



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.