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## Final Review Memo

**Final Review Memo for:**

BL125589

BABESIA MICROTI ARRAYED FLUORESCENCE IMMUNOASSAY: Clinical Studies  
Babesia microti

**Sponsor**

Imugen Inc.

**Date:** January 8, 2018

**To:** Cherry Geromino (RPM)  
Robert Duncan (Scientific Lead)

**Reviewer:** Luisa Gregori

**Through:** David M. Asher

**Specific Scientific Disciplines Reviewed:** Clinical Review BLA

**Recommendation:** Approval

**Precedent-Setting Product:** N/A

**Documents reviewed:** BLA complete response **AFIA** Clinical studies (1-6)  
001\_AFIA Response to AI p1 to 260.pdf (Dec 12, 2016)

The sponsor responded satisfactorily to all my questions. I recommend approval of this BLA.