

IHC Antibodies Including OriGene UltraMAB™

Performance, specificity, and quality are critical requirements for obtaining accurate protein detection results by IHC. SDIX has manufactured OriGene's antibodies, including UltraMAB® products, in a GMP environment and obtained CE marking for these products. The CE marking provides a level of quality, safety and performance to ensure product reliability and reproducibility. These antibodies are intended for *in vitro* diagnostic (IVD) use.*

Product Features	Featured Products
<ul style="list-style-type: none"> • Highly-specific • GMP manufactured • For use in IHC applications • Detection of protein in human tissues and cells 	<ul style="list-style-type: none"> • ALK • p53 • PD-L1 • PD-1 • Complete list at www.SDIX.com • Ki-67 • Her2 • CD4 • ERG

*The clinical interpretation of any positive staining or its absence should be complemented by morphological and histological studies with proper controls. Evaluations should be made within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

IHC Screening with new Marked Antibodies

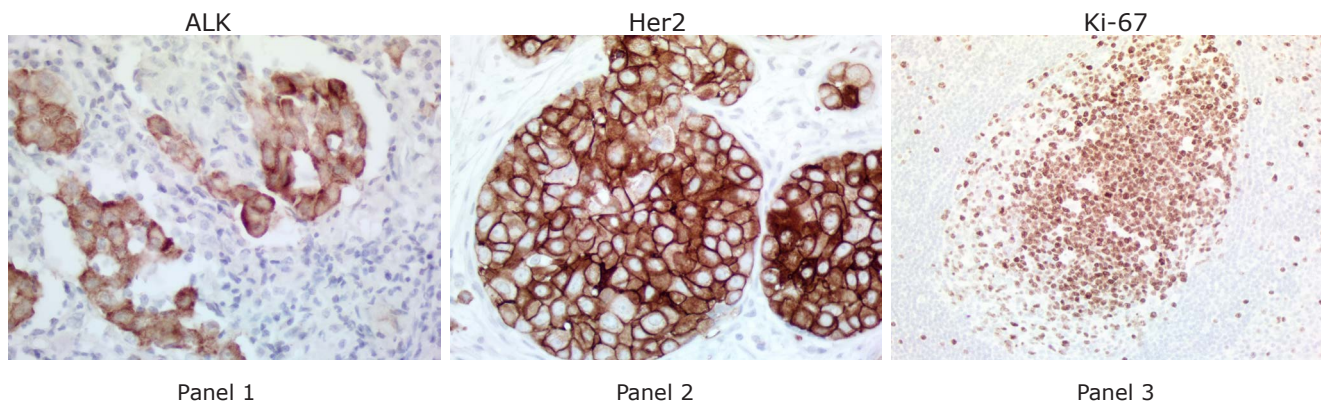


Figure 1. IHC screening presenting three new CE marked Antibodies. Panel 1 demonstrates anti-ALK staining of NSCLC; Panel 2 illustrates anti-Her2 staining of breast cancer; Panel 3 shows anti-Ki-67 staining of tonsil tissue. Antibodies were incubated on HIER pretreated paraffin embedded tissue at 1:100 (ALK and Her2) or 1:200 (Ki-67) dilution for 30 minutes at room temperature. Detection was done with RTU polymer detection kit (POLINK-2 Broad HRP) and signal shown DAB chromogen.

What is an UltraMAB®?

OriGene UltraMAB® antibodies are highly-specific monoclonal antibodies directed towards important diagnostic targets and known cancer biomarkers. OriGene has generated the largest collection, (>17,000), of overexpressed human proteins used to create a high density protein array to enable a broad and sensitive screening tool for antibody specificity. OriGene's monoclonal antibodies are systematically screened on the protein array chip and only antibodies that show monospecificity are labeled as UltraMAB®. UltraMAB® antibody performance is also tested with over 25 types of normal and cancer human tissues in applications including WB, IHC, IF/ICC, and FACS.

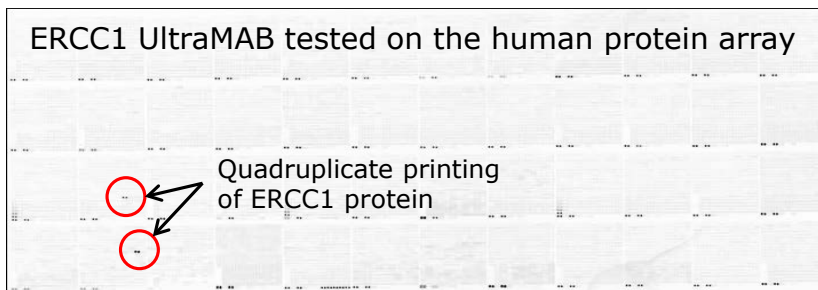


Figure 2. Protein microarray analysis of ERCC1 UltraMAB 4F9 showing monospecificity.

Why use UltraMAB® Antibodies?

Many monoclonal antibodies have the capability of binding more than one protein. The immune system selects for antibody affinity, but not specificity, and thus cross-reactive antibodies are a frequent problem. Common methods of detecting cross-reactivity are inefficient and ineffective, and some commonly used diagnostic antibodies have subsequently been shown to cross-react with other proteins. This cross-reactivity may potentially generate false positive results. High-specificity UltraMAB® antibodies reduce the risk of false positive results. (British J. of Cancer, 2013, v109 p2096-2105)

Case Study – ERCC1 UltraMAB®

ERCC1 is a prognostic marker for Cisplatin chemotherapy. Patients that express high levels of ERCC1 show resistance to Cisplatin treatment. The monoclonal 8F1 is the most commonly used antibody for measuring ERCC1 levels and has been used in >40 clinical studies. Evaluation of the 8F1 antibody on Origene’s high density protein array revealed that in addition to ERCC1, 8F1 also binds the unrelated protein PCYT1A, and was tested by WB (see figure 3).

Importantly, the cross reacting protein PCYT1A is expressed in significant levels in relevant patient samples. This cross reactivity has likely evaded prior detection because in IHC both proteins have the same subcellular localization (nuclear), and in western blot they have very similar migration.

OriGene has created an UltraMAB® against ERCC1 (4F9) which by definition shows reactivity only to ERCC1 on the high density protein array. The PCYT1A cross reactive 8F1 ERCC1 antibody has been compared in a clinical study with the ERCC1 monospecific UltraMAB® 4F9, (British J. of Cancer, 2013, v109 p2096-2105). ERCC1 levels as measured by UltraMAB® 4F9, but not 8F1, showed a correlation between ERCC1 levels and progression free survival in head and neck squamous cell carcinoma.

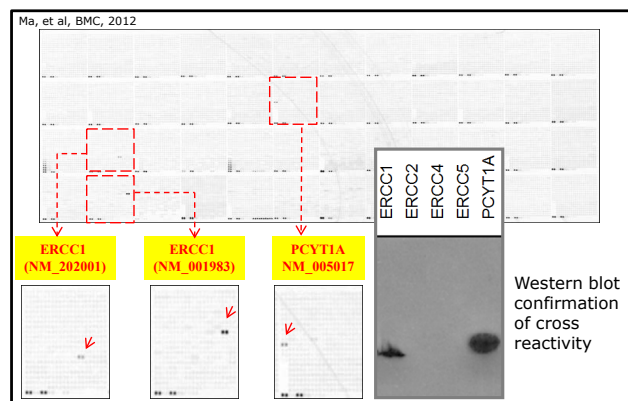


Figure 3. Protein microarray analysis reveals that ERCC1 Mab 8F1 cross reacts with PCYT1A.



SDIX LLC