Antibody characteristics:

|  |  |
| --- | --- |
| Antibody |  |
| Protein function/characteristics |  |
| Nature of epitope |  |
| Monoclonal or polyclonal |  |
| Staining pattern |  |
| Expression in normal tissues |  |

Comparator tissues:

|  |  |  |
| --- | --- | --- |
|  | Diagnoses/Anatomic Site | Notes |
| Normal tissues |  |  |
| Neoplastic tissues(see refs at end) |  |  |
| Other |  |  |

Potential pitfalls:

Provisional assay conditions:

|  |  |  |
| --- | --- | --- |
|  | Manufacturer Recommendations | Alternative conditions |
| Positive control tissue |  |  |
| Dilution |  |  |
| Antigen retrieval conditions |  |  |

|  |  |
| --- | --- |
| Optimum conditions: |  |

Test Validation Parameters:

|  |  |
| --- | --- |
| Dilution |  |
| Antigen retrieval conditions |  |
| Comparator tissues | *See above.* |
| Validation set | 10 positive, 10 negative (unless PM) |
| Operational considerations |  |
| Format |  |
| Concordance |  |

Additional comments about results of the validation set:

References: