

**Real Time Human Islet Potency
Assay Based on Oxygen
Consumption Rate**

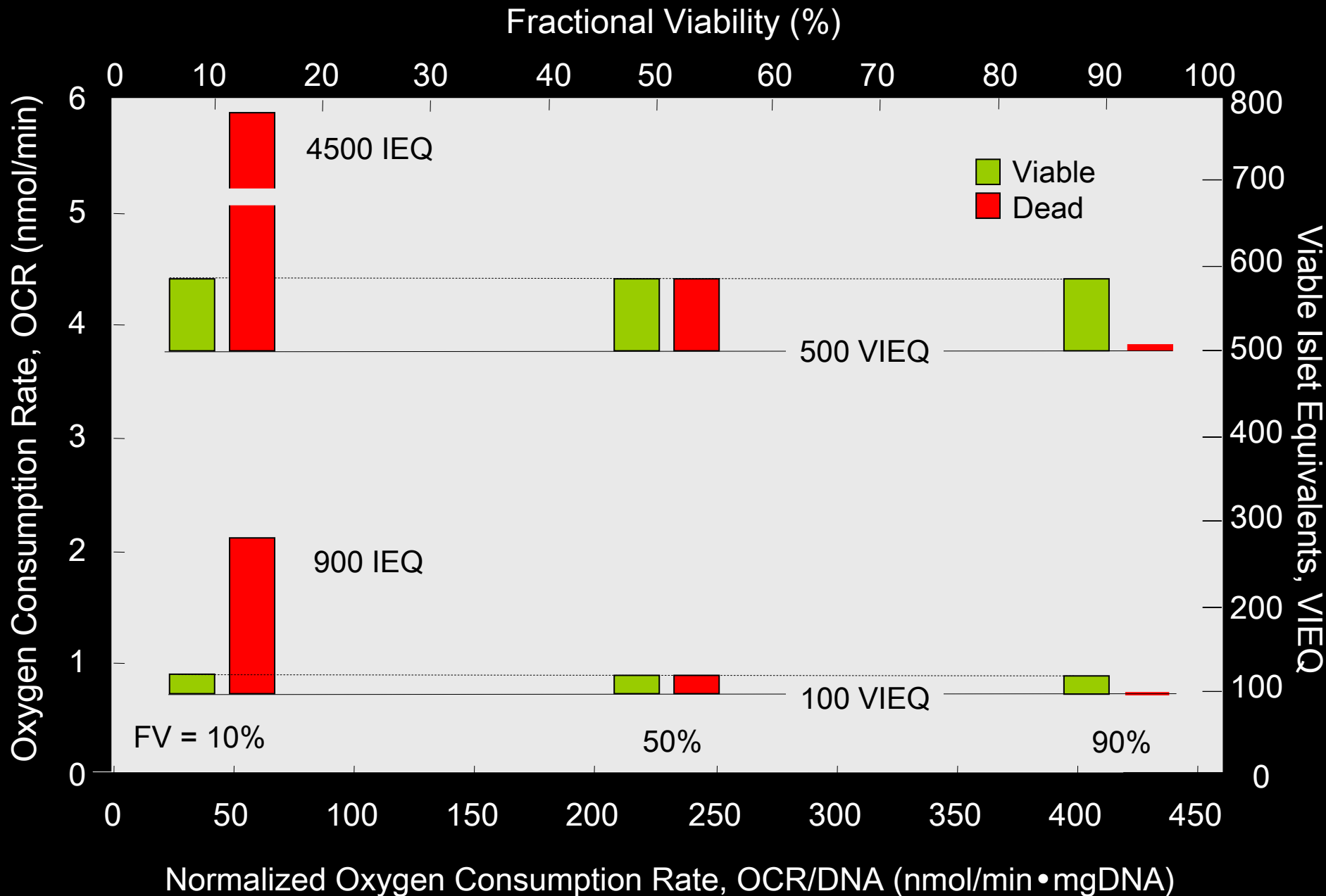
