High-quality ER and PR FLEX RTU antibodies for Dako Omnis

Developed in collaboration with experts for results you can trust.
Introducing ER and PR FLEX RTU antibodies for Dako Omnis

The new estrogen receptor α (ER) and progesterone receptor (PR) antibodies for Dako Omnis provide reliable results.

More than 1.5 million new cases of breast cancer are diagnosed each year worldwide (1), and two-thirds are ER and/or PR positive. These markers are important in determining treatment options and indicating the risk of recurrence.

Created in collaboration with well-known pathologists and experts specializing in breast cancer, the new high-quality ER and PR antibodies provide:

- Excellent specificity and sensitivity reviewed and accepted by key pathology experts
- Optimized, validated protocol that is aligned to ensure the highest throughput
- Reliable, proven reproducibility on Dako Omnis

Breast carcinoma (FFPE) stained with FLEX Anti-Estrogen Receptor α, Code GA084, on Dako Omnis

Breast Carcinoma (FFPE) stained with FLEX Anti-Estrogen Receptor α, Code GA084, on Dako Omnis

Breast carcinoma (FFPE) stained with FLEX Anti-Progesterone Receptor, Code GA090, on Dako Omnis

Breast carcinoma (FFPE) stained with FLEX Anti-Progesterone Receptor, Code GA090, on Dako Omnis
Strong staining performance

In the development of the new ER and PR FLEX RTU antibodies for Dako Omnis, concordance studies were performed by leading pathology experts.

High concordance with existing ER and PR antibodies

The new ER and PR FLEX RTU antibodies for Dako Omnis demonstrate a high concordance to existing ER and PR antibodies. The overall agreement to Agilent’s existing Dako ER and PR antibodies developed for Autostainer Link 48 are 95.8% for ER and 97.6% for PR (2). Similarly, the EP1 clone has demonstrated 94.9% overall agreement to another well-established ER clone, SP1 (3). The PR clone PgR 1294, is already marketed as part of the Dako ER and PR pharmDx Kit from Agilent.

"The staining was good, and I was completely satisfied since it is comparable or even better than what we are currently using.

It is very important to have reliable ER and PR test results. Without it, you are lost and the patient is lost. These markers are the most important to get right."

Giuseppe Viale, MD
Director, Department of Pathology and Laboratory Medicine at the European Institute of Oncology, Milan, Italy

"It’s all about patient care, and ER in particular has a direct impact on the patient. I was impressed, and they are a great addition to the market. They should in particular help labs struggling with ER/PR consistency. These antibodies are of an excellent standard according to UK NEQAS’s assessment criteria for ER and PR. Using these antibodies with the complete Dako Omnis package is preferable to mixing and matching products."

Keith Miller
Scheme Director, UK NEQAS

Excellent reproducibility results

Three separate sites in North America and Europe participated in a study designed to assess reproducibility within and between laboratories (inter-run and inter-lab).* The study confirmed that the new ER and PR for Dako Omnis provided high reproducibility for enhanced patient safety and consistent and reliable results (2).

<table>
<thead>
<tr>
<th>Antibody</th>
<th>Inter-run</th>
<th>Inter-lab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estrogen Receptor α, EP1</td>
<td>97.5%</td>
<td>94.3%</td>
</tr>
<tr>
<td>Progesterone Receptor, PgR 1294</td>
<td>98.8%</td>
<td>93.2%</td>
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</tbody>
</table>

* As part of the FDA clearance process, a fourth North American site was included in the reproducibility study. Results covering all four sites are very similar to the three-site results presented here and can be found in the Instructions for Use for GA08461-5 and GA09061-5.

"The agreement between three different pathologists in three different countries was fantastic... a real testament to the instrument and the reagents. Given the variable tissue quality from the different institutions, the staining was remarkably good.

I cannot wait to use it in our lab. Dako Omnis was a great addition for us, and these products will be as well due to the excellent quality of these stains."

David G. Hicks, MD
Professor, Department of Pathology and Laboratory Medicine, Director of Surgical Pathology, University of Rochester Medical Center, Rochester, New York
FLEX RTU - quality staining made easy

- Pre-diluted and carefully selected for specificity and sensitivity
- Proven concept since 2007
- High quality antibodies
- Broad portfolio of IVD antibodies
- Confirmed performance in EQA schemes

- Proven visualization with low complexity and very high sensitivity (4)
- Kit configuration provides
  - Flexibility
  - Consistency
  - Simplicity

- Detects high and low expressing structures
- Setup for robustness to minimize effect of pre-analytical variables

Reproducible – met all acceptance criteria for reproducibility and repeatability
High-quality results – comparison studies to reference antibodies showed very high correlation
Plug and play - validated Ready-to-Use antibodies and protocols for Dako Omnis

Integrate your ER and PR testing into the Dako Omnis workflow to achieve more time, greater choice and better patient care.

### Ordering information

<table>
<thead>
<tr>
<th>Antibody</th>
<th>Species</th>
<th>Clone</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estrogen Receptor α</td>
<td>Rabbit mAb</td>
<td>EP1</td>
<td>GA084</td>
</tr>
<tr>
<td>Progesterone Receptor</td>
<td>Mouse mAb</td>
<td>PgR 1294</td>
<td>GA090</td>
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</table>

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### References


