Health Technology Review	
Technology Ref.:	HTA23061
Technology Name:	Thermogenesis AXP II system
Approvals by International Bodies:	US FDA , EU, Malaysia, Indonesia, Thailand and MoHaP (UAE)
Company name:	Al Nawras Medi-Lab Supplies
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Short Description of the Technology:	**The AXP® II System** is a cord blood processing system intended for laboratory use in combination with a specific and compatible single-use separation kit supplied by ThermoGenesis. The AXP II System allows the fast, automated, and reproducible separation of cord blood in a closed and sterile environment. The process begins by transferring cord blood into the processing bag set, which is then carefully positioned within the AXP Device for subsequent centrifugation. The AXP Device is designed to fit into most standard blood bank centrifuge buckets, enabling the concurrent processing of up to six samples. During the centrifugation process, the components within the cord blood stratify and separate. Specifically, red blood cells (RBC) are directed into a separate sterile bag, the buffy coat housing the mononuclear cell (MNC) rich layer is skillfully directed into a separate sterile freezing bag, while the plasma remains within the original processing bag.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

The AXP® II System is designed for high-quality stem cell concentration from cord blood. It enables automated, fast, reproducible separation of cord blood in a sterile environment, without the need for hetastarch for mononuclear cell capture.
The technology is recognized for its effectiveness in separating and preserving stem cells from cord blood. It's approved by international bodies including the US FDA and MoHaP (UAE). Clinical trials and published literature support its efficacy.

Advantages	Disadvantages
Approvals by International Bodies: US FDA , EU, Malaysia, Indonesia, Thailand and MoHaP (UAE).	The acquisition and setup costs could be significant, posing financial challenges, especially for smaller healthcare facilities.
Safe and effective technology for both patients and heslthcare providers.	Requires ongoing training and certification for operators, which could be resource-intensive.
Automates the separation of stem cells from	Dependence on technology might reduce

cord blood, reducing manual errors and inconsistencies.	manual skill development in cord blood processing.
Efficiently concentrates stem cells, enhancing the quality of cord blood units.	
Maintains a sterile processing environment, which is crucial for preventing contamination.	
Supported by clinical trials and literature, showing its effectiveness in stem cell separation.	
Cost-Effectiveness as it's potentially reduces expenses related to various medical interventions in the long term.	

We recommend an **approve of using this technology** with the following conditions:

1. The technology may only be used in a laboratory setting by healthcare professionals.
2. Using the technology may only be started after completion of the required training from a qualified instructor.
3. Follow the instructions provided by the manufacturer for the users.
4. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees and patients.
5. Provision of regular updates and reports outcome about the product to DOH upon request.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image

Population, setting and intended user for Technology "Thermogenesis AXP II system"

- **Population/ Intended User**;
  - Patient elegable for stem cell therapy
  - Parents opting for vord blood banking
- **To be performed by**:
  - Trained Healthcare professionals
- **Clinical Setting:**
  - Hospitals
  - Clean environment
- **Condition of use:**
  - Operation should be conducted by individuals who have received training and certification specific to the AXP® II System
  - The system should be used in a controlled, clean, and sterile laboratory environment to maintain the integrity of the cord blood and prevent contamination.
  - Regular maintenance and calibration of the system are necessary to ensure its optimal performance and accuracy.
  - Users must adhere to the regulatory standards and guidelines set by health authorities.
  - The system should be used for its intended purpose of processing cord blood for stem cell concentration, and not for other unapproved applications.
- **Exclusion criteria:**
  - Cord blood that is visibly contaminated or of poor quality, which might not yield viable stem cells upon processing.
  - The system may require a minimum volume of cord blood to operate effectively. Samples below this threshold might be excluded.
  - If the blood donor (typically the newborn or the mother) has certain infectious diseases, this might preclude the use of the cord blood due to safety concerns.
  - Cord blood units that have exceeded their viable storage period might not be suitable for processing.