## **Quality in control**



One of the requirements of quality standardization is the appropriate use of controls. These need to be robust enough for IHC and ISH, be reproducible and cost-effective. Additionally, the control material should be consistent from batch to batch and throughout the block it is cut from. HistoCyte Laboratories cell lines are standardized cell line microarray controls and are developed and manufactured to provide consistent results throughout the block. This is what differentiates them from tissue controls.

Quality in Control

### Control Material from HistoCyte Laboratories Ltd.

- ✓ Standardized, reliable and cost-effective
- ✓ Validated with standardized assays
- ✓ Easily determine assay performance
- **✓ Dynamic Range** PR: variable protein expression to show the performance within the dynamic range of the immunhistochemical assay



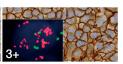
#### **HER2 Analyte Control Dynamic Range**

The specialized HER2 cell line microarray control has a full dynamic range of expression. It contains four cores: 0, 1+ (non-amplified), 2+ (equivocal), 3+ (HER2 gene amplification). HER2 Analyte ControlDR is a reliable, sensitive and accurate control for HER2 assessment.







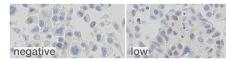


#### HER2 Analyte ControlDR

- 2 Slides ..... HCL026 5 Slides ..... HCL027
- Block ..... HCL028

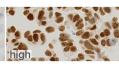
#### **Estrogen Receptor Analyte Control Dynamic Range**

The ER Dynamic Range Analyte Control contains four cores, offering a full range of expression for ER: negative, low, medium, high.









#### ER Analyte ControlDR

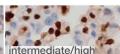
- 2 Slides ..... HCL029
- 5 Slides ..... HCL030
- Block ...... HCL031

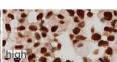
#### **Progesterone Receptor Analyte Control Dynamic Range**

The Progesterone Receptor Analyte ControlDR contains four cores, offering a dynamic range of expression for PR: negative, low/intermediate, intermediate/high, and high. The cell line low/intermediate and intermediate/high provide a suitable array of cells with varying expression that easily demonstrate whether the assay is running at a suitable sensitivity in your laboratory.









Also available: PD-L1, HPV/p16, ROS1, PR, ALK (see overleaf)

#### PR Analyte ControlDR

- 2 Slides ..... HCL032 5 Slides ..... HCL033
- Block ...... HCL034



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Cell microarray controls are available as pre-cut slides (2 or 5 slide options) and cell microarray block (ca. 300 sections).

| Product  | Information   | Status | Format   | Art-nr. |
|--|---|--------|----------|---------|
| HPV/p16 <sup>DR</sup>                                  | 4 cores <b>Dynamic Range</b> of HPV gene copies, E6/E7 mRNA levels and protein expression of p16  | RUO    | 2 Slides | HCL001  |
|  |   | RUO    | 5 Slides | HCL002  |
|  |   | RUO    | 1 Block  | HCL003  |
| HPV/p16  | 3 cores positive and negative for the HPV gene, E6/E7 mRNA and expression of p16  | RUO    | 2 Slides | HCL004  |
|  |   | RUO    | 5 Slides | HCL005  |
|  |   | RUO    | 1 Block  | HCL006  |
| ALK (lung)   | 2 cores positive and negative for the EML4-ALK translocation and expression of the fusion product   | RUO    | 2 Slides | HCL007  |
|  |   | RUO    | 5 Slides | HCL008  |
|  |   | RUO    | 1 Block  | HCL009  |
| ALK (lymphoma)   | 2 cores positive and negative for the NPM-ALK translocation and expression of the fusion product  | RUO    | 2 Slides | HCL010  |
|  |   | RUO    | 5 Slides | HCL011  |
|  |   | RUO    | 1 Block  | HCL012  |
| Breast Analyte Control                                 | 2 cores positive and negative for <i>HER2</i> gene amplification and expression of ER, PR and HER2  | RUO    | 2 Slides | HCL013  |
|  |   | RUO    | 5 Slides | HCL014  |
|  |   | RUO    | 1 Block  | HCL015  |
| Breast Analyte Control <sup>DR</sup>                   | 5 cores <b>Dynamic Range:</b> positive and negative for <i>HER2</i> amplification, dynamic range of protein expression of ER, PR and HER2 | RUO    | 2 Slides | HCL016  |
|  |   | RUO    | 5 Slides | HCL017  |
|  |   | RUO    | 1 Block  | HCL018  |
| PD-L1 Analyte Control <sup>DR</sup>                    | 4 cores <b>Dynamic Range</b> of protein expression of PD-L1   | RUO    | 2 Slides | HCL019  |
|  |   | RUO    | 5 Slides | HCL020  |
|  |   | RUO    | 1 Block  | HCL021  |
| ROS1 Analyte<br>Control                                | 2 cores positive and negative for the SLC34A2-ROS1 translocation and expression of the fusion product                                     | RUO    | 2 Slides | HCL022  |
|  |   | RUO    | 5 Slides | HCL023  |
|  |   | RUO    | 1 Block  | HCL024  |
| HER2 Analyte Control <sup>DR</sup>                     | 4 cores <b>Dynamic Range:</b> 0, 1+ (both non-amplified), 2+ (equivocal) and 3+ (amplified)   | RUO    | 2 Slides | HCL026  |
|  |   | RUO    | 5 Slides | HCL027  |
|  |   | RUO    | 1 Block  | HCL028  |
| Estrogen Receptor<br>Analyte Control <sup>DR</sup>     | 4 cores <b>Dynamic Range:</b> negative, low, medium and high expression of ER   | RUO    | 2 Slides | HCL029  |
|  |   | RUO    | 5 Slides | HCL030  |
|  |   | RUO    | 1 Block  | HCL031  |
| Progesterone Receptor<br>Analyte Control <sup>DR</sup> | 4 cores <b>Dynamic Range:</b> negative, low/intermediate, intermediate/high and high expression of PR                                     | RUO    | 2 Slides | HCL032  |
|  |   | RUO    | 5 Slides | HCL033  |
|  |   | RUO    | 1 Block  | HCL034  |



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First-hand information