

# ImmunoKnow™

## Immune Cell Function Monitoring

### FDA APPROVED



<b>Description</b>	ImmunoKnow™ is an immune cell function assay that detects cell-mediated immunity in an immunosuppressed population. <sup>1</sup> ImmunoKnow™ is a registered trademark of Cylex™ Incorporated.								
<b>Procedure</b>	ImmunoKnow™ technology combines cell stimulation, cell selection and quantification of metabolic markers (ATP) to measure cell-mediated immunity. ImmunoKnow™ 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. Because the CD4 lymphocytes orchestrate cell-mediated immunity responses through immunoregulatory signaling, the measurement of CD4 activation reflects the degree of immune function. <sup>1</sup>								
<b>Specimens</b>	<u>Whole Blood</u> : 2-3 mL. collected in a sodium heparin tube (green top)  Maintain at room temperature by packing the specimen in Styrofoam with an unfrozen ice pack. DO NOT FREEZE THE ICE PACK-IT PROVIDES INSULATION WHEN USED AT ROOM TEMPERATURE!!								
<b>Sensitivity</b>	The limit of the ATP detection of ImmunoKnow™ is 1 ng/mL. <sup>1</sup>								
<b>Assay ATP Level Ranges</b>	The ATP level ranges for ImmunoKnow™ were established by testing 155 apparently health 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. <sup>1</sup>								
<b>Courier Services</b>	<b>At 3:00 pm, Monday through Friday, <i>ClinImmune Labs</i> will send its courier to your hospital or laboratory to pick up the specimen and the ImmunoKnow™ assay will be set up immediately upon receipt.</b>								
<b>Turnaround Time</b>	<b>Results will be faxed within 48 hours of receipt of the specimen.</b>								
<b>Interpretation of Results</b>	<table border="0"> <thead> <tr> <th><u>ATP Level (ng/mL)</u></th> <th><u>Result</u></th> </tr> </thead> <tbody> <tr> <td>&lt;225</td> <td>Low Immune Response</td> </tr> <tr> <td>226-524</td> <td>Moderate Immune Response</td> </tr> <tr> <td>&gt;525</td> <td>Strong Immune Response</td> </tr> </tbody> </table> <p>The expected value in stable transplant patients is 282 with a range of 175-350. A change of &gt;20% in either direction should be considered clinically significant. Results of the ImmunoKnow™ 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.<sup>1</sup></p>	<u>ATP Level (ng/mL)</u>	<u>Result</u>	<225	Low Immune Response	226-524	Moderate Immune Response	>525	Strong Immune Response
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<sup>1</sup> ImmunoKnow™ Package Insert (Cylex™ Incorporated Immune Cell Function Assay)

Please contact Brent Palmer (Brent.Palmer @uchsc.edu or 303-315-0762) for more information.  
**ClinImmune Labs, BioScience Park Center, Ste. 300**  
**12635 E. Montview Blvd., Aurora, CO 80045**