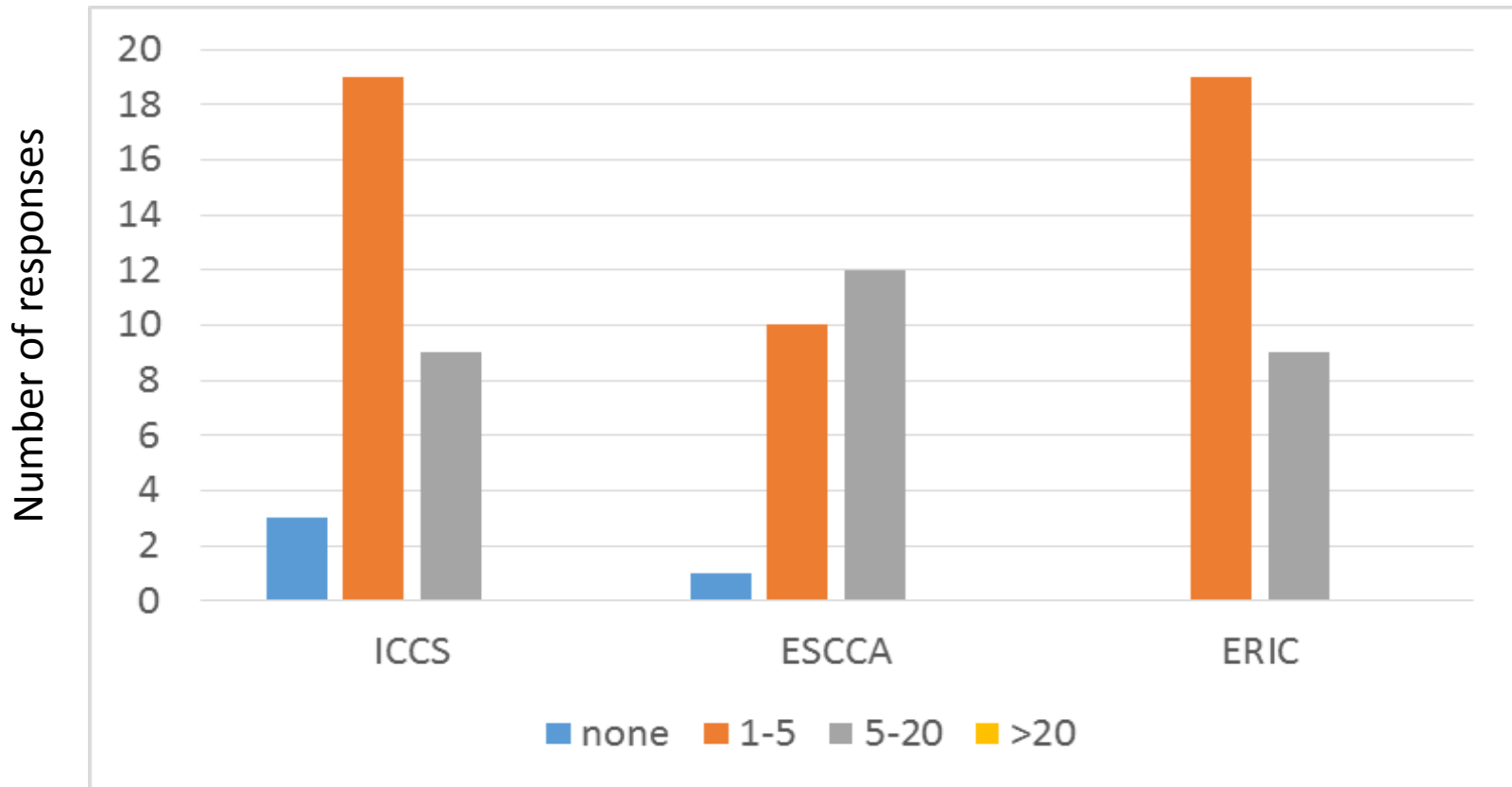


ERIC/ESCCA/ICCS survey: prospective validation of flow cytometry panels for CLL diagnosis and monitoring

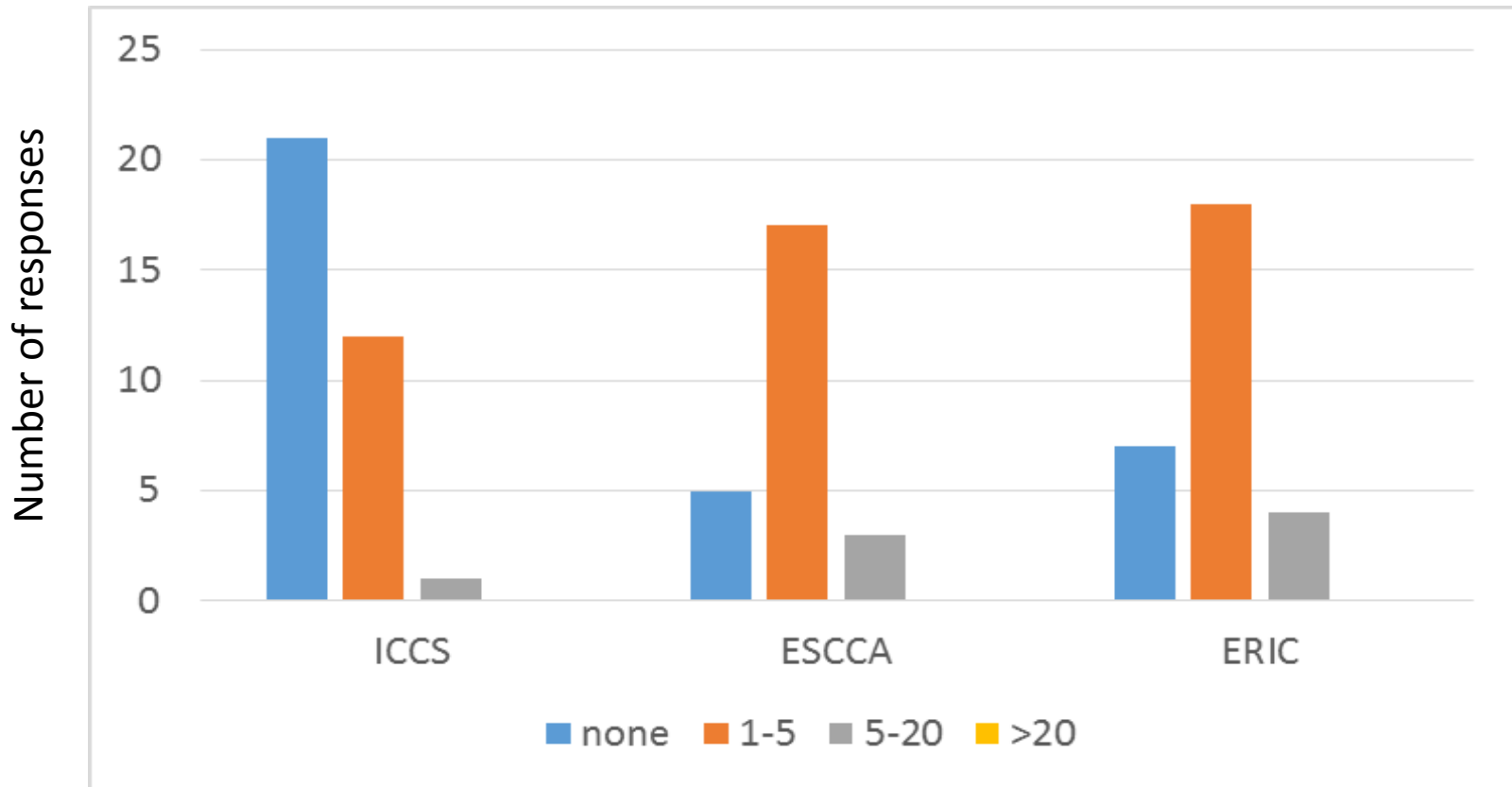
- ERIC & ESSCA proposed an approach for reproducible diagnosis of CLL (submitted to Clinical Cytometry, in first revision)
 - Diagnosis required:
 - CD19, **CD5**, **CD20**, CD23, Kappa, Lambda
 - Diagnosis recommended
 - CD10, CD200, ROR1, **CD43**, **CD79b**, **CD81**
- ERIC validated approach to reliably quantitate CLL cells to the level of 0.0010% / 10^{-5} .
 - <https://www.ncbi.nlm.nih.gov/pubmed/26639181>
 - MRD required
 - CD19 [or B-lineage gating strategy]
 - **CD5**, **CD20** or CD22, **CD43**, **CD79b**, **CD81**
- Surveys to identify the optimal composition of reagent sets that could be distributed for multi-centric testing.



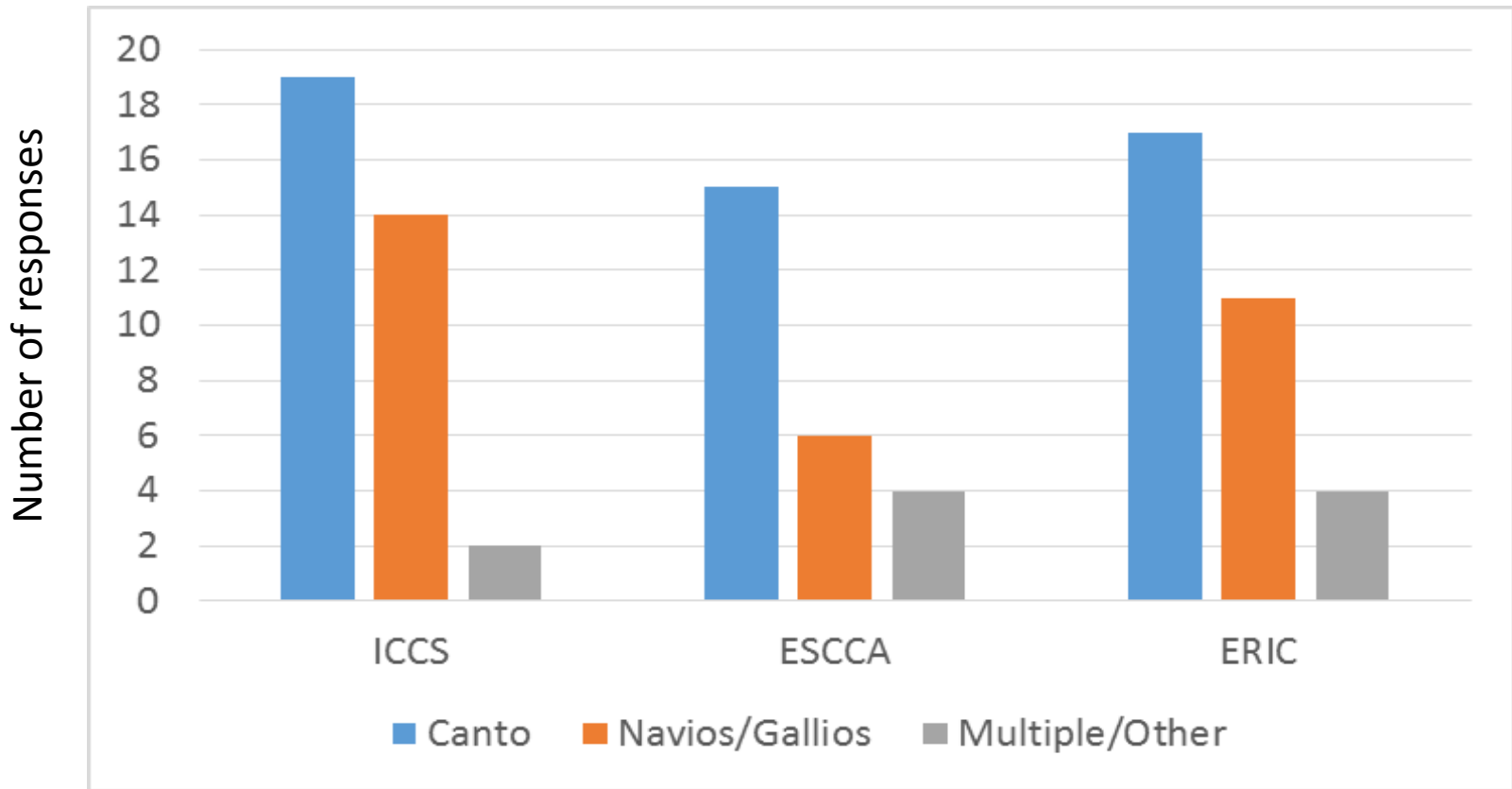
How many cases of CLL at diagnosis or relapse do you analyse per week



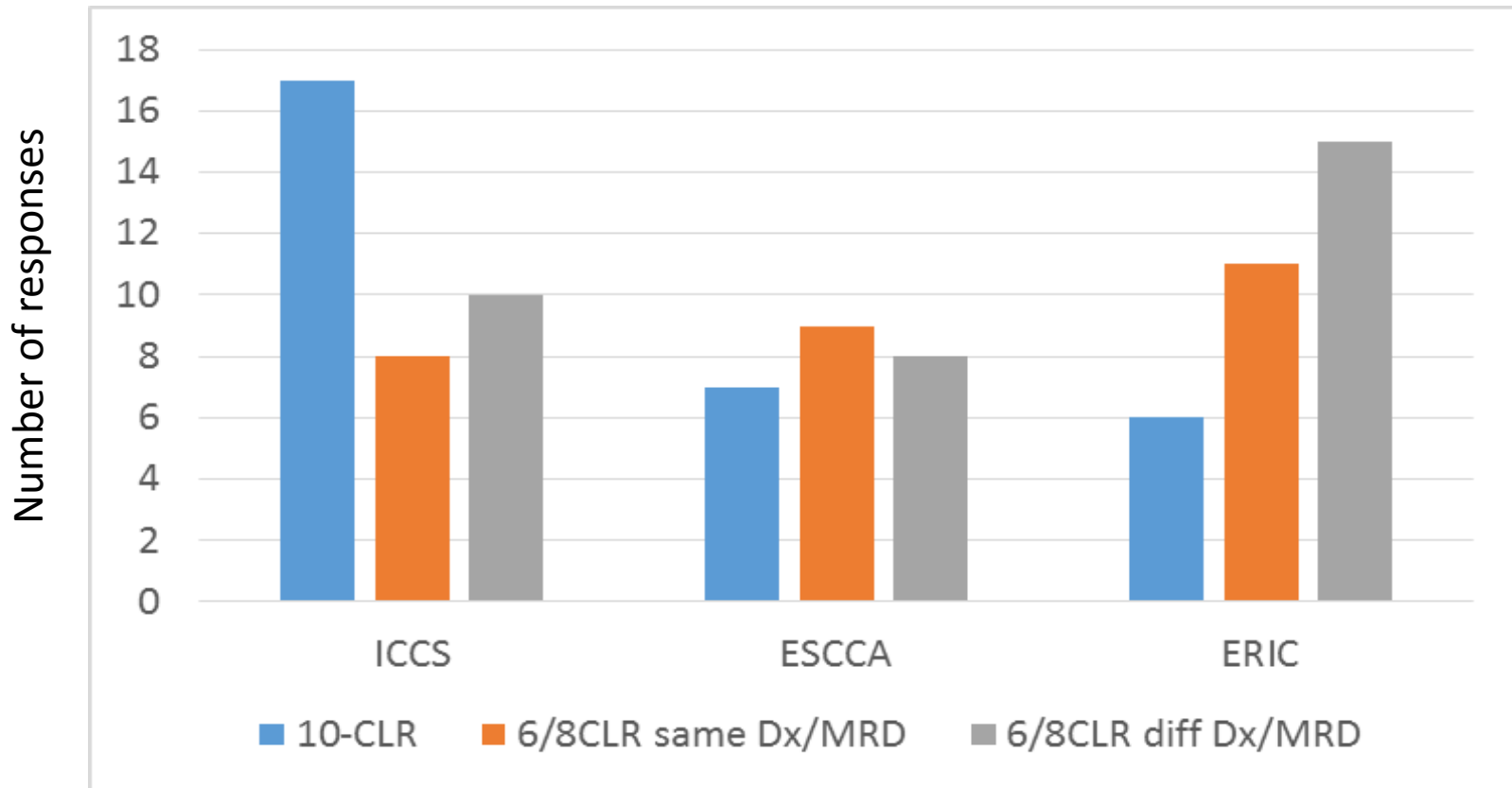
How many cases for MRD monitoring in CLL do you analyse per week



Which flow cytometer do you use for acquisition of diagnostic/MRD samples?



