TT 15: Effect of Haemolysed & Lipidemic Matrices

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Background and Aim

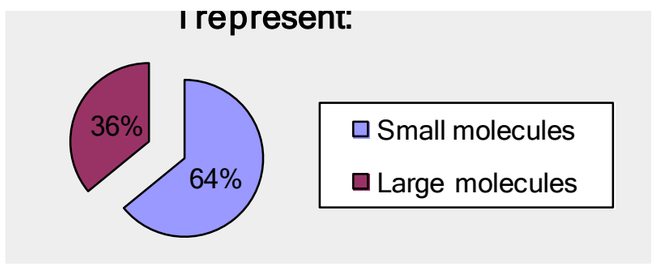
- In recent years, emerging regulatory guidances and white papers have highlighted a requirement to assess the impact of haemolysed and lipidemic matrices on assay validation.
- The challenge for the bioanalyst is then within the detail of how to execute such experiments, how to source control matrix and how to translate any assay boundaries established during validation to the analysis of real samples.
- EBF Topic Team-15 has conducted a survey to gauge common current practice across EBF member companies – the results of this survey are summarised and presented in this poster.

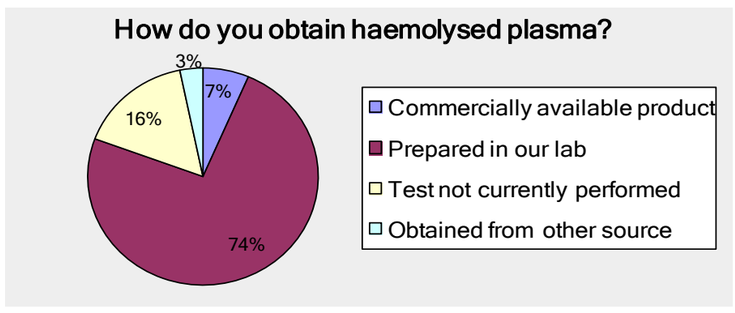
Team Members

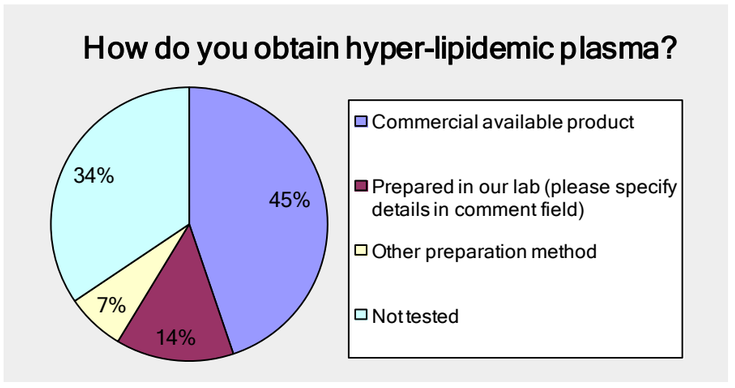
- Benno Ingelse; MSD
- Begona Barroso; Astellas
- Chris Cox; Merck Group
- Clare Kingsley; Quotient Bioresearch
- Corinna Sykora; Swiss BioQuant
- Nicholas Gray; Covance
- Petra Vinck; Janssen R&D
- Steve White; GlaxoSmithKline
- Peter van Amsterdam; Abbott

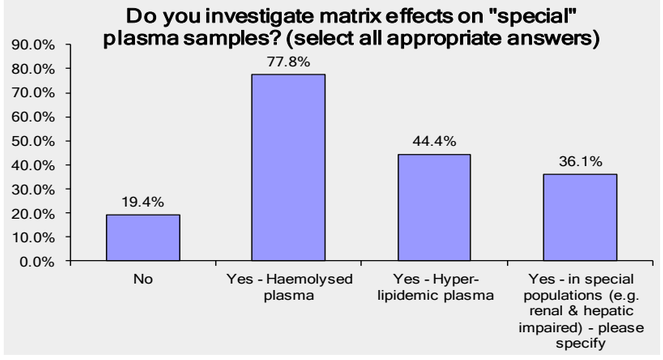
The team would like to acknowledge and thank EBF member companies for providing responses to this survey

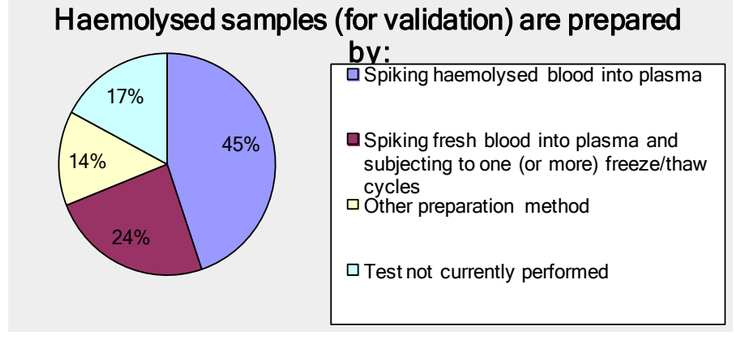
Survey Results (n=36 responses)

