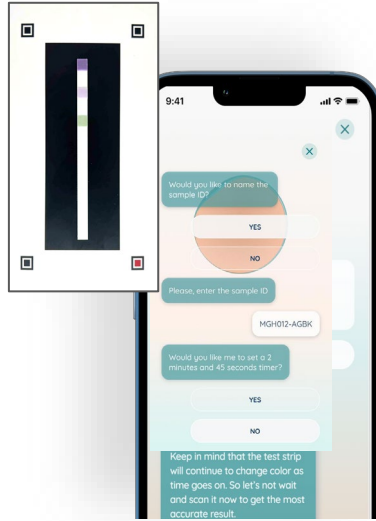


Quantitative Analysis of Human Milk Macronutrient Content



ICD 10 Coordination and Maintenance Committee Update March 2025

Emily's Care Nourish Test System

Presented by: Stephanie Canale, M.D.

Founder & CEO, Lactation Lab Inc.



Team and Key Supporters

Management Team



Stephanie Canale, M.D.
Founder & Chief Executive Officer

- Serves as Founder & Chief Executive Officer of Lactation Lab
- Member of the American Board of Family Medicine
- Education: Earned undergraduate and medical degrees from McGill University, completed residency training in Family Medicine at UCLA, and then was a part of the teaching faculty at the UCLA Family Health Center before joining UCLA Santa Monica in 2010



Nandita Shetty, BE, MS
Chief Strategy & Innovation Officer

- Serves as Chief Strategy & Innovation Officer of Lactation Lab
- Started career as a software developer at Philips, and is now focused on the commercialization of medical innovations and working in the maternal-infant health space.
- Education: Awarded a fellowship at the Stanford Graduate School of Business' Ignite program, holds a Master's in BioMedical Engineering from UT SouthWestern Medical Center and a Bachelor of Engineering degree in Medical Electronics from MS Ramaiah Institute of Technology



Eric Canale, MBA
Chief Operations & Technology Officer

- Serves as Chief Operations & Technology Officer of Lactation Lab
- Entrepreneur with an extensive technology and business background with a focus on healthcare and intelligent transportation
- Education: BA from UCLA 1993. MBA from UCLA Anderson 2004.

Supported By




Nutrition in the NICU: Key to Survival and Lifelong Health




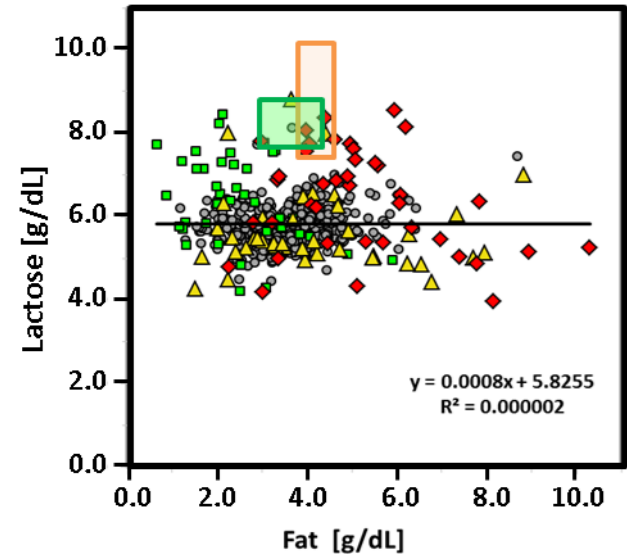
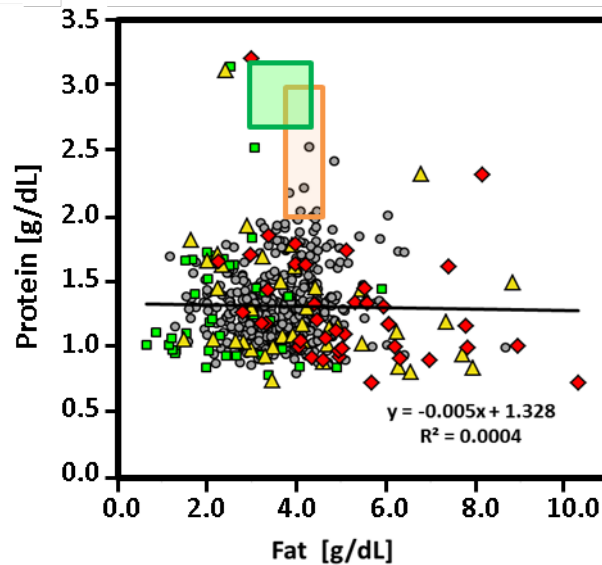
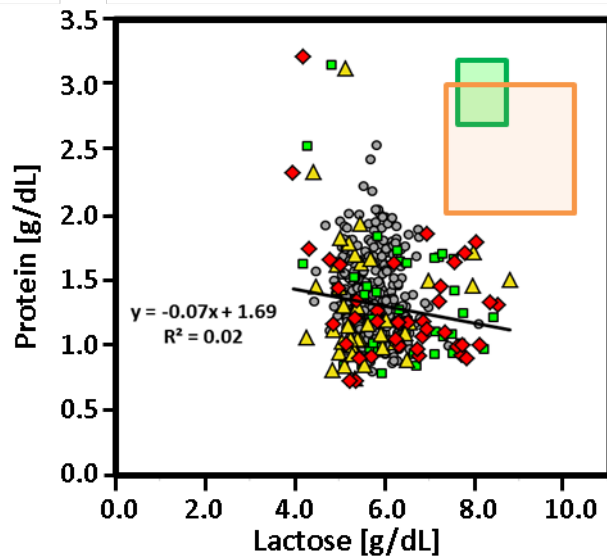
- Premature Infants Have Higher Nutritional Needs than Term Infants.
- ESPGHAN/ AAP* Guidelines Ensure Human Milk is Fortified with Macronutrients to Support Critical Growth and Development.
- Protein & Calorie Intake in 1st 2 Weeks Directly Impacts Brain Size and Neurodevelopmental Outcomes in very low birth weight (VLBW) Babies (<1500g).
- Failure to Meet Nutritional Needs Leads to Irreversible Brain Injury, Impaired Growth, and Lifelong Cognitive Deficits.
- **The Critical Need for Precise Nutrition Earned Emily's Care FDA Breakthrough Status.**

* European Society for Paediatric Gastroenterology, Hepatology and Nutrition/American Academy of Pediatrics

Breastmilk Composition: Large Macronutrient Variability and No Correlation Between Macronutrients

 ESPGHAN guidelines: Defined Amount of Protein, Fat, Carbs and Energy (kg/day)

 Commercially Available formulas



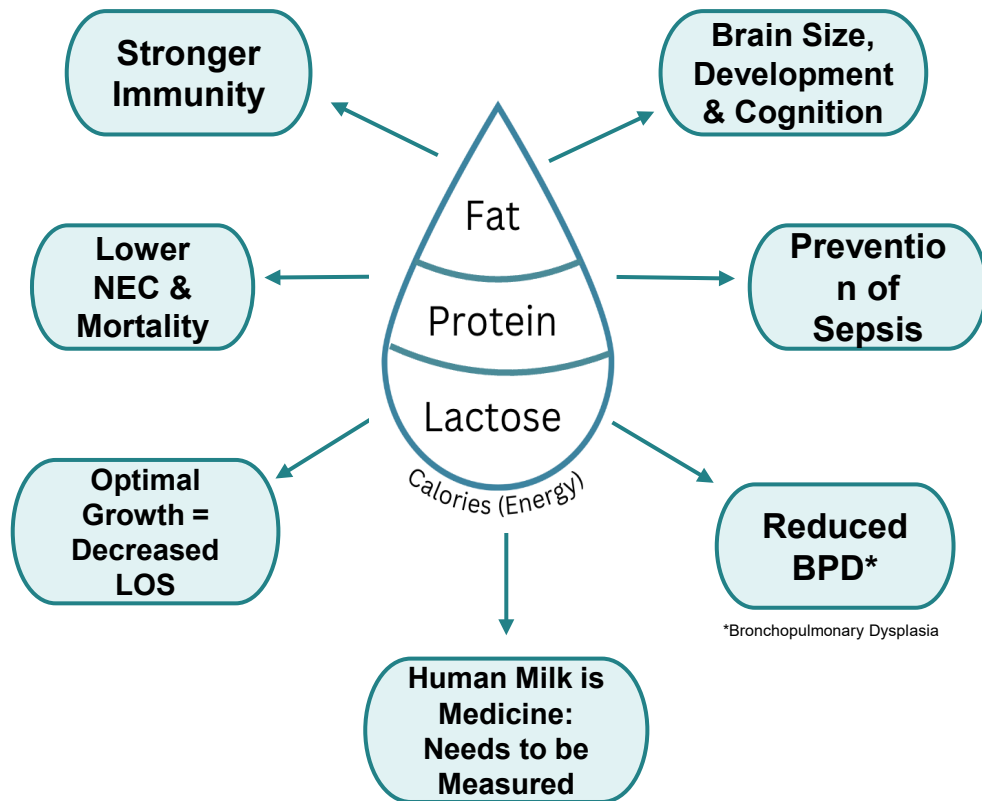
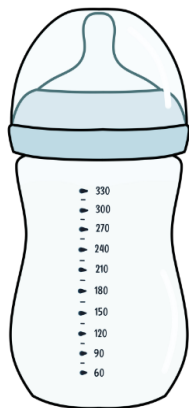
(Fusch G. et al. Acta Paediatrica, 2015)

Human Milk is Life Saving in the NICU

Human Milk is Highly Variable (12-35 kcal/oz)



All Human Milk is Fortified in the NICU



All Breastmilk is Fortified in the NICU: Standard vs. Targeted

Standard Fortification

- Baseline Content of Milk (Donor or Mother) is Assumed to be the Same (20 kcal/oz)
- ESPGHAN/ AAP Targets are Typically Not Met
- Higher rates of Metabolic Acidosis

VS.

Targeted Fortification

- Baseline Content of Milk is Measured (Range is from 12- 35 kcal/oz)
- Fortifier Added Based on Needs
- ESPGHAN/ AAP Targets are Met
- Improved Growth and Neurodevelopment

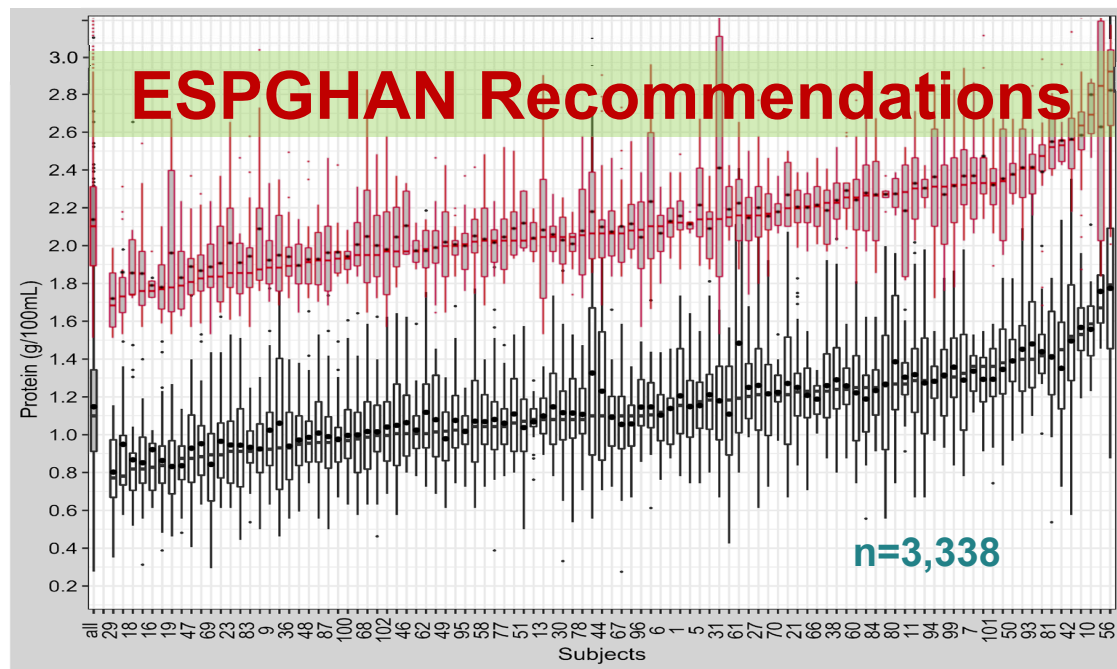
Premature Infants are Already Compromised and Face Significant Health Issues.

- Nutritional Deficits Add to the Burden: Every Feed Matters for Growth and Development.
- Without Precise Fortification, Every Feed is a Guess, Leading to Nutritional Deficiencies.
- Nutritional Gaps are Compounded: Contributing to Long-Term Health Complications.

