

EPIMUNE™
DIAGNOSTICS

i.Mune™ NEO*

Quantification of:

- T lymphocytes (CD3+)
- Helper T lymphocytes (CD3+CD4+)**
- Cytotoxic T lymphocytes (CD3+CD8+)**
- Memory Helper T lymphocytes (CD3+CD4+CD45RO+)
- B lymphocytes (CD19+)
- Natural Killer lymphocytes (CD16+CD56dim)

from Dried Newborn Blood.

*Available as RUO Test – CE-IVD Development ongoing

**Not included in i.Mune™ NEO LITE configuration



IMMUNE CELLS COUNT

epimune-dx.com



i.Mune™ **NEO**

i.Mune **NEO** is a quantitative test to determine the percentages of lymphocyte subsets in capillary whole blood specimens from newborns dried on filter paper.

The tests use real-time polymerase chain reaction (PCR) for the amplification of immune cell type specific demethylated genomic target regions.

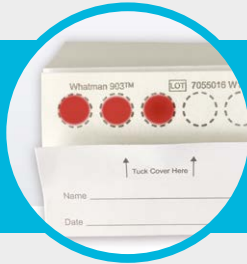


Workflow Overview



Sample Types

Dried Blood Spot (DBS) samples from newborns



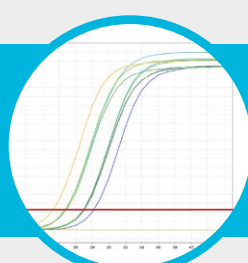
Lysis/ Bisulfite Conversion/ DNA Purification

Scalable throughput



qPCR

Validated on QuantStudio™ 6 Flex Real Time PCR System (96-well)



Data Analysis

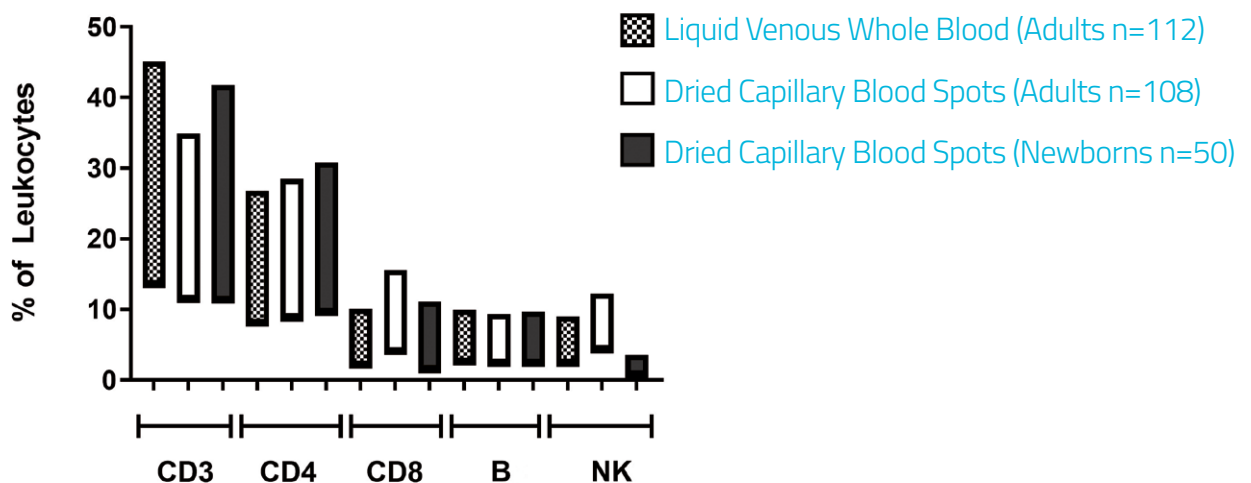
Proprietary Data Analysis Tool

Total Time: ~ 5 h 45 min per run
Hands-on Time: ~ 2 h 15 min per run
Throughput: up to 8 samples (i.Mune™ **NEO**) or up to 20 samples (i.Mune™ **NEO LITE**) per run

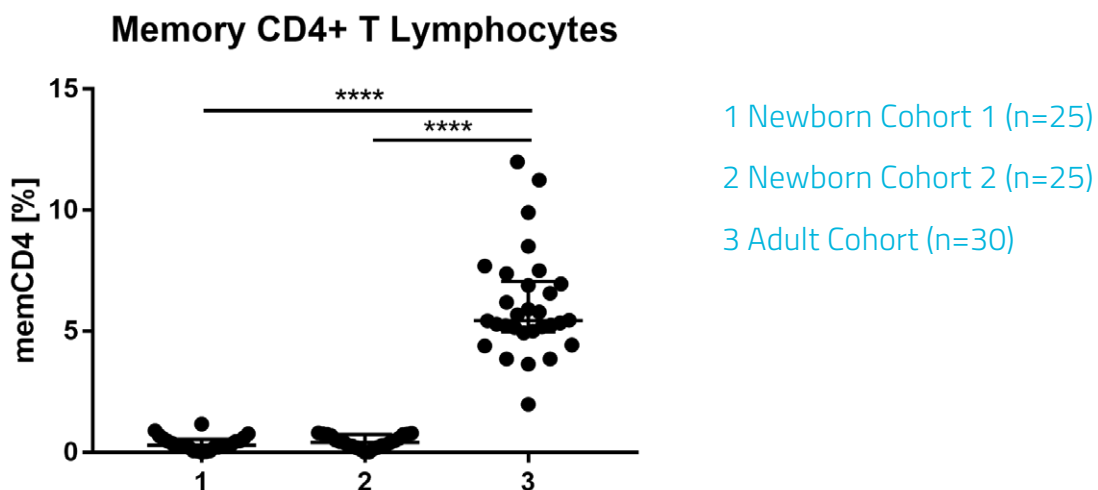
Test Configurations

	i.Mune™ NEO	i.Mune™ NEO LITE
T lymphocytes (CD3+)	✓	✓
Helper T lymphocytes (CD3+CD4+)	✓	
Cytotoxic T lymphocytes (CD3+CD8+)	✓	
Memory Helper T lymphocytes (CD3+CD4+CD45RO+)	✓	✓
B lymphocytes (CD19+)	✓	✓
Natural Killer lymphocytes (CD16+CD56dim)	✓	✓

Reference Ranges



Quantification of memory T-helper cells (to determine maternal T-cells)





IMMUNE CELLS COUNT



Contents

The kits contain sufficient reagents to perform:

- 8 runs, each with 4 samples (32 samples total) (i.Mune[™] NEO) - *or* -
- 2 runs, each with 20 samples (40 samples total) (i.Mune[™] NEO LITE)

Kit	Order-No.	Kit Size	Storage
i.Mune [™] Prep	IM-PREP-01	40 samples	Room Temperature
i.Mune [™] NEO Amp	IM-AMP-03-1	32 samples	-30°C to -15°C
i.Mune [™] NEO Amp LITE	IM-AMP-03-2	40 samples	-30°C to -15°C
i.Mune [™] NEO Amp Check	IM-CHECK-03	16 runs	-30°C to -15°C
i.Mune [™] NEO Analysis Tool	IM-AMP-03	-	-

Sample Requirements

- Capillary whole blood dried on filter paper (stored for up to 12 weeks)

References:

- Blom, M., et al., J Clin Immunol (2021). <https://doi.org/10.1007/s10875-021-01107-2>
- Baron U. et al: Sci Transl Med. 2018 Aug 1;10 (452)

For ordering please contact:

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