EPIMUNE
DIAGNOSTICS

IMMUNE CELLS COUNT

i.Mune™ TBNK

Contents

The kits contain sufficient reagents to perform six runs, each with eight samples, one i.Mune™ Negative Control and one i.Mune™ Positive Control, one i.Mune™ Standard 1 and one i.Mune™ Standard 2.

Kit	Order-No.	Kit Size	Storage
i.Mune™ Prep	IM-PREP-01	48 samples	Room Temperature
i.Mune™ TBNK Amp	IM-AMP-01	48 patient samples	-30°C to -15°C
i.Mune™ Check	IM-CHECK-01	12 runs	-30°C to -15°C
i.Mune App	IM-APP-02	-	-

Sample Requirements

- Capillary whole blood dried on filter paper (stored for up to 12 weeks)
- 40 µl liquid venous whole blood; fresh or stored at ambient temperature for up to 24 h

References:

1. Baron U. et al: Sci Transl Med. 2018 Aug 1;10 (452)
2. Hallek M. et al: Blood 2008; 111:5446-5456
3. Hillmen P, Cheson BD, Catovsky D, et al: Letter to Editor. Blood 2009;113:6497-6498
4. US Department of Health and Human Services. https://aidsinfo.nih.gov/guidelines

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EPIMUNE
DIAGNOSTICS

i.Mune™ TBNK

i.Mune™ **TBNK** [CE]

Quantification of:

- **T lymphocytes** (CD3+)
- **B lymphocytes** (CD19+)
- **Natural killer cells** (CD16+CD56dim)
- **Helper T lymphocytes** (CD3+CD4+)
- **Cytotoxic T lymphocytes** (CD3+CD8+)

from fresh or dried blood.

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EPIMUNE DIAGNOSTICS

i.Mune™ TBNK

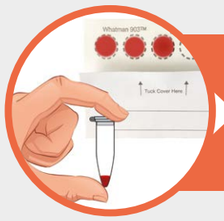
i.Mune™ **TBNK** [CE]

i.Mune™ TBNK is a quantitative in vitro diagnostic test to determine the percentages and absolute counts of human lymphocyte subsets in liquid venous whole blood and to determine the percentages of human lymphocyte subsets in capillary whole blood specimens dried on filter paper (Dried Blood Spot; DBS).

Quantification of T-/B- and NK lymphocytes can be useful for*:

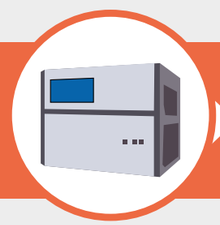
- Follow-up and diagnostic evaluation of primary immunodeficiency
- Monitoring of HIV-positive patients
- Immune monitoring following immunosuppressive therapy for transplantation, autoimmunity and other immunological conditions
- Assessment of immune reconstitution post hematopoietic stem cell transplantation
- Early screening of gross quantitative anomalies in lymphocyte subsets in infections and malignancies
- Absolute quantification of circulating B cells for diagnosis of chronic lymphocytic leukemia (CLL) patients

Workflow Overview

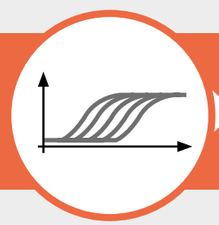


Sample Types
Fresh EDTA blood (40 µl)
or Dried Blood Spots (DBS)

Lysis/ Bisulfite Conversion/ DNA Purification
Scalable throughput



qPCR
Validated for Roche LC480 II



Data Analysis
Proprietary software for data evaluation

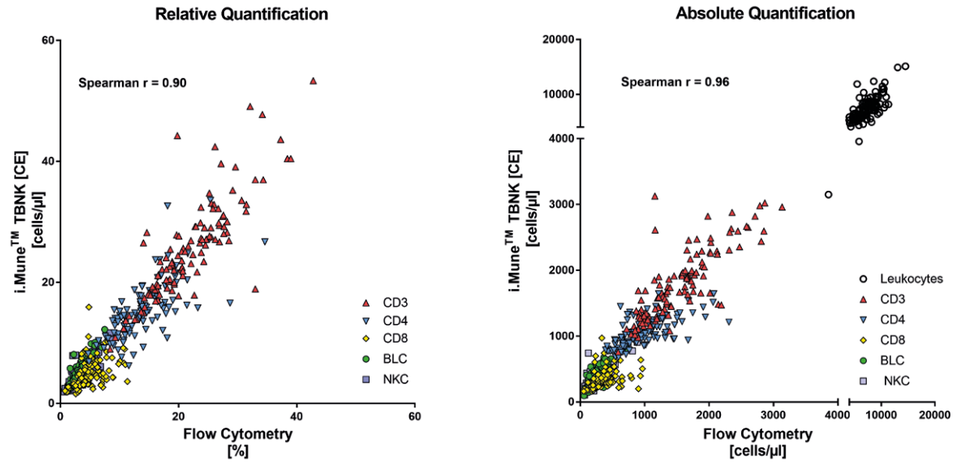
Total Time: ~ 5 h 45 min for one run with 8 patient samples, Negative and Positive Control
Hands-on Time: ~ 2 h 15 min
Number of Results: 5 cell types x 8 patient samples = 40 PCR results (96-well format)

*The above clinical applications have been established using technologies currently being employed in clinical laboratory routine (e.g. flow cytometry). Epimune has demonstrated equivalence of its epigenetic immune cell quantification method to flow cytometry in whole blood. Baron et al. (2018) demonstrated concordance of epigenetic immune cell quantification between whole blood and dried blood spots.

Performance Characteristics

of i.Mune™ **TBNK** [CE] were determined according to CLSI guidelines.

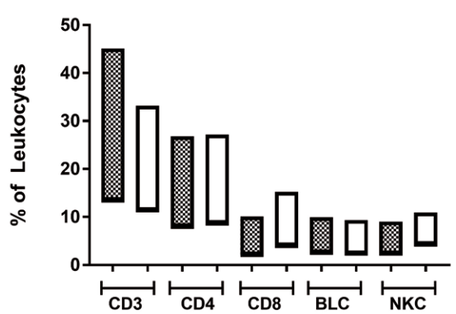
Repeatability (single-site)	CV < 12,5% (liquid venous whole blood); CV < 25% (DBS)
Within Laboratory Precision (single-site)	CV < 25% (both liquid venous whole blood and DBS)
Reproducibility (multi-site)	CV < 25% (liquid venous whole blood)
Within Laboratory Precision (multi-site)	CV < 25% (liquid venous whole blood)
Linearity	10 - 40 µl venous whole blood
Limit of Quantification	< 80 copies (liquid venous whole blood and DBS)
Reliability	99% (liquid venous whole blood and DBS)
Interference	No interference with bilirubin (0,4 mg/ml), hemoglobin (10 mg/ml), triglycerides (15 mg/ml), albumin (150 mg/ml)



Comparison i.Mune™ TBNK [CE] with flow cytometry

112 liquid venous EDTA blood samples from self-declared healthy donors were analysed using i.Mune™ **TBNK** [CE] and compared to flow cytometry. Correlation was determined using Spearman correlation coefficient (Spearman r) for both relative (%) and absolute quantification (cells/µl).

Reference Ranges
(liquid whole blood vs. dried blood)



112 liquid venous blood samples and 108 capillary whole blood samples were prospectively collected from self-declared healthy subjects (age 18 to 71; female and male) and analyzed using i.Mune™ **TBNK** [CE]. Reference ranges for the individual lymphocyte subsets were defined using the lower and upper limit for each cell type applying a 2.5 to 97.5 percentile. The figure shows the comparison between liquid venous whole blood and DBS samples.