IOMAI®
VACCINES

Travelers' Diarrhea Vaccine Patch

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IMMUNITY THAT'S MORE THAN SKIN DEEP™

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IOMAI VACCINES

> INFLUENZA

Learn more about Iomai's needle-free influenza vaccine programs

> PANDEMIC (AVIAN) FLU

Learn more about immunostimulant (IS) patches for use with vaccines for pandemic influenza.

> TRAVELERS' DIARRHEA

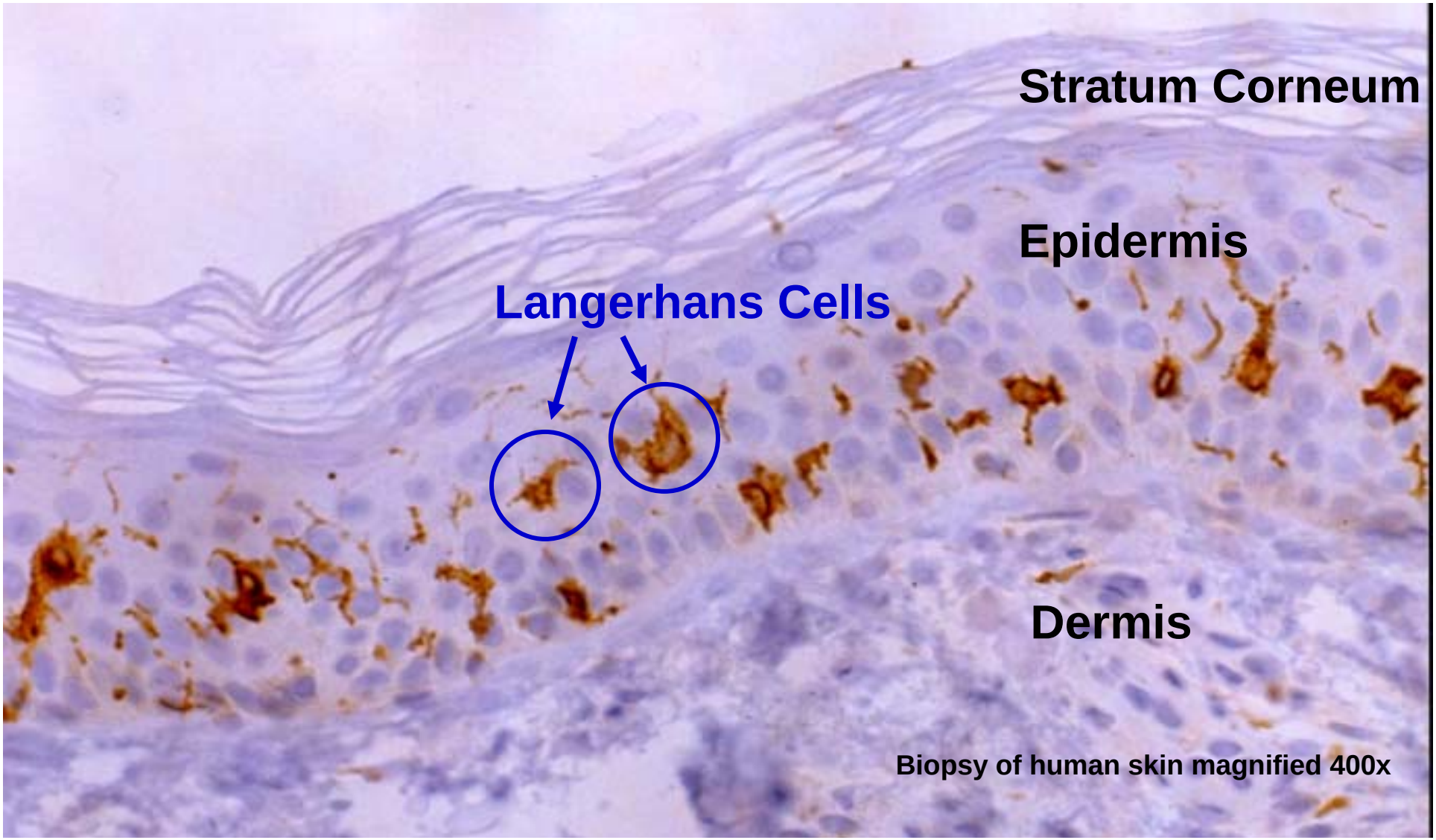
Learn more about the prevention of travelers' diarrhea caused by enterotoxigenic E. coli bacteria (ETEC).

