



Title:Real-World Distributions of ALZpath and Lumipulse Plasma p-tau217 Test Results: Experience from More Than 1,600 Tests at a Canadian Diagnostic Laboratory

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Background

- Plasma phosphorylated tau 217 (p-tau217) is an increasingly important blood-based biomarker for Alzheimer's disease (AD).
- The ALZpath and Lumipulse plasma p-tau217 assays are two commercially available tests.
- As p-tau217 assays transition into clinical practice, understanding their test-result distributions and associations with demographic factors is important for clinical interpretation.
- This study compared plasma p-tau217 test classifications obtained using the ALZpath and Lumipulse platforms in clinical practice at a Canadian diagnostic laboratory and evaluated their associations with age and sex.

Methods

Study Cohort

Plasma p-tau217 was measured using

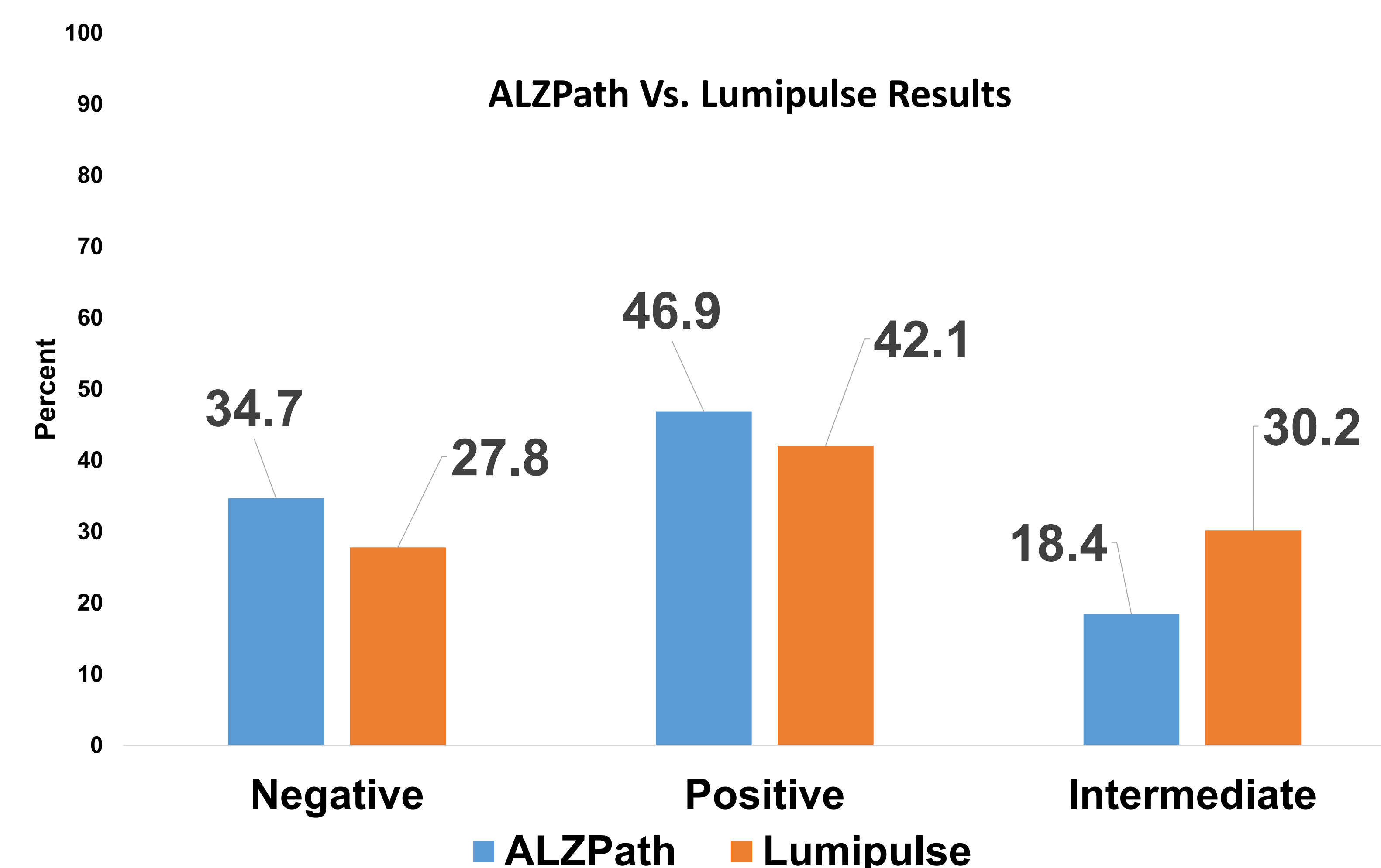
The ALZpath p-tau217 assay on the Quanterix HD-X Simoa platform

