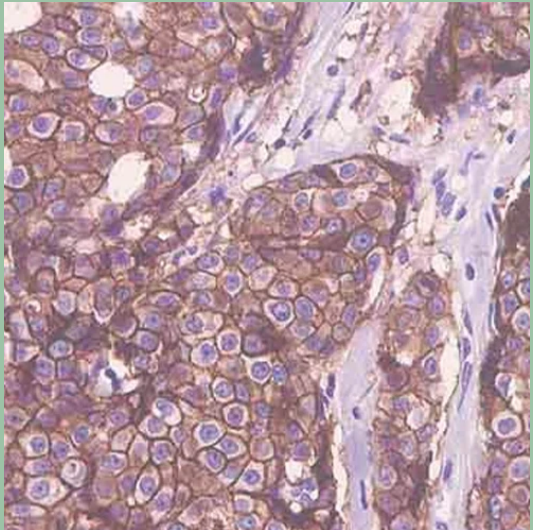


Clone SP3		REF	Volume
	Availability	PSV-IHI0148P-0003	3.0 ml Pred
		PSV-IHI0148P-0007	7.0 ml Pred
		PSV-IHI0148C-00.5	0.5 ml Conc.
		PSV-IHI0148C-0001	1.0 ml Conc.

Intended use

This antibody is intended for in vitro diagnostic (IVD) use. Primary Antibody is intended for professional laboratory use in formalin-fixed, paraffin-embedded (FFPE) tissue stained in manual qualitative immunohistochemistry (IHC) testing. A qualified pathologist must interpret the results using this product to aid diagnosis in conjunction with the patient's relevant clinical history, other diagnostic tests, and proper controls.

Specification

Antibody name: C-erbB-2(HER2)

Clone: SP3

Dilution: 1:50 - 1:50

Species of origin: Rabbit

Isotype: IgG

Control tissue: Breast carcinoma with known HER2 gene amplification

Staining: Membrane

Presentation: Anti-human c-erbB2 rabbit monoclonal antibody purified from serum and prepared in 10mM PBS, pH 7.4, with %0.2 BSA and %0.09 sodium azide

Principle of Method

1. Deparaffinization
2. Rehydration
3. Peroxide block: Block for 5 minutes at ambient temperature
4. Wash with TBS
5. Epitope Retrieval Technique: Tris-EDTA HIER
Solution pH 9.0 at 100 °C for 40 minutes using a pressure cooker. Refer to the commercially available device data sheet for specific instructions.
6. Rinse with deionized water. Wash with TBS
7. Primary antibody: Incubate for 30 minutes at ambient temperature.
8. Wash with TBS
9. Detection Polymer Incubate for 30 minutes at ambient temperature.
10. Wash with TBS. Rinse with deionized water
11. Chromogen: Incubate for 5 minutes at ambient temperature
12. Rinse with deionized water
13. Counterstain with hematoxylin. Rinse with deionized water

Materials Provided

C-erbB-2(HER2) Clone SP3

Materials Required but not Provided

The following materials are required but are not provided:

- 1- Detection system
- 2- Chromogen (ie. DAB Substrate Kit)
- 3- IHC wash buffer and blocking solution
- 4- Hematoxylin or other counterstaining reagents
- 5- Ethanol or reagent alcohol, xylene or xylene substitute and mounting medium
- 6- Antibody diluents
- 7- Positive and negative control tissue

Storage and Stability

- Stored at 2-8°C.
- Do not freeze.
- Once the packaging has been opened it can be stored until the expiration date of the reagent indicated on the label.
- If the reagent has been stored under other conditions to those indicated in this document, the user must first check its correct performance taking into account the product warranty is no longer valid.

Warnings and Precautions

1. Ensure proper reagent handling procedures are followed. Always wear laboratory coats, use disposable gloves and other appropriate personal protective equipment when handling reagents.
2. Do not ingest any antibody or reagent. Avoid contact with eyes and other mucous membranes. Should any contact occur, rinse the area with copious amounts of water and follow laboratory procedures for reporting the exposure.
3. All incubation times and temperatures must be validated by the user with first use. Any usage or storage conditions different than that specified on the package insert should also be validated by the user.
4. Treat all tissue specimens, patient autopsy/biopsy/surgical samples and any materials in contact with these as potentially biohazardous materials and handle with appropriate laboratory precautions.
5. To ensure antibody stability and the accuracy of results, ensure microbial contamination of the antibody does not occur.
6. Monitor for any changes in appearance, or clouding, of the antibody product, as this may be a sign of degradation or other contamination which will affect its efficacy.

General Limitations

1. This antibody is intended for Research Use Only use by qualified personnel in laboratories only.
2. Due to biological variability inherent to the expression of certain antigens and immunohistochemical procedures, appropriate positive and negative controls should be used alongside the tissue specimen.
3. This antibody, when used with the appropriate detection systems and reagents, detects antigen(s) that remain intact through the tissue fixation, processing and sectioning as described. Any deviation from these recommended procedures or improper handling may compromise the validity and/or analysis of the results. Do not use alcohol containing fixatives as those may result in a loss of staining tissue fixation, processing and sectioning as described. Any deviation from these recommended procedures or improper handling may compromise the validity and/or analysis of the results. Do not use alcohol containing fixatives as those may result in a loss of staining activity
4. Pathosage provides prediluted antibodies in a ready-to-use, optimally diluted format for use as instructed. Due to the potential for variation in tissue processing and fixation, it may be necessary to adjust the incubation time of the primary antibody for different tissue specimens.
5. Pathosage provides concentrated antibodies in a format that requires dilution with Pathosage Antibody Diluent. Use of a diluent different than that specified in the package insert must be validated by the user to ensure proper compatibility with the antibody.
6. Any discrepancies or unexplained results in control or tissue specimens can be reported to Pathosage Customer Service at Pathosage @arraytech.es for further assistance.
7. False positive results may occur in tissue specimens due to the possibility of non immunological binding of substrate reaction products or proteins. False positive results may also occur subject to the type of immunostaining technique used, or due to the activity of pseudoperoxidase, endogenous peroxidase, or endogenous biotin.
8. Due to the effect of autoantibodies or natural antibodies, normal sera from an animal source that is the same as the secondary antisera may result in false negative or false positive results when used in blocking s
9. Non-specific staining with horseradish peroxidase may be observed when using tissues containing hepatitis B surface antigen due to the patient's infection with the hepatitis B virus.

LABEL AND BOX SYMBOLS

Explanation of the symbols of the product label and box:

	Expiration date		Refer to the instruction of use	REF	Reference number
	Temperature limit	IVD	Medical product for in vitro diagnosis	LOT	Lot number
	Hazard warning	RUO	For Research use only	CE	A Conformité Européenne