Please state your preference for the number of markers/tubes

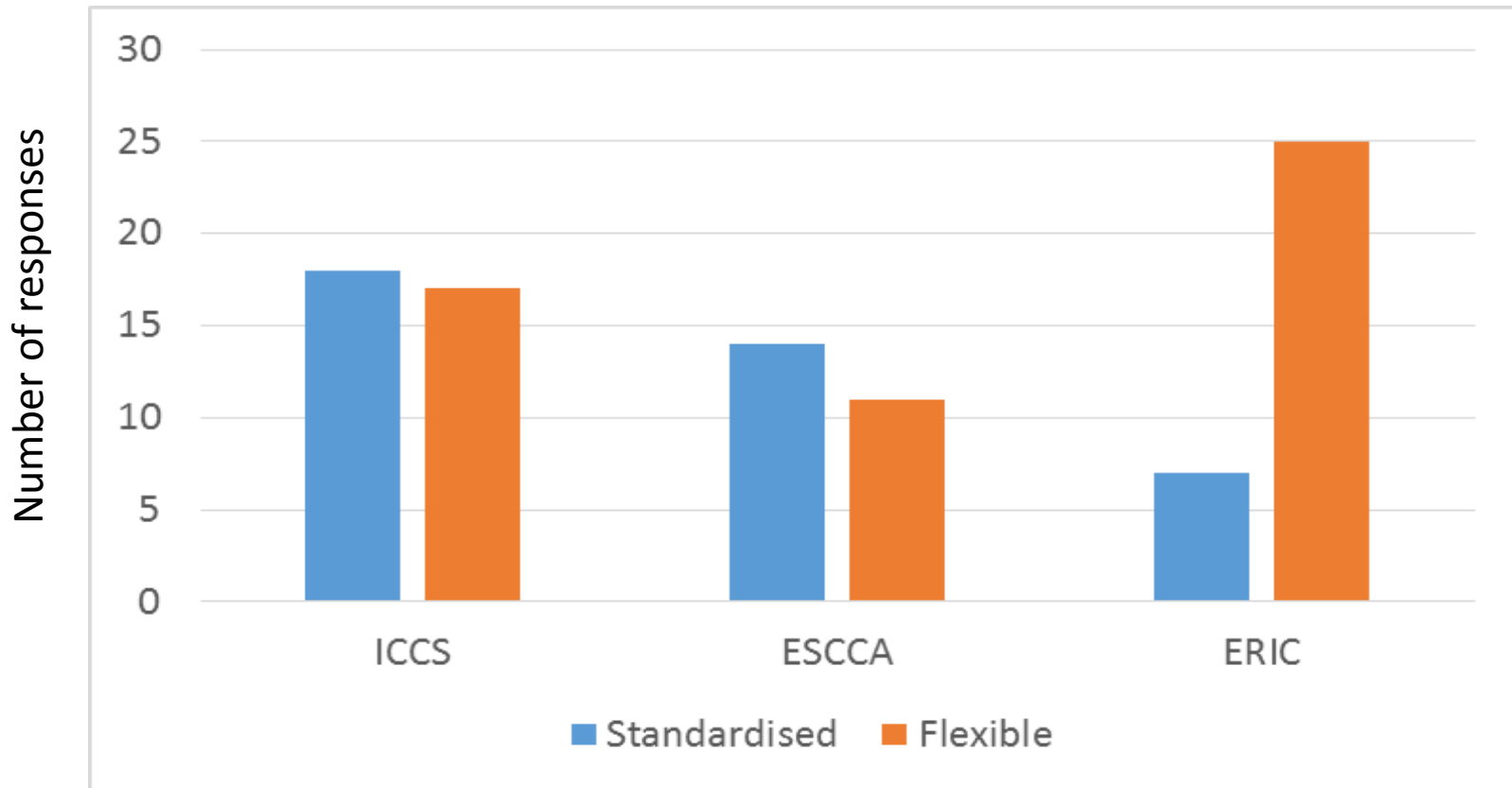


10 marker panel, one tube for both diagnosis and monitoring

6/8 marker panels, 2 tubes both of which are used at diagnosis and monitoring

6/8 marker panels, separate panels (≥ 1 tube) for diagnosis and monitoring

Please state your preference for either a flexible or fixed reagent set

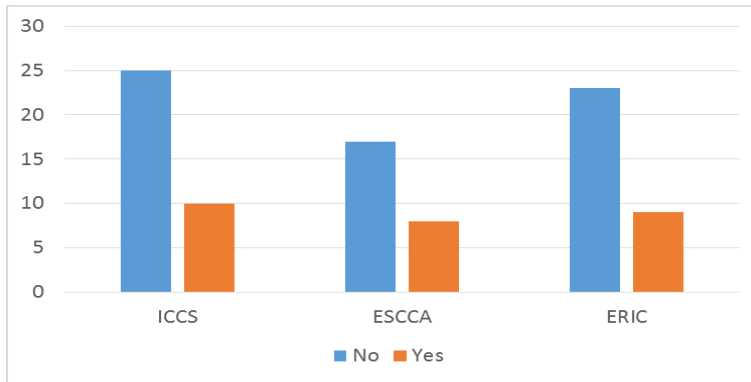


Fully validated, no flexibility permitted