ETEC Vaccine Overview

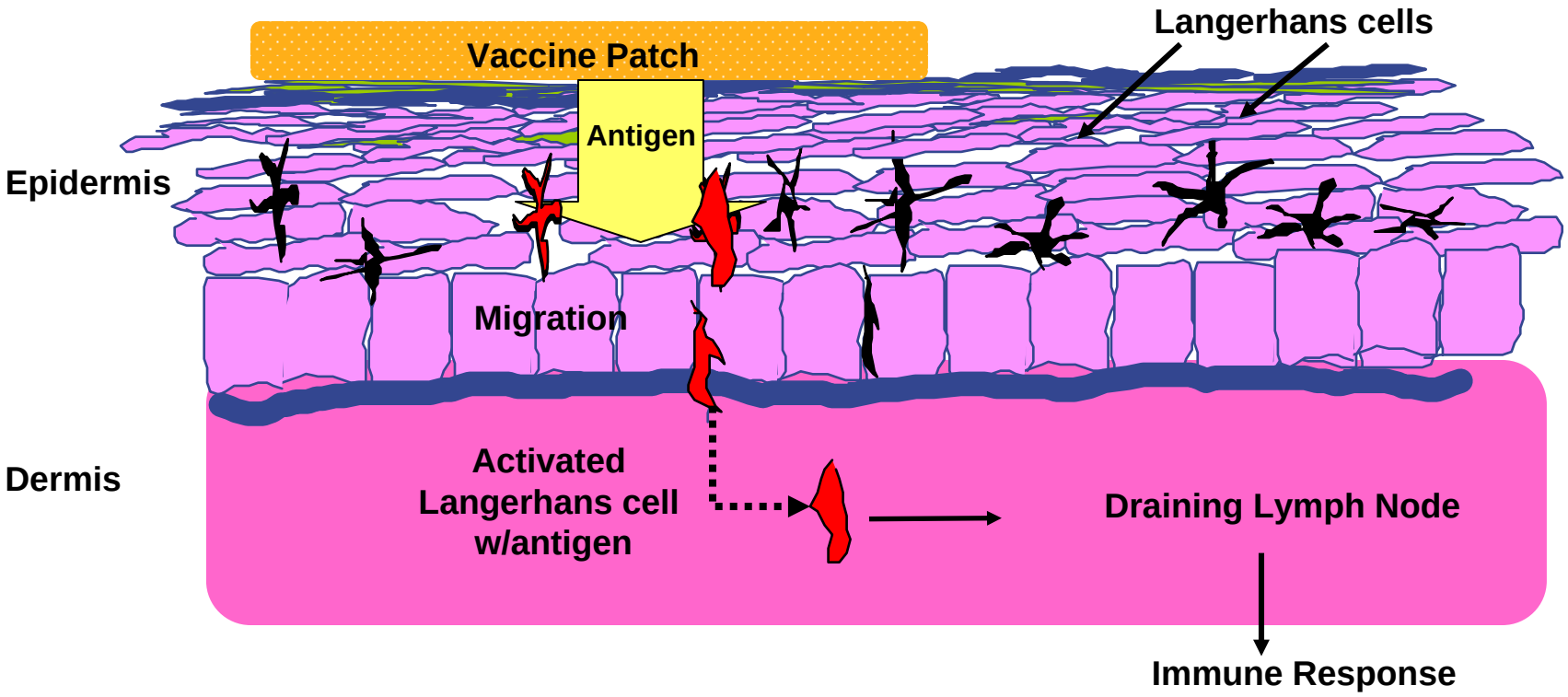
- Biologic basis for transcutaneous immunization (TCI)
- Rationale for toxin-based ETEC vaccine
- Patch technology characteristics
  - Stability
  - Ease of use
  - Immunogenicity profile and comparability
  - Self application
- Current and future clinical efforts

