

ImmuKnow

For in vitro diagnostic use

TEST ID

9000 ImmuKnow®

CPT CODE

86353, 82397

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.

SPECIMENS

Whole Blood: 2 to 3 ml submitted in a sodium heparin (green top) tube.

Ship at room temperature, priority overnight Monday through Friday. Specimen must be drawn after 5 am and shipped on the same day as collection to meet the 30 hour requirement.

CAUSES FOR REJECTION

Whole blood frozen. Blood collected in any type of tube other than sodium heparin. Specimen will be rejected if greater than 30 hours old.

SENSITIVITY

The limit of ATP detection of ImmuKnow is 1 ng/ml.

ASSAY ATP LEVEL RANGES

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.¹

INTERPRETATION OF RESULTS

ATP LEVEL (NG/ML)	RESULTS
<225	Low Immune Response
226-524	Moderate Immune Response
>525	Strong Immune Response

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.¹

TURNAROUND TIME

Within 30 hours of receiving specimen

SHIPPING

Ship Monday through Friday. Friday shipments must be labeled for Saturday delivery. All specimens must be labeled with patient's



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name and collection date. Ship specimens FedEx Priority Overnight® to:

ViraCor Laboratories, 1001 NW Technology Dr, Lee's Summit, MO 64086

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1. ImmuKnow Package Insert (Cylex Incorporated Immune Cell Function Assay) The CPT codes provided are based on ViraCor's interpretation of the American Medical Association's Current Procedural Terminology (CPT) codes and are provided for 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 assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material.

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