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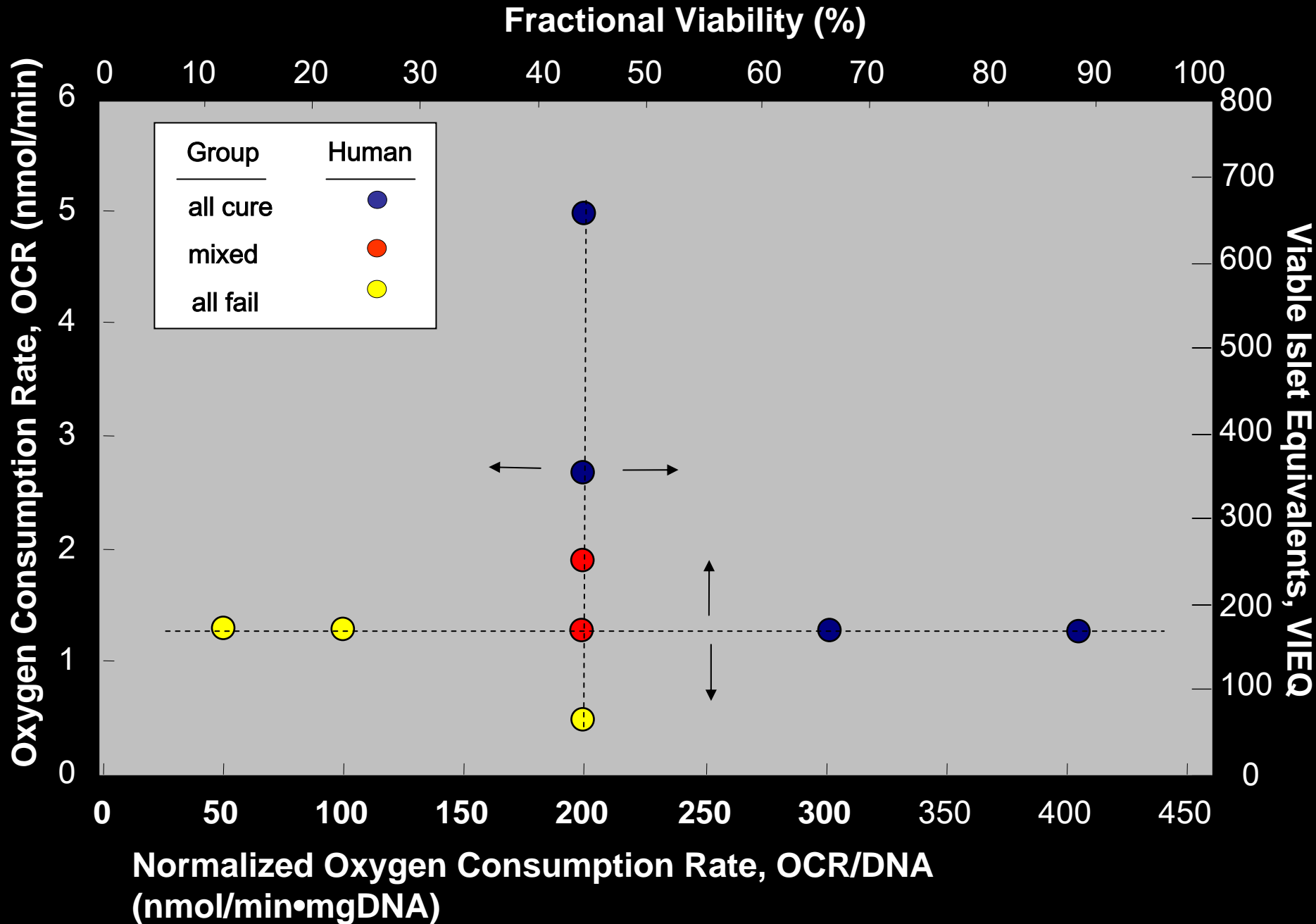
Oxygen Consumption Rate Assessment Parameters