Biologic Basis for TCI

Skin Structure

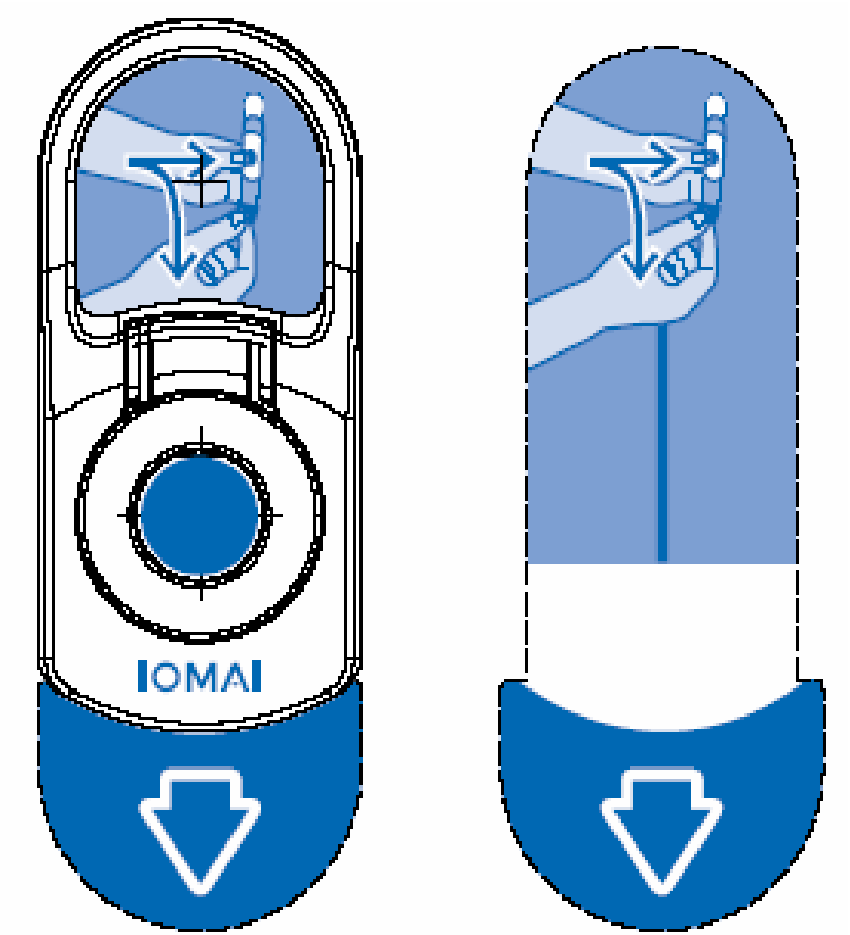


TCI: Skin Delivery of Vaccines

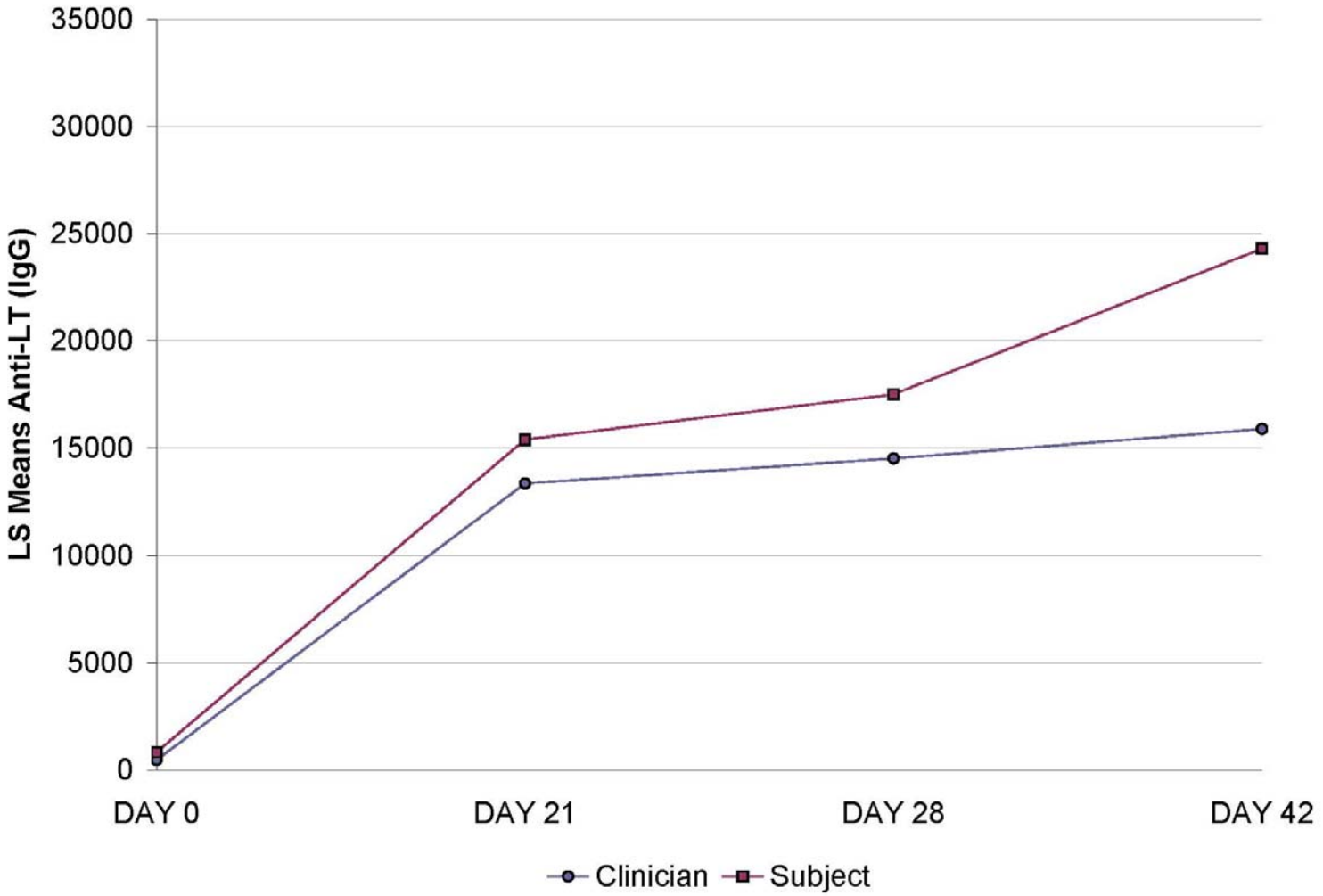


Skin Prep System

- **Disrupts the stratum corneum**
  - **Minimizes physical barrier**
  - **Enhances water loss that hydrates patch**
- **Engineered for consistency**
- **Easy to use**
- **Marks (ink) skin to aid patch**
- **Performance is reproducible between subjects**
- **Simple, non-event for recipients placement**
- **Self-application**



Self vs. Clinician



Safety of TCI on the skin

- **>30 clinical trials using LT in a patch**
  - **Approximately 3500 subjects**
  - **Good safety profile with no associated systemic adverse events**
- **Skin-provides ideal immune environment and high margin of safety**

