

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: 2021
 Last Registration Receipt Date: 12/29/2020
 Summary Report Print Date: 01/11/2021

Legal Name and Location:

Cambridge Biomedical Inc.; dba BioAgilytix
 1320 Soldiers Field Road

Boston, Massachusetts 02135
 USA

Phone: 617-456-0700

Ext.:

Reporting Official:

Verona Outerbridge, QA Director
 1320 Soldiers Field Road
 Boston, Massachusetts 02135
 USA

Phone: 617-456-0700 Ext. 737
 verona.outerbridge@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)).

Establishment Functions

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: 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):

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