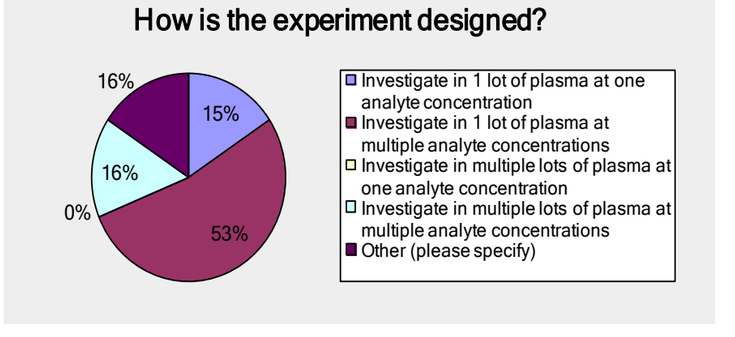


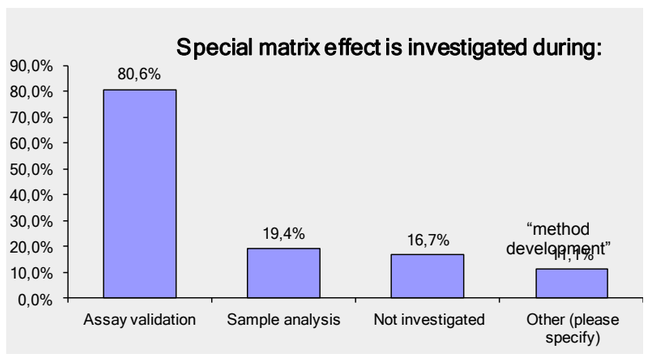


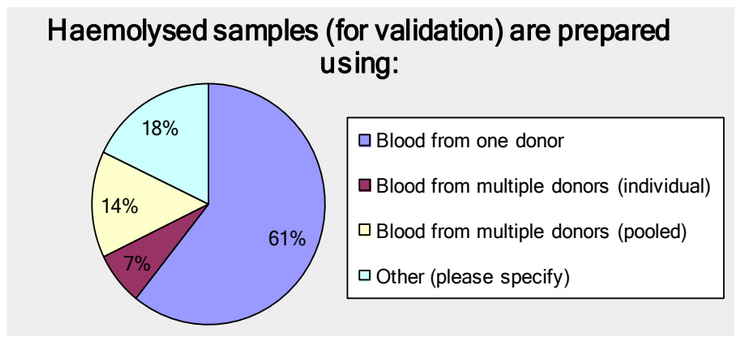


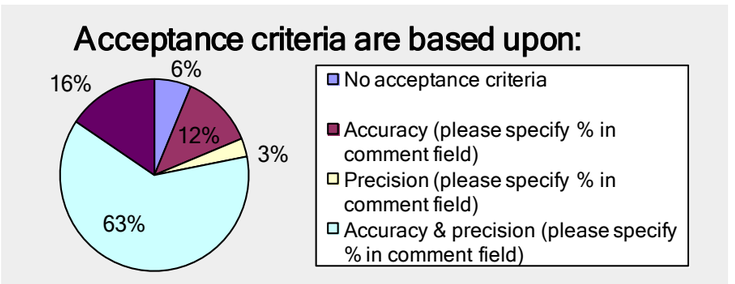


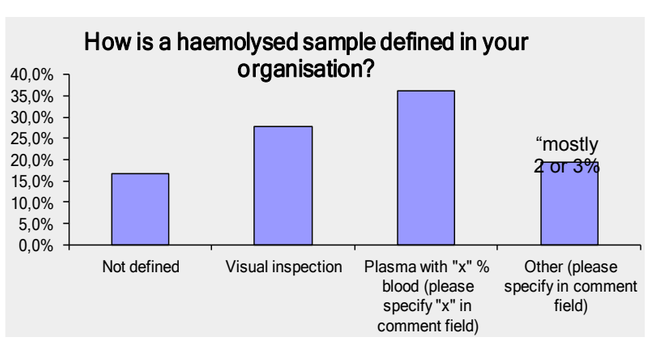


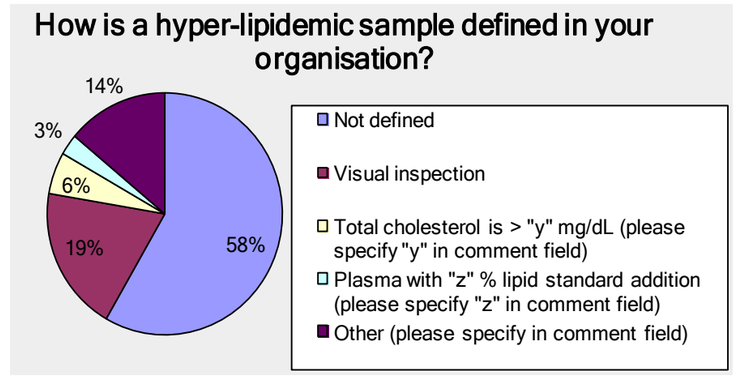


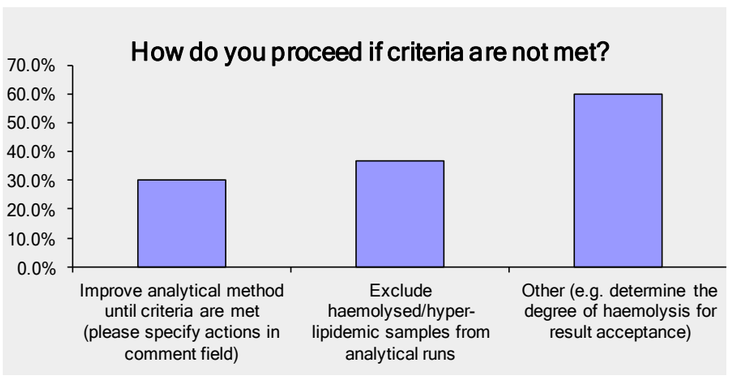












Future Plans

A follow up survey is currently being prepared to clarify some of the ambiguity from the first survey – specifically around translation of any limitations highlighted during assay validation, to the analysis of real study samples. Clarity will also be sought regarding which species are tested for haemolysed & hyper-lipidemic effects.

The team is also considering writing a recommendation paper on experiment design & conduct