March 6, 2018

Our STN: BL 125589/0 **BLA APPROVAL**

Oxford Immunotec Ltd.
Attention: Wolfgang Pieken, PhD
Oxford Immunotec Inc. d/b/a/ Imugen
315 Norwood Park South
Norwood, MA 02062

Dear Dr. Pieken:

Please refer to your Biologics License Application (BLA) for *Babesia microti* AFIA/*Babesia microti* AFIA for Blood Donor Screening dated May 12, 2015, received May 12, 2015, submitted under section 351(a) of the Public Health Service Act (PHS Act).

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2021 to Oxford Immunotec Ltd., Abingdon, Oxfordshire, UK, under the provisions of section 351(a) of the PHS Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to provide the results of the *Babesia microti* AFIA/*Babesia microti* AFIA for Blood Donor Screening, which is indicated for qualitative detection of antibodies to *Babesia microti* in human plasma (EDTA as anti-coagulant) samples, performed at your Norwood, MA facility.

MANUFACTURING LOCATION

Under this license, you are approved to manufacture *Babesia microti* AFIA/*Babesia microti* AFIA for Blood Donor Screening and perform blood donor screening at your facility located at Norwood, MA. You may label your product with the proprietary name Imugen *Babesia microti* Arrayed Fluorescence Immunoassay (AFIA) and market it as approved in your license application.

ADVISORY COMMITTEE

We did not refer your application to the BLOOD PRODUCTS ADVISORY COMMITTEE because our review of information submitted in your BLA, including the clinical study

design and trial results, did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.

DATING PERIOD

The dating period for *Babesia microti* AFIA/*Babesia microti* AFIA for Blood Donor Screening shall be 6 months from the date of manufacture when stored at the appropriate temperature indicated for each component. The date of manufacture shall be defined in accordance with 21 CFR 610.50.

FDA LOT RELEASE

Please submit lot release protocols showing the results of all applicable tests. You may not use any lots of product until you receive a notification of release from the Director, CBER.

MANUFACTURING CHANGES

You must submit information to your BLA for our review and written approval, under 21 CFR 601.12, for any changes in, including but not limited to, the manufacturing, testing, of *Babesia microti* AFIA/*Babesia microti* AFIA for Blood Donor Screening, or in the manufacturing facility.

ADVERSE EVENT REPORTING

You must submit adverse experience reports in accordance with the Medical Device Reporting (MDR) requirements for medical devices (21 CFR 803) as required by 21 CFR 600.80(k)(2). Since your product is characterized as a device as well as a biologic, submit these reports to the MedWatch System using MedWatch Reporting Form 3500A or an electronic equivalent. Please refer to the February 2014 document *Questions and Answers about eMDR – Electronic Medical Device Reporting – Guidance for Industry, User Facilities and FDA Staff* at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR–ElectronicMedicalDeviceReporting/UCM2019327.htm.

Required reports are to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
MDR Policy Branch
10903 New Hampshire Avenue
WO Bldg. 66, Room 3217
Silver Spring, MD 20993-0002

Sincerely,

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

Nicole Verdun, MD
Acting Director
Office of Blood Research and Review
Center for Biologics Evaluation and Research