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****REVISED** 12/26/2024**

ANP.22970 Annual Result Comparison - Breast Carcinoma

Phase II



For HER2 and ER immunohistochemical (IHC) tests performed on breast carcinoma that provide independent predictive information, the laboratory at least annually compares its patient results with published benchmarks.

NOTE: For estrogen receptor studies: in general, the overall proportion of ER-negative breast cancers (invasive and DCIS) should not exceed 30%. The proportion is somewhat lower in postmenopausal than premenopausal women (approximately 20% vs. 35%). The proportion of ER-negative cases is considerably lower in well-differentiated carcinomas (<10%) and certain special types of invasive carcinomas (<10% in lobular, tubular, and mucinous types). Investigation is warranted if the proportion of ER-negative cases varies significantly from the published benchmarks.

For HER2 studies, the overall proportion of HER2 positive breast cancers is 10-25%. Laboratories must monitor their results. Investigation is warranted if the proportion of HER2 positive cases varies significantly from published data.

Evidence of Compliance:

- ✓ Records of annual result comparison

REFERENCES

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****NEW** 12/26/2024**

ANP.22975 Immunohistochemical (IHC) Predictive Marker Interpretation

Phase I

Each pathologist interpreting IHC predictive markers participates in an annual analyte-specific quality assessment for each of the following predictive markers, as applicable:

- **Breast HER2**
- **Breast ER**
- **Gastric HER2**
- **Lung highly sensitive ALK**
- **Lung PD-L1 tumor proportion score (TPS)**

NOTE: This requirement applies to all pathologists in the laboratory that interpret one or more of these markers, whether in laboratories that perform both staining and interpretation or interpretation only. An individual pathologist need participate only once for each predictive marker used by that pathologist in patient care evaluation, regardless of the number of locations where the pathologist performs interpretations.

The quality assessment for each predictive marker must include a comparison of each pathologist's interpretation against the intended results. The laboratory director must define criteria for acceptable results and ensure follow up on each unacceptable result.

Examples of how this requirement can be met include the use of: