



Pilot Newborn-Screening in Guatemala – First Experience with the NeoPlex4® Assay from LUMINEX

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Pilot Plan 2013-2014

- **15,073,397 inhabitants (until 2012)**
- **23% live in the metropolitan area**
- **birth rate 26.48 births / 1,000 inhabitants**
- **mortality rate for children < 1 year: 30/1,000**
- **22 provinces**
- **334 municipalities**
- **25 different language communities**



Pilot Plan 2013-2014

- 3 months training period in 2012
- 15 public and private hospitals
- 114 pediatric residents were trained
- 286 samples were collected during that time
- 14% of samples were of bad quality
- 8% of screening cards were lost in hospital
- high rotation rate in neonatal service



Pilot Phase

Objectives

General

1. Introduce the newborn screening to the private health system.
2. Evaluate the incidence of inborn errors of metabolism in the selected areas.



Pilot Phase

Objectives

Specific

- 1. Evaluation and selection of the areas to be screened.**
- 2. Training to the health group from each hospital in charge of the neonatal units.**
- 3. Definition of the critical route from sampling to shipping.**
- 4. Standardization of the NBS laboratory protocols**
- 5. Evaluate the incidence of Congenital Hypothyroidism in the selected hospitals**
- 6. Evaluate the incidence of Cystic Fibrosis in the selected hospitals**
- 7. Evaluate the incidence of Congenital Adrenal Hyperplasia in the selected hospitals**
- 8. Evaluate the incidence of Phenylketonuria in the selected hospitals**
- 9. Evaluate the incidence of Biotinidase deficiency in the selected hospitals**



