

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10	FEI: 3003006583	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2026 Last Registration Receipt Date: 12/15/2025 Summary Report Print Date: 01/09/2026
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Legal Name and Location: Cambridge Biomedical Inc.; dba BioAgilytix Labs, LLC 1320 Soldiers Field Road Boston, Massachusetts 02135 USA Phone: 617-456-0700 Ext.:	Reporting Official: Erika M Itani, Associate Director, Corporate Compliance 2300 Englert Drive Durham, North Carolina 27713 USA Phone: 919-696-2452 Ext. erika.itani@bioagilytix.com	Satellite Recovery Establishment: No Parent Manufacturing Establishment FEI No.: Testing For Micro-Organisms Only: No Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane												
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis	Autologous, Family Related			X		X						
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells	Autologous, Family Related			X		X						
Peritoneal Membrane												
Sclera												
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: FDA inactivated registration due to establishment's failure to submit the required annual update, Date: 4/11/2024

Cambridge Biomedical Inc. was acquired by BioAgilytix, headquartered in Durham, NC, on 01Nov2019. Cambridge Biomedical remains a separate legal entity; however, doing business as (dba) BioAgilytix.

Proprietary Name(s):

FEI: 3003006583

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