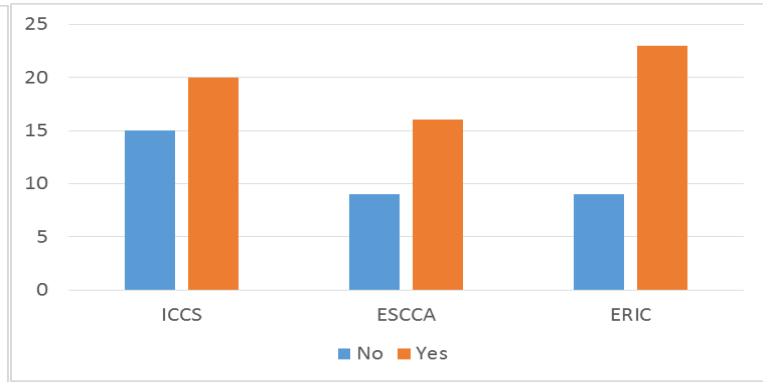
Permit additional drop-in markers (flexible but may not be fully validated)

If it were possible to provide reagents for prospective validation of the CLL diagnosis and MRD assays, which panel(s) would you be interested in (select all that would be applicable)

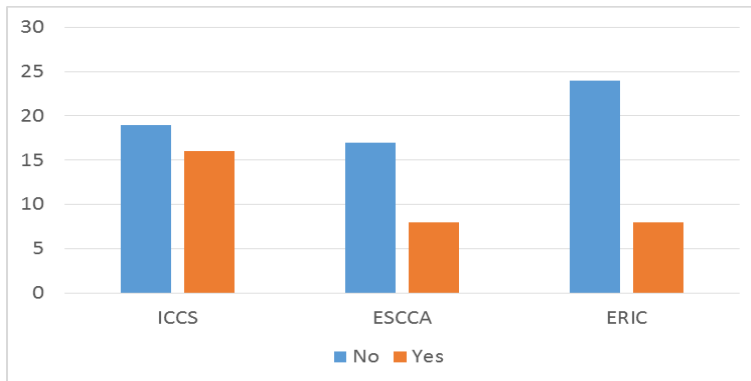
Number of responses



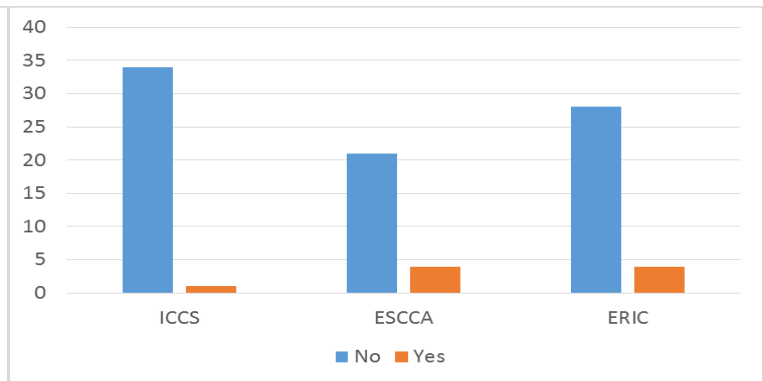
2 x 6-marker tests ± “drop-ins”