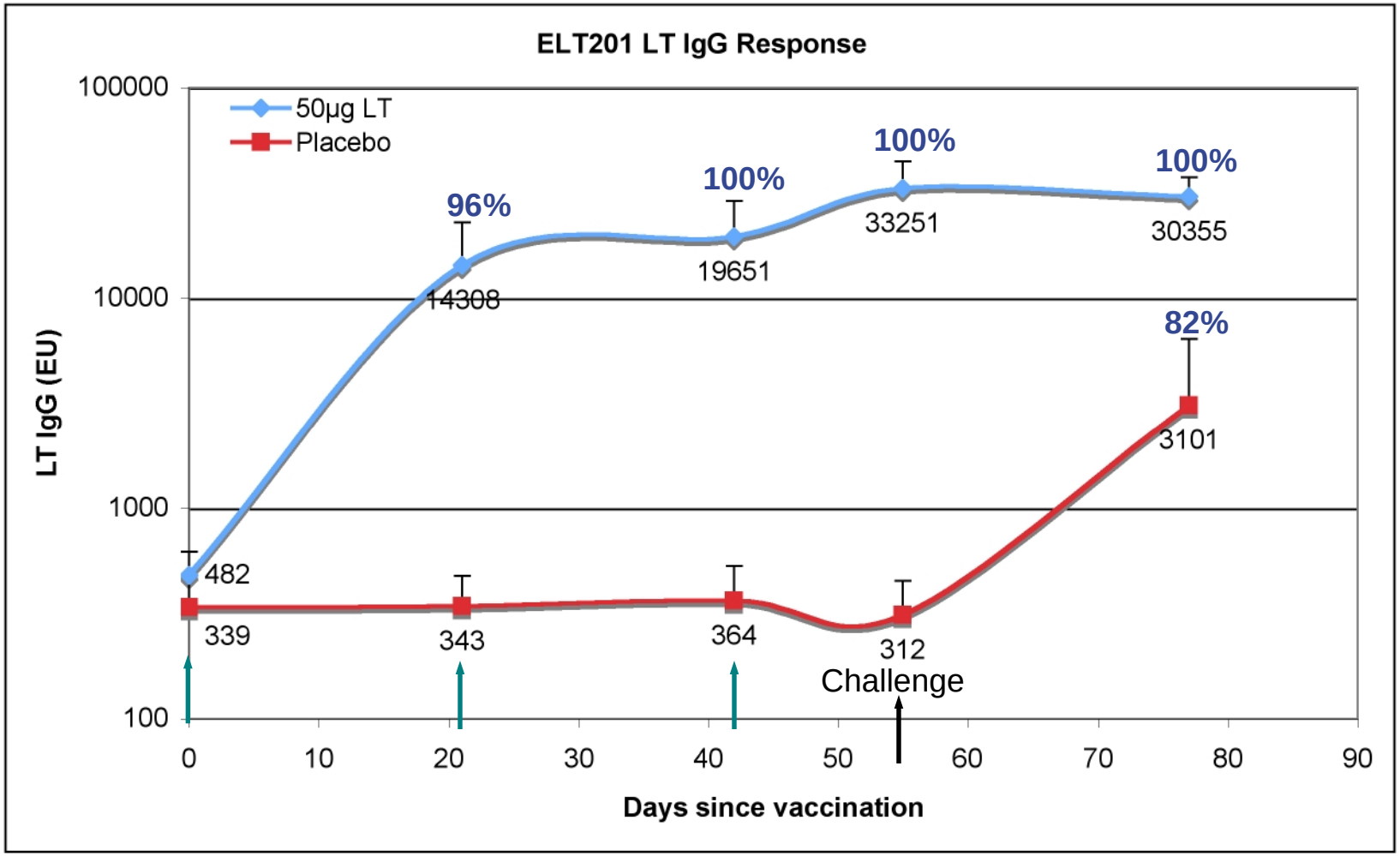
Rationale for Toxin-Based ETEC Vaccine

Historical Data

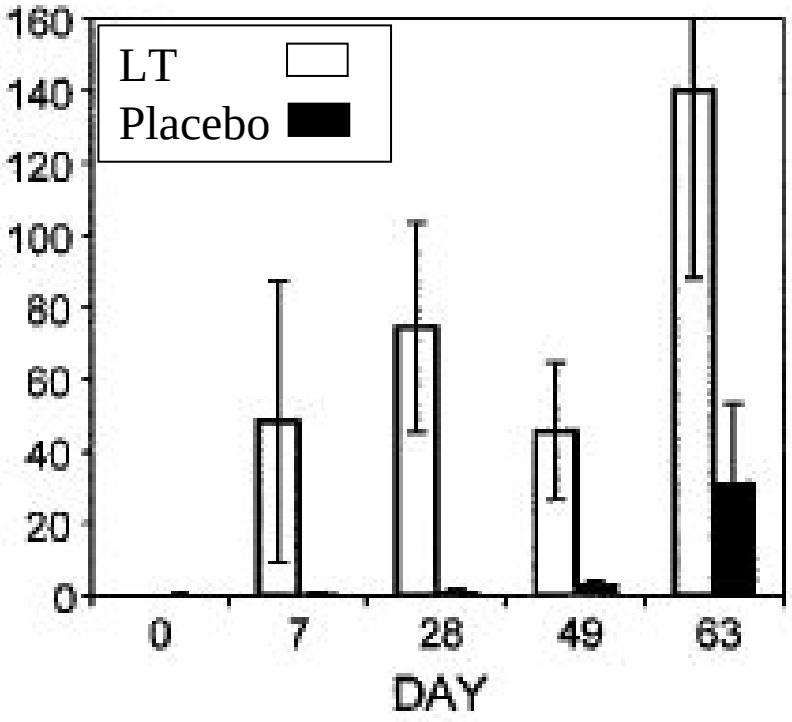
- LT antibodies neutralize toxin effects
- Natural Immunity
- Immunity in the Experimental Setting
  - Active and passive immunity (preclinical)
  - Anti-toxin immunity (field)
    - Whole Cell/rCTB
- TCI LT challenge trial data demonstrated disease modification

  (McKenzie et al, Vaccine 2007)