Pilot Phase

Congenital Hypothyroidism

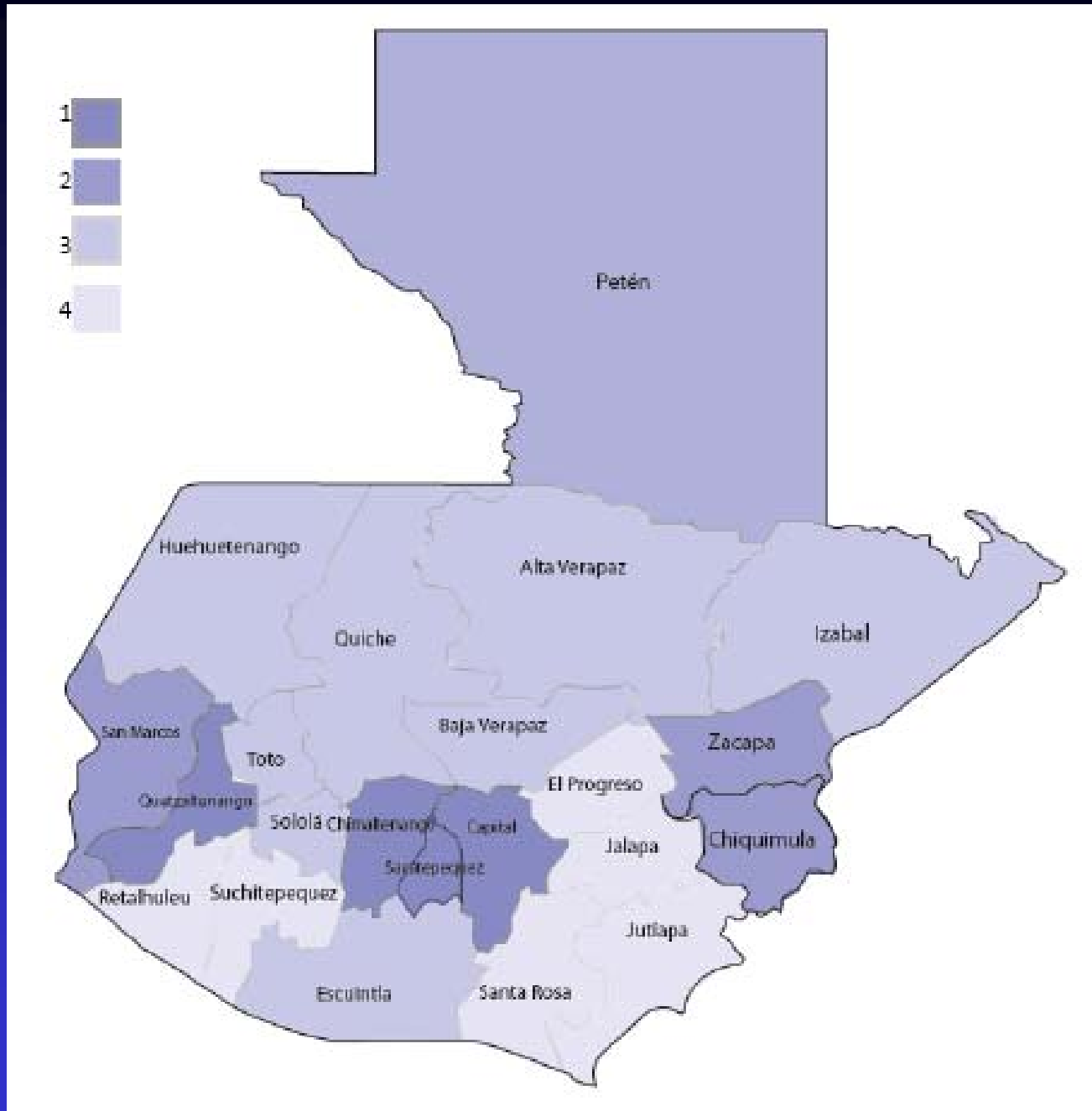
Phenylketonuria

Congenital Adrenal Hyperplasia

Cystic Fibrosis

Biotinidase deficiency





	sep-12	oct-12	nov-12	dic-12	ene-13	feb-13	mar-13	abr-13	may-13	jun-13	jul-13	ago-13	sep-13	oct-13	dic-13	ene-14	feb-14	mar-14	abr-14	may-14	
Evaluation of the Areas	█	█																			
Pre analytic logistic			█	█	█																
Analytic logistic and laboratory standardization				█	█	█															
Education and Training the personal involved in the NBS	█	█	█	█																	
Post analytic phase coordination	█	█	█	█	█																
Standarization	█	█	█	█	█																
First Sampling			█	█	█	█															
Analysis of the result from first sampling							█														
Correction to the logistic fails documented							█	█													
Second Sampling							█	█	█												
Analysis of the result from second sampling											█										
Correction to the logistic fails documented											█	█									
Mini System Implementation													█	█	█	█	█	█	█	█	█
Analysis of the result from implementation sampling													█	█	█	█	█	█	█	█	█
Correction to the logistic fails documented													█	█	█	█	█	█	█	█	█
Macro System Implementation																					█

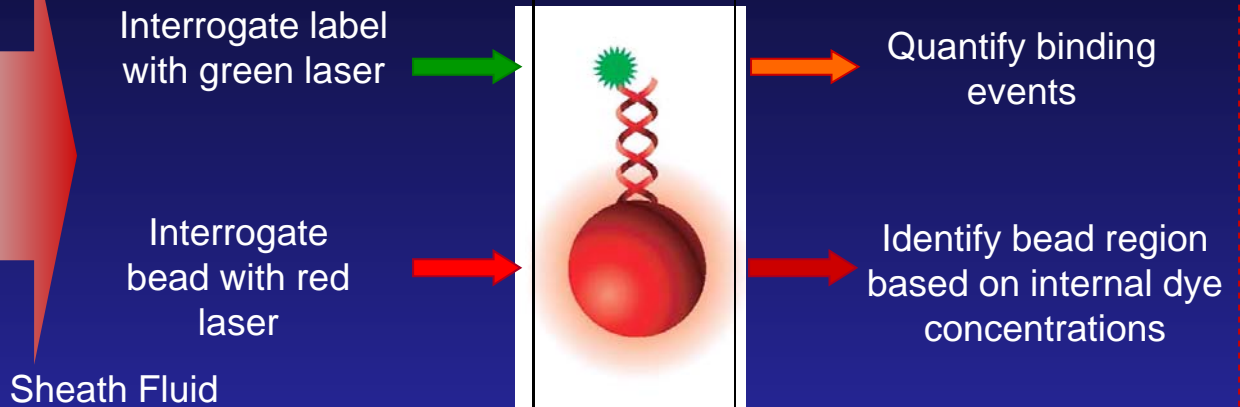
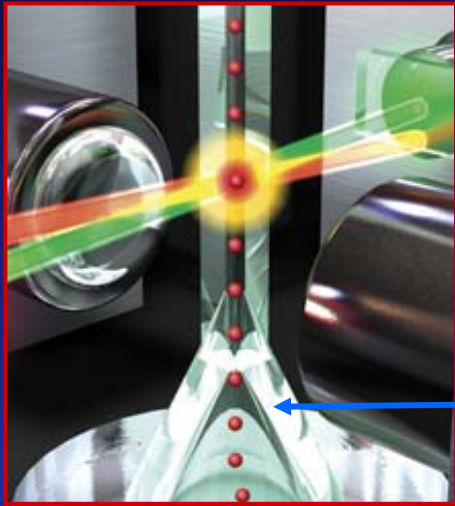


