

DIAGNOSTIC PARTNERSHIPS AND OEM SOLUTIONS BY STEMCELL TECHNOLOGIES

Supporting Your Assay Development and Workflow Needs



If you're looking for fully customizable pre-analytical workflow solutions for your diagnostic assay development, partnering with an experienced and reliable collaborator can help you achieve your objectives. At STEMCELL Technologies, we're committed to supporting your vision to improve patient care as you develop sensitive, reliable, and accurate assays that enable targeted treatments.

STEMCELL's dedicated [Diagnostic Partnerships and OEM Solutions](#) team will work with you to streamline your processes and develop robust pre-analytical solutions to meet your specific needs. Our qualified experts will collaborate with you to find the best solution for your workflow, whether that involves providing enhanced quality or regulatory support for an existing STEMCELL product, developing a customized sample preparation solution, or entering into an original equipment manufacturer (OEM) agreement to supply a component of your diagnostic assay.

With over 15 years of experience working with global regulatory bodies, including the US Food and Drug Administration (FDA), Health Canada, and the European Commission (for establishing compliance to the In Vitro Diagnostic Medical Device Regulation (IVDR)), STEMCELL can ensure our products meet the relevant global standards required for in vitro diagnostics (IVD) to help you achieve your goals.

Why Partner with Us?

EXPERTISE. Work with cell and biological enrichment specialists who have supported industries through clinical collaboration, commercialization, and regulatory submissions.

GLOBAL REACH. Get support from a team that has partnered with several customers worldwide to meet their country- and region-specific requirements.

DIVERSE PORTFOLIO. Leverage our diverse range of products and scalable solutions to optimize your IVD development.

ACCESSIBLE. Connect directly with our scientists specialized in whole blood processing and our dedicated clinical alliance team.

STREAMLINED. Get help with developing a customized workflow to meet the specific needs of your laboratory.

Partners and Collaborators We've Worked With



Diagnostic Partnerships and OEM Solutions

Our program combines the capabilities of STEMCELL products with the specialized knowledge of our scientists to provide customized services and support, including, but not limited to, the following:

- Pre-analytical sample enrichment solutions (off-the-shelf or customized OEM sample) encompassing technical and regulatory support from product conception through IVD commercialization
- In vitro diagnostic registration of STEMCELL products intended for use upstream or downstream of your assay

Personalized Support and Tailored Solutions

After working with you to understand your needs and requirements through an initial consultation, your Diagnostic Partnerships and OEM Solutions Manager will provide you with a customized proposal and facilitate the service through to completion.

“As the developers of an FDA-cleared, first-of-its-kind device for pre-analytical hematopoietic cell enrichment, we’re excited to bring our regulatory expertise and technical knowledge on sample preparation to new strategic partnerships focused on developing innovative diagnostic workflows.”

Mike Jones, Director, Clinical Services & Alliances

Table 1. Examples of Quality Services Provided by the Diagnostic Partnerships and OEM Solutions Program

Custom Quality Services	
Quality Measure	Partner with Us to:
Good Manufacturing Practices (GMP)	Ensure conformance to guidelines recommended by the relevant agencies
IVD Registration	Obtain regulatory clearance for the use of STEMCELL products in diagnostic workflows, if required
Quality and Regulatory Support	Understand STEMCELL products and their level of compliance for use within your diagnostic workflow
Quality and Supply Agreements	Ensure adherence to specifications tailored to your application
Customizable Product Formulations	Obtain custom pre-analytical product formulations to enrich your analyte of interest
Customizable Product Format	Access packaging and reagents that best fit your workflow needs
Extended Product Shelf Life	Secure products with improved shelf-life, reducing lot-to-lot verification testing for diagnostic laboratories
Label Qualification	Ensure conformance to requirements under ISO 20417
Additional QC Testing	Set up customized QC testing, including the use of compendial methods



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