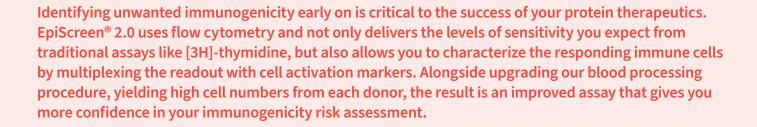


# **Immunogenicity Testing Evolved**

EpiScreen® 2.0 delivers all the required sensitivity, plus detailed data on specificity and mechanism of action, without the need for radioactive markers.

markers: CD25, OX-40



### **EpiScreen®2.0 Time Course Assay**

EpiScreen® 2.0 helps you identify the best lead candidate and confirm any potential immunogenicity by assessing the whole molecule.

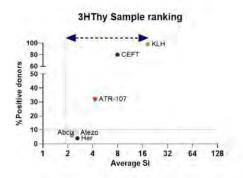
# **Blood source:** Leukopaks РВМС Aliquots taken Time point 1 Time point 2 Time point 3 • Phenotype-specific • Phenotype-specific markers: CD3, CD4 markers: CD3, CD4 Phenotype-specific • Proliferation: EdU Activation-specific

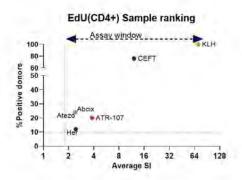
markers: CD3, CD4

**Proliferation:** EdU

## Just as Sensitive as [3H]-thymidine

EpiScreen® 2.0 delivers on the essentials with sensitivity comparable to traditional [3H]-thymidine assays, but without any need for radioactive markers.





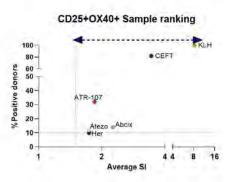
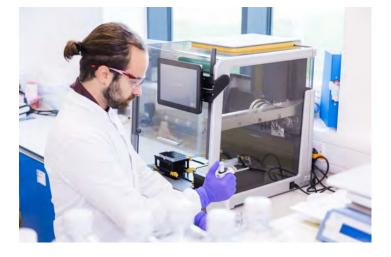


Figure 1. EpiScreen® 2.0 EdU readout has a wider assay window than [3H]-thymidine, offering better ranking of immunogenicity. The activation-induced markers CD25 and OX-40 help to pinpoint samples with higher risk of immunogenicity (early responses). Graphs show average stimulation index (SI) for positive responding donors vs % positive donors.

Proliferation and activation responses in PBMC (non-CD8 <sup>+</sup> depleted)				
Sample	% Response <sup>3</sup> H-Thy	% Response EdU	% Response CD25/OX-40	Expected ADA (%)
Abciximab	6	24	14	6-44
Atezolizumab	8	22	12	13-36
ATR-107	32	20	32	76 (37.5*)
CEFT	80	76	82	70-90
Herceptin <sup>®</sup>	4	12	10	10
KLH	98	100	100	90-100

Table 1. EpiScreen® 2.0 EdU readout has comparable sensitivity to [3H]-thymidine, including for clinically relevant samples with high reported ADA rates. The addition of CD25/OX-40 activation marker status improves sample ranking.

\*Reported response in vitro





#### Monitor Specific CD4+ and CD8+ T-cell Behaviour

Episcreen 2.0 specifically assesses CD4+ T-cell proliferation via flow cytometry, giving you more relevant information than a bulk readout. Furthermore, it allows you to monitor other cell populations as well, such as CD8+ activation, giving insight into the mechanism of action – particularly useful for gene therapy where vectors can enter an indirect antigen processing pathway.

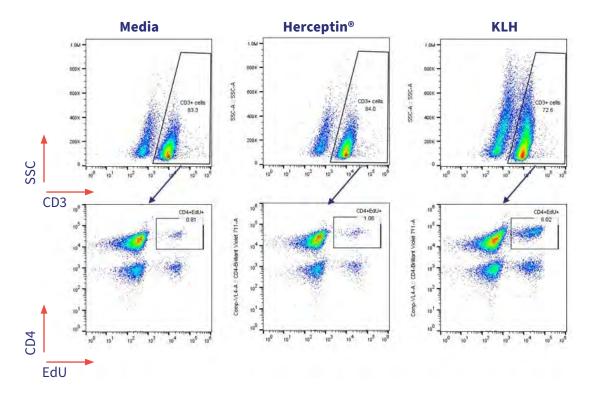


Figure 2. Using EpiScreen® 2.0 to monitor CD4+ T-cell proliferation. Flow cytometry gating strategy to determine EdU+ cells in response to Media, Herceptin® (low immunogenicity control), and KLH (high immunogenicity control).

#### **Customize and Assess Activation Markers**

With sensitivity and proliferation covered, EpiScreen® 2.0 also allows you to look at activation markers, giving you more detailed information on the triggered response and confirming the activation of specific T-cell populations. With EpiScreen® 2.0 you can also customize your selection of cell-surface markers or assess cytokine release:

- Extend cell-surface markers to monitor other cell populations or activation mechanisms of your choice (up to 3).
- Assess cytokine release by Luminex xMAP or FluoroSpot. Standardized or fit for purpose cytokine analysis to assess PBMC responses to a given drug candidate, which can improve the interpretation of immunogenicity risk.

#### **Better Immunogenicity Testing**

To avoid issues later in the drug development process, you need to start smart. That means you need more data-rich assays at the start of your project. EpiScreen® 2.0 allows you to assess immunogenicity via flow cytometry focusing on specific cell proliferation, alongside customizable activation markers, without ever compromising on assay sensitivity.

EpiScreen® 2.0 gives you better immunogenicity testing, which means better, more granular, candidate selection with fewer potential problems later down the line. Start smart, progress fast.

#### **EPISCREEN® 2.0 TIME COURSE ASSAY**

- Sensitive
- √ Specific
- ✓ Data-rich
- ✓ MoA-reflective
- ✓ Customisable
- √ Repeatable