Technology

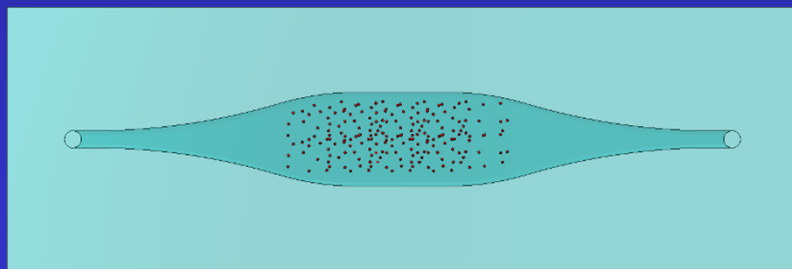


MAGPIX: Technology – LED's instead of Lasers

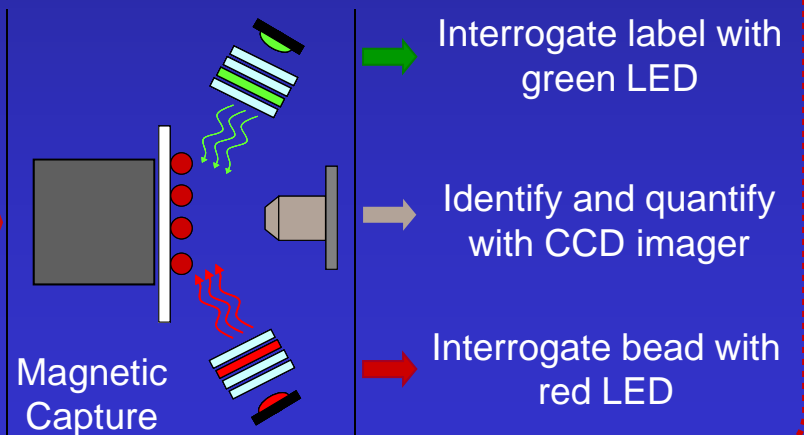
Flow Cytometry-Based Analysis (traditional Luminex detection)



