

Plasma Fractionation by HaemaFrac[®] Technology

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Tangential Flow Electrophoresis (TFE) is an electroseparation technique that separates molecular entities based on charge and/or size. The technique is particularly suited for the separation of proteins from complex mixtures, but could be applied to the separation of vesicles, exosomes, nanoparticles and other charged species.

Aegros has developed a large-scale system based on TFE called HaemaFrac[®]. Using HaemaFrac[®] technology, plasma can be fractionated to produce a host of blood products. Yields of major plasma proteins albumin and immunoglobulins (IVIG) are approximately double that obtained by conventional Cohn fractionation, based on cold ethanol protein precipitation.

In a novel application, pooled COVID-19 convalescent plasma (CP) was fractionated by HaemaFrac[®] to yield an anti-SARS-CoV-2 hyperimmune globulin (HIG). The HIG, CovImmune[™], was produced with a yield and purity of around 85% and >95%, respectively, while meeting European Pharmacopeia (EP) standards. Importantly, CovImmune[™] Ig subclass distribution reflected that of original pooled CP, retaining the IgG3 subclass, known to be diminished during traditional Cohn plasma fraction. CovImmune[™] is now undergoing clinical trial.

With the failure of monoclonal antibodies to confer passive immunity to SARS-CoV-2, there is currently little to offer immunocompromised individuals, incapable of eliciting an effective immune response to vaccines. CovImmune[™] provides the opportunity to provide prophylactic protection for these individuals, who are at greater risk of morbidity and mortality to COVID-19.