n= 1419

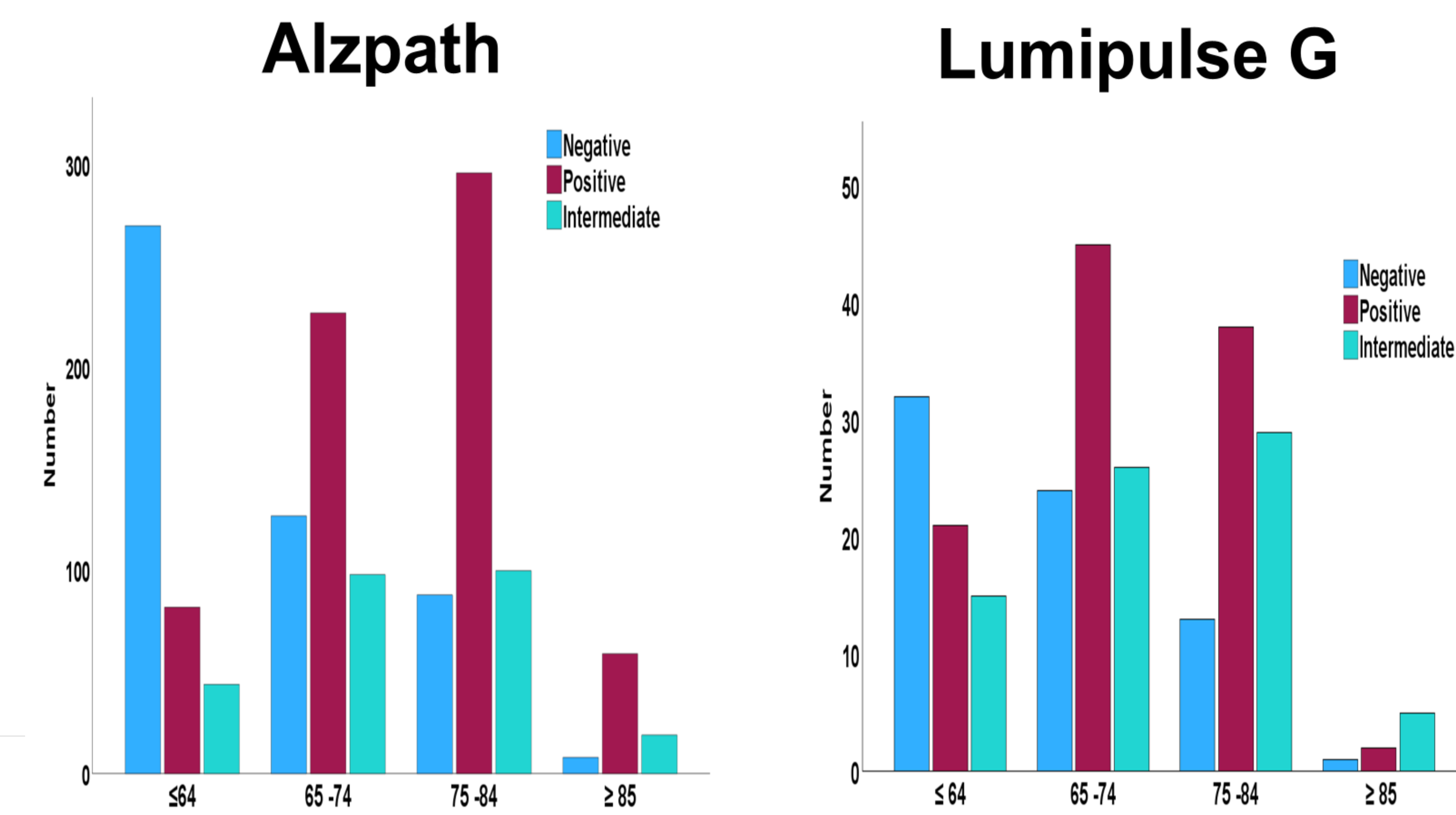
Lumipulse G p-tau217 on the Lumipulse G1200 platform
n= 252

Age was categorized as ≤64, 65-74, 75-84, and ≥85 years. Associations between age, sex, and p-tau217 test results were assessed using chi-square analyses and multinomial logistic regression using SPSS 32 Software. Because measurements were obtained from separate cohorts, comparisons between platforms were descriptive.

Results



Results



Conclusion

- Both ALZpath and Lumipulse plasma p-tau217 testing, age, but not sex, was significantly associated with test result classification, with negative results becoming progressively less frequent with advancing age.
- Differences were observed in the distribution of positive and intermediate results, with a higher overall proportion of intermediate classifications with Lumipulse than ALZpath.
- Further studies using paired samples tested on both platforms are required to directly assess assay agreement and determine the clinical significance of these differences.

Acknowledgments

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References

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