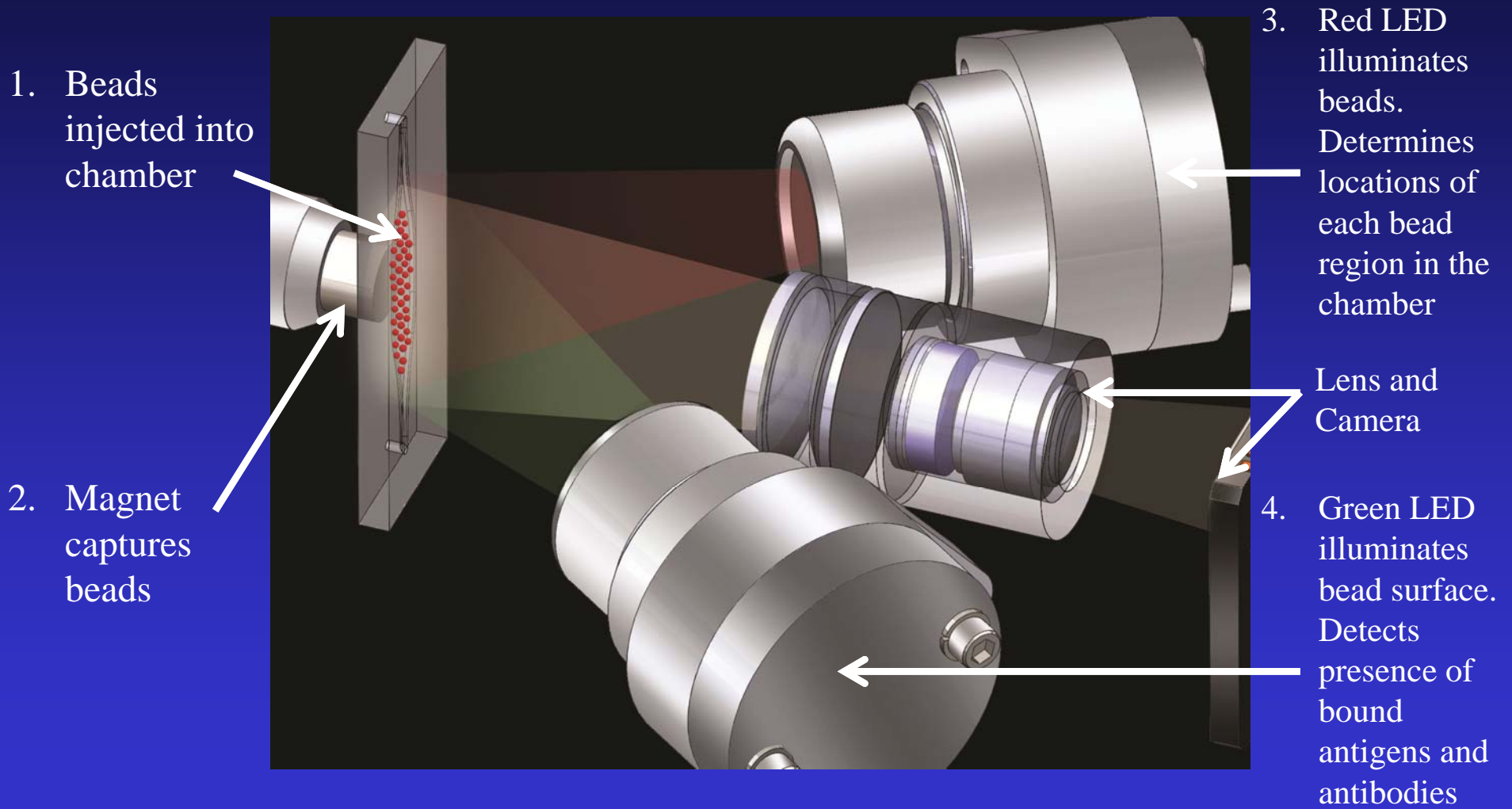
LED/Camera-Based Analysis (MagPix detection)



Beads in Chamber



MAGPIX: Detection Module



Results

	target	mean	sd	cv	recovery
TSH (C1)	12.3	12.7	1.6	12.7	103.3
TSH (C2)	39.5	38.2	4.0	10.4	96.6
TSH (C3)	79.3	81.4	10.2	12.6	102.7
T4 (C1)	2.5	2.8	1.0	34.8	112.0
T4 (C2)	6.3	6.6	1.2	18.6	104.8
T4 (C3)	16.0	15.7	1.7	10.8	98.2
17-OHP (C1)	15.1	20.2	4.8	23.6	133.8
17-OHP (C2)	52.5	60.2	9.4	15.6	114.7
17-OHP (C3)	78.1	93.5	11.4	12.2	119.8
IRT (C1)	21.6	23.3	5.2	22.2	107.9
IRT (C2)	62.3	63.6	10.0	15.8	102.1
IRT (C3)	122.2	140.3	30.3	21.6	114.8

TSH in [mU/L] (Serum)

T4 in [µg/dL] (Serum)

17-OHP in [ng/mL] (Serum)

IRT in [ng/mL] (Blut)

Recovery in [%]



Results (Zurich – Guatemala)

	range	mean diff. [%]	n	pos.
17-OHP	2.0-350	3.5	118	+
TSH	1.3-300	38	26	+
T4	0.55-21	6.4	17	+
IRT	30-600	6.3	22	+



Acknowledgement for Support



Laboratory Staff



Our Screening Laboratories