2 x 8-marker tests



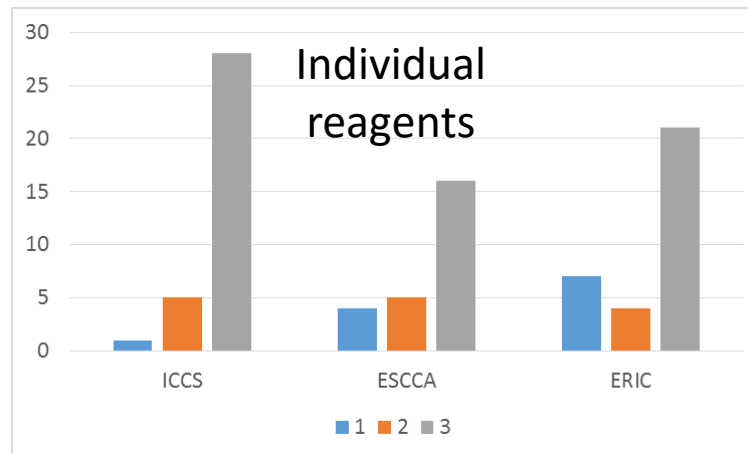
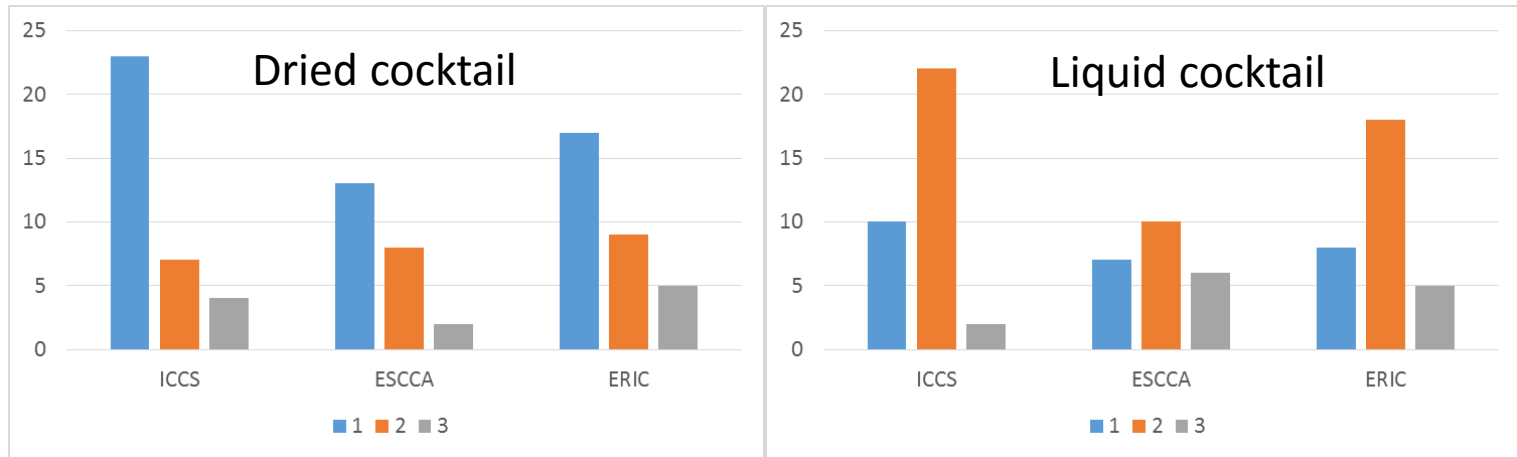
1 x 10-marker test