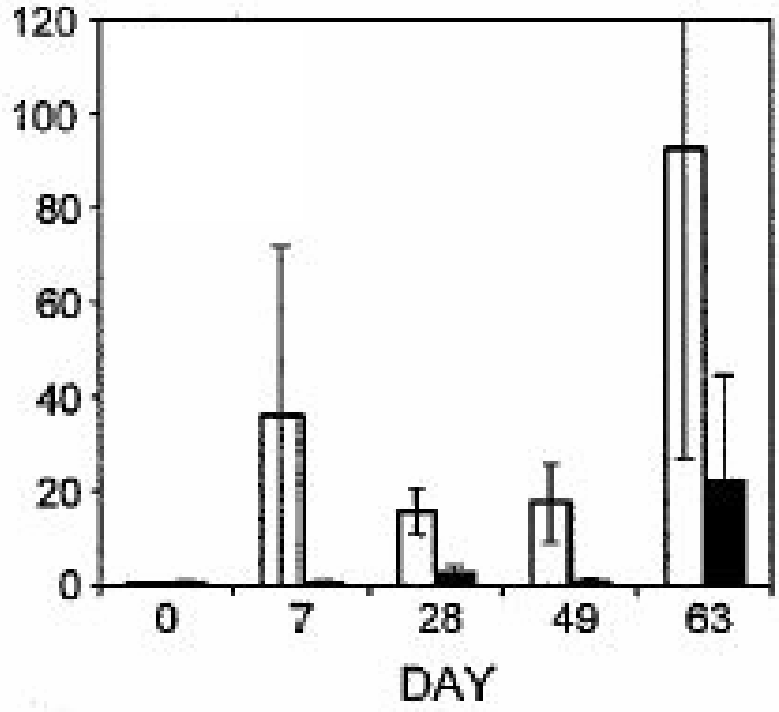
LT Patch Induces Immunity Superior to Live ETEC Challenge



Challenge Trial LT ASCs



LT IgG ASCs

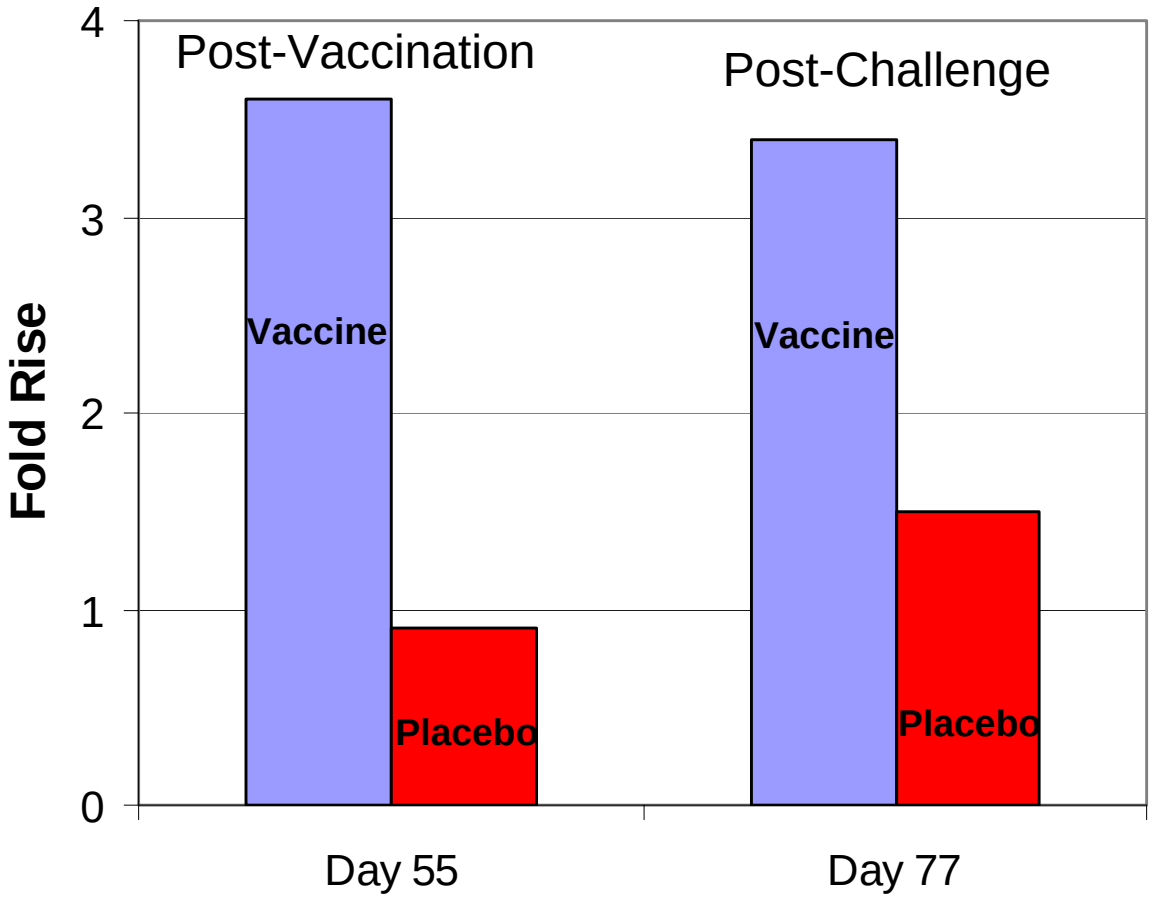


LT IgA ASCs

- Blood taken 7-10 days post dose or challenge
- Post challenge, the number of ASCs for vaccinees was 8-10 fold higher