Emily's Care: A Solution That Ends the Guesswork: NICU Babies Deserve Precision

Standard Fortification: Does Not Meet ESPGHAN Recommendations

Box Plots Represent Data from an Interventional Study of 3,338 Samples from 103 Mothers



Standard Fortified Breastmilk

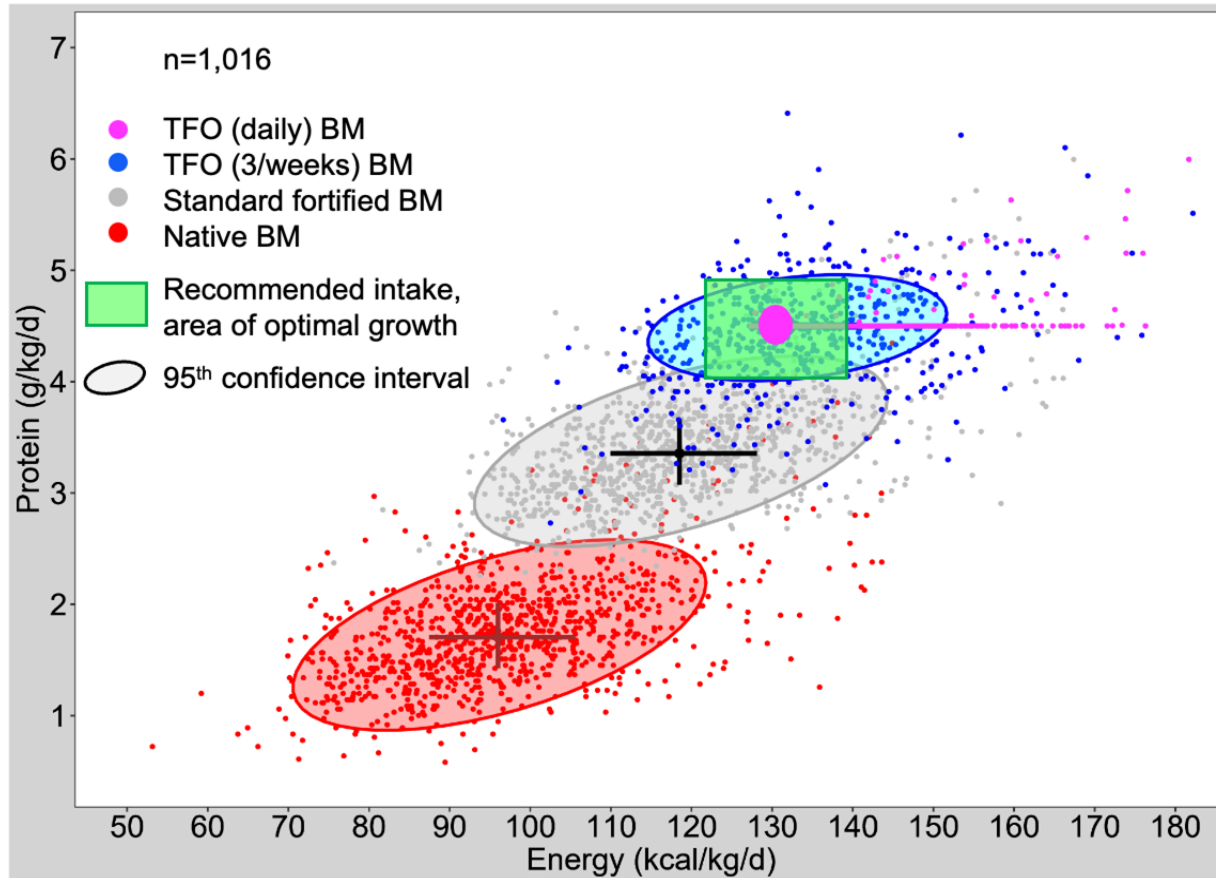


Native Breastmilk

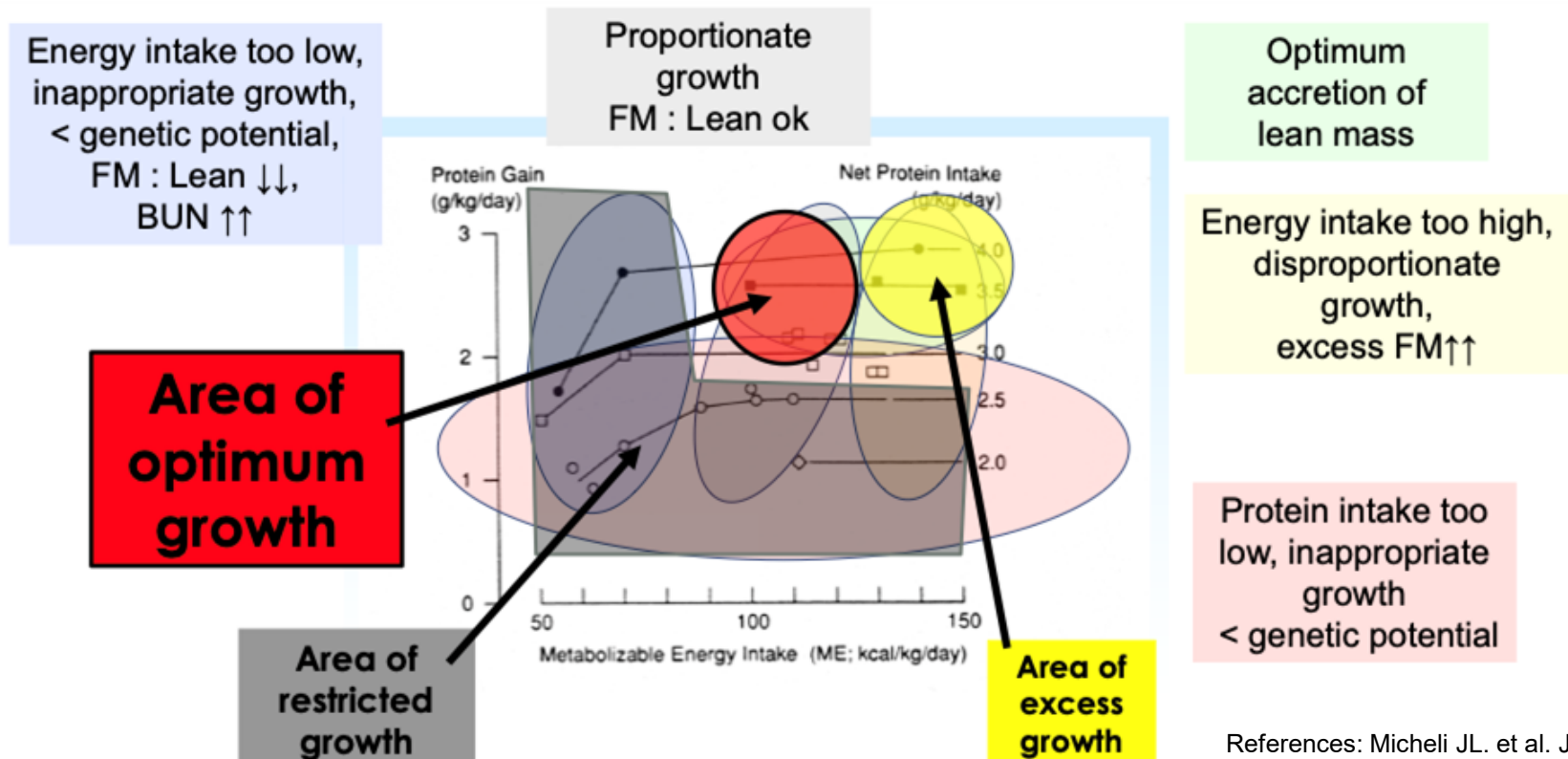
- Standard Fortification (Assuming all Milk is the Same) is a Common Feeding Practice.
- 58% of Preterm Infants Receiving Standard Fortification have Poor Growth Upon NICU Discharge
- Higher Risk for Chronic Diseases and Worse Neurodevelopmental Outcomes.

Targeted Fortification with Daily Measurements:


All Infants meet ESPGHAN / AAP Targets with Daily Measurements



Impact of Nutritional Composition on Growth: Balance is Key



Solution: Moving from a Laboratory to a Point of Care



Technology:
Physics
Optics/
Infrared
Absorption of
Chemical
Bonds

Bulky/ Loud
Lab
Equipment

Extensive
Training
Required


3ml Sample

Preprocessing
of Sample
Required

Requires
Maintenance

Expensive
(Upfront Costs)