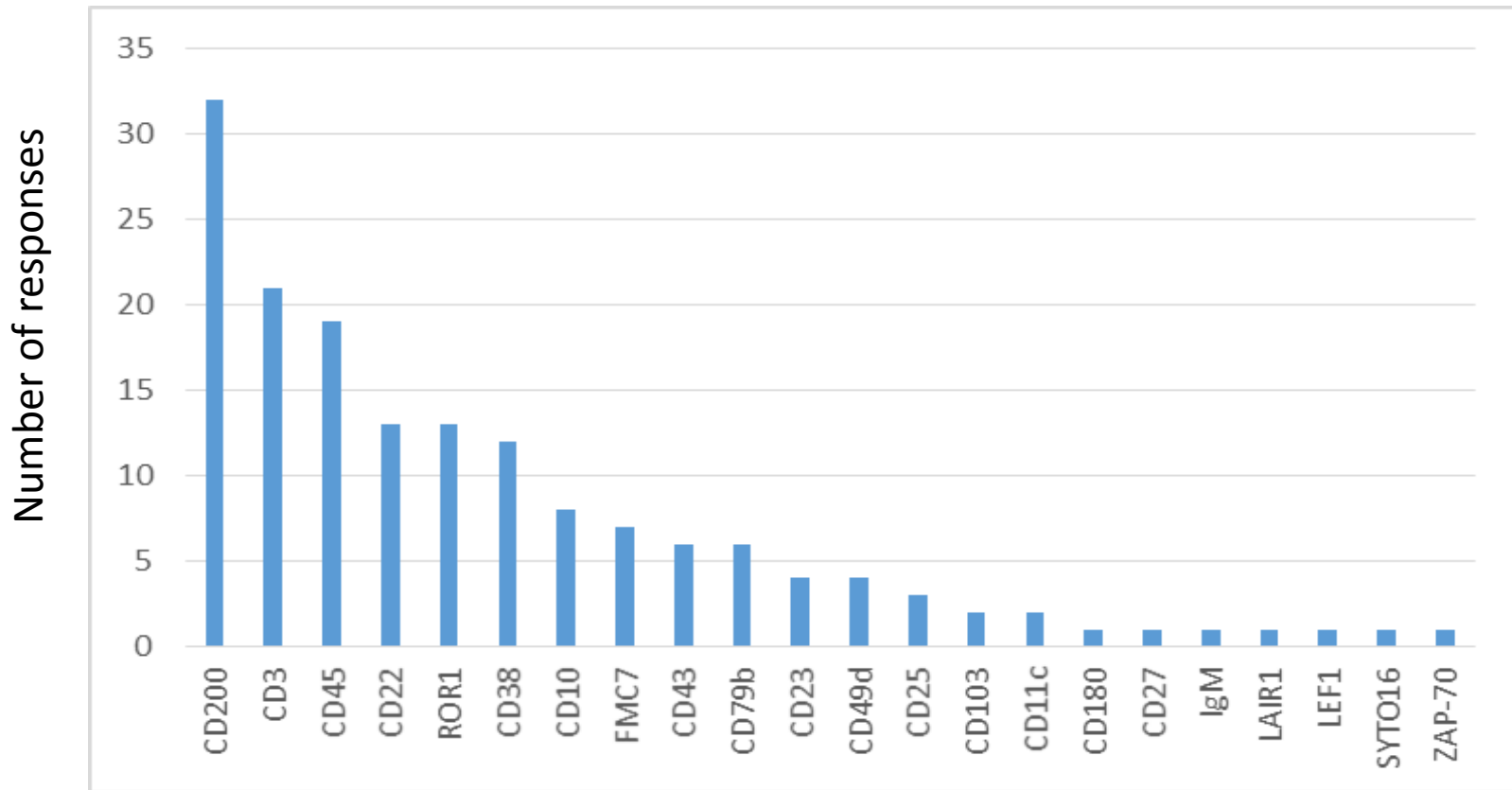
Alternative panel

Please rank these formats in order of preference, with #1 being your most preferred

Number of responses



If 2x8 or 1x10 marker tests are provided, which additional reagent(s) would you include



Summary

focus on development of standardised kits

- ≥ 8 -CLR preferable, relatively few centres restricted to 6-CLR
- Similar level of interest in both fully standardised *and/or* flexible kits
- Preference for dried > liquid cocktail, limited interest for separate reagents
- Requests for additional markers:
 - >10 for CD200, CD3, CD45, CD22, ROR1, CD38 (CD200 & ROR1 already recommended for diagnosis)
 - 5-10 for CD10, FMC7, CD43, CD79b (CD10, CD43 & CD79b already required/recommended for diagnosis/monitoring)
- ? Value of diagnostic tube when many centres have a bespoke screening tube
- Proposal for additional survey, dependent on feedback from survey report
 - Fixed tube: CD19, CD5, CD20, CD43, CD79b, CD81, CD200, ROR1
 - Potential to test drop-ins in parallel at centres with ≥ 10 -CLR cytometers:
 - CD23 & CD10 – diagnostic cases only for prospective validation
 - CD22 & HLADR – MRD only, particularly situations with reduced CD19
 - CD45 &/or CD3 – if requested
 - Kappa & Lambda – if requested

