Viracor | Eurofins Clinical Diagnostics

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# ImmuKnow®*

Test Code: 9000

## Clinical and Procedure

### Clinical Utility

ImmuKnow is an immune cell function assay that detects cell-mediated immunity in an immunosuppressed population. The assay detects cell mediated immunity by measuring the concentration of ATP from CD4 cells following stimulation.

### Procedure

ImmuKnow technology combines cell stimulation, cell selection, and quantification of metabolic markers (ATP) to measure cell-mediated immunity. ImmuKnow measures early response to stimulation by detecting intracellular ATP synthesis in CD4 cells selected from blood by monoclonal antibody-coated magnetic beads. The amount of ATP present in stimulated blood specimens is a measure of lymphocyte activity. Since the CD4 lymphocytes orchestrate cell-mediated immunity responses through immunoregulatory signaling, the measurement of CD4 activation reflects the degree of immune function. This test has been cleared or approved for diagnostic use by the U.S. Food and Drug Administration.

### Specificity

Sensitivity: The limit of ATP detection of ImmuKnow is 1 ng/mL.

## Turnaround Time

36 – 48 hours from receipt of specimen.

## Specimen Information

| Specimen Type | Order Code | CPT Code | NY Approved | Volume | Assay Range |
|---|---|---|---|---|---|
| whole blood | 9016 | 86352 | Yes | 2 mL (min. 0.5 mL) | Low immune response: ATP level ≤225 ng/mL.<br><br>Moderate immune response: ATP level 226-524 ng/mL.<br><br>Strong immune response: ATP level ≥525 ng/mL. |

Special Instructions

- 2 to 3 mL whole blood collected and shipped in original sodium heparin (green top) tube.
- Ship at ambient temperature, priority overnight Monday through Friday.
- Specimen must be drawn after 4:00 A.M. (CST) and shipped on the same day as collection to meet the 30 hour requirement.

The ATP level ranges for ImmuKnow were established by testing 155 apparently healthy adults and 127 transplant recipients. A cumulative frequency of differences was used to select the ATP levels that give the best balance of results between immunosuppressed and non-immunosuppressed individuals. The cutoffs for the ATP level ranges are 225 and 525 ng/mL.

**Interpretation of Results**

Low immune response: ATP level ≤225 ng/mL.

Moderate immune response: ATP level 226-524 ng/mL.

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Strong immune response: ATP level ≥525 ng/mL.

Results of the ImmuKnow assay should be used in conjunction with clinical presentation, medical history, and other clinical indicators when establishing the immune status of a patient. This is a qualitative assay; therefore, the result does not quantify the level of immunosuppression.

## Shipping

Ship Monday through Friday. Friday shipments must be labeled for Saturday delivery or specimens will not meet the 30 hour time requirement. All specimens must be labeled with patient's name, collection date and time. A Viracor Eurofins test requisition form must accompany each specimen. Multiple tests can be run on one specimen. Ship specimens FedEx Priority Overnight® to: Viracor Eurofins, 1001 NW Technology Drive, Lee's Summit, MO 64086

## Causes for Rejection

Whole blood frozen or received in transfer tube. Specimen will be rejected if greater than 30 hours old. Specimen type other than heparinized whole blood collected in sodium heparin tube.

# Disclaimer

Specimens are approved for testing in New York only when indicated in the Specimen Information field above.

The CPT codes provided are based on Viracor Eurofins' interpretation of the American Medical Association's Current Procedural Terminology (CPT) codes and are provided for general informational purposes only. CPT coding is the sole responsibility of the billing party. Questions regarding coding should be addressed to your local Medicare carrier. Viracor Eurofins assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material. * ImmuKnow is a registered trademark. ImmuKnow technology is patented by Viracor Eurofins' Laboratories. Use of intellectual property owned by Viracor Eurofins' to recreate or replicate the ImmuKnow® assay is strictly prohibitied and may be considered infringement of U.S. Patent numbers 5, 773, 232, 6, 630, 316, 7, 169, 571, 7, 476, 514, and all applicable international patents. Further, use or past use of ImmuKnow kits and/or information provided within the kits to reverse engineer or replicate the ImmuKnow test, or use of ImmuKnow test results to evaluate, validate or certify a competing assay, may violate the terms under which the kits or results were supplied. Please contact Viracor Eurofins' at 800-305-5198 with any questions regarding its ImmuKnow patents, or visit www.uspto.gov for general information on patent and IP law policy.