<u>Parameter</u>	<u>Proportional To</u>	<u>Measure of</u>
OCR	Number of viable cells Volume of viable tissue	Amount of good tissue
DNA	Number of cells Total tissue volume	Total amount of tissue
$\frac{\text{OCR}}{\text{DNA}}$	$\frac{\text{Viable tissue volume}}{\text{Total tissue volume}}$	Quality of the tissue
$\frac{\text{OCR/DNA}}{(\text{OCR/DNA})_v} =$	Fractional viability	

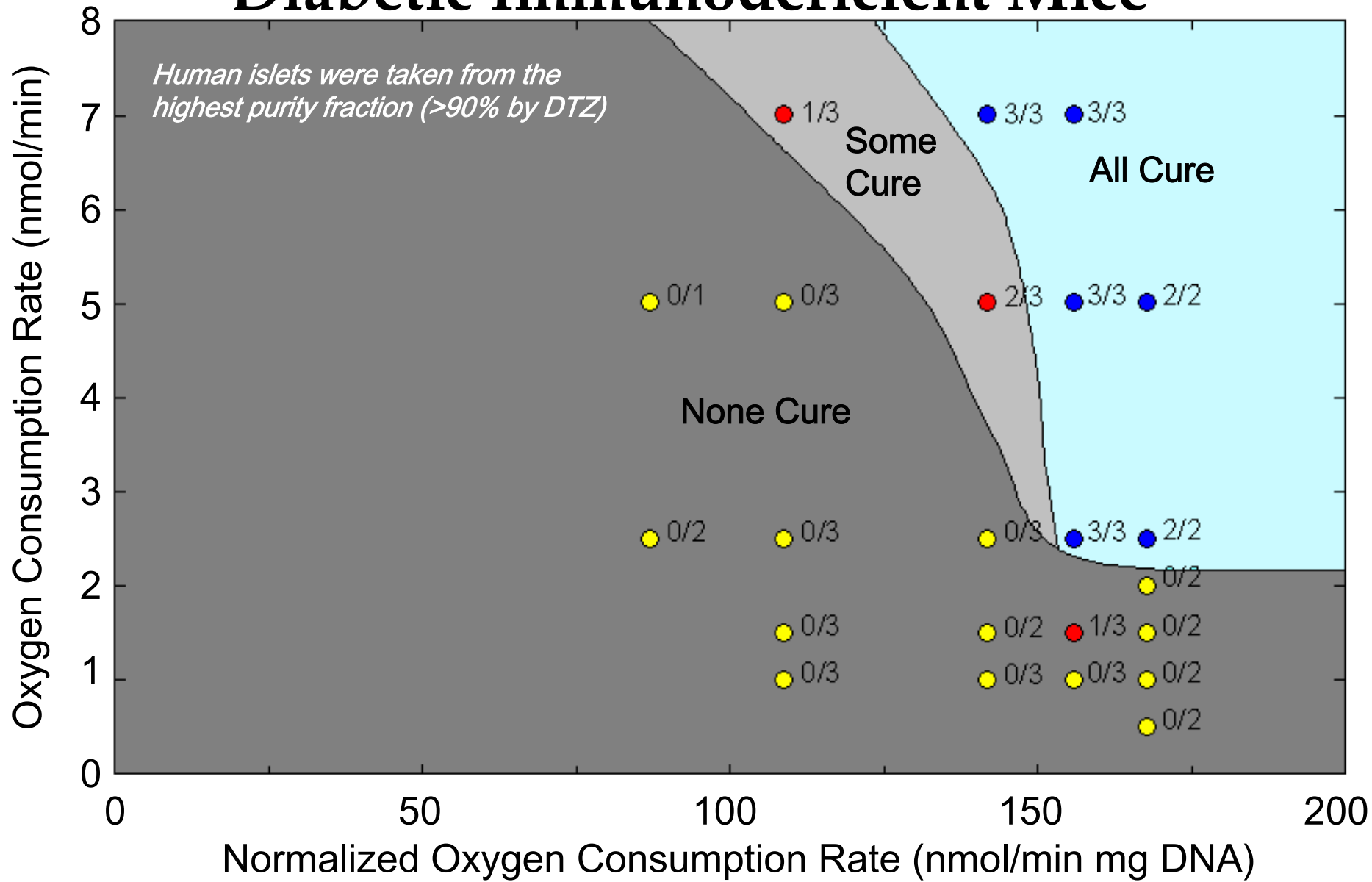
Response to Rat Islet Transplants in Diabetic Balb/C Mice (Anti-CD4)