Challenge Trial Fecal Antibody

ELT201 Fecal IgA



Challenge Study

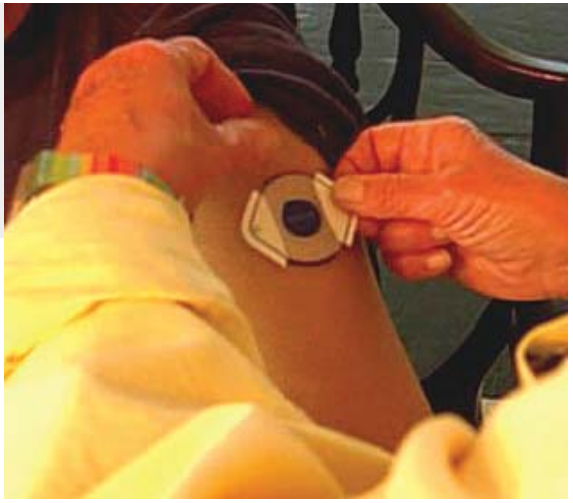
- **Safety, robust immunogenicity**
- **96% had grade 3-5 stools (diarrhea)**
  - **20/20 placebos and 25/27 vaccinees**
- **Vaccine effects:**
  - **Decreased number of loose stools per subject in vaccinees vs placebo**
    - **6.8 (range 2-15) vs 9.7(3-39), p=0.035**
  - **Decreased average stool weight per subject in vaccinees vs placebo**
    - **840g (range 389-2033g) vs 1147g (range 506-4508g), p=0.0499**
  - **Decreased need for IV fluids**
    - **14% (vaccine) vs. 40% (placebo), p = 0.03**
    - **Given to subjects who were on course to dehydrating disease**

