

## Adverse Reaction Report

**DIN:**

**Product Code:**

**FIN(P):**

The Receiving Surgeon is responsible for reporting any adverse reaction to the appropriate eye bank facility within 30 days of the occurrence. A reportable adverse reaction is any communicable or other disease transmissible by, and attributable to, transplantation of donor eye tissue, including infection (as manifested by endophthalmitis, keratitis, or systemic viral disease) and biologic dysfunction (such as immediate donor endothelial failure or donor corneal dystrophy). The Distributing Eye Bank is responsible for verifying completion of all the items below and reporting information to the EBAA within a reasonable time.

SURGERY INFORMATION	RECIPIENT INFORMATION
Surgeon Name: _____  Surgery Location: _____   Phone: _____	Patient Name: _____ Patient ID: _____ Age: _____ Gender: _____ Pre-Operative Diagnosis: _____  Surgery Date: _____ Procedure: _____ Lamellar Cut Source: _____ Lamellar Cut Type: _____
DONOR INFORMATION	ADVERSE REACTION
Distributing Eye Bank: <b>CorneaGen</b> Tissue ID: _____ Cell Count (per mm <sup>2</sup> ): _____ Donor Age: _____ Cause of Death: _____ Death-Preservation Interval: _____ Recovery Method: _____ Preservation Method: _____ Media Lot Number: _____	Date of Diagnosis: _____ (month, day, year) <i>(Check One)</i> <input type="checkbox"/> Primary Graft Failure Did graft ever clear post-operatively? _____ Duration of Clarity: _____ Did surgical manipulation have a role in the graft failure? _____ If EK, did the lamellar tissue dislocate from the recipient? _____ If EK, was the tissue rebubbled? _____ <input type="checkbox"/> Intraocular Infection (microbial endophthalmitis) <input type="checkbox"/> Corneal Infection (microbial or viral keratitis) <input type="checkbox"/> Transmission of Systemic Disease <input type="checkbox"/> Evidence Suggestive of Prior Refractive Surgery <input type="checkbox"/> Other _____ <i>(Check One)</i> <input type="checkbox"/> Probably due to donor tissue <input type="checkbox"/> Probably not due to donor tissue <input type="checkbox"/> Reportable to EBAA <input type="checkbox"/> Reportable to FDA Comments: _____
TISSUE SOURCE INFORMATION	RECIPIENT OUTCOME
Tissue Obtained From: _____ Originating Eye Bank: _____ ID: Tissue Distributed: _____	Additional Surgery <i>(Check Applicable)</i> : <input type="checkbox"/> Regraft <input type="checkbox"/> Enucleation <input type="checkbox"/> Other _____  Recent Vision <i>(Check Applicable)</i> : <input type="checkbox"/> NLP <input type="checkbox"/> LP-CF / 20 - 400 <input type="checkbox"/> 20/200 or better
RECIPIENT OUTCOME	MICROBIOLOGY
Additional Surgery <i>(Check Applicable)</i> : <input type="checkbox"/> Regraft <input type="checkbox"/> Enucleation <input type="checkbox"/> Other _____  Recent Vision <i>(Check Applicable)</i> : <input type="checkbox"/> NLP <input type="checkbox"/> LP-CF / 20 - 400 <input type="checkbox"/> 20/200 or better	Donor Cultures <i>(Check Applicable)</i> : <input type="checkbox"/> Preservation Medium <input type="checkbox"/> Corneoscleral <input type="checkbox"/> Other _____ <input type="checkbox"/> Not Done Results: _____  Patient Cultures <i>(Check Applicable)</i> : <input type="checkbox"/> Aqueous <input type="checkbox"/> Cornea <input type="checkbox"/> Vitreous <input type="checkbox"/> Other _____ <input type="checkbox"/> Not Done Results: _____
CONTACT INFORMATION	
Contact Name: _____ Signature: _____ Date Rec'd by EBAA (if appl.): _____	Phone: _____ Date: _____ Date Rec'd by Registry (if appl.): _____