- Strip lot numbers higher than 334499xx and Code Key S_344 have been re-calibrated to the rTF/09 WHO Standard.
- The remaining rTF/16 strips that may still be in circulation currently will be from 272167xx – 334499xx.

Conclusion

This data highlights the important role of EQA in post market vigilance, and the importance of collaboration with the manufacturers in identifying the causal effect and in addressing the issues.



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Any questions?