



## Final Review Memo

**Final Review Memo for:** BL125588

BABESIA MICROTI NUCLEIC ACID TEST: Clinical Studies

**Sponsor** Imugen Inc.

**Date:** January 8, 2018

**To:** Cherry Geromino (RPM)  
Babita Mahajan (Scientific Lead)

**Reviewer:** Luisa Gregori

**Through:** David M. Asher

**APPROVED**

*By GregoriL at 7:34 pm, Jan 09, 2018*

*By asher at 6:41 pm, Jan 09, 2018*

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

**Recommendation:** approval

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

**Documents reviewed:** BLA complete response **NAT** Clinical studies (1-8)

In conclusion, the sponsor has satisfactorily responded to all but one of my questions. I have no other comments. I recommend approval of this BLA.