



February 17, 2021

Notice of Intent to Sole Source
Human Intestinal Organoids/Colonoids Cell Line
FDA_SS_1238931

The Food and Drug Administration (FDA) intends to award a Sole Source firm-fixed price purchase order to The John Hopkins University, 3400 N. Charles Street, Baltimore, MD 21218. In accordance with FAR part 6.302-1, the contractor is the only responsible source who can provide the required services as no other source has been identified to satisfy the agencies requirements.

The purpose of this notice is to inform the public that the FDA anticipates issuing an award to procure Human Intestinal Organoids/Colonoids Cell Line that is capable of long term primary intestinal epithelial cell culture recapitulating the structure and function of intestinal physiology after multiple passages.

The associated North American Industrial Classification System (NAICS) Code is 541380: Testing Laboratories.

MINIMUM REQUIREMENTS:

- A. Shall provide Human organoid/colonoids cultures derived from male and/or female adult healthy donors that recapitulate the normal organ physiology, with limited genetic or physiologic alterations, even after many generations.
- B. Shall provide three (3) separate colonoids to ensure consistency.
- C. Shall provide cells from distal colon.
- D. Shall not have a cell line that results in significant change in physiology and structure upon long-term propagation of the intestinal colonoid/organoid.
- E. Shall have intestinal colonoids/organoids to be grown in an undifferentiated state to mimic intestinal epithelial cells (IECs) in crypt or differentiated to mimic villus cells composed of mature colonocytes, enteroendocrine cells, and goblet cells.
- F. Shall have colonic organoids that can create a mucus layer.
- G. Shall have colonoids to be grown as monolayers with apical and basolateral surfaces.
- H. Shall have the ability to withstand fluid shear stress and repetitive mechanical deformation (2-10% cell strain, 0.1-0.2Hz frequency) in monolayer culture form.
- I. Shall have the colonoids be free from any contamination.
- J. Shall provide a cell line previously demonstrated on the Emulate system.
- K. Shall have a lab that has Institutional Review Board (IRB) approval for the organoids and provide documentation of such.
- L. Shall provide information for proper delivery and storage.
- M. Shall provide storage temperature recommendations.
- N. Shall provide virtual training on handling of cell line for up to three (3) End Users.
- O. Shall have the ability to replace colonoids that do not meet the requirements within three (3) weeks of notification.
- P. Shall provide one (1) year warranty from date of acceptance.

This notice is not a request for competitive proposals. However, any party that believes it can meet this requirement as stated herein may submit a written capability statement that clearly supports and demonstrates their ability to perform the requirement.



Capability statements must be received by the response date and time of this notice. Submissions will be reviewed to determine if they can meet the requirement. A determination by the Government to compete this proposed contract based upon responses to this notice is solely within the discretion of the Government.

It is anticipated that an award will be issued to Agilent Technologies, within approximately ten (10) days after the date of this notice unless the Government determines that any other organization has the capability to meet this requirement.

Response Date: February 27, 2021 by 10:00AM Eastern Time. Please email responses to Nicole Craig at nicole.craig@fda.hhs.gov. No phone calls will be accepted.