Technology:
Chemistry
Colorimetric/
Enzymatic



Test Strip,
Read by App

Results in 3
Minutes

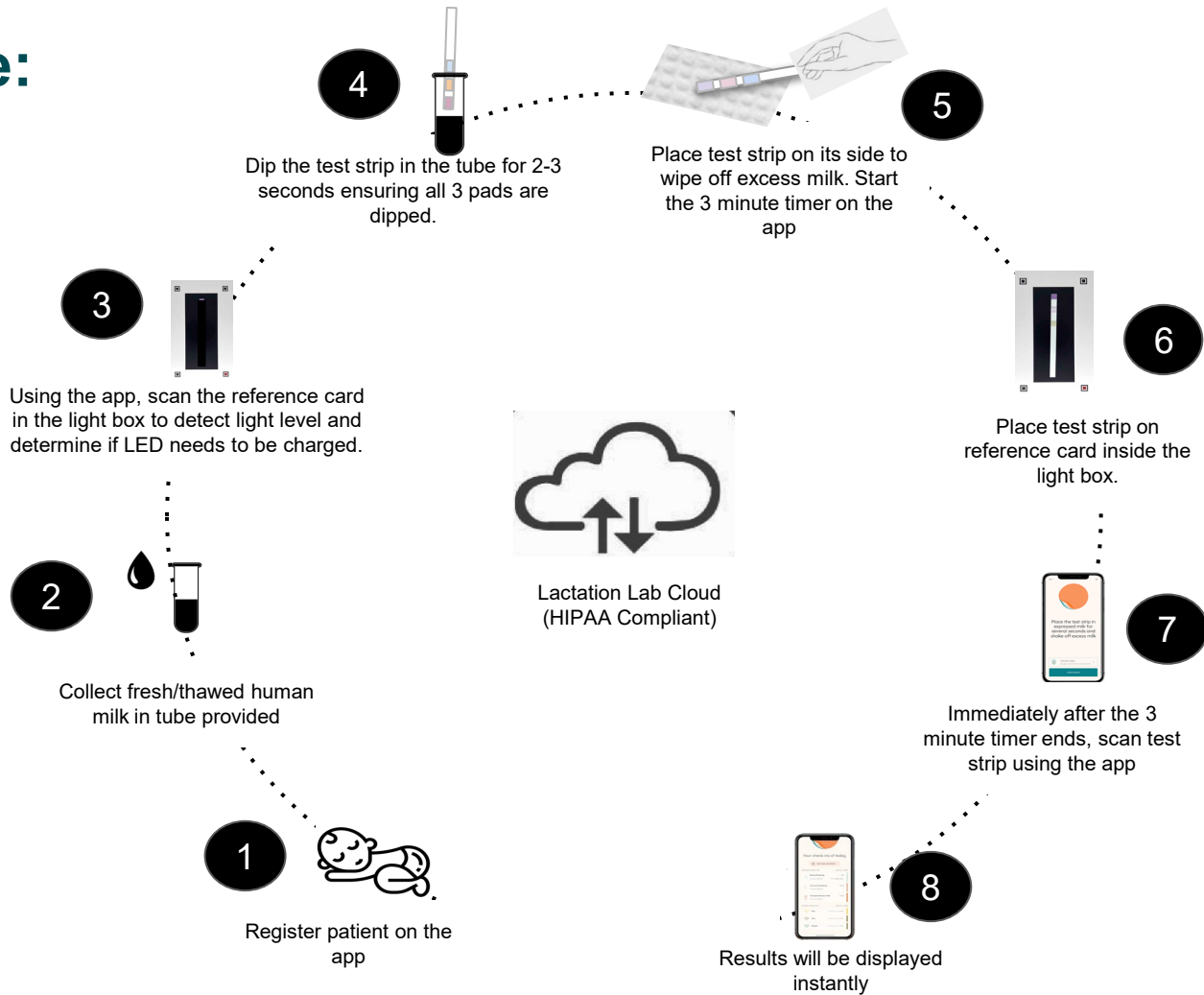
Minimal
Training
Required

No
Maintenance

0.03 ml
Sample

Improved
Accuracy

Emily's Care: Procedure



Emily's Care Nourish Test System

Human Milk Macronutrient Test Strip read by Smartphone

Macronutrient	Measured on Strip	Typical Range in Human Milk	Device Measurable Range
Protein	Modified BCA Assay	0.9 - 1.2 g/dl	0.6 - 2.4 g/dl
Fat	Triglycerides (98% of fat)	2.0 - 3.3 g/dl	0.6 - 6.0 g/dl
Carbohydrates	Lactose	5.5 - 7.5 g/dl	4.5 - 9.5 g/dl
Calories (Energy)	Calculated in app Based on Concentration of Macronutrients	70 - 90 kcal/dl	55 - 120 kcal/dl