Response to Human Islet Transplants in Diabetic Nude Mice



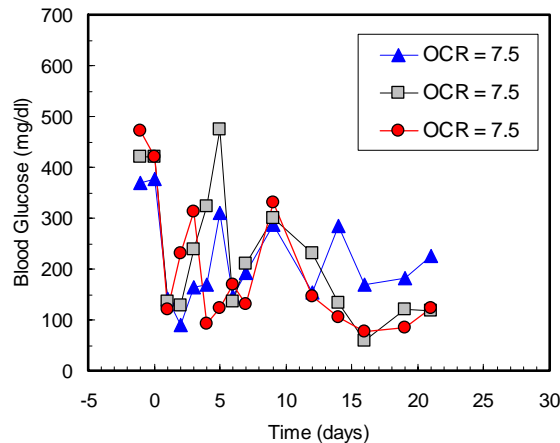
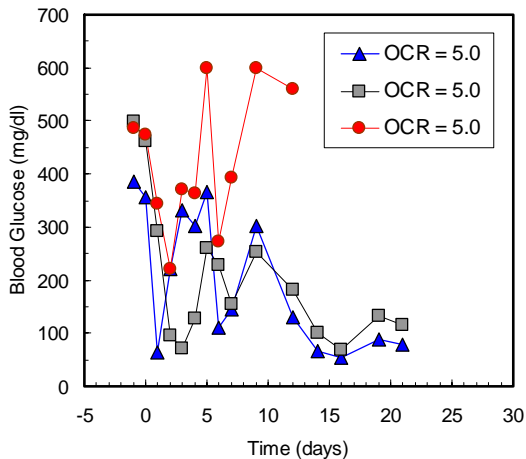
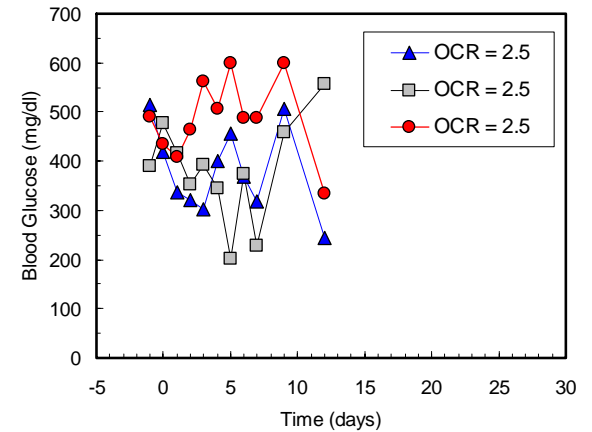
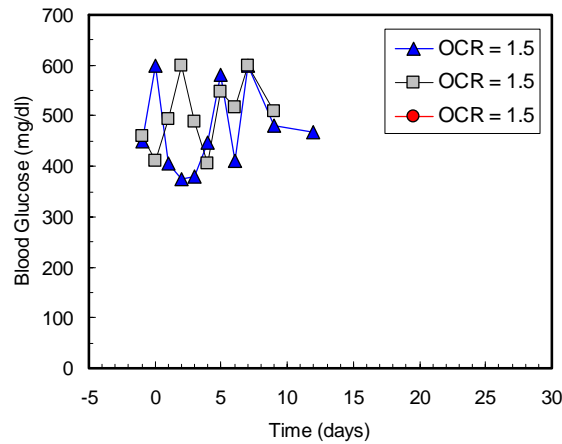
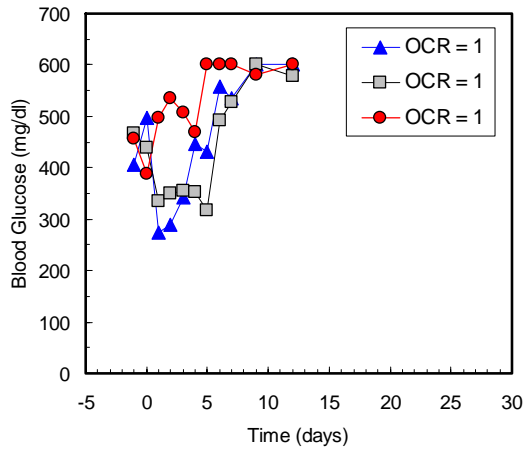
Response to Human Islet Transplants in Diabetic Immunodeficient Mice