Patch Technology Characteristics

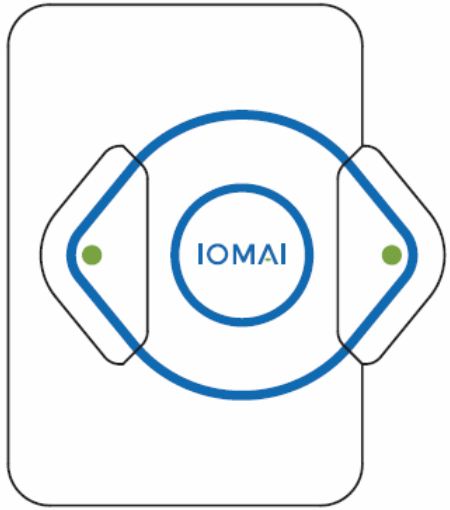
Patches

Skin Prep System

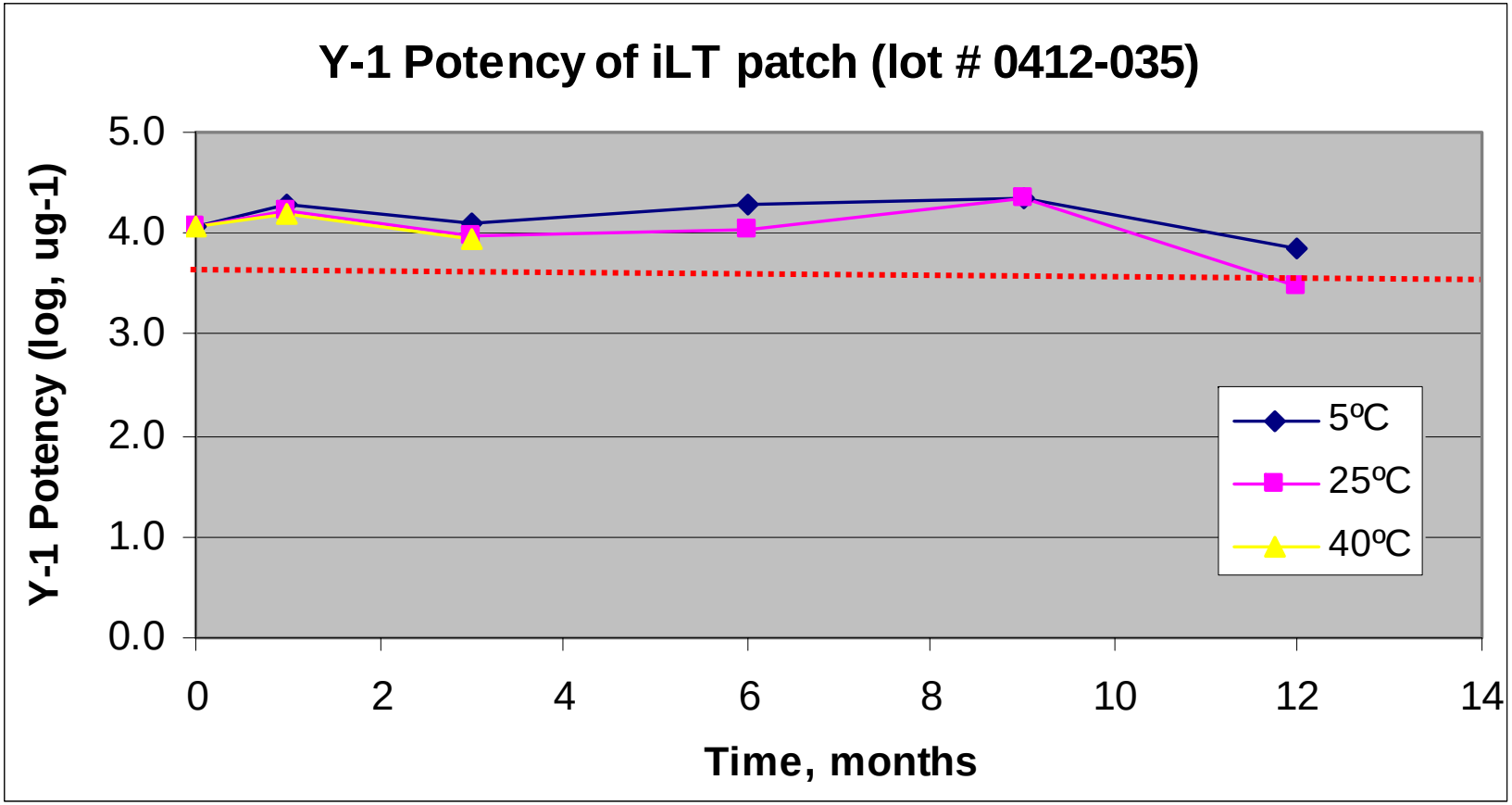
Patches



- **Simple, reliable application**
- **Dry, stable formulation**
- **Consistent delivery, even at low doses**



Stable LT Patches



Y-1 potency of GMP 50ug LT patches

ETEC Dose-Ranging Study

- Double blind, placebo controlled dose ranging study
- >400 subjects enrolled
  - Doses 7.5ug – 50ug
- Objective: Identify optimal dose for product
- Endpoints
  - Immunogenicity
  - Safety

LT IgG Results

	Dose Ranging Trial					Other Comparisons		
	7.5ug	22.5ug	37.5ug	50ug		WC/ rCTB(1)	Challenge(1)	Challenge(2)
GMT (EU)	9617	11667	20246	16549		6741	3245	3101
Fold Rise	19	19	36	32		3	11	9
Sero-conversion	95%	97%	100%	97%		54%	88%	82%

*Data from three weeks after second vaccination

(1) Glenn et al, Infection and Immunity 2007

(2) McKenzie et al, Vaccine 2006

Current Clinical Efforts

Phase 2 Logistics Study

Group	# Subjects	LT dose (µg)
1	100	37.5
2	200	0

- **Objectives:**
  - **ETEC epidemiology of travelers'**
  - **Evaluate Ph 3 infrastructure and study logistics**
- **Vaccinated twice**
  - **Travel to Mexico and Guatemala a minimum of 5 weeks after first vaccination**
- **Mexico and Latin American surveillance**
  - **Co-primary endpoints: placebo incidence of ETEC illness; safety**
  - **Secondary endpoints: vaccine immunogenicity, comparison of stool testing (DNA hybridization vs PCR)**
- **Preparation for Phase 3 2008**

Conclusions

- **TCI elicits robust immune responses**
- **TCI technology for LT delivery is in an advanced stage**
  - **Ambient temperature stability**
  - **Simple application (self administration possible)**
- **Technology applicable for travelers and endemic pediatric diarrhea**
- **Ready for field testing**

Thanks

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