Color Intensity changes on each reagent pad as concentration increases

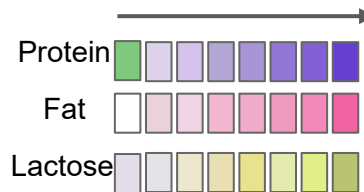
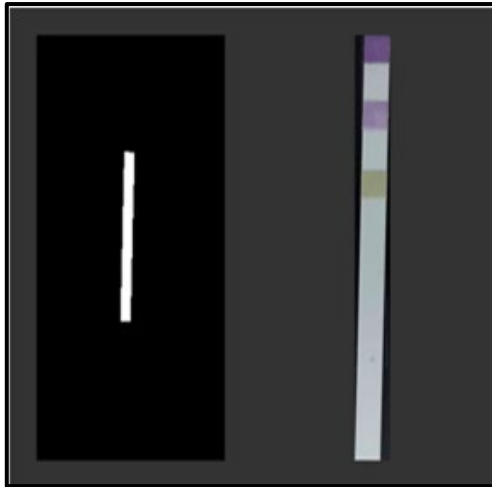


Image Processing Steps



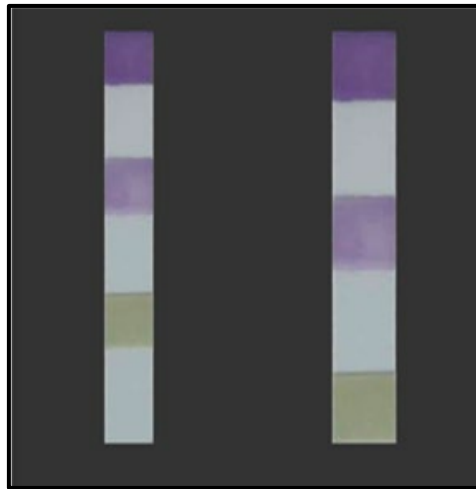
A

A. Activated Test Strip is Placed on Reference Card.



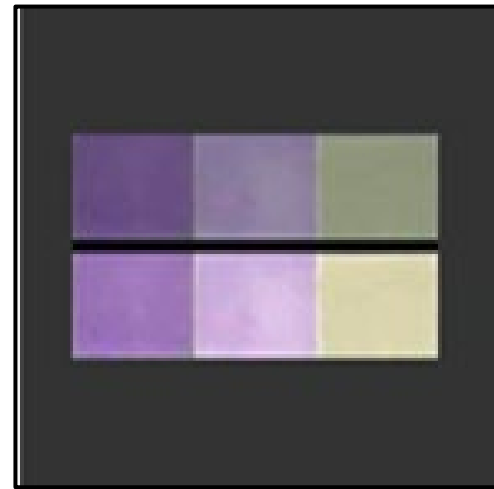
B

B. Left: Test Strip Mask; Right: Extracted Test Strip Before Angle Correction Occurs.



C

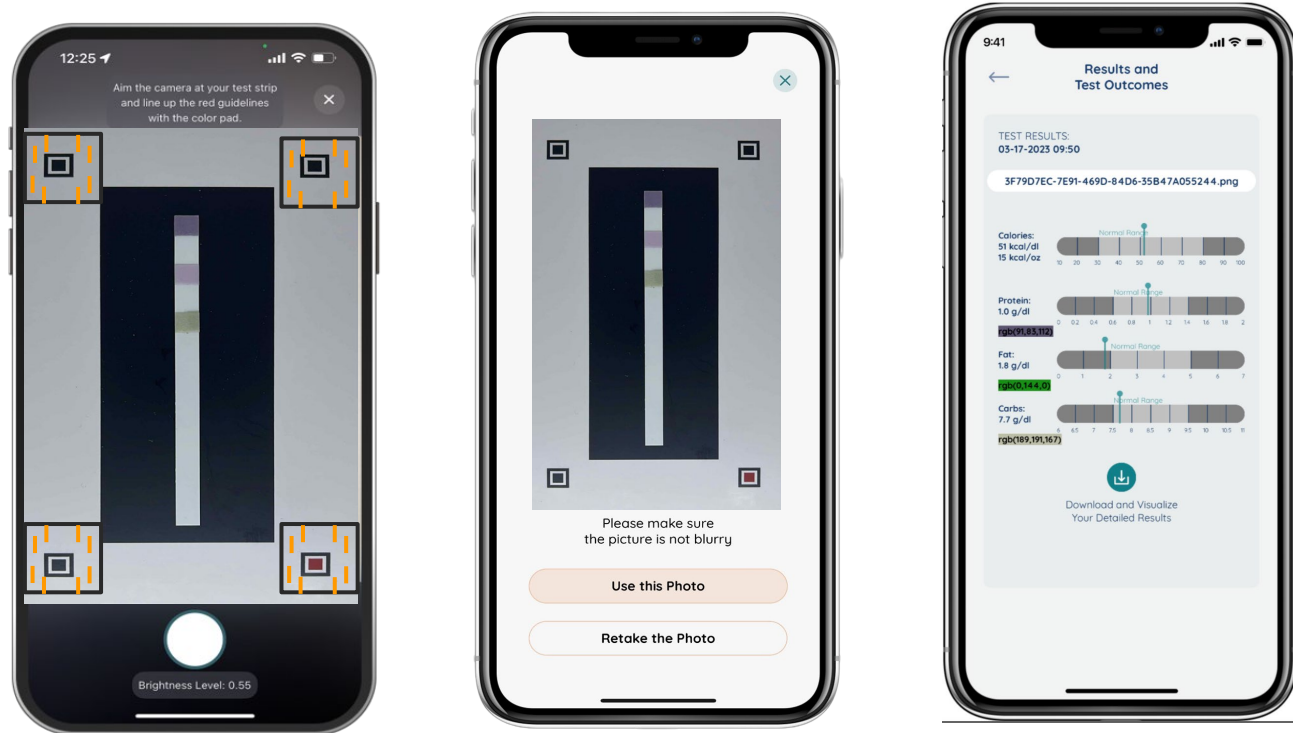
C. Left: Extracted Test Strip After Adjusting the Angle and Trimming; Right: Test Strip Further Cropped to the Regions of Interest Only.



D

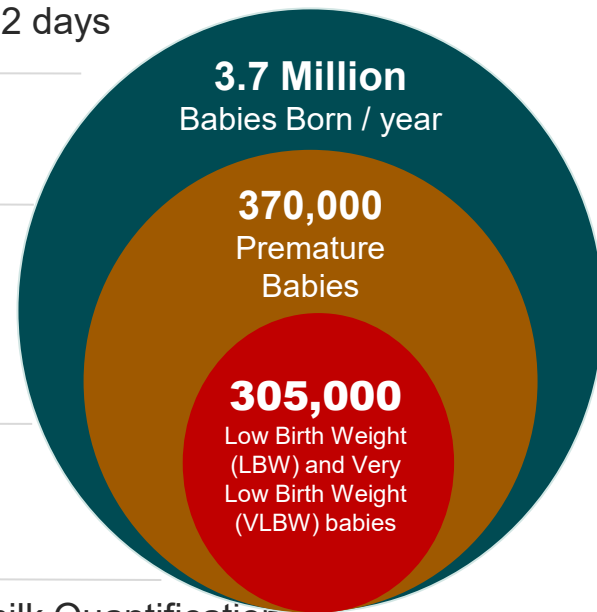
D. Top row: Reagent Pads Extracted Before Color Balancing; Bottom row: Reagent Pads Extracted After Color Balancing.

Emily's Care App: Accurate, User Friendly, and HIPAA Compliant



Impact & Clinical Documentation

Impact	VLBW: 50,000 / year VLBW: 255,000 / year	Length Of Stay (LOS) VLBW: 23-74 days Avg: 43 days LBW: Avg. 12 days
Device Facilitates Precise Nutrition	Decreased LOS: 2 - 3 days, Improved Short & Long-Term Outcomes	
Indications for Use	To Aid the Nutritional Management of VLBW and LBW Neonates and Infants < 6 months. in the NICU.	
Device Use	Prescription Device to be Used in NICUs	
Documentation	MRN / H&P, Progress Notes, Discharge Summaries, Feeding Protocols, Fortification Documentation	
Terminology	Emily's Care Nourish Test System, Human Milk/ Breastmilk Quantification, Breastmilk Macronutrient POC Measurement, Targeted Fortification	
Adverse Events	No Serious Adverse Events are Associated with the Device	





Thank You!

Stephanie Canale, M.D.
scanale@lactationlab.com