Transplantation Studies

OCR/DNA = 142 nmoles/min/mgDNA

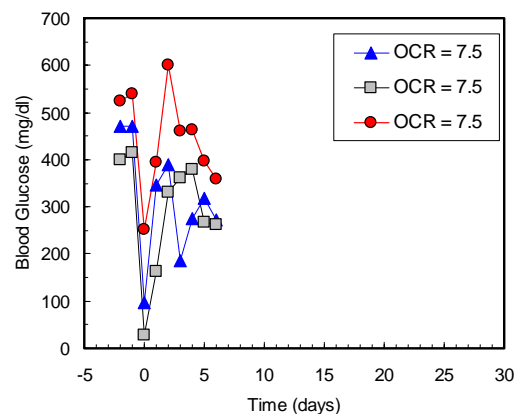
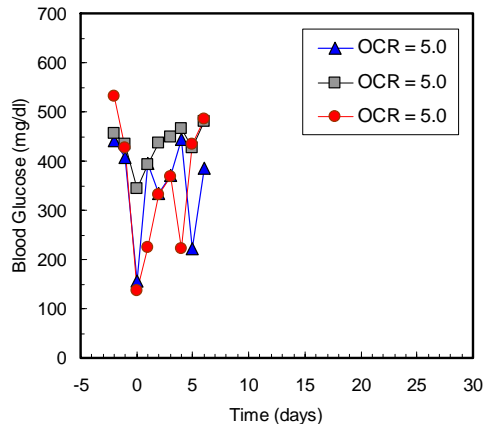
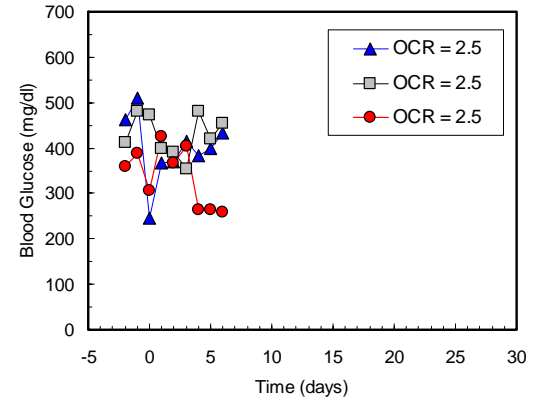
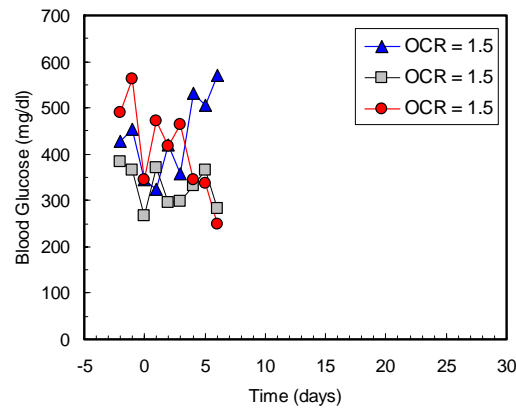
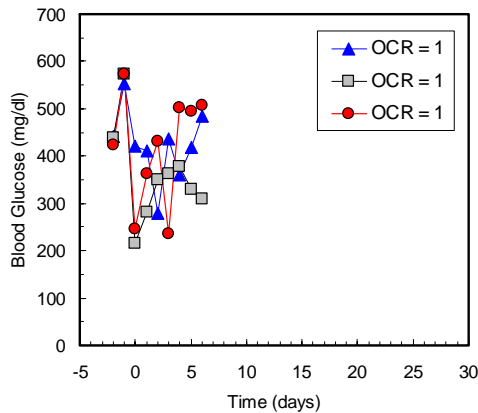
OCR Dose Transplanted = 1.0 - 7.5 nmoles/min



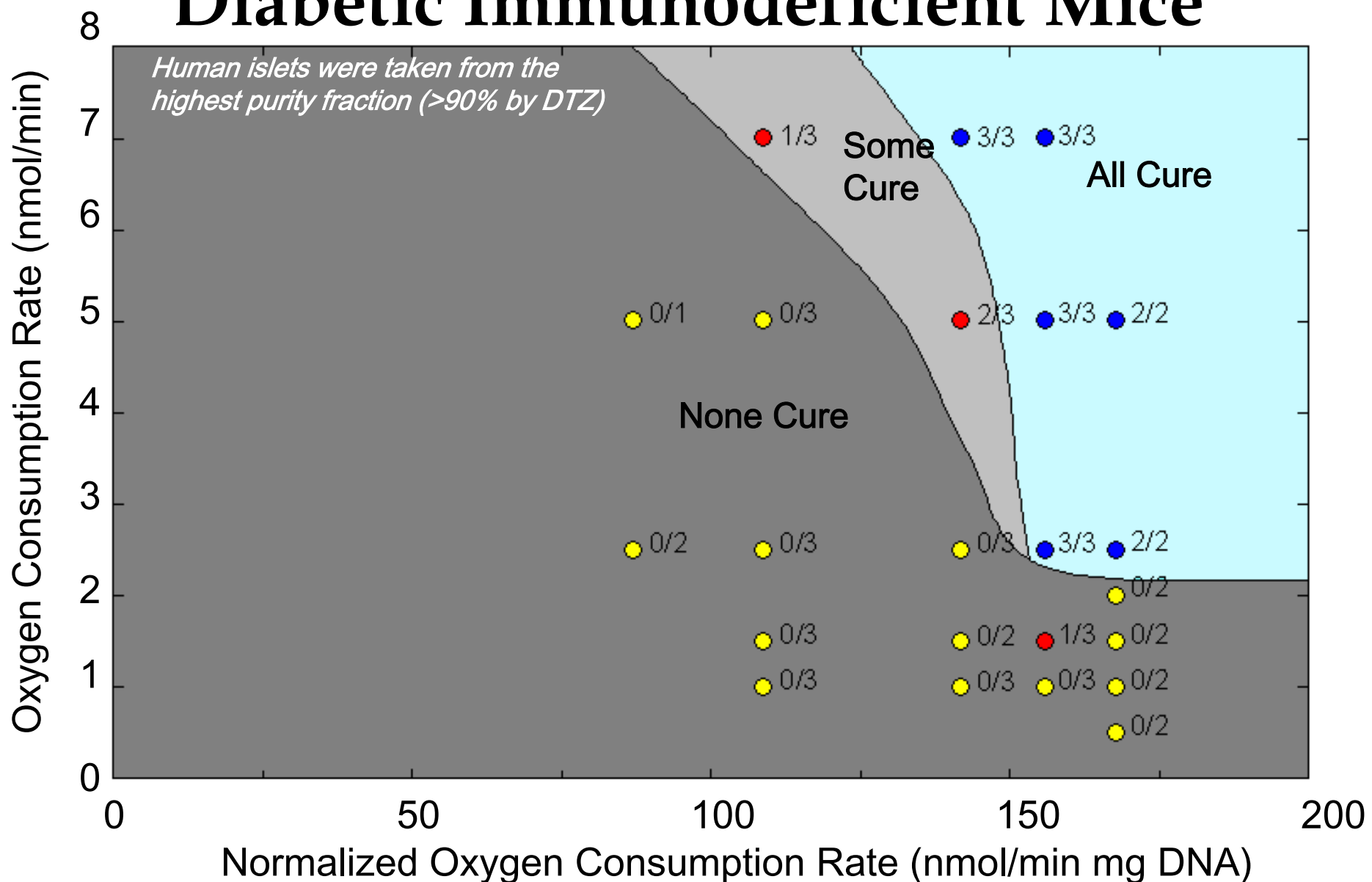
Transplantation Studies

OCR/DNA = 109 nmoles/min/mgDNA

OCR Dose Transplanted = 1.0 - 7.5 nmoles/min

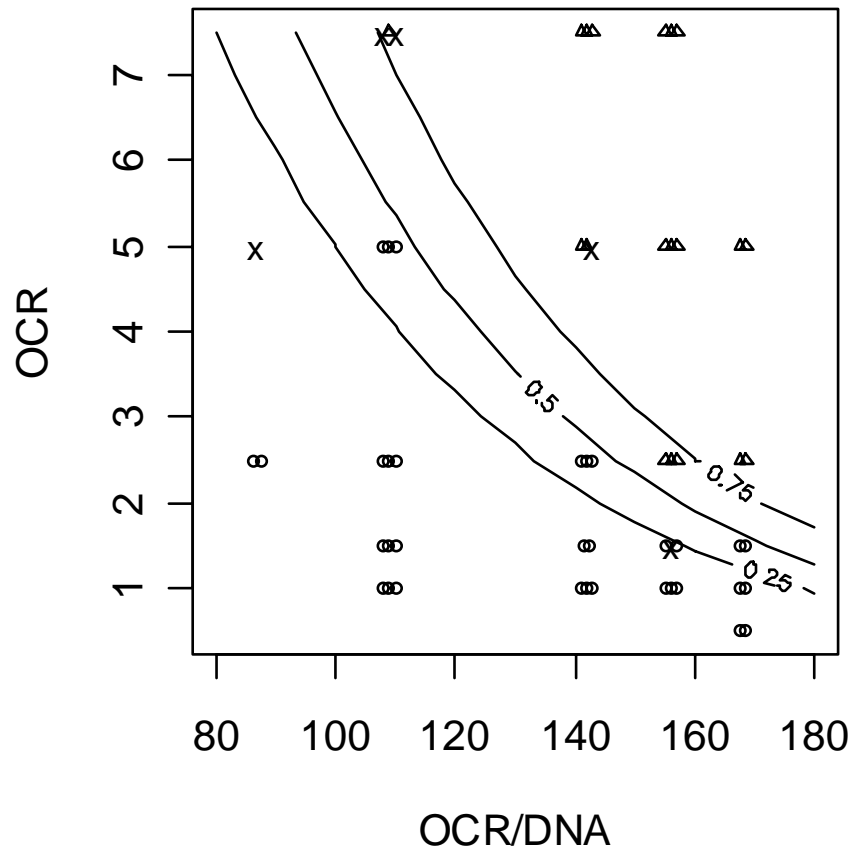


Response to Human Islet Transplants in Diabetic Immunodeficient Mice



Statistical Analysis by City of Hope ABCC

Sensitivity of 91.7% and a specificity of 90.5%



Conclusion

- **Human islet potency assay based on OC and DNA measurements is highly sensitive and highly specific to the mouse transplantation outcome**